SOUTHERN ADJUSTMENT SERVICES, INC.

PRIVACY SECURITY FRAUD DETECTION & IDENTITY THEFT PROGRAM DOCUMENTS

2013

INTRODUCTION

Recognizing that Identity Theft is the number one white collar crime in America today and in compliance with recent rulings of the Federal Trade Commission, Southern Adjustment Services, Inc. has established and implemented programs to prevent fraud and identity theft.

This program covers the requirements of the FTC and was designed with the aid and guidelines as presented in the FTC Guide, "Protecting Personal Information, A Guide for Business". Each step recommended in the guide was discussed by our management and compliance personnel and, where required, programs established and implemented. The Guide itself then became part of our basic program related to fraud and identity protections.

The Southern Adjustment Services, Inc. Compliance officers are fully trained prior to setting up the necessary security programs to protect consumer data given to Southern Adjustment Services, Inc. by clients and are required to participate in a continuing education program which includes other programs related to data protection and security

These Southern Adjustment Services, Inc. Compliance officers will continue to monitor the fraud and identity theft policies and procedure and update as is necessary.

Included in this package are the documents used pursuant to FDCPA, FCRA/FACTA, HIPPA, TCPA, TRPPA, GLBA and the "RED FLAG RULES" to ensure compliance. These documents are proprietary to Southern Adjustment Services, Inc. and any unauthorized use or distribution is strictly prohibited.

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PROTECTING PERSONAL INFORMATION A Guide for Business

Most companies keep sensitive personal information in their files----names, Social Security numbers, credit card, or other account data-----that identifies customers or employees.

This information often is necessary to fill orders, meet payroll, or perform other necessary business functions. However, if sensitive data falls into the wrong hands, it can lead to fraud, identity theft, or similar harms. Given the cost of a security breach-----losing your customers' trust and perhaps even defending yourself against a lawsuit-----safeguarding personal information is just plain good business.

Some businesses may have the expertise in-house to implement an appropriate plan. Others may find it helpful to hire a contractor. Regardless of the size----or nature----of your business, the principles in this brochure will go a long way toward helping you keep data secure.



A sound data security plan is built on **5 key principles**:

- 1. Take stock. Know what personal information you have in your files and on your computers.
- 2. Scale down. Keep only what you need for your business.
- **3.** Lock it. Protect the information that you keep.
- 4. Pitch it. Properly dispose of what you no longer need.
- 5. Plan ahead. Create a plan to respond to security incidents.

Use the checklists on the following pages to see how your company's practices measure up---and where changes are necessary. You also can take an interactive tutorial at <u>www.ftc.gov/infosecurity</u>.



1. TAKE STOCK. Know what personal information you have in you files and on you computers.

Effective data security starts with assessing what information you have and identifying who has access to it. Understanding how personal information moves into, through, and out of your business and who has – or could have – access to it is essential to assessing security vulnerabilities. You can determine the best ways to secure the information only after you've traced how it flows.

- Inventory all computers, laptops, flash drives, disks, home computer, and other equipment to find out where your company stores sensitive data. Also inventory the information you have by type and location. Your files cabinets and computer systems are a start, but remember: your business receives personal information in a number of ways – through websites, from contractors, from call centers, and the like. What about information saved on laptops, employees' home computers, flash drives, and cell phones? No inventory is complete until you check everywhere sensitive data might be stored.
- Track personal information through your business by taking with your sales department, information technology staff, human resources office, accounting personnel, and outside service providers. Get a complete picture of:
 - Who sends sensitive personal information to your business. Do you get it from customers? Credit card companies? Banks or other financial institutions? Credit bureaus? Other businesses?
 - How your business receives personal information. Does it come to your business through a website? By email? Through the mail? Is it Transmitted through cash registers in stores?
 - What kind of information you collect at each entry point. Do you get credit card information online? Does your accounting department keep information about customers' checking accounts?

✓ SECURITY CHECK

Question:

Are there laws that require my company to keep sensitive data secure?

Answer:

Yes. While you're taking stock of the Data in your files, take stock of the law, too statutes like the Gramm-Leach-Bliley Act, the Fair Credit Reporting act, and the Federal Trade Commission Act may require you to provide reasonable security for sensitive information.

To find out more, visit www.ftcgov/privacy.

Where you keep the information you collect at each entry point. Is it in a central computer database? On individual laptops? On disks or tapes? In file cabinets? In branch offices? Do employees have files at home?

- Who has or could have access to the information. Which of your employees has permission to access the information? Could anyone else get a hold of it? What about vendors who supply and update software you use to process credit card transactions? Contractors operating your call center?
- Different types of information present varying risks. Pay particular attention to how you keep personally identifying information: Social Security numbers, credit card or financial information, and other sensitive data. That's what thieves use most often to commit fraud or identity theft.

2. SCALE DOWN. Keep only what you need for your business.

If you don't have a legitimate business need for sensitive personally identifying information, don't keep it. In fact, don't even collect it. If you have a legitimate business need for the information, keep it only as long as it's necessary.

 Use Social Security numbers only for required and lawful purposes — like reporting employee taxes. Don't use Social Security numbers unnecessarily — for example, as an employee or customer identification number, or because you've always done it.

✓ SECURITY CHECK

Question:

We like to have accurate information about our customers, so we usually create a permanent file about all aspects of their transactions, including the information we collect from the magnetic stripe on their credit cards. Could this put their information at risk.

Answer:

Yes. Keep sensitive data in your system only as long as you have a business reason to have it. Once that business need is over, properly dispose of it if it's not in your system, it can't be stolen by hackers.

- The law requires you to shorten or truncate the electronically printed credit and debit card receipts you give your customers. You may include no more than the last five digits of the card number, and you must delete the expiration date.
- Don't keep customer credit card information unless you have a business need for it. For example, don't retain the account number and expiration date unless you have an essential business need to do so. Keeping this information — or keeping it longer than necessary — raises the risk that the information could be used to commit fraud or identity theft.
- Check the default setting on your software that reads customers' credit card numbers and processes the transactions. Sometimes it's preset to keep information permanently. Change the default setting to make sure you're not keeping information you don't need.
- If you must keep information for business reasons or to comply with the law, develop a written records retention policy to identify what information must

 be kept, how to secure it, how long to keep it and how to dispose of it securely when you no longer need it. **3.** LOCK IT. Protect the information that you keep.



What's the best way to protect the sensitive personally identifying information you need to keep? It depends on the kind of information and how it's stored. The most effective data security plans deal with four key elements: physical security, electronic security, employee training, and the security practices of contractors and service providers.

PHYSICAL SECURITY

Many data compromises happen the old-fashioned way — through lost or stolen paper documents. Often, the best defense is a locked door or an alert employee.

- Store paper documents or files, as well as CDs, floppy disks, zip drives, tapes and backups containing personally identifiable information in a locked room or in a locked file cabinet. Limit access to employees with a legitimate business need. Control who has a key, and the number of keys.
- Require that files containing personally identifiable information be kept in locked file cabinets except when an employee is working on the file. Remind employees not to leave sensitive papers out on their desks when they are away from their workstations.

- Require employees to put files away, log off their computers, and lock their file cabinets and office doors at the end of the day.
- Implement appropriate access controls for your building. Tell employees what to do and whom to call if they see an unfamiliar person on the premises.
- If you maintain offsite storage facilities, limit employee access to those with a legitimate business need. Know if and when someone accesses the storage site.
- If you ship sensitive information using outside carriers or contractors, encrypt the information and keep an inventory of the information being shipped. Also use an overnight shipping service that will allow you to track the delivery of your information.

ELECTRONIC SECURITY

Computer security isn't just the realm of your IT staff. Make it your business to understand the vulnerabilities of your computer system, and follow the advice of experts in the fields.

General Network Security

- Identify the computers or servers where sensitive personal information is stored.
- Identify all connections to the computers where you store sensitive information. These may include the Internet, electronic cash registers, computers at your branch offices, computers used by service providers to support your network, and wireless devices like inventory scanners or cell phones.
- Assess the vulnerability of each connection to commonly known or reasonable foreseeable attacks. Depending on your circumstances, appropriate assessments may range from having knowledgeable employee run off-the-shelf security software to having an independent professional conduct a full-scale security audit.
- Don't store sensitive consumer data on any computer with an Internet connection unless it's essential for conducting your business.
- Encrypt sensitive information that you send to third parties over public networks (like the Internet), and consider encrypting sensitive information that is stored on your computer network or on disks or portable storage deices used by your employees. Consider also encrypting email transmissions within your business if they contain personally identifying information.
- Regularly run up-to-date anti-virus and anti-spyware programs on individual computers and on servers on your network.

- Check expert websites (such as <u>www.sans.org</u>) and your software vendors' websites regularly for alerts about new vulnerabilities, and implement policies for installing vendor-approved patches to correct problems.
- Scan computers on your network to identify and profile the operating system and open network services.
 If you find services that you don't need, disable then to prevent hacks or other potential security problems.
 For example, if email service or an Internet connection is not necessary on a certain computer, consider closing the ports to those services on that computer to prevent unauthorized access to that m

✓ SECURITY CHECK

Question:

We encrypt financial data customers submit on our website. But once we receive it, we decrypt it and email it over the intranet to our branch offices in regular text is there a safer practice?

Answer:

Yes. Regular email is not secure method for sending sensitive data. The better practice is to encrypt any transmission that contains information that could be used by fraudsters or ID thieves.

unauthorized access to that machine.

- When you receive or transmit credit card information or other sensitive financial data, use Secure Sockets Layer (SSL) or another secure connection that protects the information in transit.
- Pay particular attention to the security of your web application the software used to give information to visitors to your website and to retrieve information from them. Web applications may be particularly vulnerable to a variety of hack attacks. In one variation called an "injection attack", a hacker inserts malicious commands into what looks like a legitimate request for information. Once in your system, hackers transfer sensitive information from your network to their computers. Relatively simple defenses against these attacks are available form a variety of sources.

Password Management

- Control access to sensitive information by requiring that employees use "strong" Passwords. Tech security experts say the longer the password, the better. Because simple passwords — like common dictionary words — can be guessed easily, insist that employees choose passwords with a mix of letters, numbers, and characters. Require an employee's user name and password to be different, and require frequent changes in passwords.
- Explain to employees why it's against company policy to share their passwords or post them near their workstations.
- Use password-activated screen savers to lock employee computers after a period of inactivity.
- Lock out users who don't enter the correct password within a designated number of log-on attempts.

✓ SECURITY CHECK

Question:

Our account staff needs access to our database of customer financial information. To make it easier to remember, we just use our company name as the password. Could that create a security problem?

Answer:

Yes. Hackers will first try words like "password", your company name, the software's default password, and other easy-to-guess choices. They'll also use programs that run through common English words and dates To make it harder for them to crack your system, select strong password — the longer, the better — that use a combination of letters, symbols, and numbers. And change passwords often.

- Warn employees about possible calls from identity thieves attempting to deceive them into giving out their passwords by impersonating members of your IT staff. Let employees know that calls like this are always fraudulent, and that no one should be asking them to reveal their passwords.
- When installing new software, immediately change vendor-supplied default passwords to a more secure strong password.
- Caution employees against transmitting sensitive personally identifying data — Social Security numbers, password, account information — via email. Unencrypted email is not a secure way to transmit any information.

Laptop Security

- Restrict the use of laptops to those employees who need them to perform their jobs.
- Assess whether sensitive information really needs to be stored on a laptop. If not, delete it with a "wiping" program that overwrites data on the laptop. Deleting files using standard keyboard commands isn't sufficient because data may remain on the laptop's hard drive. Wiping programs are available at most office supply stores.
- Require employees to store laptops in a secure place. Even when laptops are in use, consider using cords and locks to secure laptops to employees' desks.
- Consider allowing laptop users only to access sensitive information, but not to store the information on their laptops. Under this approach, the information is stored on a secure central computer and the laptops function as terminals that display information from the central computer, but do not store it. The information could be further protected by requiring the use of a token, "smart card," thumb print, or other biometric — as well as a password — to access the central computer.
- If a laptop contains sensitive data, encrypt it and configure it so users can't download any software or change the security settings without approval from your IT specialists. Consider adding an "auto-destroy" function so that data on a computer that is reported stolen will be destroyed when the thief uses it to try to get on the Internet.
- Train employees to be mindful of security when they're on the road. They should never leave a laptop visible in a car, at a hotel luggage stand, or packed in checked luggage unless directed to by airport security. If someone must leave a laptop in a car, it should be locked in a trunk. Everyone who goes through airport security should keep an eye on their laptop as it goes on the belt.

Firewalls

- Use a firewall to protect your computer from hacker attacks while it is connected to the Internet. A firewall is software or hardware designed to block hackers from accessing your computer. A properly configured firewall makes it tougher for hackers to locate your computer and get into your programs and files.
- Determine whether you should install a "border" firewall where your network connects to the Internet. A border firewall separates your network from the internet and may prevent an attacker from gaining access to a computer on the network where you store sensitive information. Set "access controls"—settings that determine who gets through the firewall and what they will be allowed to see — to allow only trusted employees with a legitimate business need to access the

network. Since the protection a firewall provides is only as effective as its access controls, review them periodically.

If some computers on your network store sensitive information while others do not, consider using additional firewalls to protect the computers with sensitive information.

Wireless and Remote Access

- Determine if you use wireless devices like inventory scanners or cell phones to connect to your computer network or to transmit sensitive information.
- If you do, consider limiting who can use a wireless connection to access your computer network. You can make it harder for an intruder to access the network by limiting the wireless devices that can connect to your network.
- Better still; consider encryption to make it more difficult for an intruder to read the content. Encrypting transmissions from wireless devices to your computer network may prevent an intruder from gaining access through a process called "spoofing"— impersonating one of your computers to get access to your network.
- Consider using encryption if you allow remote access to your computer network by employees or by service providers, such as companies that troubleshoot and update software you use to process credit card purchases.

Detecting Breaches

- To detect network breaches when they occur, consider using an intrusion detection system. To be effective, it must be updated frequently to Box 4424, Youngstown, OH 44515 new types of hacking.
- Maintain central log files of security-related information to monitor activity on your network so that you can spot an respond to attacks. If there is an attack on your network, the log will provide information that can identify the computers that have been compromised.
- Monitor incoming traffic for signs that someone is trying to hack in. Keep an eye out for activity from new users, multiple log-in attempts from unknown users or computers, and higher-than-average traffic at unusual times of the day.
- Monitor outgoing traffic for signs of a data breach. Watch for unexpectedly large amounts of data being transmitted from your system to an unknown user. If large amounts of information are being transmitted from your network, investigate to make sure the transmission is authorized.
- ✤ Have in place and implement a breach response plan.

EMPLOYEE TRAINING

Your data security plan may look great on paper, but it's only as strong as the employees who implement it. Take time to explain the rules to your staff, and train them to spot security vulnerabilities. Periodic training emphasizes the importance you place on meaningful data security practices. A well-trained workforce is the best defense against identity theft and data breaches.

- Check references or do background checks before hiring employees who will have access to sensitive data.
- Ask every new employee to sign an agreement to follow your company's confidentiality and security standards for handling sensitive data. Make sure they understand that abiding by your company's data security plan is an essential part of their duties. Regularly remind employees of your company's policy—and any legal requirement—to keep customer information secure and confidential.
- Know which employees have access to consumers' sensitive personally identifying information. Pay particular attention to data like Social Security numbers and account numbers. Limit access to personal information to employees with a "need to know"
- Have a procedure in place for making sure that workers who leave your employ or transfer to another part of the company no longer have access to sensitive information. Terminate their passwords, and collect keys and identification cards as part of the check-out routine.

✓ SECURITY CHECK

Question:

I'm not really a "tech" type Are there steps our computer people can take to protect our system from common hack attacks?

Answer:

Yes. There are relatively simple fixes to protect your computers from some of the most common vulnerabilities for example, a threat called an "SOL injection attack" can give fraudsters access to sensitive data on your system, but can be thieved with a simple change to your computer. Bookmark the websites of groups like the Open Web Application Security Project, <u>www.owasp.org</u>., SANS (SysAdmin, Audit, Network, Security) Institute's Most Critical Internet Security Vulnerabilities, <u>www.sans.org/top20</u> for up-to-date information on the latest threats—and fixes. And check with your software vendors for patches that address new vulnerabilities.

- Create a "culture of security" by implementing a regular schedule of employee training. Update employees as you find out about new risks and vulnerabilities. Make sure training includes employees at satellite offices, temporary help, and seasonal workers. If employees don't attend, consider blocking their access to the network.
- Train employees to recognize security threats. Tell them how to report suspicious activity and publicly reward employees who alert you to vulnerabilities.
- Consider asking your employees to take the FTC's plain-language, interactive tutorial at <u>www.ftc.gov/infosecurity</u>.
- Tell employees about your company policies regarding keeping information secure and confidential. Post reminders in areas where sensitive information is used or stored, as well as where employees congregate. Make sure your policies cover employees who telecommute or access sensitive data from home or an off site location.
- Warn employees about phone phishing. Train them to be suspicious of unknown callers claiming to need account numbers to process an order or asking for customer or employee contact information. Make it office policy to double-check by contacting the company using a phone number you know is genuine.
- Require employees to notify you immediately if there is a potential security breach, such as a lost or stolen laptop.
- Impose disciplinary measures for security policy violations.
- For computer security tips, tutorials and quizzes for everyone on your staff, visit <u>www.OnGuardOnline.gov</u>.

SECURITY PRACTICES OF CONTRACTORS AND SERVICE PROVIDERS Your company's security practices depend on the people who implement them, including contractors and service provider.

- Before you outsource any of your business functions—payroll, web hosting, customer call center operations, data processing, or the like investigate the company's data security practices and compare their standards to yours. If possible, visit their facilities.
- Box 4424, Youngstown, OH 44515 security issues for the type of data your service providers handle in your contract with them.
- Insist that your service providers notify you of any security incidents they experience, even if the incidents they experience, even if the incidents may not have led to an actual compromise of your data.

4. PITCH IT. Properly dispose of what you no longer need.



What looks like a sack of trash to you can be a gold mine for an identity thief. Leaving credit card receipts or papers or CD's with personally identifying information in a dumpster facilitates fraud and exposes consumers to the risk of identity theft. By properly disposing of sensitive information, you ensure that it cannot be read or reconstructed.

 Implement information disposal practices that are reasonable and appropriate to prevent unauthorized access to—or use of—personally identifying information. Reasonable measures for your operation are based on the sensitivity of the information, the costs and benefits of different disposal, methods, and changes in technology.

✓ SECURITY CHECK

Question:

My company collects credit applications from customers. The form requires them to give us lots of financial information. Once we're finished with the applications we're careful to throw them away. Is that sufficient?

Answer:

No. Have a policy in place to ensure that sensitive paperwork is unreadable before you throw it away. Burn it, shred it, or pulverize it to make sure identity thieves can't steal it from your trash.

- Effectively depose of paper records by shedding, burning, or pulverizing them before discarding. Make shredders available throughout the workplace, including next to the photocopier.
- When disposing of old computers and portable storage devices, use wipe utility programs. They're inexpensive and can provide better results by overwriting the entire hard drive so that the files are no longer recoverable. Deleting files using the keyboard or mouse commands usually isn't sufficient because the files may continue to exist on the computer's hard drive and could be retrieved easily.
- Make sure employees who work from home follow the same procedures for disposing of sensitive documents and old computers and portable storage devices.
- If you use consumer credit reports for a business purpose, you may be subject to the FTC's Disposal Rule. For more information, see Disposing of Consumer Report Information? New Rule Tells How at <u>www.ftc.gov</u> (just enter the title into the search engine).

5. PLAN AHEAD. Create a plan for responding to security incidents.

Taking steps to protect data in your possession can go a long way toward preventing a security breach. Nevertheless, breaches can happen. Here's how you can reduce the impact on your business, your employees, and your customers:

- Have plan in place to respond to security incidents. Designate a senior member of your staff to coordinate and implement the response plan.
- If a computer is compromised, disconnect it immediately from the Internet.

✓ SECURITY CHECK

Question:

I own a small business Aren't these precautions going to cost me a mint to implement?

Answer:

No. There's no one-size-fits all approach to data security, and what's right for you depends on the nature of your business and the kind of information you collect from your customers. Some of the most effective security measures—using strong passwords, locking up sensitive paperwork, training your staff etc.—will cost your next to nothing and you'll find free or low cost security tools at non-profit websites dedicated to data security furthermore, it's cheaper in the long run to invest in better data security that to lose the goodwill of your customers defend yourself in legal actions, and face other possible consequences of a data breach.

- Investigate security incidents immediately and take steps to close of existing vulnerabilities or threats to personal information.
- Consider whom to notify in the event of an incident, both inside and outside your organization. You may need to notify consumers, law enforcement, customers, credit bureaus, and other businesses that may be affected by the breach. In addition, many states and the federal bank regulatory agencies have laws or guidelines Box 4424, Youngstown, OH 44515ing data breaches. Consult your attorney.

ADDITIONAL RESOURCES

These websites and publications have more information on securing sensitive data:

- Federal Trade Commission's Interactive Tutorial <u>www.ftc.govinfosecurity</u>
- National institute of Standards and Technology (NIST)'s Computer Security Resource Center <u>www.cstc.nist.gov</u>
- NIST's Risk Management guide for Information Technology Systems <u>www.csrc.nist.gov/publications/</u> nistpubs/800-30/sp800-30.pdf
- Department of Homeland Security's National Strategy to Secure Cyberspace <u>www.dhs.gov/xlibrary/assets/</u> National_Cyberspace_Strategy.pdf
- SANS (SysAdmin, Audit, Network, Security) Institute's Most Critical Internet Security Vulnerabilities <u>www.sans.org/top20</u>
- United States Computer Emergency Readiness Team (US-CERT) <u>www.us-cert.gov</u>
- Carnegie Mellon Software Engineering Institute's CERT Coordination Center <u>www.cert.org/orther_sources</u>
- Center for Internet Security (CIS) <u>www.cisecurity.org</u>
- The Open Web Application Security Project <u>www.owasp.org</u>
- OnGuard Online <u>www.OnGuardOnline.gov</u>

The FTC works for the consumer to prevent fraudulent, deceptive, and unfair business practices in the marketplace and to provide information to help consumers spot, stop, and avoid them. To file a complaint or to get free information on consumer issues, visit ftc.gov or call toll-free 1-877-FTC-HELP (1-877-832-4357); TTY: 1-866-653-4261. The FTC enters Internet, telemarketing, identity theft, and other fraud-related complaints into Consumer Sentinel, a secure online database available to hundreds of civil and criminal law enforcement agencies in the U.S. and abroad.

Opportunity to Comment

The National Small Business Ombudsman and 10 Regional Fairness Boards collect comments form small businesses about federal compliance and enforcement activities. Each year, the Ombudsman evaluates the conduct of these activities and rates each agency's responsiveness to small businesses. Small businesses can comment to the Ombudsman without fear of reprisal. To comment, call toll-free 1-888-REGFAIR (1-888-734-3247) or go to www.sba,gov/ombudsman.

Information Compromise and the Risk of Identity Theft:

Guidance for Your Business

These days, it is almost impossible to be in business and not collect or hold personally identifying information – names and Box 4424, Youngstown, OH 44515, Social Security numbers, credit card numbers, or other account number – about your customers, employees, business partners, student, or patients. If this information falls into the wrong hand, it could put these individual at risk for identity theft.

Still, not all personal information compromises result in identity theft, and the type of personal information compromised can significantly affect the degree of potential damage. What steps should you take and whom should you contact if personal information is compromised? Although the answers vary from case to case, the following guidance from the Federal Trade Commission (FTC), the nation's consumer protection agency, can help you make smart, sound decisions.

Check federal and state laws or regulation for any specific requirement for your business.

NOTIFYING LAW ENFORCEMENT

When the compromise could result in harm to a person or business, call your local police department immediately. Report your situation and the potential risk for identity theft. The sooner law enforcement learns about the theft, the more effective they can be. If your local police are not familiar with investigating information compromises, contact the local office of the FBI or the U.S. Secret Service. For incidents involving mail theft, contact the U.S. Postal Inspection Service. Check the blue pages of your telephone directory or an online search engine for the number of the nearest field office.

NOTIFYING AFFECTED BUSINESSES

Information compromises can have an impact on your businesses other than yours, such as banks or credit issuers. If account access information – say, credit card or bank account numbers – has been stolen from you, but you do not maintain the accounts, notify the institution that does so that if can monitor the accounts for fraudulent activity. If you collect or store personal information on behalf of other business, notify them of any information compromise, as well.

If names and Social Security numbers have been stolen, you can contact the major credit bureaus for additional information or advice. If the compromise may involve a large group of people, advise the credit bureaus if you are recommending that people request fraud alerts for their files. Your notice to the credit bureaus can facilitate customer assistance.

Equifax

U.S. Customer Services Equifax Information Services, LLC Phone: 1-800-685-1111 Email: <u>businessrecordsecurity@equifax.com</u>

Experian

Experian Security Assistance P.O. Box 72 Allen, TX 75013 Email: BusinessRecordsVictimAssistance@experian.com

TransUnion

Phone: 1-800-372-8391

If the information compromise resulted from the improper posting of personal information on your website, immediately remove the information from your site. Be aware that Internet search engines store, or "cache," information for a period of time. You can contact the search engines to ensure that they do not archive personal information that was posted in error.

NOTIFYING INDIVIDUALS

Generally, early notification to individuals whose personal information has been compromised allows them to take steps to mitigate the misuse of their information. In deciding if notification is warranted, consider the nature of the compromise, the type of information taken, the likelihood of misuse, and the potential damage arising from misuse. For example, thieves who have stolen names and social Security numbers can use this information to cause significant damage to a victim's credit record. Individuals who are notified early can take some steps to prevent or limit harm.

When notifying individuals, the FTC recommends that you:

- consult with your law enforcement contact about the timing of the notification so it does not impede the investigation.
- designate a contact person within your organization for releasing information. Give the contact person the latest information about the breach, your response, and how individuals should respond. Consider using letters, websites, and toll-free numbers as methods of communication with those whose information may have been compromised.

It is important that your notice:

- describes clearly what you know about the compromise. Include how it happened; what information was taken, and, if you know, how the thieves have used the information; and what actions you have taken already to remedy the situation. Explain how to reach the contact person in your organization. Consult with your law enforcement contact on exactly what information to include so your notice does not hamper the investigation.
- explains what responses may be appropriated for the type of information taken. For example, people whose Social Security numbers have been stolen should contact the credit bureaus to ask that fraud alerts be placed on their credit reports.

See <u>www.ftc.govidtheft</u> for more complete information on appropriate follow-up after a compromise.

- includes current information about identity theft. The FTC's website at <u>www.ftc.gov/idtheft</u> has information to help individuals guard against and deal with identity theft.
- provides contact information for the law enforcement officer working on the case (as well as your case report number, if applicable) for victims to use. Be sure to alert the law enforcement offices working your case that you are sharing this contact information. Identity theft victims often can provide important information to law enforcement. Victims should request a copy of the police report and make copies for creditors who have accepted unauthorized charges. The police report is important evidence that can help absolve a victim of fraudulent debts.
- encourages those who discover that their information has been misused to file a complaint with the FTC at <u>www.ftc.gov/idtheft</u> or at 1-877-ID-THEFT (877-438-4338). Information entered into the Identity Theft Data Clearinghouse, the FTC's database, is made available to law enforcement.

MODEL LETTER

The letter is a model for notifying people whose names and Social Security numbers have been stolen. In cases of stolen Social Security numbers, it is important that people place a fraud alert on their credit reports. A fraud alert may hinder identity thieves from getting credit with stolen information because it is a signal to creditors to contact the consumer before opening new accounts or changing existing accounts. Potential victims of a theft also should review their credit reports periodically to keep track of whether their information is being misused. For some victims, weeks or months may pass between the time the information is stolen and the time it is misused.

FOR MORE INFORMATION

This publication provides general guidance for an organization that has experienced information compromised. If you would like more individualized guidance, you may contact the FTC at <u>idt-brt@ftc.gov</u>. Please provide information regarding what has occurred, including the type of information taken, the number of people potentially affected, your contact information, and contact information for the law enforcement agent with whom you are working. The FTC can prepare its Consumer Response Center for calls from the people affected, help law enforcement with information from its national victim complaint database, and provide you with additional guidance as necessary. Because the FTC has a law enforcement role with respect to information privacy, if you prefer to seek guidance anonymously, you may do so. The FTC works for the consumer to prevent fraudulent, deceptive, and unfair business practices in the marketplace and to provide information to help consumers spot, stop, and avoid them. To file a complaint or to get free information on consumer issues, visit ftc.gov or call toll-free, 1-877-FTC-HELP (1-877-382-4357); TTY: 1-866-653-4261. The FTC enters Internet, telemarketing, identity theft, and other fraud-related complaints into Consumer Sentinel, a secure, online database available to hundreds of civil and criminal law enforcement agencies in the U.S. and abroad.

YOUR OPPORTUNITY TO COMMENT

The National Small Business Ombudsman and 10 Regional Fairness Boards collect comments from small businesses about federal compliance and enforcement activities. Each year, the Ombudsman evaluates the conduct of these activities and rates each agency's responsiveness to small businesses. Small businesses can comment to the Ombudsman without fear of reprisal. To comment, call toll-free 1-888-REGFAIR (1-888-734-3247) or go to www.sba.gov/ombudsman.

MODEL LETTER FOR THE COMPROMISE OF SOCIAL SECURITY NUMBERS

Dear____:

We are contacting you about a potential problem involving identity theft. [Describe the information compromise and how you are responding to it.]

We recommend that you place a fraud alert on your credit file. A fraud alert tells creditors to contact you before they open any new accounts or change your existing accounts. Call any one of the three major credit bureaus. As soon as one credit bureau confirms your fraud alert, the others are notified to place fraud alerts. All three credit reports will be sent to you, free of charge, for your review.

EquifaxExperianTransUnionCorp800-685-1111888-397-3742800-680-7289

Even if you do not find any suspicious activity on your initial credit reports, the Federal Trade Commission (FTC) recommends that you check your credit reports periodically. Victim information sometimes is held for use or shared among a group of thieves at different times. Checking your credit reports periodically can help you spot problems and address them quickly.

If you find suspicious activity on your credit reports or have reason to believe your information is being misused, call [insert contact information for law enforcement] and file a police report. Get a copy of the report; many creditors want the information it contains to absolve you of the fraudulent debts. You also should file a complaint with the FTC at <u>www.ftc.gov/idtheft</u> or at 1-877-ID-THEFT (877-438-4338). Your complaint will be added to the FTC's Identity Theft Data Clearinghouse, where it will be accessible to law enforces for their investigations.

We have enclosed a copy of *Take Charge: Fighting Back Against Identity Theft,* a comprehensive guide from the FTC to help you guard against and deal with identity theft.

[Insert closing] Your Name

Southern Adjustment Services, Inc.

Code of Conduct: The mission of each and every employee of **Southern Adjustment Services, Inc.** is to serve the needs of our clients and their customers with respect, integrity, and always within laws and regulations governing our industry. **Southern Adjustment Services, Inc.** has established a code of conduct setting forth principles and guidelines with respect to ethics and integrity expected to be followed at all times when representing **Southern Adjustment Services, Inc.**. The following code of conduct is to be read, understood, and signed as a condition of employment with **Southern Adjustment Services, Inc.**

EAGLE GROUP XX Mission Statement Southern Adjustment Services, Inc. is a nationally recognized firm focused on providing Asset Management and Recovery Services to financial and commercial customers. We are committed to our customer's complete satisfaction as we help them profitably manage their accounts receivable. Our goal is to partner with our customers by providing what they want, when they want it properly and cheerfully. On a scale of 1-10, we expect to rate a 10!

Our reputation in the marketplace is defined by our Service, Integrity, and Results.

We will measure our success in terms of our clients' satisfaction. We will seek out the expected results that each individual client requires of our partnership and we will hold ourselves accountable to delivering these results, whatever they may be, to the level of excellence that delights our customers.

Our vision is to be the best company, to be the best employee, and to be the best person! This has been the tradition of our company, this is what our clients deserve, and this is what makes **Southern Adjustment Services**, **Inc.** superior to our competition.

Vision Statement

Our vision at **Southern Adjustment Services**, **Inc.** is to be the best company, to be the best employee, and to be the best person!

Southern Adjustment Services, Inc. CONSUMER COMPLAINT POLICY

INTRODUCTION

An effective customer complaint system is an essential part of our business, members of Southern Adjustment Services, Inc., as it indicates to our customers that quality service is a vital part of what we do. Our complaint handling system is an organized way of responding to, recording, reporting and using complaints to improve service to our customers. It includes procedures for customers to make complaints and guidelines for staff to resolve complaints and provides information to managers and staff that can be used by them to prevent customer dissatisfaction in the future.

An effective customer complaint handling system is an essential part of providing quality service. It is a measure of customer satisfaction. It provides positive feedback about aspects of our service that work well and is a good source of information for improvement.

An effective complaint system creates a second chance to provide service and satisfaction to customers, identifies areas that need improvement, and provides opportunities to strengthen our standing in the industry.

Quality customer service consists of doing the job right and providing appropriate service at the outset. If things go wrong in the process, they can only be made right and quality service must be delivered. Quality service and making things right are the hallmarks of our organization.

Customer complaints represent the experience and feelings not just of the complainants, but of others in similar circumstances who have chosen not to complain. Customer complaints should be acted on in two ways. First, the specific grievance must be resolved, if at all possible. Secondly, information about the nature of the complaint must be kept to provide feedback about our system and processes. Often complaints are an early warning of system concerns held by a larger percentage of customers who experienced similar dissatisfaction but had not bothered to complain.

COMPLAINT HANDLING

The majority of complaints should be handled immediately by the frontline staff. When handling a complaint, the staff must:

- Understand a complainant's needs
- Build rapport
- Listen effectively
- Demonstrate empathy
- Ask the right questions

<u>Guidelines that the staff should always keep in mind when dealing with</u> <u>a customer complaint are:</u>

- Treat complainants respectfully, pleasantly and professionally at all times
- Give their names, greet the person courteously and ask in a positive manner how they can help
- Listen to what the person has to say
- Use good listening skills
- Seek clarification of any points that are not clear and do so in a non-judgmental way
- Provide any relevant information that will assist the complainant to better understand the decision or action
- Show empathy

- Try to meet any reasonable request that would solve the problem
- Offer solutions that can be delivered
- Take responsibility for solving the problem on the spot
- Handle complaints quickly, within established timeframes
- Log the complaint and action taken for future analysis

CONSUMER DISPUTE FORM

All customer complaints received must be addressed on our approved Consumer Dispute Form. All relevant information needs to be completed and once completed the form must be turned into our compliance officer.

It is the company's policy to make this Consumer Dispute Form open and accessible to our customers. Our employees are never permitted to dissuade or discourage a customer from making a complaint of any kind.

COMPLAINT HANDLING PROCESS

Any customer that wishes to file a complaint, will be presented with the Consumer Dispute Form (CDF) that is made available in this manual. In the event that a customer cannot pick up the form in person, the form is also available, upon request via USPS, fax, email or from our website. Customers will also have the ability to file a complaint via the telephone. If a customer needs assistance in filling out the CDF, it is our policy to provide assistance to that customer. Upon receipt of the completed CDF, it shall be forwarded to our Compliance Officer for review and resolution. Within five (5) days of receipt of the CDF by the Compliance Officer, the customer will be sent, via certified mail, a letter outlining the results of the investigation and what, if any, action was or will be taken. In addition, a copy of the CDF and customer letter will be sent the client, if the complaint relates to a matter involving a specific client concern.

While complaints will be handled by our Compliance Officer, procedures for resolving, investigating and handling complaints will be escalated to the company ownership depending on their seriousness and complexity. This decision will be made upon the initial review of the complaint by the Compliance Officer.

When reviewing each CDF, the Compliance Officer shall review all relevant information related to the complaint, including but not limited to the customer's statement, statements from involved employees, and any photos and/or video that may be available, if applicable to the complaint.

In order to protect the confidentiality of CDFs, all CDF details are not to be shared with anyone other than those parties directly involved in the CDF. Any and all CDFs will be filed and stored in a secure area where only the Compliance Officer and company ownership will have access. All CDFs will be maintained for a period of seven years.

CDF LOG

All CDFs will be kept and updated in our CDF log. Every month, the Compliance Officer and our ownership shall review the CDF log and decide if additional training is needed among the staff, if policies need to be updated or changed, or if any other issue that is presented by the CDFs needs to be addressed.

OWNERSHIP RESPONSIBILITY

Nothing in this procedures manual changes the fact that the ultimate responsibility for all customer complaints is with ownership. Our ownership takes our customer complaints very seriously and believes addressing and resolving them is of utmost importance to our business, our clients, our customer and our industry.

Application

This Policy applies to all employees, officers, director, representatives and advisors of the firm. These policies are to be made available to all employees, officers, directors, representatives, advisors, regulatory boards, customers, clients and the general public. These policies are reviewed annually and are written and updated in plain, understandable English.

Control Objective

This Policy's objective is to minimize damage to our reputation and reduce the risk of litigation by handling complaints from our customers and/or clients in a timely, effective and consistent manner, while identifying areas of where we can increase our level of service.

Person Responsible

The Compliance Officer is hereby designated as responsible for the application of this policy, and to review this policy on a regular basis to ensure that it continue to comply with industry laws, regulations, guidelines and best practices. *The Compliance Officer* is also responsible to communicate this firm's policy to all employees, officers, director, representatives and advisors of the firm.

When the firm receives a complaint, an acknowledgment letter must be sent to the customer and/or client within 5 business days. This letter must include the following elements:

- Name of the person responsible for handling the customer and/or client's complaint;
- Key elements of the firm's Complaint Policy;
- Option to give detail account of complaint;
- Expected delay of the outcome.
- Suggestion box that gives complainant the opportunity to give our company suggestions to improve our customer service.
- All Complaints must be immediately reported to the Compliance Officer.
- All complaints must be logged in the Complaint Log. The Complaint Log must, at least, include the following information:

DDDDate of complaint;

Complainant's name;

complaint;

Output Output Output Constant Const

The date and conclusions of the decision

rendered in

connection with the complaint.

• Complaints in the Complaint Log must be maintained for a period of 7 years, following the resolution date.
CONSUMER DISPUTE FORM
Consumer Name
Date of Complaint
Specific Nature of Dispute:
specific Nature of Dispute.
·
Responsible Party to Investigate Dispute
Date of Investigation
Action Taken:
For supervisor use only

Name of reviewing supervisor
Was the consumer notified of the action taken in response to the complaint? YES NO
Was the complaint handled in accordance with our complaint handling procedures manual.
If not, explain why it was not and what action has been taken to ensure compliance in the future.
Is any further action required in reference to the dispute?
If yes, what additional steps are being taken:
Has the dispute been logged in the consumer dispute log YES NO

Г

Change of Procedures and Disciplinary Measures

Compliance Officer, Senior Management and Company Ownership must monitor the complaint log and ensure that appropriate disciplinary measures are taken if necessary and provide recommendations for change in the company's procedures if appropriate.

	Third	Party Disagre	eme	nt / P	roble	m Repor	ť		
Open Date:	Time:		Res	olved I	Date:	L	og #:		
Name of initial contact pers (if applicable)	son			Acco	unt #				
Name of Supervisor Taking Call:]			Clien	t:				
Supervisor Assigned To:				R/P I	Name:				
Third Party Name:						Attorney's plicable):			
NATU	IRE O	F THIRD PARTIE	es di	SAGR	EEME	ENT / PRO	BLE	M	
 ✓ Agency Related 		✓ Identity Relat	ted	~		yment elated	~	Cli	ent Related
Agent's Attitude		Wrong Party		B	alance				e Goods or orized Charge
Recovery Practice	R	Consumer esponsibility		В	illing E	rror			
Recovery Practice (face to face)	, ∟]			harge	or fees		Dispute	ed
Good Recovery Call]						Obsole	te Debt
]					🗆	Insurar	ice
Remarks: Describe Incider	it								
ACTION TAKEN (if anv):									
Corrective Action Req.?		lf Yes, Targeted Date	Resol	ution		Correct	ive Ac No.	ction	

Compliance Procedures

Written Consumer Disputes Concerns and Issues

1.0 PURPOSE

This procedure is to ensure all consumer, approved third party, or consumer's attorney disputes are handled in accordance with the Fair Debt Collection Practices Act (FDCPA), the Fair Credit Reporting Act (FCRA), state laws and regulations and the company's philosophies.

2.0 SCOPE

This procedure applies to all company personnel who deal with written consumer or consumer's attorney disputes.

3.0 DEPARTMENTS RESPONSIBLE FOR IMPLEMINTATION

- 3.1 Director of Compliance (DOC)
- 3.2 Compliance Assistant (CA)
- 3.3 Recovery
- 3.4 Client Services

4.0 GENERAL

- 4.1 All written disputes are directed to the Director of Compliance / Compliance Assistant for review.
- 4.2 DOC or CA will log the issue in an appropriate manner.
- 4.3 DOC or CA will fill out third party disagreement report when necessary.
- 4.4 If it is determined to continue collection of the debt, a written response is prepared and sent to the consumer, approved third party or consumer's attorney by the DOC or CA assigned.
- 4.5 If the consumer, approved third part or consumer's attorney writes that we cease all communications and recovery efforts, or write that they will not pay the debt, all precautions are taken to ensure we never contact the consumer or consumer's attorney again.
- 4.6 If it is determined that it is not beneficial to respond to the dispute, the account will be returned to the client as disputed.

5.0 PROCEDURE

- 5.1 The person opening the mail will direct all written disputes to the DOC or CA as appropriate.
 - 5.2 The DOC OR CA
 - 5.2.1 Will notate the account describing the consumer or consumers attorney's dispute and review the dispute
 - 5.2.2 Will fill out third party disagreement report when necessary and direct the issue to the employee's manager (if applicable)
 - 5.2.3 Will log dispute in an appropriate manner.
 - 5.2.4 Disputes requesting the agency to cease communications the DOC or CA will:
 - Return the account to the client as a disputed account; or
 - Cease any and all recovery attempts
 - Flag all phone numbers as do not call numbers;
 - Notate account with dispute information;
 - Indicate we are to cease communication and recovery efforts with the consumer or consumer's attorney;
 - Review account to determine if this is a good prospect for legal action;
 - Request the consumer reporting agency to flag the account as disputed on the consumer's credit report; and
 - Image the dispute letter.
 - 5.2.5 Disputes requesting verification of the debt the DOC or CA assigned to the claim will:
 - Obtain a complete and accurate Itemized Statement either electronically or from Client Services and send it to the consumer, approved third party or consumer's attorney.
 - 5.2.6 Specific disputed requiring client resolution the DOC or CA assigned will turn over the Client Services to obtain the pertinent information
 - 5.2.7 Work with Client Services and the client to investigate the dispute and obtain any necessary information including a complete and accurate itemized statement

- 5.2.8 Formulate a written response to mail with the itemized statement
- 5.2.9 Disputes determined to be valid or the balance does not warrant extensive investigation, the Compliance Manager or CA will return the account to the client as disputed

6.0 RECORDS

A digital image of the written dispute and, if applicable, the written response is attached to the consumer's account. Third party disagreement report log is maintained by QA for 12 months.

7.0 FORMS

7.1 CF_806-1	Third Party disagreement/Problem Report
7.2 CF_806-3	Third Party Disagreement Compliance Log Worksheet
7.3 CF_806-6	Agency Compliance Log Worksheet

1.0 PURPOSE

This procedure is to ensure all verbal consumer, consumer's attorney, or third party disagreements are handled in accordance with the Fair Debt Collection Practices Act (FDCPA), the Fair Credit Reporting Act (FCRA), state laws and regulations and the company's philosophies.

2.0 SCOPE

This procedure applies to all company personnel who deal with verbal consumer, consumer's attorney, or third party disagreements.

3.0 DEPARTMENTS RESPONSIBLE FOR IMPLEMENTATION

- 3.1 Quality Assurance
- 3.2 Direct of Compliance
- 3.3 Department Manager
- 3.4 All Staff

4.0 GENERAL

- 4.1 When a claim escalates to Manager/Supervisor, the Manage/Supervisor will complete the third Party Disagreement/Problem Report. It is then given to Quality Assurance.
- 4.2 Quality Assurance logs and turns the dispute over to appropriate Department Manager. Upon total resolution will shred all Third Party Disagreements.
- 4.3 Department Manager determines if corrective action is necessary and initiates follow-up. Will present closed Third Party Disagreements at regularly scheduled meeting.

5.0 PROCEDURE

- 5.1 The Third Party disagreement/Problem Report is completed by the Manager/Supervisor taking the escalated call and given to Quality Assurance.
- 5.2 Department Manager/Supervisor taking the escalated call.
 - 5.2.1 Will notate the account in FACS describing the consumers, consumer's attorneys or third party disagreement.
 - 5.2.2 Will listen to the call if available, coach and mentor the Recovery Agent.

- 5.2.3 Will fill out the Third Party Disagreement/Problem Report and submit the report to Quality Assurance.
- 5.2.4 Will work with Client Services and/or Sales if the disagreement needs resolution from the client when applicable.
- 5.2.5 Will attend regularly scheduled monthly meetings.
- 5.3 Quality Assurance
 - 5.3.1 Will log the disagreement on the Third Party Disagreement Log.
 - 5.3.2 Will direct the Third Party Disagreement to the employee's manager.
 - 5.3.3 Log the resolution date of the Third Party Disagreement and shred all Verbal Third Party Disagreements once the disagreement has been discussed in the monthly meeting.
 - 5.3.4 Will coordinate the monthly meeting so the Supervisor or Manager who took the call can present third party disagreements.
- 5.4 Department manager
 - 5.4.1 Will review the Third party Disagreement.
 - 5.4.2 Will determine if corrective action is required.
 - 5.4.3 Will attend all regularly scheduled monthly meetings.
 - 5.4.4 Upon resolution of a Third Party Disagreement, will be present and discuss solutions at scheduled monthly meetings when the original Supervisor or individual that took the call is not in attendance.

Will return Third Party Disagreements to Quality Assurance with a resolution date.

6.0 RECORDS

The Third Party Disagreement/Problem Reports are shredded when deemed obsolete. The Consumer Dispute log is maintained by Quality Assurance for 12 months.

7.0 FORMS

7.1 CF 806-1Third Party Disagreement/Problem Report

7.2 CF 806-3 Third Party Disagreement compliance Log Worksheet

7.3 CF 806-6 Agency Compliance Log Worksheet

7.4 CF 1201-1Non-Conformity Log

1.0 PURPOSE

The purpose of this procedure is to give direction on following recovery regulations.

2.0 SCOPE

This procedure applies to recovery regulations for FDCPA, FCRA, HIPAA and all other state and federal laws and regulations.

3.0 DEPARTMENTS RESPONSIBLE FOR IMPLEMENTATION

3.1.1 ALL

4.0 GENERAL

All employees must be educated in and educated in and follow the requirements of any and all recovery agency regulations.

5.0 PROCEDURE

- 5.1 All employees will adhere to the requirements of:
 - 5.1.1 The Fair Debt Collection Practices Act (FDCPA)
 - 5.1.2 The Fair Credit Reporting Act (FCRA)
 - 5.1.3 Gramm-Leach-Bliley Act (GLBA)
 - 5.1.4 All other applicable state and federal laws
- 5.2 Compliance:
 - 5.2.1 Will notify all employees of any changes in the regulatory requirements and update all reference materials used by **EAGLE GROUP XX** staff.
 - 5.2.2 Have all notices in use reviewed and approved as compliant with regulatory requirements by our company attorney.
 - 5.2.3 Inspect automated processes (i.e., Credit Bureau Reporting, Written disputes and Direct disputes via e-Oscar) to ensure compliance with all regulatory requirements.
 - 5.2.4 Will Update Trainers of any new laws.
- 5.3 Training will:
 - 5.3.1 Hold regular training classes to review laws.

6.0 RECORDS

All records are maintained in accordance with Management of Records and Data.

7.0FORMS

- 7.1 CF 807-1 Credit Bureau Data Change Form
- 7.2 CF_806-2 CONSUMER DISPUTE LOG

7.3 CF_806-3 THIRD PARTY DISAGREEMENT COMPLIANCE LOG WORKSHEET

7.4 CF_806-6 AGENCY COMPLIANCE LOG WORKSHEET

Assignment of Access Privileges

RESPONSIBILITY: Director of Information Systems, Chief of Operations

BACKGROUND:

Not all members of the **Southern Adjustment Services**, **Inc.** workforce need to have access to all protected information or non-public financial information about consumers. Our Agency assigns minimum access profiles to all job titles on the basis of how much information, pertaining to which types of claims, is needed to accomplish work assignments.

These access profiles are used for two purposes:

- 1. For NPPI that is entered or stored electronically, the access *profile* determines which information an individual member of the workforce may read through a computer terminal.
- 2. Also, access profiles are incorporated into job descriptions and training materials so that all members of the workforce will know which protected information, whether electronic or not, they are permitted to see or use. A supervisor may request that an access profile be expanded, creating a new access profile, for a member of the workforce who has a greater 'need to know," based upon additional job responsibilities.

POLICY:

Southern Adjustment Services, Inc. will maintain access profiles to specify which protected information may be used by workforce members in each job class. These profiles will specify the data elements that comprise protected information.

Access profiles are based upon two principles: First, that access to information must not be so restricted as to interfere with the quality or efficiency of Access profiles will comply with the **MINIMUM NECESSARY RULE**.

Access profiles will be used to limit electronic access to protected information.

Access profiles will also be incorporated into job descriptions and training materials, to assure that each member of the workforce is aware of what information he or she may and may not see and use.

Access profiles will include types of information (e.g., personal, financial, or demographic), types of consumers (e.g., from a particular area, at a particular site, or from any restricted site), dates of service (e.g., within this month, or paid in last 90 days), and other pertinent identifiers that define which data may or may not be read.

Upon successful demonstration of need, a specific access profile may be modified for members of the workforce who have a demonstrated need to read additional information to accomplish their work assignments. Access profiles will be reviewed and revised annually, or upon request of a member of management when a new job is created, when a job or class of jobs changes significantly, or when experience shows a need to make a modification.

REVIEW PROCEDURE;

- 1. An ad hoc access profile committee will be comprised of the following, or their designees;
 - Director of Information Systems (chair)
 - Designated Privacy Official
 - Designated Security official
 - Chief of Operations
- 2. The ad hoc access profile committee will
 - Review job descriptions and assign them to job classes, based on the NPPI required to accomplish the job efficiently.
 - Assign NPPI data elements to categories
 - Assign categories of NPPI to job categories, to form access profiles
 - Review access profiles annually, or when requested
 - Have new access profiles and job classifications reviewed by managers to whom the affected jobs report, and make such changes as are warranted to satisfy the two principles of quality and efficient care and patient privacy.
- 3. The Human Resource Coordinator will incorporate each job's access profile into the job description and into training materials, to assure that each member of the workforce is aware of what information he or she may see and use, and which he or she is not permitted to see or use.
- 4. The Director of Information Systems will assure that members of the workforce have electronic access to NPPI that is consistent with their access profiles. Records of how this is achieved will be retained for as long as a given access profile is in effect, until the date it is supplanted by a revised profiled, plus six years.
- 5. Job classes, NPPI classification, access profile composition, and access profile assignments will be recorded. The record will include brief descriptions of the rationale behind classification and assignment decisions. Each of these records will be kept for six years after the date it is superseded by a revision.

- 6. In situations where a member of the workforce requires additional access based upon work assignments, that person's supervisor may submit a request for modification of that employee's access profile. All requests should include evidence of additional responsibilities and training to support the need for modified access.
- 7. The access profile committee will keep minutes. Minutes will be retained for six years.

RATIONALE:

Southern Adjustment Services, Inc. may use role-based *access control*, while recognizing that, in some circumstances, a person's job may be so unique as to constitute a role in its own right.

Job and data classification if entrusted to a committee representative of the principal areas of expertise necessary to achieve the objective of this classification system.

Two principles guide the development of access profiles: the quality and efficiency of claim management, and the privacy and security of consumer information.

The same access profiles are used to develop electronic access controls, and training and job standards, to guide access to any NPPI in whatever medium: paper, voice, electronic, or other medium.

See also: MINIMUM NECESSARY RULE ROUTINE AND RECURRING DISCLOSURES OF PROTECTED NON PUBLIC PERSONAL INFORMATION

NPPI Sec	urity P&F	P Checkli	st		
	Have it already?	Is it current?	GLBA compliant	Updated?	Training done?
1. General Guidelines to Safeguard			•	•	
Protected Information					
2. Risk Analysis and Ongoing Risk					
Management					
3. Sanctions for Violation Privacy and					
Security Policies and Procedures					
4. Activity Review of Information System Security					
5. Assignment of Security Responsibility					
6. Assignment and Management of					
Information Access Privileges					
7. Termination or Modification of access					
to Protected Information: Facility Controls and Electronic Systems					
8. Training Program: Security Awareness					
and Training to Safeguard Electronic					
Protected Information					
9. Security Incident Procedures:					
Response and Reporting 10. Contingency Planning: Response to					
Unexpected Negative Events					
11. Evaluation of the Security of Protected					
Information					
12. Business Associates Contracts and					
Other Arrangements					
13. Maintenance of Privacy and Security					
Policies and Procedures					
14. Assignment of Facility Access					
Controls or Privileges 15. Policies and Guidelines on Work					
Station Use and Security					
16. Device and Media Controls					
17. Access Control	1				
18. Audit Controls	1				
19. Integrity					
20. Authentication of Person or Entity					
21. Electronic Transmission Security of PHI					
22. E-Mail and Protected Information					
23. Facsimile Machines and Protected Information					

Written Disputes

- **Description:** Working guide to receiving, processing, and following up on written disputes from consumers and their attorneys. Also includes description of common dispute types, as well as the time deadlines associated with each type as outlined in the FDCPA and FCRA.
- **Scope:** Applicable to any written correspondence from consumers, attorneys, and authorized third parties that contains dispute language.

System Used: FACS (DEF, BEL, SEN), FACSWORD.

Who is Responsible: This process is interdepartmental, and is networked between Business Support, Compliance, and Client Services.

Frequency of work: Daily

Important Information

An understanding of the implications of FDCPA and FCRA as they pertain to written disputes is a key part of this process, so please read the following carefully.

FDCPA

For the purposes of this instruction, the FDCPA applies as follows:

- a. Any dispute received and postmarked within 30 days of the initial validation notice *must* be verified unless we are ceasing all recovery efforts.
- b. There is no time period within which the debt must be verified.
 - i. It is the opinion of the Compliance Department that a consumer is unlikely to pay the debt without verification.
- c. A dispute received at any time must be reported to the consumer reporting agency.
- d. When an account is placed into XDIS or X5DS FACS automatically stamps the account as disputed.

For the purposes of this instruction, the FCRA applies as follows:

a. **Southern Adjustment Services, Inc.** has a duty to perform a reasonable investigation

upon receiving an inquiry regarding what is being reported to the consumer reporting agency.

- b. The investigation and response to the inquiry must be completed within 30 days of receipt of the inquiry.
- c. It *is not* necessary to provide an itemized statement in response to the inquiry.
- d. It *is* necessary to mark the account as disputed.

Procedure

Once received and scanned by Business Support Representative, disputes will be forwarded to the Compliance Assistant.

1. FACS operation

- a. Enter menu 8.1.1 or 7.1.1 depending on access.
- b. Located the account number and enter it at the account prompt.
 - Be sure that the dispute is being worked in the correct directory (DEF, BEL, OR SEN).
- c. Verify that the dispute has been imaged in the 47 or IM window.
- d. Verity that the name in the responsible party field matches the name on the dispute.
 - If the dispute is from an attorney, verity that the correspondence references the responsible party, or the attorney who is listed in the **22** or **DA** window.
 - If attorney who wrote the letter is dispute is not listed in the 22 or DA window, list them there and place an "H" on all phone fields.

2. "Slot" the dispute

- a. Read the dispute in its entirety, being sure to note any attached documentation (i.e., copies of cancelled checks, EOB's client correspondence, etc.).
- b. Determine the reason the account is being disputed and refer to the instructions contained in the corresponding "slot" in Appendix i: Dispute Types*

3. Complete the 666 window (if applicable)

- a. If the account needs further attention from Client Services be sure to leave written instructions in the **666** window.
 - **Note:** A synopsis of the dispute is not necessary at this juncture of the process, simply detail the steps to be followed by the Representative once they receive the account.
- b. Fill in the "Request Type:" field at the bottom of the window with the number that corresponds to the reason the account is being forwarded to Client Services.

4. Notate FACS

- a. Once the steps outlined in *Appendix i* have been completed, created a note in the **8** or **N** window detailing the contents of the dispute correspondence and what action was taken.
- b. Also note any new location information included within the correspondence.
- c. Place the account in the proper disposition with the appropriated wait date as outlined in *Appendix i.*

5. Update the dispute Log

- a. The log is contained in (Your File Code) \Company\Disputes.
- b. Locate the account number in the "Dispute Image to Account #:" column.
- c. Fill in the "Dispute Reviewed By:" column with initials.
- d. Fill in the "Date:" column with the date the dispute was worked.
- e. Save and close log once finished.

6. Shred documents.

a. Shred all dispute correspondence including attachments *For a visualization of the Dispute Process, and a list of letters used, see appendices ii – iii

Appendix: Dispute Types

When step 2 of the Procedure process has been completed, match up the dispute with the corresponding list of dispute types below. Consider the language, intent or implied request, and the "spirit" of the FDCPA and FCRA when taking any action on a dispute. If unable to it a particular dispute into a single slot, or any slot at all, submit it to Compliance for review.

Dispute Type "Standard" dispute includes "I dispute" somewhere, or is a form letter mentioning a "confusing item" on a consumer report or "I am informed that your company must provide verification"	 Who Handles the Dispute and How Received within 30 days of list: Make a note in the 666 window that an itemized statement needs to be sent to the consumer. Place the account in X5DS with no wait date, and Client Services will respond. Received outside 30 days of list: Send the balance due letter (201) to the consumer. Return the account to last known call disposition with a wait date of 30 days.
Repeated disputes written either directly to ABC or to the consumer reporting agencies via E-Oscar, without any new information	If a consumer continually sends disputes, refer to the guidelines listed in <i>Appendix iii:</i> Letter List. If letters regarding the dispute have been sent previously, simply note FACS that another letter of dispute was received, place in last call disposition and log the dispute.
Paid in full claims consumer states balance been paid previously	Make a note in the 666 window stating that consumer made the claim, and include any proof of payment information included (check number, date, amount, etc.) Place account into X5DS with no wait date, where it will be reviewed by Client Services and verified with the client.
Disputing based on insurance consumer states insurance was never billed, billed incorrectly, etc.	Notate any new insurance information in the 667 window (insurance cards, Medicare/Medicaid numbers, etc.) Make note in the 666 window stating new insurance information is available and place the account in S5DS with no wait date.

Client issues consumer states won't pay due to negligence in services provided, threatening to file complaint or legal action against client, etc.	Make a very specific note in the 844 window notifying the client of the contents of the dispute. Keep in mind that the 844 letter pulls directly from this window, so the client will read whatever is printed there. Print the letter and forward it to Client Services.
Identity theft or forgeries consumer claims services were not rendered to them, ID was stolen, never been to client's hospital, etc.	If the dispute contains a police report or supporting documentation of any kind, make a note in the 666 window requesting that the imaged material be reviewed by Client Services, and place the account in X5DS. If no supporting documentation is provided, make a note on the account for a collector to call and ask consumer to forward that information to State. Put in XATT and forward to Collection Supervisor.
Ceases Consumer states wants no more calls, no more correspondence, "stop harassing me," "I refuse to pay," etc.	Place holds on all phone fields using the "!" character not the "H." Place the account in 3600 with no wait date. If balance is large enough and the consumer is employed, place account in 0040 with a 30 day wait date to pursue possible legal action.
Bankruptcies the account is disputed due to bankruptcy filing	Note any bankruptcy information received in the 807 or BANKO window and follow normal bankruptcy procedures. If no information is included, call VCIS to locate it.
Collection practices dispute Consumer is upset by the action of a collector, actions of ABC as a whole, or threatens any sort of recourse against State	Handle any requests or demands the consumer lists as stated in above slots. When finished forward the document to the Compliance Manager who will in turn investigate the claim and open a Third Party Disagreement/Problem. Quality Assurance will then log the Third Party Disagreement/Problem.
Divorce consumer states not responsible due to divorce.	Check to see if date of divorce is included on account or dispute. If it is, determine if consumer or ex-spouse (or both) is responsible. If it is not, check CCAP or forward to Collection Supervisor to have collector call consumer to locate proper information. Make sure to include detailed note in FACS.
Deceased Spouse or third party such as an attorney or family member disputes an account based on the fact that the consumer is deceased	Follow standard probate procedures (see work instruction "Filing A Probate Claim" located in company/ppmsworkinstructions/specialservices).
Miscellaneous consumer states we have wrong person, reporting on incorrect consumer report, divorced, minor on date of service, not responsible, etc.	Forward to Compliance Assistant for review.

System Security

1.0 PURPOSE

The purpose of this procedure is to define security measures within the computer systems.

2.0 SCOPE

This procedure applies to all security issues relating to computer systems used for collection purposes.

3.0 DEPARTMENTS RESPONSIBLE FOR IMPLEMENTATION 3.1 ALL

3.1 ALL

4.0 GENERAL

- 4.1 Information Systems will set up new users and remove security at employee termination.
- 4.2 Department Managers will provide all employees in their department with the minimum security access required to perform their jobs, and this security will be reviewed upon a change in job position.
- 4.3 Compliance will inform information Systems of any regulatory changes.
- 4.4 Information Systems will maintain the system security access to comply with regulatory requirements.

5.0 PROCEDURE

5.1 Information Systems will

- 5.1.1 Set up new employees' workstations with the most basic level of security required to run the workstation.
- 5.1.2 Set up all new users with the most basic level of security in the FACS system.
- 5.1.3 Remove workstation and FACS security at time of employee's termination.
- 5.1.4 Assign user passwords at workstations and in FACS.
- 5.1.5 Change password after initial setup if necessary.

5.2 Human Resources will

- 5.2.1 Notify Information Systems when a new user needs to be added to the system.
- 5.2.2 Notify Information Systems to remove user security at an employee's termination.

5.3 Department Managers/Supervisors will

- 5.3.1 Determine the minimum security required for each employee to perform their job and assign that security to their own employees.
- 5.3.2 Only give security to their employee after the employee has been fully trained on how to do the job.
- 5.3.3 Determine whether security should be removed, or more training is necessary if a non-conformity arises relating to security issues.
- 5.3.4 Review the employee's security at time their job functions change to ensure they have only the security required to perform their job duties.
- 5.4 All employees will
 - 5.4.1 Sign the Security Access Request Form when new security is required and give it to their Department Manager.
 - 5.4.2 Be provided with and use the minimum level of system security access required to perform their job duties.
 - 5.4.3 Use the security they are given for only the job functions for which they are responsible.
- 5.5 Collection Manager will maintain and assign company wide security access to adhere to collection regulatory requirements (i.e., disposition and letter control lists, etc.)

6.0 RECORDS

All Records are kept in accordance with ALL_CP_1401 Management of Records and Data.

7.0 FORMS

7.1 CF_1301-1 Computer Access Request Form

8.0 REFERENCE DOCUMENTS

8.1

Skiptracing and Asset Searching

1.0 PURPOSE

The purpose of this procedure is to provide instructions for management of skiptracing and asset searching actions.

2.0 SCOPE

This procedure applies to all skiptracing and asset searching processes and individuals who participate in the skiptracing and asset searching process.

3.0 DEPARTMENTS RESPONSIBLE FOR IMPLEMENTATION

3.1 Recovery Services Department

- 3.2 Compliance
- 3.3 Special Services

4.0 GENERAL

4.1 Acquisition of location information on consumers in the recovery services department.

- 4.2 Acquisition of location information for our clients who have received returned mail on their customers.
- 4.2 Adhere to all regulatory requirements.

5.0 PROCEDURE

- 5.1 Regular Recovery, Financial Recovery and Commercial Recovery, Special Services.
 - 5.1.1 May at any time throughout the recovery process need to locate a consumer's phone number, address or place of employment. Primarily responsible on new business accounts to do this utilizing the work instructions as outlined in the Master Flow Chart.
 - 5.1.2 May utilize specific work queues and pools designed to identify consumers for whom we need to re-establish communication with and recovery of collateral upon those they are able to locate.
 - 5.1.3 Verifies employment for accounts within the special services department so that further post judgment remedies may be taken.

5.2 Recovery Department Supervisors Perform random audits of the recovery services.

5.2.1 Assists in any task given by the Recovery Department Manager in implementing or monitoring any skiptracing or asset searching function in any of the above named departments involved.

5.3 Compliance

5.3.1 Will ensure all departments adhere to the regulatory requirements (in accordance with COM_CP_807).

6.0 RECORDS

All records are maintained in accordance with Management of Records and Data Procedures.

COMMUNICATION IN THE ERA OF CYBERSPACE

In today's world of cyber space communications the professional recovery specialist is faced with many challenges. The majority of the consumer protections laws, both state and federal, were written before any of these cyber space communication tools and web sites were even thought of and therefore are antiquated in application.

I am asked daily about communication via e-mail or voicemail and if there are laws which prohibit this type of communication. My answer is always the same, "**BE VERY CAREFULL AND ERR ON THE SIDE OF CAUTION**".

The advantages of using e-mail, instant messaging and social web sites such as **MYSPACE** and **FACEBOOK** are numerous and indisputable. In today's era of **CYBERBABIES** who only have cell phones, i-pods and computers we often find this is the only method of communication.

But where do we draw the line?

If your agency falls under the auspices of the Fair Debt Collection Practices Act there is the definite risk of third party disclosure and the use of false of misleading statements if you set up a bogus social site account.

If you do not fall under the **FDCPA** then you still have to contend with your state consumer protection law.

When I mention the state law to a lot of recovery specialist I get a blank stare, like duh...what law is that?

Every state has a consumer protection law and as a professional it is your obligation to know what this law says and avoid violations which might occur when using **CYBER SPACE**

COMMUNICATION TOOLS.

If you choose to communicate with a consumer through e-mail then you must absolve or at least minimize your risk. This can be accomplished in several ways, (1) if you are able to obtain express consent and permission from the consumer to receive communications via e-mail. Many of the current credit applications now have a space and check off box for an e-mail Box 4424, Youngstown, OH 44515 and permission to communicate via electronic communication methods. (2) a web site in your name with a check off box and (3) oral permission granted in person or telephonically.

If you choose to communicate via social sites be sure to remember that all those communications are subject to viewing by third parties and there must be so mention of an indebtness, pending legal action or pending repossession.

The methods of communication, cyber tracking and skip tracing are changing daily at a breakneck speed and if we, as **PROFESSIONAL RECOVERY SPECIALISTS**, must change and adapt accordingly in order to continue to operate our business in a profitable manner.

	Sally Student		Graduatio	Graduation Reguirements	nents	
Instructor Name:			Knowledge	Assessme	Knowledge Assessments = 85% Overall	
Class Dates:	09-10-07 to 9-28-07		Quality Ass	Quality Assurance = 75% Overall	% Overall	
			FDCPA Re	equirements	FDCPA Requirements = 100% Overall	- - 1
			Scorecard	Competenc	Scorecard Competencies = 85% (85/100)	
	System Competencies	Week 1	Week 2	Week 3		
	Log in/out - Network	2	2	2	Totals	s
	Log in/out Account Management System	2	2	2	ScoreCard	96.0%
	Log in/out Phone System	2	2	2	Week 1-KA	103%
	Log in/out Dialer	2	2	2		
	Access accounts via Account inquiry	2	2	2	Week 1-QA %	84%
	Identify info on Account Detail Screen	2	2	2	Week 2-KA	
	Properly notes accounts	2	2	2	Week 3-FDCPA	-
	Uses proper transfer procedures	2	2	2	Week 3-KA	97.0%
	Use correct smart codes	2	Ļ	-	Week 3-QA %	84.0%
	Demonstrates knowlegde of Function					
	"F" keys	2	2	2		
	Set Client Web Site Payments		2	2	ATTENDANCE (2)	NCE (2)
	Set up proper Payment Arrangements		2	2	Date	Points
	Set up ACH and Credit Card Payments		2	2		
	Identifies and works linked accounts		2	2		
	Total	20	27	27		
	Role Playing Competencies	Week 1	Week 2	Week 3		
	Demonstrates Communication Skills &					
	Etiquette	2	2	2		
	Demonstrates and applies FDCPA	2	2	2		
	Demonstrates eight steps of collection call				Date	Behavior
	Demonstrates Industry billing practices		2	2		
	Can handle frauds, disputes,		Ţ	,		
	Demonstrates knowledge of Client		-			
	specifics and CIC		2	2		
	Total	4	6	<u>о</u>		

Training Log				
Training Conducted:	:p			Date:
New	Refresher	Required	Optional	Time:
Instructor:				Location:
Attendance Roster:				Attendance Roster:
F				16
2				17
3				18
4				19
5				20
6				21
7				22
8				23
6				24
10				25
11				26
12				27
13				28
14				29
15				30
* Attach progra	m outline with le	arning objecti	ves that meet a spe	* Attach program outline with learning objectives that meet a specific training need or other documentation on how this training meets
			criteria tied to you	criteria tied to your compliance program.

Compliance Issue Tracking Form	
Collections	
Quarter End Legal Incidents Reports BOI	BOLDFACE INDICATES NEW ITEM OR STATUS CHANGE
	INDICATES SPECIAL INTEREST ITEM
	INDICATES ITEM TO BE ARCHIVED
Type / Party Date Account Compliance PSWS Priority Item # Name Reported Number Incident No. Number or A	Case, Filing Nature of Action Deadline Current Date or Action No. / Complaint (if Applicable) Disposition Closed
Legal Actions	
Regulatory Complaints	
Regulatory Inquiries And Letters	
Atorney Communications & Probate Actions	
Consumer Communications with Legal Issues	
Legal Questions, Contracts Letter Approvals & Analysis Requested by:	
Licenses & Registrations	

Month & Year			{S}=	{S} = Satisfactory	SU)	{US} = Unsatisfactory	
Compliance	{s}	Ĵ S	Week 1	Week 2	Week 3	Week 4	Week5
E-Oscar–Queue Completed Daily							
Review of Outbound Mail Daily							
Review and Send Collection Faxes Daily							
Process Mail Disputes Daily							
Respond to DFI & Other Govt Inquiries Timely							

		Client name							
Third Party Disagreement Compliance Log Spreadsheet	N/C or C/I #								
	Category								
		Status							
		Date closed							
		Employee assigned to							
		Agency staff							
		Employee taking complaint							
		Date Received							
		Date discussed							
		Log #							

	Compliar	Compliance Audit Form (Verbal Disputes)	Disputes)	
Collector:		Supervisor:		
Account Number	(Legal / Ethical / Professional)	Requirements Met (FDCPA, FCRA, HIPPA)	Resolution	Comments
Audit Completed By:		Date:		
•				

GLBA / FDCPA / FCRA COMPLIANCE PACKET INSTRUCTION SHEET

Read through all the documents as well as the instruction sheet prior to starting your final procedures.

The number of security officers will depend on the size of your operation as well as the depth of your security checks.

All Security Officers should read pages 33656 through 33659 o 16 CFR 313 (I have provided a hyperlink to the FTC GLBA web site... <u>http://www.ftc.gov/privacy/glbact/glbsub1.htm</u> ... so they have a clear understanding of the data they are charged with protecting.

There are some added forms used to comply with the FDCPA and for general usage.

GLBA Declaration of Compliance – To be signed by the person appointed as "Director of Information Security" and a copy provide to each client.

GLBA Employee Compliance Agreement – To be signed by each employee of your company, no exception. Copy 1 to Personnel File and Copy 2 to the employee.

GLBA Employee/Agent Agreement – To be signed by any outside vendors or agents used by your agency whom might have access to NPPI. Copy 1 to file, Copy 2 to the signor.

DUE DILIGENCE WITH PROTECTED INFORMATION – copy to every employee.

GLBA Information Security and Confidentiality Officer – To be completed and signed as indicated. Copy 1 to file, Copy 2 to ISCO, Copy 3 to Client.

GLBA Security Check Sheets (Administrative, Technical, Physical) – Complete as indicated, Copy 1 to file, Copy 2 to ISCO/s. Perform these checks on a 6 month schedule.

GLBA Federal Register Part III, 16 CFR Part 313 – Copy to file, Copy to each ISCO.

FDCPA – Personal Property Release Receipt – To be signed anytime a consumer pays money to the agency for any reason.

Notice of Intent – Used prior to lien title procedures Voluntary Surrender Receipt – Used when Consumer surrenders property.

INNOVATION IN ACTION UPDATES ON CRITICAL ISSUES AND CHANGES IN THE LAWS AFFECTING YOUR BUSINESS

The FTC's "Red Flag Regulations" To Combat Identity Theft Go Into Effect On November 1, 2008

In 2003, Congress enacted sweeping amendments to the Fair Credit Reporting Act known as the Fair and Accurate Credit Transactions Act ("FACTA"). One of the principal purposes of FACTA is to combat the growing problem of identity theft.

FACTA contains several mechanisms to Box 4424, Youngstown, OH 44515 identity theft. These requirements, which are set forth in 15 U.S.C. §§ 1681 m(e) and 1681c(h), mandate that:

- Financial institutions and other creditors develop and follow comprehensive policies to identify and prevent identity theft.
- Credit card issuers develop and follow policies for issuing additional or replacement cards in response to a request for such cards made shortly after a change of Box 4424, Youngstown, OH 44515 notice is received.
- Users of consumer reports develop and follow procedures to verity the identity of a consumer when the Box 4424, Youngstown, OH 44515 given by the consumer substantially differs from the Box 4424, Youngstown, OH 44515 contained in the consumer report.

Congress left the job of defining the precise contours of the law to a group of regulatory agencies, including the Office of the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, the Office of Thrift Supervision, the National Credit Union Administration and the Federal Trade Commission. These agencies have now issued joint and final rules and guidelines for compliance with §§ 114 and 315 of FACTA, which are known as the "Red Flag Regulations." The Red Flag Regulations take effect on November 1, 2008.

Who is subject to and must comply with the Red Flag Regulations?

The regulations apply to (1) every financial institution or creditor that offers or maintains "covered accounts," (2) credit card issuers and (3) users if consumer reports. Covered accounts include typical consumer accounts, such as mortgage and auto loans, checking accounts, credit card accounts etc.

What are some of the thing that entities subject to the Red Flag Regulations must do to comply?

All financial institutions and creditors who offer covered accounts must develop and implement a program designed to detect, prevent and mitigate identity theft in connection with the opening or operation of those accounts. There are four basic elements that must be included in any compliance program. (1) Identifying relevant "red flags" for covered accounts and incorporating those red flags into an identity theft prevention policy. A red flag is a pattern, practice or specific activity that indicates the possible existence of identity theft. Examples of red flags include the following:

- A fraud or active duty alert include on a consumer report.
- A notice of "credit freeze" on a consumer report.
- A consumer reporting agency providing a notice of Box 4424, Youngstown, OH 44515 discrepancy.
- Documents provided by the consumer that appear to have been altered or forged.
- The failure of the consumer opening the covered account to provide all required personal identifying information on an application.
- The use of a covered account in a manner that is not consistent with established patterns of activity on the account.
- The use of a new revolving credit account in a manner commonly associated with know patterns of fraud, including the use of a majority of the available credit for cash advances or merchandise that is easily convertible to cash, such as jewelry.
- The return of mail sent to the consumer as undeliverable, although transactions continue to be conducted in connection with the account.

(2) Detecting red flags that have been incorporated into the program. In other words, the financial institution or credit grantor must have in place a plan to check for the red flags of identity theft.

(3) Responding appropriately to red flags that are detected.

(4) Ensuring that the program is updated periodically to reflect changes in risk to customers.

Credit card users must establish and implement reasonable policies and procedures to assess the validity of Box 4424, Youngstown, OH 44515 changes that are followed by a request for additional or replacement cards. The new or replacement cards may not be issued until:

• The card issuer clearly and conspicuously notifies the cardholder at his/her former Box 4424, Youngstown, OH 44515 (or by other means of communication previously agreed to) and provides the cardholder with a reasonable means of promptly reporting incorrect Box 4424, Youngstown, OH 44515 changes; or

• The card issuer otherwise assesses the validity of the Box 4424, Youngstown, OH 44515 in accordance with the policies and procedures established as a part of its program.

Users of consumer reports must:

- Develop and implement reasonable policies and procedures that enable them to form a "reasonable belief" that the consumer report relates to the consumer about whom it requested the report when the user receives a notice of Box 4424, Youngstown, OH 44515 discrepancy.
- Under certain circumstances, develop and implement policies and procedures for furnishing an Box 4424, Youngstown, OH 44515 that it has reasonable confirmed is accurate to the consumer reporting agency that provided the notice of Box 4424, Youngstown, OH 44515 discrepancy.

What are the penalties for failure to comply with the Red Flag Regulations?

Financial institutions covered by the Red Flag Regulations are subject to oversight by the appropriate federal banking regulators, which may impose penalties consistent with their regulatory authority.

For those creditors that are not federally regulated financial institutions, the Federal Trade Commission provides oversight. In the event of a knowing violation, which constitutes a pattern or practice of violations, the FTC may commence a civil action to recover a civil penalty in a federal district court. Penalties imposed by the FTC for violations of FACTA may not exceed \$2,500 per infraction.

In addition to regulatory enforcement actions, users of consumer reports who fail to comply with the Box 4424, Youngstown, OH 44515 discrepancy regulation are subject to civil liability under §§ 616 and 617 of the Fair Credit Reporting Act.

The information contained in this Legal alert is not intended as legal advice or as an opinion on specific facts. For more information about these issues, please contact the author(s) of this Legal alert or your existing firm contact.

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can also contact us through our web site at www.kilpatrickstockton.com							

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The Gramm-Leach-Bliley Act and Your Responsibility to the Client

Numerous federal, state and local statues relate to the protection and safekeeping of information provided by consumers to financial institutions and other types of businesses who provide financing or engage in the practice of lending money. There are also overlapping statues which relate to personal health information, credit reporting agencies, third party debt collectors and recovery specialists when a financial institution provides personal information to these service providers.

Service providers are recognized as *"Business Associates"* and may have access to any personal information the financial institution has obtained from the consumer as is required for the **service provider** to perform it's requested task.

It is then the responsibility of the *"Business Associates",* its employees and agents to offer the same protection to the personal information supplied to it to perform the requested task as would be required of the original financial institution.

To ensure proper due diligence with the consumers information held by our agency, its employees, agents and vendors and to properly protect the integrity of our information security system GLBA information should be distributed to all employees, agents and vendors who in any way would have access to a consumers personal information.

GRAMM – LEACH – BLILEY ACT (GLBA)

This is a relatively new federal privacy regulation. The date for the "Final Rule" implementation was May 24, 2004 and the law has been in full effect since that date. The GLBA imposes new obligation regarding disclosure of information sharing practices, but with limited exceptions does not bar the sharing of information with affiliates and business associates. GLBA extends these disclosure rules to a broader range of business firms and a broader range of information than the FCRA and FDCPA.

All requirements of the GLBA on covered businesses extended to any business associate who works for or with protected information.

It is important that we, as business associates, clearly understand the definition of certain terms as they apply to this statue.

"FINANCIAL INSTITUTION" is broadly defined to include any institutions, the business of which is engaging in financial activities. Apparently the definition encompasses "institutions" even if they are not affiliated with financial services, holding companies or bank holding companies, but are merely engaged in a listed activity which is "financial in nature".

"NONPUBLIC PERSONAL INFORMATION" means personally identifiable information provided by a consumer to a financial institution, resulting from any transaction between a financial institution and the consumer or otherwise obtained by a financial institution, but not publicly available information. In the "Final Rule" Non Public Personal Information (NPPI) is clarified as information that is not "official public record", "available through widely distributed media". and "information required to be disclosed by federal, state or local law". As is obvious the issues of clarification are endless.

Although some of this information might be defined as "Public Information" much of the information is "not publicly available" and it should your firm's policy that the list of NPPI that you develop should include but not be limited to the following:

Social Security Numbers Dates of Birth **Telephone Numbers Drivers License Numbers** Any Derogatory Information Any Financial Information (original balances, payment amounts past due amounts, etc.) Any account numbers relating to financial transactions (checking/savings/accounts, credit/debit cards, loan numbers) Name of Relatives or References Dated of Transactions Consumer Address Vehicle Information Child Support Information Income Information Insurance Information Employment Information Health Information Bankruptcy Information

When sending any of the above information to a consumer or their legal representative it shall always be your company's policy to require the request to be in writing and approved by management staff.

To ensure proper compliance with this act your agency should appoint a designated employee or employees as Information Security and Confidentiality Officer/s.

These designates shall be responsible for identifying reasonably foreseeable internal and external risks to the security, confidentiality, and integrity of customer information that could result in the unauthorized disclosure, misuse, alteration, destruction or other compromise of such information, and assess the sufficiency of any safeguards in place to control these risks.

These designates shall design and implement safeguards to control the risks identified through risks assessment, and regularly test or otherwise monitor the effectiveness of the safeguards' key controls, systems, and procedures.

These designates should oversee all service providers to your agency by taking reasonable steps to select and retain service providers that are capable of maintaining appropriate safeguards for the customer information at issue and requiring the selected service providers, by contract, to implement and maintain such safeguards.

These designates shall evaluate and adjust the information security program in light of the results of the testing and monitoring requirements of this section, any material changes to the operations or business arrangements, or any other circumstances that is known or should be known which might have a material impact on the information security program.
These designates should read all of the above and sign a statement stating that they understand their responsibilities as Information and Security Officer/s and agree to fulfill those duties as are set forth.

Minimum Necessary Rule

RESPONSIBILITY: Privacy Official or Compliance Officer

BACKGROUND;

Protected Non-Public Personal Information (NPPI) must be treated with the utmost confidentiality. Members of the **Southern Adjustment Services, Inc.** workforce are required to limit the amount of protected information they use, request, or disclose to others, to the minimum amount necessary to achieve the specific purpose of that use, request, or disclosure.

This policy establishes the general rule regarding the *minimum necessary* limitation on the use or disclosure of protected information.

POLICY;

Members of the **Southern Adjustment Services**, **Inc.** workforce may not use, request, disclose to others, any protected health information that is more than the minimum necessary to accomplish the purpose of the use, request, or disclosure.

Members of the workforce are required to comply with specific policies and procedures established to limit used of, requests for, or disclosures of protected health information to the minimum amount necessary.

Exception. Southern Adjustment Services, Inc. is not limited in the amount of protected information that it may disclose to the Consumer.

When federal or state law requires a disclosure of protected information, the minimum necessary amount of information is that which is required in order to comply with such law.

When disclosing a consumer's own information to that consumer, the minimum necessary rule does not apply.

Southern Adjustment Services, Inc. EMPLOYEE CONFIDENTIALITY AGREEMENT

I, ______ acknowledge and agree that I will not disclose, disseminate, publish or in any way compromise the integrity of any confidential information to which I have access by virtue of my employment with **Southern Adjustment Services, Inc.** I understand that "Confidential Information" includes, but is not limited to:

consumer reports and related data protected healthcare information proposals billing status/financial data personnel files (for other employees) research and development Consumers' accounts – anything related price list computer programs technological data marketing plans business and trade secrets client lists

I acknowledge and agree that in the event that I violate this Employee Confidentiality Agreement, I may be disciplined or terminated and that civil and /or criminal action may be taken against me for which I may be personally liable.

I acknowledge that I have been trained and understand all aspects of FDCPA, FCRA, FACTA, GLBA, TCPA and TRPPA and will be in compliance with all company procedures related to these laws.

I acknowledge that my employment with **Southern Adjustment Services**, **Inc.** is contingent upon my execution of and compliance with Employee Confidentiality Agreement. I also understand that this **Employee Confidentiality Agreement is not a contract for employment** and does not in any way alter the at-will nature of my employment which is such that I or **Southern Adjustment Services**, **Inc.** may terminate my employment at any time.

Signature

GRAMM-LEACH-BLILEY EMPLOYEE COMPLIANCE AGREEMENT

Date / /

I hereby confirm that I have been trained in the requirements of the Gramm-Leach-Bliley Act.

I understand the definition of "non-public personal information" and the restrictions related to the disclosure of any information given to me in the course of my employment.

I acknowledge that it is my responsibility to protect and guard any "non-public information given to me in the course of my employment with

I acknowledge that any inadvertent or intentional violation of the GLBA will be reported to my immediate supervisor immediately after such occurrence might happen.

I acknowledge that any violation of company policy related to the protection of "non-public personal information may be cause for immediate termination.

Signature_____

.

Job Title_____

GLBA/HIPAA BUSINESS ASSOCIATE/EMPLOYEE AGREEMENT

AGREEMENT made this ____day of _____, 201___, between Southern Adjustment Services, Inc., hereafter Business Associate and ______hereafter Employee.

WHEREAS, Business associate performs recovery services for a covered Entity, as defined by the Gramm-Leach-Bliley Act it's Implementing Regulations, and HIPAA and it's implementing procedures subsection 160.103 and has entered into a Business Associate Agreement ("Agreement") permitting the use and disclosure of Non Public Personal Information (NPPI) and Protected Health Information (PHI); and

WHEREAS, the Agreement further provides circumstances under which the Business Associate may disclose to an employee, agent or subcontractor NPPI and/or PHI received or created, subject to the provisions and limitations imposed under the Acts,

NOW, THEREFORE, the parties hereto agree as follows:

- 1. Employee may receive from the Business Associate NPPI/PHI only as necessary to perform its obligations to Business Associate and to be used only for the purpose for which it is disclosed to the Employee.
- 2. Employee agrees to maintain the confidentiality of the NPPI/PHI and to affirmatively notify Business Associate of any breach thereof.
- 3. Employee agrees to the same condition and conditions that apply to the Business Associate With respect to such NPPI/PHI.
- 4. Employee may disclose information if required or permitted by law.

EMPLOYEE

(Southern Adjustment Services, Inc.)

GLBA EMPLOYEE/AGENT AGREEMENT FOR BUSINESS ASSOCIATES

AGREEMENT made this	day of	, 201	, between	
hereafter Business Associa	te and		-	
hereafter Employee/Agent.				

WHEREAS, Business Associate performs certain recovery services for a covered Entity, as defined by the Gramm-Leach-Bliley Act and has entered into a Business Associate Agreement ("Agreement") permitting the use and disclosure of Non-Public Information (NPPI); and

WHEREAS, the Agreement further provides circumstance under which the Business Associate may disclose to an employee, agent or subcontractor NPPI received or created, subject to the provisions and limitations imposed under the Act.

NOW, THEREFORE, the parties hereto agree as follows:

- 1. Employee/Agent may receive from the Business Associate NPPI only as necessary to perform its obligations to Business Associate and to be used only for the purpose for which it is disclosed to the Employee/ Agent.
- 2. Employee/Agent agrees to maintain the confidentiality of the NPPI and to affirmatively notify Business Associate of any breach thereof.
- 3. Employee/Agent agrees to the same condition and conditions that apply to the Business Associate with respect to such NPPI.
- 4. Employee/Agent may disclose information if required or permitted by law.

EMPLOYEE/AGENT

DIRECTOR OF INFORMATION SECURITY COMPANY EMPLOYEE CONFIDENTIALITY AGREEMENT Organizational information that may include, but is not limited to, financial, consumer identifiable, employee identifiable, intellectual property, financially non-public, contractual, including without limitation information of a competitive advantage nature, and from any source or in any form (i.e., paper, magnetic or optical media, conversations, film, etc.), may be considered confidential. It is my job to preserve information's confidentiality and integrity as well as maintain its availability. The value and sensitivity of information is protected by law and by the strict policies of **Southern Adjustment Services, Inc.** (sometimes called the "Company").

The intent of these laws and policies is to assure that confidential information will remain confidential through its use, only as a necessity to accomplish the company's mission.

As a condition to receiving a computer sign-on code and allowed access to a system, and/or being granted authorization to access <u>any</u> form of confidential information identified above, I, the undersigned, agree to comply with the following terms and conditions:

- 1. My Sign-On Code is equivalent to my LEGAL SIGNATURE and I will not disclose this code to anyone or allow anyone to access the system using my Sign-On Code.
- 2. I am responsible and accountable for all entries made and all retrievals accessed under my Sign-On Code, even if such action was made by me or by another due to my intentional or negligent act or omission. Any data available to me will be treated as confidential information.
- 3. I will not attempt to learn or use another's Sign-On Code.
- 4. I will not access any on-line computer system using a Sign-On Code other than my own.
- 5. I will not access or request any information I have no responsibilities for. In addition, I will not access any other confidential information, including personnel, billing, financial, health or other private information I do not need to perform the duties assigned me by the Company or its client.
- 6. If I have reason to believe that the confidentiality of my User Sign-On Code/password has been compromised, I will immediately change my password and notify our company's security administration area.
- 7. I will not disclose any confidential information unless required to do so in the official capacity of my employment or contract. I also understand that I have no right or ownership interest in any confidential information.
- 8. I will not leave a secured computer application unattended while signed on.
- 9. I will comply with all policies and procedures and other Company rules about the confidentiality of information and Sign-On Codes.

- 10.1 understand that my use of the system will be periodically monitored to ensure compliance with this agreement.
- 11.1 agree not to use the information in any way detrimental to the Company and will keep all such information confidential.
- 12. I will not disclose protected information or other information that is considered proprietary, sensitive, or confidential unless there is a need to know basis or unless I am otherwise required by law to do so.
- 13.1 will limit distribution of confidential information to only parties with a legitimate need in performance of our Company's mission.
- 14. I agree that disclosure of confidential information is prohibited indefinitely, even after termination of employment or business relationship, unless specifically waived in writing by the authorized party.
- 15. This agreement shall survive the termination, expiration, or cancellation of this agreement or my employment at the Company.

I further understand that if I violate any of the above terms, I may be subject to disciplinary action, including discharge, loss of privileges, termination of contract, legal action for monetary damages or injunction, or both, or any other remedy available to the Company or its clients.

User's Name_____

Date:

(Please Print)

User's Signature_____

If I have any questions about this document or the policies and procedures it mentions, I will notify my immediate supervisor, a compliance officer, or another manager and seek assistance.

- All hardware (includes owned and not owned by **Southern Adjustment Services, Inc.** used to access **Southern Adjustment Services, Inc.** network must be used only for **Southern Adjustment Services, Inc.** business.
- Southern Adjustment Services, Inc. must approve all hardware purchased with Southern Adjustment Services, Inc. funds.
- Southern Adjustment Services, Inc. must approve all hardware not owned by Southern Adjustment Services, Inc. that is used to access Southern Adjustment Services, Inc. network.
- Internet and email usage will only be for **Southern Adjustment Services**, Inc. business and is subject to monitoring.
- Southern Adjustment Services, Inc. must approve all software loaded onto hardware owned by Southern Adjustment Services, Inc. or any piece of hardware used to access Southern Adjustment Services, Inc. network. This includes wallpaper screensavers, music downloads, or any other piece of software.

I agree to comply with **Southern Adjustment Services**, **Inc.** computer usage policy at all times, or otherwise approved by **Southern Adjustment Services**, **Inc.**, with the understanding that **Southern Adjustment Services**, **Inc.** will periodically scan assets for viruses and unauthorized software. I understand that if I violate the policy, I may be subject to further disciplinary action up to and including termination. In addition, I acknowledge if necessary, **Southern Adjustment Services**, **Inc.** will advise appropriate legal officials of any illegal violations.

Employee Name (Please Print)

Employee Signature

Supervisor/Manager Signature

Date

Date

INFORMATION SECURITY AND CONFIDENTIALITY OFFICER

Date__/_/__/

As of this date the following person/persons shall be designated as Information Security and Confidentiality Officer/s.

1.

2.

3.

These designates shall be responsible for identifying reasonably foreseeable internal and external risks to the security, confidentiality, and integrity of customer information that could result in the unauthorized disclosure, misuse, alteration, destruction or other compromise of such information, and assess the sufficiency of any safeguards in place to control these risks.

These designates shall design and implement safeguards to control the risks identified through risk assessment, and regularly test or otherwise monitor the effectiveness of the safeguards' key controls, systems, and procedures.

These designates should oversee all service providers by taking reasonable steps to select and retain service providers that are capable of maintaining appropriate safeguards for the customer information at issue and requiring the selected service providers, by contract, to implement and maintain such safeguards.

These designates shall evaluate and adjust the information security program in light of the results of the testing and monitoring requirements of this section, any material changes to the operations or business arrangements, or any other circumstances that is known or should be known which might have a material impact on the information security program.

I have read all of the above understand my responsibilities as Information and Security Officer and agree to fulfill those duties as are set forth.

1.

2.

3.

SECURITY CHECK SHEET / INFORMATION SECURITY PROGRAM

Date__/__/

Physical: This will include all areas of physical procedures, including but not limited to the physical security of data outside the office with field employees, supervision, monitoring, retrieval and storage of all printed data.

Employees in this area of operations:

Assessment:

Possible Breaches of Security:

Recommended Changes to Protect Information Security:

Response to Recommendations:

SECURITY CHECK SHEET / INFORMATION SECURITY PROGRAM

Date__/__/

Administrative: This will include all areas of administrative procedures, including but not limited to receiving and inputting data from clients, production and distribution of data to other areas of the operations, retrieval of data once assignment has been closed, storage of data, billing and crediting to clients accounts.

Employees in this area of operations:

Assessment:

Possible Breaches of Security:

Recommended Changes to Protect Information Security:

Response to Recommendations:

SECURITY CHECK SHEET / INFORMATION SECURITY PROGRAM

Date__/_/__/

Technical: This will include all areas of technical procedures, including but not limited to computer operations and maintenance and storage of data. Selection and supervision of policies of all outside vendors and sub-contractors:

Employees in this area of operations:

Assessment:

Possible Breaches of Security:

Recommended Changes to Protect Information Security:

Response to Recommendations:

A SUMMARY OF APPLICABLE STATUTES

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

The HIPAA rules set the "floor" for national privacy standards relating to *personal health information*. It shall be our firms policy to give no *personal health information* to anyone other than the patient or their legal representative and then only with a written request and management approval. It shall be the policy of our firm that any personal health information obtained through any source shall be protected until same can be returned to its owner or destroyed in an appropriate manner.

FAIR DEBT COLLECTIONS PRACTICES ACT (FDCPA)

The FDCPA is very clear as to the information which may or may not be given out to third parties. Our firm and all employees, when and if it is applicable, shall explicitly and with no exceptions follow all the requirements of section 804, Acquisition of Location Information, when skip tracing and the requirements of section 805, Communication In Connection With Debt Collection, when communicating with a consumer regarding a debt.

FAIR CREDIT REPORTING ACT (FCRA)

The Fair Credit Reporting Act lists the permissible purposes under which a party may pull Consumer Report from a Consumer Reporting Agency. The permissible purposes are listed in sub section 604 (15 USC 1681b) and our firm and its employees shall explicitly and with no exceptions follow all the requirements of The Fair Credit Reporting Act and any amendments relating to same.

FRAUD / IDENTITY THEFT CLIENT NOTIFICATION FORM

Pursuant to 15 USC 1681m (g) of the FACT Act you are hereby notified of a claim of Fraud and/or Identity Theft related to this debt.

Date	Case #
Client	
Contact	
Consumer	
Amount	-
Date Turned	_
Statement	

This report generated by	
Computer Notes Entered	

CONSUMER DISPUTE INVESTIGATION

Client	(Case #
Consumer		
Date Listed	M/Notification Date	Dispute Date
Specified Nature of Dis	pute:	
Date of Investigation Investigated By		
Client Response		
Back Up Documents		
Action Taken		

NOTIFICATION OF FINDINGS

Case #_____

Client	Consumer
In regards to your written dis	pute received by our office on//
Pursuant to the requirements abovementioned client that the	of 15 USC 1681m (g) our firm has notified the nis is a disputed claim.
	sonable investigation of your dispute as a) (8) and our finding and action taken are as
Findings	
Action Taken	

Do not get "TRPPA'd" into sharing a cell with your Recovery Agent!

H.R. 4709, Telephone Records and Privacy Protection Act of 2006 (TRPPA) is now federal law and could be your one way ticket to a huge fine, imprisonment or both.

If you, the lender, use a Recovery Agent or Skip trace Company who violated the strict guidelines of this new law then it is possible that you and your lender institution could face enhanced fines as well as a term in a federal prison of up to 5 years.

This new law criminalizes and makes it a federal offence to use pretexting in order to obtain customer information form the telephone services providers or their customers. It also prohibits and criminalizes the sale and transfer of telephone call records without prior authorization of the customer.

Typical of government bills "confidential phone records" is not clearly defined, however from prior ruling it can be identified to include ID or Account Numbers, Phone Numbers, Post Office Boxes and Toll Call Records.

Many Skip tracing companies have used this type of information on the past and continue to use it in violation of this law to locate missing consumers and mortgaged property. The new law makes it very clear that if your or lending institution have knowledge of fraudulent statements being used to gain the information or if you have not used due diligence in selection your recovery agent or skip trace company then you and your entity will be held liable and subject to the same penalties as the person or company committing the overt act.

This law passed the House and Senate and has been signed into law by President George Bush. It is in time and to protect yourself and your lending institution you should ask your Recovery Agency for a "H.R. 4709, TRAPP Statement of compliance".

Southern Adjustment Services, Inc. H.R. 4709 TELEPHONE RECORDS AND PRIVACY PROTECTION ACT OF 2006 EMPLOYEE COMPLIANCE AGREEMENT

Date__/_/

I hereby confirm that I have been fully trained in all the requirements for compliance as related to H.R. 4709.

I understand the violation of any section of H.R. 4709 is a violation of federal law may result in a fine and/or imprisonment of up to 10 years

I acknowledge that it is my responsibility to operate and trace within the guidelines of H.R. 4709 and all other applicable federal, state and municipal statutes in the course of my employment with Southern Adjustment Services, Inc..

I acknowledge that any inadvertent or intentional violation of the H.R. 4709 will be reported to my immediate supervisor immediately after such occurrence might happen.

I acknowledge that any violation of company policy related to the adherence to the statutes and requirements of H.R. 4709 may be cause for immediate termination as well as civil and/or criminal litigation.

Signature _____

Job Title_____

GRAMM-LEACH-BLILEY ACT DECLARATION OF COMPLIANCE

Southern Adjustment Services, Inc., its Employees and Agents do hereby agree to keep all nonpublic personal information (NPPI), as defined in 16 CFR 313.3(n), about a customer of any client, whether in paper, electronic, or other form, confidential and shall not make any unauthorized disclosure of such information.

Furthermore, Southern Adjustment Services, Inc., its' Employees and Agents agree not to use such nonpublic personal information for any purpose other than what is reasonably necessary to fulfill the purpose for which information was provided by said client.

Furthermore in compliance with the requirements of 16 CFR 314.4, Southern Adjustment Services, Inc., does hereby declare that a program has been developed and instituted to implement and maintain a comprehensive written information security program that contains administrative, technical, and physical safeguards to achieve the required goals of 314.4.

Director of Information Security

FDCPA DECLARATION OF COMPLIANCE

Southern Adjustment Services, Inc., its Employees and Agents do hereby agree to abide by all rules, requirements and regulations of FDCPA including but not limited to all required disclosures and protection of covered data.

Furthermore Southern Adjustment Services, Inc., its' Employees and Agents acknowledge that they fully understand the purpose and intent of FDCPA and agree follow the dictates to ensure compliance in all areas.

Furthermore in compliance with the requirements of FDCPA Southern Adjustment Services, Inc. does hereby declare that a program has been developed and instituted to implement and maintain a comprehensive Monitoring program that contains administrative, technical, and physical safeguards and programs to achieve the required goals FDCPA.

Director of Compliance and Security

FCRA DECLARATION OF COMPLIANCE

Southern Adjustment Services, Inc., its Employees and Agents do hereby agree to abide by all rules, requirements and regulations of FCRA including but not limited to all required disclosures and protection of covered data.

Furthermore, Southern Adjustment Services, Inc., its' Employees and Agents acknowledge that they fully understand the purpose and intent of FCRA and agree follow the dictates to ensure compliance in all areas.

Furthermore in compliance with the requirements of FCRA, Southern Adjustment Services, Inc. does hereby declare that a program has been developed and instituted to implement and maintain a comprehensive Monitoring program that contains administrative, technical, and physical safeguards and programs to achieve the required goals FCRA.

Director of Compliance and Security

FACTA DECLARATION OF COMPLIANCE

Southern Adjustment Services, Inc., its Employees and Agents do hereby agree to abide by all rules, requirements and regulations of FACTA including but not limited to all required disclosures and protection of covered data.

Furthermore, Southern Adjustment Services, Inc., its' Employees and Agents acknowledge that they fully understand the purpose and intent of FACTA and agree follow the dictates to ensure compliance in all areas.

Furthermore in compliance with the requirements of FACTA, Southern Adjustment Services, Inc. does hereby declare that a program has been developed and instituted to implement and maintain a comprehensive Monitoring program that contains administrative, technical, and physical safeguards and programs to achieve the required goals FACTA.

Director of Compliance and Security

Southern Adjustment Services, Inc. <u>HIPAA</u> DECLARATION OF COMPLIANCE

Southern Adjustment Services, Inc., its Employees and Agents do hereby agree to abide by all rules, requirements and regulations of HIPPA including but not limited to all required disclosures and protection of covered data.

Furthermore, Southern Adjustment Services, Inc., its' Employees and Agents acknowledge that they fully understand the purpose and intent of HIPPA and agree follow the dictates to ensure compliance in all areas.

Furthermore in compliance with the requirements of HIPPA, Southern Adjustment Services, Inc. does hereby declare that a program has been developed and instituted to implement and maintain a comprehensive Monitoring program that contains administrative, technical, and physical safeguards and programs to achieve the required goals HIPPA.

Director of Compliance and Security

TCPA DECLARATION OF COMPLIANCE

Southern Adjustment Services, Inc., its Employees and Agents do hereby agree to abide by all rules, requirements and regulations of TCPA including but not limited to all required disclosures and protection of covered data.

Furthermore, Southern Adjustment Services, Inc., its' Employees and Agents acknowledge that they fully understand the purpose and intent TCPA and agree follow the dictates to ensure compliance in all areas.

Furthermore in compliance with the requirements TCPA, and Southern Adjustment Services, Inc. does hereby declare that a program has been developed and instituted to implement and maintain a comprehensive Monitoring program that contains administrative, technical, and physical safeguards and programs to achieve the required goals TCPA.

Director of Compliance and Security

Date

TRPPA DECLARATION OF COMPLIANCE

Southern Adjustment Services, Inc., its Employees and Agents do hereby agree to abide by all rules, requirements and regulations of TRPPA including but not limited to all required disclosures and protection of covered data.

Furthermore, Southern Adjustment Services, Inc., its' Employees and Agents acknowledge that they fully understand the purpose and intent of TRPPA and agree follow the dictates to ensure compliance in all areas.

Furthermore in compliance with the requirements of TRPPA, Southern Adjustment Services, Inc. does hereby declare that a program has been developed and instituted to implement and maintain a comprehensive Monitoring program that contains administrative, technical, and physical safeguards and programs to achieve the required goals TRPPA.

Director of Compliance and Security

____/____/_____

Date

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Southern Adjustment Services, Inc. HITECH COMPLIANCE PROGRAM INTRODUCTION

Southern Adjustment Services, Inc., in compliance with Title XIII of the American Recovery and Reinvestment Act of 2009, 42 U.S.C. §§ 17921-17954(ARRA), called the Health Information Technology for Economic and Clinical Health (HITECH) Act, realizes the need for compliance with expanded requirements promulgated by the Department of Health & Human Services (DHHS) pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) in order to protect the privacy and security of protected health information (PHI).

Therefore Southern Adjustment Services, Inc. has established and implemented programs to ensure compliance with this new amendment in order to protect and avoid breaches of security related to PHI and to comply with the imposed regulations on business associates.

The amended HIPAA program, as required by HITECH, covers the specified requirements and was designed with the aid of the NIST Special Publication 800-66 Revision 1, "An Introductory Resource for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Rule", "INFORMATION SECURITY". This publication has become part of our program material. This program has been overseen by our Credit and Compliance Officer and established and implemented by our management and compliance staff. Southern Adjustment Services, Inc. has designed an "Amendment to Southern Adjustment Services, Inc. Business Associate Agreement" which meets the required HITECH requirements and this amendment has been properly distributed to any covered entity. A copy of this amendment has also become a part of our program material.

The Southern Adjustment Services, Inc. Management and Compliance team will continue to monitor, test and adjust where required, to ensure compliance with the

HITECH Amendment and ensure that all PHI is adequately protected.

Southern Adjustment Services, Inc. HITECH COMPLIANCE STATEMENT

Date_/_/_

On behalf of Southern Adjustment Services, Inc., as the Credit and Collections Compliance Officer, I represent that:

- (1) Southern Adjustment Services, Inc. has taken, and will continue to take, that action necessary, consistent with HITECH, to ensure Southern Adjustment Services, Inc. has access to information necessary to perform its required functions in the proper protection of Protected Health Information (PHI) in the control of Southern Adjustment Services, Inc. employees and associates.
- (2) Any and all business associate agreements between Southern Adjustment Services, Inc. and any covered entity will be reviewed and maintained by the Vice-President of Operations and the CCCO Officer of Southern Adjustment Services, Inc.
- (3) Southern Adjustment Services, Inc. will notify the covered entity if there has been or there is reasonable belief that PHI has been acquired, accessed, used or disclosed in a manner that compromises the security, privacy or integrity of that PHI.
- (4) All PHI will be disposed of in a reasonable manner to render all data unreadable, undecipherable and unrecoverable.
- (5) Southern Adjustment Services, Inc. will limit the distribution of PHI to only the amount and type that is the "minimum necessary" to accomplish the purpose underlying the disclosure.
- (6) Southern Adjustment Services, Inc. will comply with the aspects of HITECH in the establishment of reasonable written policies and procedures with respect to physical, technical and administrative safeguards which protect, detect and respond to possible breaches.

Southern Adjustment Services, Inc.

Vice-President of Operations_____

CCCO_____

AMENDMENT TO EAGLE GROUP XX BUSINESS ASSOCIATE AGREEMENT

This Amendment amends the HIPAA EAGLE GROUP XX Business Associate Agreement Between EAGLE GROUP XX And Any Provider of "PROTECTED HEALTH INFORMATION" (PHI) Herein Referred to as "COVERED ENTITY".

WHEREAS, EAGLE GROUP XX and the Covered Entity entered into the Existing BAA as a business associate agreement for purposes of the Privacy Rule and Security Rule;

WHEREAS, the Health Information Technology for Economic and Clinical Health Act and its implementing regulations (collectively "<u>HITECH</u>"), adopted as part of the American Recovery and Reinvestment Act of 2009, 42 U.S.C. §§17921-17954, imposes certain requirements on business associates;

WHEREAS, EAGLE GROUP XX is providing this Amendment in order to facilitate compliance with HITECH in an efficient manner for itself and for the covered entities with which EAGLE GROUP XX agreements prior to the general effective date of HITECH; and

WHEREAS, the Existing BAA contemplates that it will be amended from time to time to continue to comply with the Privacy Rule and other applicable law, and this Amendment is consistent with that commitment.

NOW, THEREFORE, in consideration of the foregoing and other good and valuable consideration, the sufficiency of which is hereby acknowledged, this Amendment is entered into to amend and supplement the Existing BAA as follows:

1. Defined terms used herein without definition shall have the respective meanings assigned to such terms in the Existing BAA. Capitalized terms not otherwise defined in the Existing BAA or this Amendment have the meanings established for purposes of HIPAA and HITECH, as each is amended from time to time.

(a) "Breach" shall mean the acquisition, access, use or disclosure of PHI in a manner not permitted by the Privacy Rule that compromises the security or privacy of the PHI as defined, and subject to the exceptions set forth, in 45 C.F.R. Section 164.402

2. HITECH imposes certain requirements on business associates with respect to privacy, security and breach notification and contemplates that such requirements shall be implemented by regulations to be adopted by the Department of Health and Human Services ("HHS"). Such provisions of HITECH and the regulations adopted there under applicable to business associates may be referred to collectively herein as the "<u>HITECH BA PROVISIONS</u>". Each of the HITECH BA Provisions applies commencing on February 17, 2010 or on such other respective dates as may be specified in the applicable HITECH BA Provision (the "<u>Applicable Effective Dates</u>").

3. EAGLE GROUP XX shall be subject to each of the HITECH BA Provisions with respect to EAGLE GROUP XX'S role as a business associate of the Covered Entity commencing on the respective Applicable Effective Date of each HITECH BA Provision.

4. The provisions of HITECH that apply to business associates and are required to be incorporated by reference in a business associate agreement are hereby incorporated into the Existing BAA as of the respective Applicable Effective Dates including, without limitation, 42 S.S.C. Sections 17935(b), (c), (d) & (e) and 17936(a) & (b).

5. Without limitation of the foregoing, as of the respective Applicable Effective Dates:

(a) Pursuant to 42 U.S.C. Section 1793(a), the following sections of the Security Rule shall apply to COA in the same manner as they apply to the Covered Entity:

- Section 164.308 Administrative safeguards;
- Section 164.310 Physical safeguards;
- Section 164.312 Technical safeguards; and
- Section 164.316 Policies and procedures and documentation requirements.

(b) Pursuant to 42 U.S.C. Section 17934(a), EAGLE GROUP XX may use or disclose PHI that it obtains or creates only if such use or disclosure, respectively, is in compliance with each applicable requirement of Section 164.504(e) of the Privacy Rule.

(c) Pursuant to 42 U.S.C. Sections 17931(b), 17934(b) & 17934(c), Section 164.504(e)(1)(ii) of the Privacy Rule shall apply to EAGLE GROUP XX with respect to compliance with such subsection, in the same manner that such section applies to the Covered Entity, with respect to compliance with the standards in sections 164.502(e) and 164.504(e) of the Privacy Rule, except that in applying such Section 164.504(e)(1)(ii) each reference to EAGLE GROUP XX with respect to a contract, shall be treated as a reference to the Covered Entity involved in such contract. To the extent necessary to achieve the purposes of the foregoing, EAGLE GROUP XX shall have the right to terminate the Existing BAA and all contracts to which it relates if the Covered Entity is in material breach of violation of the Existing BAA and fails to cure such breach or violation.

(d) 42 U.S.C. Sections 17931(b) & 17934(c) each apply to EAGLE GROUP XX with respect to its status as a business associate to the extent set forth in each such Section.

(e) Pursuant to 42 U.S.C. Section 17932, without unreasonable delay, and in any event no later than sixty (60) calendar days after Discovery, EAGLE GROUP XX shall notify Covered Entity of any Breach of Unsecured PHI. The notification shall include, to the extent possible and subsequently as the information becomes available, the identification of all individuals whose Unsecured PHI is reasonably believed by EAGLE GROUP XX to have been Breached along with any other available information that is required to be included in the notification to the Individual, HHS and/or the media, all in accordance with the data breach notification requirements set forth in 42 U.S.C. § 17932 and 45 C.F.R. Parts 160 & 164 subparts A,D, & E.

6. (a) The existing BAA is hereby amended to add the following sentence to the end: "Terms used but not otherwise defined in the Agreement, shall have the same meanings as set forth in the Privacy Rule or Security Rule."

The section

of the existing BAA regarding the Covered Entities request for an accounting disclosure of PHI information is hereby deleted in its entirety and replaced by the

(b) following: "Within fifteen (15) days of receiving a request from Covered Entity, make available the information necessary for Covered Entity to make an accounting of Disclosures of PHI about an individual;" (c) The Survival section of the Existing BAA is hereby deleted in its entirety and replaced by the following: "<u>Survival</u>. The obligations of Accrediting Entity under any section of this Agreement shall survive any termination of this Agreement."

7. The Existing BAA is hereby amended in the Conflict section of this Amendment. Except as specifically amended and modified by this Amendment and to the extent not inconsistent therewith, all terms and conditions of the Existing BAA shall remain in full force and effect. To the extent that this Amendment conflicts with, is inconsistent with or addresses matters not addressed by the Existing BAA or any other agreement between EAGLE GROUP XX and the Covered Entity, it shall supersede and take precedence over such provisions. The terms of this Amendment to the extent that they are unclear shall be construed to allow for compliance by Covered Entity and EAGLE GROUP XX with HIPAA and HITECH. Except as otherwise agreed in writing by both parties, the Existing BAA as amended hereby, constitutes the entire understanding and obligation of the parties with respect to the subject matter thereof and supersedes any prior agreements, writings or understandings, whether oral or written with respect to the subject matter thereof.

8. This Amendment is provided to document EAGLE GROUP XXS obligations and to comply with HITECH.

9. This Amendment may be executed in counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same document. Signatures delivered by facsimile, e-mail or other electronic means shall be deemed originals for all purposes.

10. The obligations of EAGLE GROUP XX under section 7 of this Amendment shall survive any termination or expiration of this Amendment.

11. This Amendment is made effective as of the ____ day of _____, 2012.

IN WITNESS WHEREOF, this Amendment has been executed by Covered Entity this _____ day of _____, 2012.

 EAGLE GROUP XX
Southern Adjustment Services, Inc.

 Name of Covered Entity
 By: _______

 By: _______
 By: _______

 Name: _______
 Name: _______

 Title: _______
 Title: ________

 Date: _______
 Date: _________

HIPAA PRIVACY AND SECURITY RULES

Unless otherwise noted, all revisions to the HIPAA privacy and security rules go into effect on **February 17, 2010**, which is one year from the HITECH enactment date. Please note that the breach notification provisions, described in Section II below, apply to breaches occurring on or after **September 23, 2009**.

I. Who is covered by HIPAA?

By way of refresher, HIPAA applies only to health care providers who transmit health information electronically. Electronic transmission means transmission via the Internet, leased lines, dial-up lines, private networks, and the use of magnetic tape, computer discs or compact disks. An electronic transaction includes hiring a billing company to submit bills electronically or having the hospital where a provider is admitted to practice submit electronic claims on the provider's behalf. Once a provider engages in at least one electronic transaction, all health information the provider maintains or transmits becomes subject to HIPAA forever, including paper and oral information.

In addition, any provider will be a covered entity if a hospital, clinic or other health care facility where the provider is employed or works as a consultant bills electronically for services under the providers name and provider ID number, even if the facility retains the fees received for the services. However, transmitting health information via a fax machine will constitute an electronic transmission of data *only* if the information is exchanged between **two** computer systems (such as those used by a managed care company). If a provider sends a fax from a paper fax machine, it will not constitute electronic transmission of data, regardless of whom or what type of machine receives the fax.

II. Business Associates

Under current law, business associates are required only by contract to appropriately safeguard the personal health information ("PHI") they receive in the course of their work for covered entities. Now, under HITECH, all of the privacy and security provisions in the HIPAA regulations will apply directly to business associates and they will be subject to the same civil and criminal penalties that apply to covered entities. In addition, a business associate may be subject to further penalties if it becomes aware of a violation

made by a covered entity and does not take action. Finally, business associates also will be subject to the new breach notification requirements described in more detail below.

HITECH also clarifies that any organization that provides data transmissions services, such as a health information exchange organization, a regional health information organization, an e-prescribing gateway or any vendor that offers a personal electronic health record to patients is to be treated as a business associate and must sign a business associate agreement.

III. <u>New Notification Requirements</u>

On August 24, 2009, HHS issued an interim final rule entitled Breach Notification for Unsecured Protected Health Information ("Breach Notification Rule"). The Breach Notification Rule applies to all breaches of unsecured PHI occurring on or after September 23, 2009. Yet, in the preamble to the Rule, HHS stated that it will delay enforcement of the Breach Notification Rule until February 22, 2010, to give covered entities additional time to implement the new breach notification procedures. During the interim period, HHS will work with covered entities to achieve compliance through technical assistance and voluntary corrective action.

A. Definition of Terms "Breach" and "Unsecured"

Effective September 23, 2009, covered entities are required to provide notification of a breach of "unsecured" PHI. No notice is required in the event of a breach of PHI that is "secured."

The term "breach" means the acquisition, access, use or disclosure of PHI in a manner not permitted by HIPAA which compromises the security or privacy of such information. The phrase "compromises the security or privacy of health information" means poses a significant risk of financial, reputational or other harm to the individual.

If a breach occurs and a covered entity determines that the breach poses significant harm to the individual, the covered entity must provide written notice to the individual affected as described below. In order to determine whether the breach poses significant harm to the individual, the covered entity should perform a fact-based risk assessment that includes consideration of the following factors: (i) who or what type of entity received access to the information; (ii) steps taken to mitigate harm, such as obtaining satisfactory assurances (e.g., a confidentiality agreement) from the recipient that the information will not be further used or disclosed, or will be destroyed; (iii) if the information was returned prior to it being accessed for an improper purpose; and (iv) the nature, type and amount of information used or disclosed.

As part of HITECH, Congress directed HHS to issue guidance on specific encryption technologies and methodologies to be utilized to "secure" unsecured PHI. Unsecured PHI is defined as PHI that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by HHS. In April, 2009, HHS issued a Guidance and Request for Information that identified two methods for rendering PHI unusable, unreadable or indecipherable: encryption and destruction.

Encryption is the process of transforming data into a form in which there is a low probability of assigning meaning without use of a confidential process or key. The National Institute of Standards and Technology (NIST) has identified valid encryption processes both for data at rest and data in motion. Destruction includes (i) shredding or destruction of paper, film or other hard copy media so that PHI cannot be read or otherwise reconstructed and (ii) clearing, purging or destruction of electronic media consistent with NIST guidelines.

In the April guidance, HHS indicated that use of either of these two methods to "secure" PHI creates a safe harbor that eliminates the need for covered entities and business associates to provide notice in the event of a breach. At the same time, HHS reminded covered entities and business associates to work to mitigate any collateral harmful effects resulting from the breach of "secured" information.

In addition, HHS has identified three specific exceptions to the definition of breach:

- an unintentional acquisition, access or use by a workforce member or person acting under authority of a covered entity or business associate, if made in good faith and within the scope of authority;
- (ii) an inadvertent disclosure by a person at a covered entity or business associate who is authorized to access PHI to another person at the same covered entity or business associate; or
- (iii) a disclosure of PHI where a covered entity or business associate has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

Finally, HHS explicitly excludes "limited data sets" from the breach notification requirement. A limited data set is PHI that excludes 16 direct identifiers, including name, address, telephone number, fax number, email address, social security number, medical record number and others. Under HIPAA, a covered entity may use or disclose a limited data set for research, public health or health care operations purposes without an authorization as long as the intended recipient signs a data use agreement. Under the Breach Notification Rule, unauthorized or inadvertent use or disclosure of a limited data set *that does not also include date of birth or zip code* will not constitute a breach that compromises the security or privacy of PHI.

B. Notification Required

1. Notice to Individuals 103

In the event of a breach that causes significant harm to the individual, the covered entity must notify the individual in writing. In addition, any business associate that becomes aware of a breach must notify the covered entity of the breach and identify all individuals whose information has been accessed, acquired or disclosed.

The required notice must be sent without unreasonable delay and in no case later than 60 calendar days after discovery of a breach. A breach will be treated as discovered by the covered entity as of the first day on which the breach is known to the covered entity or would have been known to a covered entity exercising reasonable diligence. The notice must be written in plain language and must contain the following information: (i) brief

description of what happened, the date of the breach and the date of discovery, if known; (ii) the type of PHI involved in the breach; (iii) any precautionary steps the individual should take; (iv) description of what the covered entity is doing to investigate and mitigate the breach and prevent future breaches; and (v) contact information for the covered entity, including a toll-free telephone number, e-mail address, website or postal address.

The notice must be sent by first-class mail or by email, if the individual has specified a preference for communication by email. If contact information for the individual in question is insufficient or out-of-date, the covered entity may use a substitute form of notice reasonably calculated to reach the individual. In the event there is insufficient or out-of-date contact information for fewer than 10 individuals whose information was breached, substitute notice may be provided by an alternative form of written notice, telephone or other means.

In the event there is insufficient or out-of-date contact information for 10 or more individuals whose information was breached, the covered entity must post a notice on the homepage of its website for at least 90 days or post conspicuous notice in major print or broadcast media in the geographic area where the affected individuals likely reside and, in both cases, include a toll-free contact number for potentially affected individuals to use. NYSPA understands that these requirements may seem rather onerous and costly for a sole practitioner. Hopefully, when HHS issues additional guidance on these provisions, it will take these concerns into account.

Finally, if the notification is of an urgent nature because of possible imminent misuse of unsecured PHI, a covered entity may contact the individual by telephone or other means, as appropriate, in addition to the written or other forms of notice.

2. Notice to the Media

In the event of a breach affecting more than 500 residents of a State or jurisdiction, the covered entity must, without unreasonable delay and in no case later than 60 calendar days after discovery of the breach, notify prominent media outlets serving the State or jurisdiction.

3. Notice to HHS

For breaches affecting fewer than 500 individuals, a covered entity is required to maintain an annual log of such breaches and provide notice to HHS within 60 days of the end of the calendar year. For breaches affecting 500 or more individuals, a covered entity is required to notify HHS at the same time notice is provided to the individual.

4. Notice provided by Business Associates

If a business associate discovers a breach of unsecured PHI, it must notify the covered entity of such breach without unreasonable delay and in no case later than 60 calendar
days after the discovery of the breach. The business associate shall endeavor to include in its notice identification of each individual whose unsecured PHI was or reasonably believed to have been accessed, acquired, used or disclosed. In addition, the business associate is required to provide the covered entity with any other available information that will assist the covered entity in providing the required notice to the individual(s) affected.

5. Law Enforcement Delay

Following a breach, a covered entity or business associate is required to delay transmission of any of the required forms of notice if it is informed by a law enforcement official that such notice would impede a criminal investigation or cause damage to national security.

6. Special Rules for PHR Vendors/Service Providers

HITECH also requires vendors of personal health records (e.g., Google Health) to provide notice of a breach of security of any identifiable health information maintained in a personal health record (PHR). The vendor must provide notice (i) to each individual whose information was breached and (ii) to the Federal Trade Commission, which, in turn, must notify HHS. A notice requirement is also placed on any third party service providers who provide software support services to a PHR vendor. In the event that the third party service provider discovers a breach, it is required to notify the vendor. PHR vendors must provide notice subject to the same procedures that apply to covered entities and business associates.

C. Interaction with State Breach Notification Laws

In general, any HIPAA rule or regulation that is contrary to a provision of State law will preempt the contrary State law, unless an exception¹ applies. In order to determine whether a state law is contrary to a federal law one must determine whether "a covered entity could find it impossible to comply with both the State and federal requirements." With respect to the federal Breach Notification Rule, HHS has taken the position that "in most cases, a single notification can satisfy the notification requirements under State laws and this regulation."

Law requires notice to be sent in the most expedient time possible and the federal rule requires notice to be sent without unreasonable delay, but no later than 60 days from date of discovery of the breach. Notice sent as soon as reasonably practicable after discovery of the breach will comply with both the State and federal requirements. Second, there is no apparent conflict between the required content of the notice. Since the Breach Notification Rule requires more elements to be included in the notice, compliance with the federal rule automatically constitutes compliance with the State rule.

IV. Expanded Individual Rights Under HITECH

¹For example, state laws relating to the privacy of health information that are more stringent than the privacy requirements under HIPAA will not be preempted by HIPAA. However, in the preamble to the rule, HHS states that none of the exceptions to the general HIPAA preemption rule will apply in the case of the Breach Notification Rule.

A. Restrictions on Disclosures

Under current law, individuals are entitled to request that a covered entity restrict certain uses and disclosures of their health information for treatment, payment and health care operations, but the covered entity is not required to agree to a requested restriction. Under HITECH, a covered entity *must* comply with a patient's request to restrict information if the information is to be sent to a health plan for payment or health care operations purposes and the disclosure relates to products or services that were paid for solely out-of-pocket (unless the disclosure is otherwise required by law).

B. Minimum Necessary Rule

Under current law, health care providers using, disclosing or requesting PHI are required to use, disclose or request only the minimum necessary amount of information, in other words, the least amount of information required to achieve the purpose of the use, disclosure or request. In order to clarify this term, HITECH directs HHS, within 18 months, to issue guidance on what constitutes "minimum necessary." Until such guidance is issued, covered entities may comply with the minimum necessary rule by limiting the use of PHI to a limited data set, or, if needed, to whatever is the minimum necessary to accomplish the intended purpose. As stated in Section III.A.2. above, a limited data set is PHI that excludes certain direct identifiers of the individual, such as name, address, telephone number, social security number, accounts number, and others.

C. Accounting of Certain Disclosures

Under HIPAA, patients may request that a covered entity provide an accounting of disclosures of their PHI. However, this right to receive an accounting does not apply to routine disclosures for treatment, payment or health care operations. Now, under HITECH, individuals will be entitled to receive an accounting of routine disclosures of PHI that is maintained in an electronic health records system, for the three year period prior to the date of the accounting request. For disclosures made by a business associate, the covered entity can provide the accounting itself or in the alternative provide the individual with contact information for the business associate.

For those covered entities using electronic health records systems as of January 1, 2009, the effective date of the new accounting requirement is January 1, 2014. If the covered entity began using an electronic health records system after January 1, 2009, the effective date of the new requirement will be January 1, 2011, or the date the covered entity acquires the electronic health records system, whichever is later.

D. Prohibition on Sale of Electronic Health Records or PHI

Under HITECH, covered entities and business associates will be prohibited from receiving direct or indirect remuneration in exchange for PHI, unless a valid HIPAA authorization has been signed by the patient, which includes such permission. Exceptions to the authorization requirement include sale of PHI in connection with:

(i) public health activities;(ii) research;(iii) treatment of the individual;

(iv) sale, transfer, merger or consolidation of the covered entity;
(v) services provided by a business associate, pursuant to a business associate agreement;
(vi) providing an individual with a copy of their PHI; and
(vii) other purposes deemed necessary and appropriate by HHS.

This change will take effect six months after promulgation of final rules implementing this section of HITECH.

E. Access to Information in Electronic Format

If a covered entity maintains an electronic health record for an individual, HITECH requires that the individual be permitted to request access to the information in an electronic format or may have the information transmitted electronically to a designated recipient. Any fee charged by the covered entity for the document production cannot exceed the entity's labor costs in responding to the request.

F. Marketing and Health Care Operations

Under HIPAA, marketing means a communication about a product or service that encourages recipients to purchase or use the product or service. Normally, a covered entity is required to obtain patient authorization prior to making a marketing communication. However, if certain conditions are met, the marketing communication will come under the umbrella of health care operations activities and may be made without patient authorization.

HITECH clarifies that marketing communications are not health care operations (and will require patient authorization) if direct or indirect payment is made in exchange for the marketing communication. However, even if payment is involved, the marketing communication may be considered to be a health care operations activity if *one* of the following three exceptions are met: (i) the communication describes a medication to be prescribed to the recipient and the payment to be made to the covered entity is reasonable in amount; (ii) the communication is made by the covered entity and a valid authorization is obtained; or (iii) the communication is made by a business associate pursuant to a valid business associate agreement.

G. Opt-Out of Fundraising

Under HITECH, the current requirement for covered entities to provide individuals with the chance to "opt-out" of receiving fundraising communications is enhanced. Now, the opt-out language must be presented in a clear and conspicuous manner and any such opt-outs will be treated as a revocation of any prior authorizations.

V. <u>Enhanced Enforcement Activities</u>

Category	Penalty
Violations made where the person had no	\$100 per violation, not to exceed \$25,000
knowledge (and by exercising reasonable	annually
diligence would not have known)	
Violations due to reasonable cause and not	\$1,000 per violation, not to exceed
due to willful neglect	\$100,000
	annually
Violations due to willful neglect that are	\$10,000 per violation, not to exceed
corrected within 30 days	\$250,000 annually
Violations due to willful neglect but not	\$50,000 per violation, not to exceed
corrected within 30 days	1,500,000
	annually

HITECH increases HIPAA civil monetary penalty amounts as follows:

In addition, HITECH grants State Attorneys General the ability to bring a civil action enjoining HIPAA violations and seeking damages of \$100 per violation (capped at \$25,000 per year), including costs and attorneys' fees. The HHS Office of Civil Rights is permitted to use corrective action without a penalty in cases where the individual in violation did not know and, by exercising reasonable diligence, would not have known about the violation. Finally, HITECH provides for the addition of criminal penalties for individuals or employees of covered entities who violate HIPAA rules.

EAGLE GROUP XX HITECH ACT CHECK LIST

Administrative Safeguards	
HIPAA Resource Guide	Pages 134-159
Physical Safeguards	
HIPAA Resource Guide	Pages 159-166
Technical Safeguards	
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HIPAA resource Guide	Appendix A1
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Information Security and Confidentiality Office	r Guide Page 82
Required Documents	
HITECH Compliance Document (Client)	Guide Page 101
Physical Security Check Sheet	Guide Page 83
Administrative Security Check Sheet	Guide Page 84
Technical Security Check Sheet	Guide Page 85
HIPAA Business Associate Agreement	Guide Page 77
HIPAA Compliance Declaration	Guide Page 96
HITECH Amendment Contract	Guide Page 102-104

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An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule

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U.S. Department of Commerce Carlos M. Gutierrez, Secretary National Institute of Standards and Technology Patrick D. Gailagher, Deputy Director An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA)

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Reports on Information Systems Technology

The Information Technology Laboratory (ITL) at the National Institute of Standards and Technology (NIST) promotes the U.S. economy and public welfare by providing technical leadership for the nation's measurement and standards infrastructure. ITL develops tests, test methods, reference data, proof of concept implementations, and technical analyses to advance the development and productive use of information technology. ITL's responsibilities include the development of management, administrative, technical, and physical standards and guidelines for the cost-effective security and privacy of other than national security-related information in federal information systems. The Special Publication 800-series reports on ITL's research, guidelines, and outreach efforts in information system security, and its collaborative activities with industry, government, and academic organizations.

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Authority

This document has been developed by the National Institute of Standards and Technology (NIST) to further its statutory responsibilities under the Federal Information Security Management Act (FISMA) of 2002, P.L. 107-347. NIST is responsible for developing standards and guidelines, including minimum requirements, for providing adequate information security for all agency operations and assets, but such standards and guidelines shall not apply to national security systems. This guideline is consistent with the requirements of the Office of Management and Budget (OMB) Circular A-130, Section 8b(3), Securing Agency Information Systems, as analyzed in A-130, Appendix IV: Analysis of Key Sections. Supplemental information is provided in A-130, Appendix III.

This guideline has been prepared for use by federal agencies. It may also be used by nongovernmental organizations on a voluntary basis and is not subject to copyright. (Attribution would be appreciated by NIST.) Nothing in this document should be taken to contradict standards and guidelines made mandatory and binding on federal agencies by the Secretary of Commerce under statutory authority. Nor should these guidelines be interpreted as altering or superseding the existing authorities of the Secretary of Commerce, Director of the OMB, or any other federal official.

There are references in this publication to documents currently under development by NIST in accordance with responsibilities assigned to NIST under the Federal Information Security Management Act of 2002. The methodologies in this document may be used even before the completion of such companion documents. Thus, until such time as each document is completed, current requirements, guidelines, and procedures (where they exist) remain operative. For planning and transition purposes, agencies may wish to closely follow the development of these new documents by NIST. Individuals are also encouraged to review the public draft documents and offer their comments to NIST. All NIST documents mentioned in this publication, other than the ones noted above, are available at http://csrc.nist.gov/publications. Certain commercial entities, equipment, or materials may be identified in this document in order to describe an experimental procedure or concept adequately. Such identification is not intended to imply recommendation or endorsement by the National Institute of Standards and Technology, nor is it intended to imply that the entities, materials, or equipment are necessarily the best available for the purpose. iii

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Acknowledgments

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This publication is intended as general guidance only for federal organizations, and is not intended to be, nor should it be construed or relied upon as legal advice or guidance to non federal entities or persons. This document does not modify the Health Insurance Portability and Accountability Act of 1996 (HIPAA) or any other federal law or regulation. The participation of other federal organizations with the National Institute of Standards and Technology (NIST) and NIST workgroups in the development of this special publication does not, and shall not be deemed to, constitute the endorsement, recommendation, or approval by those organizations of its contents.

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An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule

Executive Summary

Some federal agencies, in addition to being subject to the Federal Information Security Management Act of 2002 (FISMA), are also subject to similar requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule (the Security Rule), if the agency is a covered entity as defined by the rules implementing HIPAA.

The HIPAA Security Rule specifically focuses on the safeguarding of electronic protected health information (EPHI). Although FISMA applies to all federal agencies and all information types, only a subset of agencies are subject to the HIPAA Security Rule based on their functions and use of EPHI. All HIPAA covered entities, which include some federal agencies, must comply with the Security Rule, which specifically focuses on protecting the confidentiality, integrity, and availability of EPHI, as defined in the Security Rule. The EPHI that a covered entity creates, receives, maintains, or transmits must be protected against reasonably anticipated threats, hazards, and impermissible uses and/or disclosures. In general, the requirements, standards, and implementation specifications of the Security Rule apply to the following covered entities:

Covered Healthcare Providers—Any provider of medical or other health services, or supplies, who transmits any health information in electronic form in connection with a transaction for which the Department of Health and Human Services (DHHS) has adopted a standard.

Health Plans—Any individual or group plan that provides, or pays the cost of, medical care, including certain specifically listed governmental programs (e.g., a health insurance issuer and the Medicare and Medicaid programs).

Healthcare Clearinghouses—A public or private entity that processes another entity's healthcare transactions from a standard format to a nonstandard format, or vice versa.

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Medicare Prescription Drug Card Sponsors –A nongovernmental entity that offered an endorsed discount drug program under the Medicare Modernization Act. This fourth category of "covered entity" remained in effect until the drug card program ended in 2006.

NIST publications, many of which are required for federal agencies, can serve as voluntary guidelines and best practices for state, local, and tribal governments and the private sector, and may provide enough depth and breadth to help organizations of many sizes select the type of implementation that best fits their unique circumstances. NIST security standards and guidelines (Federal Information Processing Standards [FIPS], Special Publications in the 800 series), which can be used to support the requirements of both HIPAA and FISMA, may be used by organizations to help provide a structured, yet flexible framework for selecting, specifying, employing, and evaluating the security controls in information systems. This Special Publication (SP), which discusses security considerations and resources that may provide value when implementing the requirements of the HIPAA Security Rule, was written to:

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Help to educate readers about information security terms used in the HIPAA Security Rule and to improve understanding of the meaning of the security standards set out in the Security Rule;

Direct readers to helpful information in other NIST publications on individual topics addressed by the HIPAA Security Rule; and

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Aid readers in understanding the security concepts discussed in the HIPAA Security Rule. This publication does not supplement, replace, or supersede the HIPAA Security Rule itself.

An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule

1.

Introduction

The National Institute of Standards and Technology (NIST) is responsible for developing standards and guidelines, including minimum requirements, used by federal agencies in providing adequate information security for the protection of agency operations and assets. Pursuant to this mission, NIST's Information Technology Laboratory (ITL) has developed guidelines to improve the efficiency and effectiveness of information technology (IT) planning, implementation, management, and operation.

NIST publishes a wide variety of publications on information security. These publications serve as a valuable resource for federal agencies, as well as public, nonfederal agencies and private organizations, seeking to address existing and new federal information security requirements. One such set of federal information security requirements are the security standards adopted by the Secretary of Health and Human Services (HHS) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA, Public Law 104-191). HIPAA required the Secretary to adopt, among other standards, security standards for certain health information. These standards, known as the HIPAA Security Rule (the Security Rule), were published on February 20, 2003. In the preamble to the Security Rule, several NIST publications were cited as potentially valuable resources for readers with specific questions and concerns about IT security.

Congress enacted the Administrative Simplification (part of Title II) provisions of HIPAA to, among other things, promote efficiency in the healthcare industry through the use of standardized electronic transactions, while protecting the privacy and security of health information. Pursuant to the Administrative Simplification provisions of HIPAA, the Secretary of HHS adopted standards relating to:

Electronic healthcare transactions and code sets;

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Privacy of protected health information;

Security of electronic protected health information (EPHI); and

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Unique health identifiers.

This Special Publication summarizes the HIPAA security standards and explains some of the structure and organization of the Security Rule. The publication helps to educate readers about information security terms used in the HIPAA Security Rule and to improve understanding of the meaning of the security standards set out in the Security Rule. It is also designed to direct readers to helpful information in other NIST publications on individual topics addressed by the HIPAA Security Rule. Readers can draw upon these publications for consideration in implementing the Security Rule. This publication is intended as an aid to understanding security concepts discussed in the HIPAA Security Rule, and does not supplement, replace, or supersede the HIPAA Security Rule itself. While the Centers for Medicare and Medicaid Services (CMS) mentioned several NIST publications in the preamble to the HIPAA Security Rule, CMS does not require their use in complying with the Security Rule.1

1 The HIPAA Security Rule mentions NIST documents as potentially helpful guidance but not mandatory for compliance, at 68 Federal Register pages 8346, 8350, 8352, and 8355 (February 20, 2003).

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This document addresses only the security standards of the Security Rule and not other provisions adopted or raised by the Rule, such as 45 CFR § 164.105.

Figure 1 shows all the components of HIPAA and illustrates that the focus of this document is on the security provisions of the statute and the regulatory rule.

Figure 1. HIPAA Components

Readers should refer to the CMS Web site,

http://www.cms.hhs.gov/HIPAAGenInfo/, for more detailed information about the passage of HIPAA by Congress, specific provisions of HIPAA, determination of the entities covered under the law, the complete text of the HIPAA Security Rule, the deadline for compliance with the Rule, and enforcement information.

1.1. Durm a co

Purpose and Scope

The purpose of this publication is to help educate readers about the security standards included in the HIPAA Security Rule. It provides a brief overview of the HIPAA Security Rule, directs the reader to additional NIST publications on information security, and identifies typical activities an agency should consider in implementing an information security program. 2

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Security Rule

This publication is intended as an aid to understand security concepts discussed in the HIPAA Security Rule and does not supplement, replace, modify, or supersede the Security Rule itself. Anyone seeking clarifications of the HIPAA Security Rule should contact the Office of E-Health Standards and Services (OESS) at CMS. For general HIPAA Security Rule information, visit the CMS HIPAA Web site at: http://www.cms.hhs.gov/SecurityStandard/.

The NIST publications available as of the publication date of SP 800-66 Revision 1 were used in preparing this document. NIST frequently publishes new standards and guidelines, or updates existing publications that may also serve as useful references. To remain current with the latest available list of NIST security publications, the reader should periodically review the NIST Computer Security Resource Center (CSRC) Web site at http://csrc.nist.gov. 1.2.

Applicability

The guidelines provided in this publication are applicable to all federal information systems,2 other than those systems designated as national security systems as defined in 44 United States Code (U.S.C.), Section 3542.3 The guidelines included in this publication have been broadly developed from a technical perspective so as to be complementary to similar guidelines issued by agencies and offices operating or exercising control over national security systems. State, local, and tribal governments, as well as private sector organizations composing the critical health infrastructure of the United States are encouraged to consider using these guidelines, as appropriate.

NIST publications may be useful to any agency seeking to understand the security issues raised by the HIPAA Security Rule regardless of that agency's size, structure, or distribution of security responsibilities. Specific agency missions, resources, and organizational structures, however, vary greatly, and agencies' approaches to implementing the HIPAA Security Rule may diverge significantly. Federal agencies use different titles to identify roles that have security-related responsibilities and may also assign particular responsibilities for implementing information security controls (those required by HIPAA and others) differently. NIST SP 800-66 assists all agencies seeking further information on the security safeguards discussed in the HIPAA Security Rule, regardless of the particular structures, methodologies, and approaches used to address its requirements.

2 A federal information system is an information system used or operated by an executive agency, by a contractor of an executive agency, or by another organization on behalf of an executive agency.

3 A national security system is any information system (including any telecommunications system) used or operated by an agency or by a contractor of an agency, or other organization on behalf of an agency—(i) the function, operation, or use of which: involves intelligence activities, involves cryptographic activities related to national security; involves command and control of military forces; involves equipment that is an integral part of a weapon or weapons system; or is critical to the direct fulfillment of military or intelligence missions (excluding a system that is to be used for routine administrative and business applications); or (ii) is protected at all times by procedures established for information that have been specifically authorized under criteria established by an Executive Order or an Act of Congress to be kept classified in the interest of national defense or foreign policy. Agencies should consult NIST Special Publication 800-59, Guide for Identifying an Information System as a National Security System, for guidance on determining the status of their information systems.

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The preamble of the Security Rule states that HHS does not rate or endorse the use of industry-developed guidelines and/or models. Organizations that are not required to use this NIST special publication (by other regulation, law, or requirement) yet choose to use it, must determine the value of its content for implementing the Security Rule standards in their environments. The use of this publication or any other NIST publication does not ensure or guarantee that an organization will be compliant with the Security Rule.

1.3.

Audience

This publication is intended to serve a diverse audience of individuals with HIPAA Security Rule implementation, management, and oversight responsibilities and organizations, federal and nonfederal, considered to be a "Covered Entity" under 45 C.F.R. Sec.160.103.

1.4.

Document Organization

The remaining sections and appendices of this publication include the following: Section 2 - Background explains the key concepts included in the HIPAA Security Rule and provides an overview of NIST's role in information security, as well as descriptions of its various information security publications.

Section 3 – Risk Management Framework introduces a structured, flexible, extensible, and repeatable process for managing organizational risk and achieving risk-based protection related to the operation and use of information systems, and the protection of EPHI.

Section 4 –Considerations When Applying the HIPAA Security Rule highlights key activities a covered entity may wish to consider when implementing the Security Rule.

Appendix A – Glossary defines terms used in this document.

Appendix B – Acronyms identifies and defines acronyms used within this document.

Appendix C – References provides references and related source material.

Appendix D – Security Rule Standards and Implementation Specifications

Crosswalk provides a catalog of the HIPAA Security Rule standards and implementation specifications, and crosswalks each to relevant NIST publications and security controls detailed in NIST SP 800-53, Recommended Security Controls for Federal Information Systems.

Appendix E – Risk Assessment Guidelines provides a methodology for conducting a risk assessment, the results of which will enable covered entities to identify appropriate security controls for reducing risk to the organization and its data and information systems.

Appendix F – Contingency Planning Guidelines identifies fundamental planning principles and practices to help covered entities develop and maintain effective information system contingency plans.

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Appendix G – Sample Contingency Plan Template provides a template for preparing an information technology (IT) contingency plan.

Appendix H – Resources for Secure Remote Use and Access provides an overview of NIST publications discussing security technologies that may provide value for organizations facing challenges in securing remotely accessible, stored, or transmitted EPHI.

Appendix I – Telework Security Considerations provides considerations and tips for securing external devices used for telework and remote access. 1.5.

How and Why to Use This Document

Users are encouraged to use this document as a resource that provides concepts and tools to assist covered entities, including federal agencies, to comply with the HIPAA Security Rule.

NIST publications, many of which are required for federal agencies, can serve as guidelines and best practices for state, local, and tribal governments, and the private sector, and may provide enough depth and breadth to help organizations of many sizes select the type of implementation that best fits their unique circumstances.

This document can support the compliance efforts of covered entities in many ways, including:

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Ensuring that each organization is selecting methods and controls which adequately and appropriately protect EPHI of which they are the steward;

Informing the development of compliance strategies that are in concert with the size and structure of the entity;

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Providing guidelines on best practices for developing and implementing a Risk Management Program; and

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Creating appropriate documentation that demonstrates effective compliance with the HIPAA Security Rule.

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2.

Background

2.1.

HIPAA Security Rule

The HIPAA Security Rule specifically focuses on the safeguarding of EPHI. Although FISMA applies to all federal agencies and all information types, only a subset of agencies is subject to the HIPAA Security Rule based on their functions and use of EPHI. All HIPAA covered entities, which includes some federal agencies, must comply with the Security Rule. The Security Rule specifically focuses on protecting the confidentiality, integrity, and availability of EPHI, as defined in the Security Rule. The EPHI that a covered entity creates, receives, maintains, or transmits must be protected against reasonably anticipated threats, hazards, and impermissible uses and/or disclosures. In general, the requirements, standards, and implementation specifications of the Security Rule apply to the following covered entities:

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Covered Healthcare Providers— Any provider of medical or other health services, or supplies, who transmits any health information in electronic form in connection with a transaction for which HHS has adopted a standard.

Health Plans— Any individual or group plan that provides or pays the cost of medical care (e.g., a health insurance issuer and the Medicare and Medicaid programs).

Healthcare Clearinghouses— A public or private entity that processes another entity's healthcare transactions from a standard format to a nonstandard format, or vice versa.

Medicare Prescription Drug Card Sponsors – A nongovernmental entity that offers an endorsed discount drug program under the Medicare Modernization Act. This section identifies the main goals, explains some of the structure and organization, and identifies the purpose of the sections of the Security Rule. 2.1.1.

Security Rule Goals and Objectives

As required by the "Security standards: General rules"4 section of the HIPAA Security Rule, each covered entity must:

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Ensure the confidentiality, integrity, and availability of EPHI that it creates, receives, maintains, or transmits;

•

Protect against any reasonably anticipated threats and hazards to the security or integrity of EPHI; and

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Protect against reasonably anticipated uses or disclosures of such information that are not permitted by the Privacy Rule.

4 See 45 C.F.R. § 164.306(a).

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In complying with this section of the Security Rule, covered entities must be aware of the definitions provided for confidentiality, integrity, and availability as given by § 164.304:

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Confidentiality is "the property that data or information is not made available or disclosed to unauthorized persons or processes."

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Integrity is "the property that data or information have not been altered or destroyed in an unauthorized manner."

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Availability is "the property that data or information is accessible and useable upon demand by an authorized person."

2.1.2.

Security Rule Organization

To understand the requirements of the HIPAA Security Rule, it is helpful to be familiar with the basic security terminology it uses to describe the security standards. By understanding the requirements and the terminology in the HIPAA Security Rule, it becomes easier to see which NIST publications may be appropriate reference resources and where to find more information. The Security Rule is separated into six main sections that each include several standards and implementation specifications that a covered entity must address.5 The six sections are listed below.

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Security standards: General Rules - includes the general requirements all covered entities must meet; establishes flexibility of approach; identifies standards and implementation specifications (both required and addressable); outlines decisions a covered entity must make regarding addressable implementation specifications; and requires maintenance of security measures to continue reasonable and appropriate protection of electronic protected health information.

Administrative Safeguards - are defined in the Security Rule as the "administrative actions and policies, and procedures to manage the selection, development, implementation, and maintenance of security measures to protect electronic protected health information and to manage the conduct of the covered entity's workforce in relation to the protection of that information."

Physical Safeguards - are defined as the "physical measures, policies, and procedures to protect a covered entity's electronic information systems and related buildings and equipment, from natural and environmental hazards, and unauthorized intrusion."

Technical Safeguards - are defined as the "the technology and the policy and procedures for its use that protect electronic protected health information and control access to it."

5 Sections of the HIPAA regulations that are included in the Security Rule and therefore addressed in this document but do not have their own modules are Part 160 — General Administrative Requirements § 160.103, Definitions; Part 164 — Security and Privacy §§ 164.103, Definitions; 164.104, Applicability; 164.105, Organizational requirements (discussed in section 4 of this document), 164.302 Applicability; 164.304, Definitions; 164.306, Security standards: General rules (discussed in section 3.1 of this document), and 164.318, Compliance dates for the initial implementation of the security standards. 7

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Organizational Requirements - includes standards for business associate contracts and other arrangements, including memoranda of understanding between a covered entity and a business associate when both entities are government organizations; and requirements for group health plans.

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Policies and Procedures and Documentation Requirements - requires implementation of reasonable and appropriate policies and procedures to comply with the standards, implementation specifications and other requirements of the Security Rule; maintenance of written (which may be electronic) documentation and/or records that includes policies, procedures, actions, activities, or assessments required by the Security Rule; and retention, availability, and update requirements related to the documentation.

Within the Security Rule sections are standards and implementation specifications. Each HIPAA Security Rule standard is required. A covered entity is required to comply with all standards of the Security Rule with respect to all EPHI. Many of the standards contain implementation specifications. An implementation specification is a more detailed description of the method or approach covered entities can use to meet a particular standard.6 Implementation specifications are either required or addressable. However, regardless of whether a standard includes implementation specifications, covered entities must comply with each standard. A required implementation specification is similar to a standard, in that a covered entity must comply with it.

For addressable implementation specifications, covered entities must perform an assessment to determine whether the implementation specification is a reasonable and appropriate safeguard for implementation in the covered entity's environment. In general, after performing the assessment, a covered entity decides if it will implement the addressable implementation specification; implement an equivalent alternative measure that allows the entity to comply with the standard; or not implement the addressable specification or any alternative measures, if equivalent measures are not reasonable and appropriate within its environment. Covered entities are required to document these assessments and all decisions. For federal agencies, however, all of the HIPAA Security Rule's addressable implementation specifications will most likely be reasonable and appropriate safeguards for implementation, given their sizes, missions, and resources.

Where there are no implementation specifications identified in the Security Rule for a particular standard, such as for the "Assigned Security Responsibility" and "Evaluation" standards, compliance with the standard itself is required. Appendix D of this document provides a crosswalk of the HIPAA Security Rule standards and implementation specifications to relevant NIST publications and security controls detailed in NIST SP 800-53.

6 For more information on the required analysis used to determine the manner of implementation of an implementation specification, see § 164.306(d) of the HIPAA Security Rule (Security standards — General rules: Flexibility of approach). 8 An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA)

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For general HIPAA Security Rule information, visit the CMS HIPAA Web site at http://www.cms.hhs.gov/SecurityStandard/.

2.2.

NIST and its Role in Information Security

Founded in 1901, NIST is a non-regulatory federal agency within the U.S. Department of Commerce. NIST's mission is to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life. NIST is composed of several laboratories that conduct research in a wide variety of physical and engineering sciences. Lab researchers respond to industry needs for measurement methods, tools, data, and technology, and collaborate with colleagues in industry, academic institutions, and other government agencies.

The Computer Security Division (CSD), a component within NIST's Information Technology Laboratory (ITL), provides standards and technology to protect information systems against threats to the confidentiality of information, the integrity of information and processes, and the availability of information and services in order to build trust and confidence in IT systems.

CSD develops and issues standards, guidelines, and other publications to assist federal agencies in implementing the requirements of FISMA and in managing costeffective security programs to protect their information and information systems. Table 1 identifies and describes the types of NIST publications.

 Table 1: NIST Publication Types

Publication Type

Description

Federal Information Processing Standards (FIPS)

Developed by NIST in accordance with FISMA. They are approved by the Secretary of Commerce and are compulsory and binding for federal agencies. Since FISMA requires that federal agencies comply with these standards, agencies may not waive their use. FIPS may be used voluntarily by nonfederal organizations (e.g., state/local/tribal governments, industry).

Special Publication (SP) 800-series

Reports on ITL's research, guidelines, and outreach efforts in information system security and its collaborative activities with industry, government, and academia. Office of Management and Budget (OMB) policies state that for other than national security programs and systems, federal agencies must follow NIST guidelines. SPs may be used voluntarily by nonfederal organizations.

Other Security Publications

Other publications including interagency reports (NISTIRs) and ITL bulletins that provide technical and other information about NIST's activities.

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3.

A Framework for Managing Risk

The HIPAA Security Rule is all about implementing effective risk management to adequately and effectively protect EPHI. The assessment, analysis, and management of risk provides the foundation of a covered entity's Security Rule compliance efforts, serving as tools to develop and maintain a covered entity's strategy to protect the confidentiality, integrity, and availability of EPHI.

All EPHI created, received, maintained, or transmitted by a covered entity is subject to the Security Rule. Covered entities are required to implement reasonable and appropriate security measures to protect against reasonably anticipated threats or vulnerabilities to the security of EPHI. Under the Security Rule, covered entities are required to evaluate risks and vulnerabilities in their environments and to implement security controls to address those risks and vulnerabilities.

The selection and specification of security controls can be accomplished as part of an organization-wide information security program that involves the management of organizational risk - that is, the risk to information, individuals, and the organization as a whole. The management of risk is a key element in the organization's information security program and provides an effective framework for selecting the appropriate security controls for an information system - the security controls necessary to protect individuals and the operations and assets of the organization.

This section describes a process of managing risk to organizational missions and business functions that arise from the operation and use of information systems by discussing each phase of the NIST Risk Management Framework7 and providing a mapping of this framework to complementary requirements of the HIPAA Security Rule.

3.1.

NIST Risk Management Framework (RMF)

The NIST RMF, illustrated in Figure 2, provides the covered entity with a disciplined, structured, extensible, and repeatable process for achieving risk-based protection related to the operation and use of information systems and the protection of EPHI. It represents an information security life cycle that facilitates

continuous monitoring and improvement in the security state of the information systems within the organization.

The activities that compose the NIST RMF are paramount to an effective information security program and can be applied to both new and legacy information systems within the context of a system development life cycle. A riskbased approach to security control selection and specification considers effectiveness, efficiency, and constraints due to applicable laws, directives, Executive Orders, policies, standards, or regulations.

The flexible nature of the NIST RMF allows other communities of interest (e.g., state, local, and tribal governments and private sector entities) to use the framework voluntarily either with the NIST security standards and guidelines or with industry-specific standards and guidelines. The RMF provides organizations with the flexibility needed to apply the right security controls to the right information systems at the right time to adequately

7 NIST Special Publication 800-39, Managing Risk from Information Systems: An Organizational Perspective, (Second Public Draft), April 2008. 10

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protect the critical and sensitive information, missions, and business functions of the organization.

Figure 2. NIST Risk Management Framework 3.2.

The NIST RMF and Links to the Security Rule

The NIST RMF consists of six steps that are paramount to the effective

management of risk resulting from the operation and use of information systems. Many Security Rule standards and implementation specifications correspond to the steps of the NIST RMF. Using these corresponding requirements in an integrated fashion can provide a methodical, repeatable, risk-based approach for selecting, specifying, and implementing security controls to adequately protect EPHI. Table 2 describes each step in the NIST RMF as well as the related standards and implementation specifications found in the Security Rule.

Repeat as necessary

RISK MANAGEMENT **FRAMEWORK Security Life Cycle** Step 1 **CATEGORIZE Information Systems** FIPS 199 / SP 800-60 Step 6 MONITOR **Security State** SP 800-37 / 800-53A Step 3 **IMPLEMENT Security Controls** SP 800-70

Step 2 **SELECT Security Controls** FIPS 200 / SP 800-53 **Security Plan** Step 5 **AUTHORIZE Information Systems** An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule Table 2: Linking the NIST RMF and the Security Rule **RMF Phase RMF Step Description Security Rule Link Categorize Information Systems** Security categorization, the first and arguably the most important step in the RMF. employs FIPS 199 and NIST SP 800-60 to determine the criticality and sensitivity of the information system and the information being processed, stored, and transmitted by the system. This exercise aids in determining priorities for organizational information systems and subsequently applying appropriate measures to adequately protect the organizational missions and business functions supported by those missions. The security controls applied to a particular information system should be commensurate with the potential impact on organizational operations and assets, individuals, or other organizations should there be a loss of confidentiality, integrity, or availability. Identify assets and information systems that create, receive, transmit, or maintain EPHI. **Related Standards and Implementation Specifications:** 164.308(a)(1)(i) – Security Management Process **Select Security Controls** Security control selection, the second step in the RMF, employs FIPS 200 and NIST SP 800-53 to identify and specify appropriate security controls for the information system. The selection of security controls for an organization's mission/business processes and the information systems supporting those processes is a risk mitigation activity. The security control selection process consists of three activities: Selection of baseline security controls for each information system from NIST SP 800-53 in accordance with FIPS 199 impact levels determined during the security categorization process: Application of security control tailoring guidance for the information systems to allow organizations to adjust the initial security control baselines with respect to specific mission and business processes,

Select the standards and required implementation specifications as the initial security control set. These required security controls establish the baseline from which to assess risk to EPHI.

Once the baseline is established, perform a risk assessment and analysis to evaluate whether the standards and required implementation specifications alone are reasonable and appropriate to provide adequate protection against reasonably anticipated threats or hazards to the confidentiality, integrity, or availability of EPHI. The results of this risk assessment and analysis will drive the selection of addressable implementation specifications to adequately supplement the baseline. Supplement the initial set of standards and required implementation specifications (baseline) with addressable implementation specifications. The decisions to supplement

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RMF Step Description organizational requirements, and environments of operations; and

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Supplementation of tailored baseline security controls with additional controls based on an assessment of risk and local conditions including specific and credible threat information, organization-specific security requirements, cost-benefit analyses, and special circumstances.

Key to this process is documenting the selection and specification of security controls. A documented security plan provides an overview of the security requirements for the information systems within the organization and describes the security controls in place or planned for meeting those requirements. Additionally, the security plans for organizational information systems describe how individual security controls are implemented within specific operational environments. It is important for organizations to document the decisions taken during the security control selection process, providing a sound rationale for those decisions. The resulting set of security controls along with the supporting rationale for security control selection decisions and any information system use restrictions are documented in the security plans for the information system. This provides a clear description of the risk mitigation deemed necessary in order to adequately ensure mission accomplishment and success of business functions potentially impacted by the operation and use of the systems.

the security control baseline should be based on an assessment of risk and local conditions including organization-specific security requirements, specific threat information, cost-benefit analyses, or special circumstances.

The agreed-upon set of security controls will consist of the standards, required implementation specifications, and the risk-based selection of addressable implementation specifications.

Each covered entity must document the security controls determined to be reasonable and appropriate, including analysis, decisions, and rationale for decisions made to refine or adjust the security controls

Related Standards and Implementation Specifications:

164.308(a)(1)(i) – Security Management Process

164.308(a)(1)(ii)(A) - Risk Analysis

164.308(a)(1)(ii)(B) - Risk Management

164.316(b)(1)-Documentation

164.316(b)(2)(ii) – Updates

Implement Security Controls

Security control implementation, the third step in the RMF, employs enterprise architectures, the System Development Lifecycle (SDLC), and various NIST publications to guide the implementation of security controls in organizational information systems.

Implement the security controls that have been determined to be reasonable and appropriate for the organization.

Related Standards and Implementation Specifications:

164.308(a)(1)(ii)(B) – Risk Management

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RMF Phase RMF Step Description Security Rule Link

Assess Security Controls

Security Controls Assessment, the fourth step in the RMF, employs NIST SP 800-53A to evaluate the information system security controls for effectiveness using appropriate methods and procedures to determine the extent to which the controls are implemented correctly, operating as intended, and producing the desired outcome with respect to meeting the security objectives and requirements for the system.

Evaluate the implemented specifications using assessment methods and procedures to determine the extent to which the controls are implemented correctly and operating as intended with respect to protecting EPHI.

Related Standards and Implementation Specifications:

164.308(a)(8) – Evaluation

Authorize Information System

Authorize information system operation (with implemented security controls) based upon a determination of the risk to organizational operations, organizational assets, individuals, and other organizations, and an explicit decision to accept this risk. Inherent in any risk management process is the acceptance of those identified risks

that are deemed acceptable to the organization.

Related Standards and Implementation Specifications:

164.308(a)(1)(ii)(B) - Risk Management

Monitor Security State

Threats and vulnerabilities to an operating environment, as well as safeguards designed to combat them, can change frequently. The assessment and evaluation of security controls on a continuous basis provides oversight and monitoring of the security controls to ensure that they continue to operate effectively and as intended. Monitor and assess selected security controls in the information system on a continuous basis including documenting changes to the system, conducting security impact analyses of the changes, and reporting the system security status to appropriate organizational officials on a regular basis.

A covered entity must periodically review and update its security measures and documentation in response to environmental and operational changes that affect security of its EPHI.

Related Standards and Implementation Specifications:

164.308(a)(8) – Evaluation

164.308(a)(1)(ii)(D) – Information System Activity Review

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Considerations when Applying the HIPAA Security Rule

In this section, security measures from NIST publications that are relevant to each section of the Security Rule are presented. Each standard is presented in a consistent tabular format.

The following tables, organized by HIPAA Security Rule standard, are designed to initiate the thought process for implementing the requirements of the Security Rule. These tables highlight information a covered entity may wish to consider when implementing the Security Rule; they are not meant to be prescriptive. The tables may also not be considered all-inclusive of the information available in NIST publications.

In addition to the HIPAA Security Rule standard name and description, each table includes the following information:

Key Activities - The Key Activities column suggests, for each HIPAA Security Rule standard, actions that are usually associated with the security function or functions suggested by that standard. Some of these key activities are also the implementation specifications for that particular standard. Each key activity that is also an implementation specification has been identified as such in the table (in italics in the Description section of the table), along with a note as to whether the implementation specification is required or addressable. Other key activities would normally be performed as part of one or more of the related implementation specifications under the standard, but are listed separately for clarity of presentation. Where such a relationship exists, it is indicated in an accompanying footnote.

Other key activities are not implementation specifications. These activities are not specifically discussed or required by the HIPAA Security Rule, and their inclusion here is in no way meant to expand upon the intent or requirements of the Security Rule. Many of these activities, however, are usually included in a robust security process, and many will be required of federal entities under other federal laws, regulations, or procedures that may or may not be discussed within this document. The tables address all HIPAA Security Rule standards and all associated implementation specifications, both required and addressable. Seven of the standards include all the necessary instructions for implementation and have no associated implementation specifications.8 However, as noted earlier in this document, even if there are no implementation specifications outlined in the Security Rule, such as with Assigned Security Responsibility and Evaluation, compliance with the standard itself is still required.

The key activities are illustrative and not all-inclusive. There may be many additional activities an organization will need to consider, specific to its own operations, which are not included in the key activities of the tables. Each entity will need to identify what activities beyond those listed in the tables are necessary and appropriate in its environment, implement those activities, and document them. 8 Standards that do not contain implementation specifications—that "themselves also serve as the implementation specification," as stated in the preamble to the HIPAA Security Rule—are those described in Sections 4.2 (HIPAA Standard: Assigned Security Responsibility); 4.8 (HIPAA Standard: Evaluation); 4.11 (HIPAA Standard: Workstation Use); 4.12 (HIPAA Standard: Workstation Security), 4.15 (HIPAA Standard: Audit Controls); 4.17 (HIPAA Standard: Person or Entity Authentication); and 4.21 (HIPAA Standard: Policies and Procedures). 15 An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule 16

The tables are meant to serve as only a general introduction to the security topics raised by the HIPAA Security Rule. For more detailed information about the key activities, consult one or more NIST publications referenced for the subject HIPAA standard.

Description - The Description column in each table includes an expanded explanation about the key activities. The descriptions include types of activities an organization may pursue in addressing a specific security function. These are abbreviated explanations designed to help get an organization started in addressing the HIPAA Security Rule. The first description bullet of each key activity that is also an implementation specification includes the Security Rule implementation specification text in italics. When relationships exist between description bullets and other Security Rule standards or implementation specifications, it is indicated in an accompanying footnote.

Sample Questions - The Sample Questions column includes some questions to determine whether or not the elements described have actually been considered or completed. These sample questions are not exhaustive but merely indicative of relevant questions that could be asked. Affirmative answers to these questions do not imply that an organization is meeting all of the requirements of the HIPAA security standards. Negative answers to these questions should prompt the covered entity to consider whether it needs to take further action in order to comply with the standards. In fact, it is expected that many organizations with existing information security infrastructure already in place will have considered most of the Sample Questions. The questions an organization asks in assessing and developing its security program should be tailored to fit the unique circumstances of each entity. This document does not discuss Section 164.105 of the HIPAA Security Rule, Organizational Requirements, in detail as they do not set out general security principles. HIPAA covered entities are encouraged to review this section of the HIPAA Security Rule in full and seek further guidance.

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Administrative Safeguards

4.1.

Security Management Process (§ 164.308(a)(1))

HIPAA Standard: Implement policies and procedures to prevent, detect, contain, and correct security violations.

Key Activities

Description

Sample Questions

1.

Identify Relevant Information Systems

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Identify all information systems that house EPHI.

•

Include all hardware and software that are used to collect, store, process, or transmit EPHI.

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Analyze business functions and verify ownership and control of information system elements as necessary.

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Are all hardware and software for which the organization is responsible periodically inventoried?

Have hardware and software that maintains or transmits EPHI been identified? Does this inventory include removable media and remote access devices?

Is the current information system configuration documented, including connections to other systems?

Have the types of information and uses of that information been identified and the sensitivity of each type of information been evaluated? (See FIPS 199 and SP 800-60 for more on categorization of sensitivity levels.)

2.

Conduct Risk Assessment9

Implementation Specification (Required)

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Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of EPHI held by the covered entity.

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A risk assessment methodology, based on NIST SP 800-30, is included in Appendix E of this document.

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Are there any prior risk assessments, audit comments, security requirements, and/or security test results?

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Is there intelligence available from agencies, the Office of the Inspector General (OIG), the US-CERT, virus alerts, and/or vendors?

What are the current and planned controls?

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Is the facility located in a region prone to any natural disasters, such as earthquakes, floods, or fires?

•

Has responsibility been assigned to check all hardware and software, including hardware and software used for remote access, to determine whether selected security settings are enabled?

Is there an analysis of current safeguards and their effectiveness relative to the identified risks?

•

Have all processes involving EPHI been considered, including creating, receiving, maintaining, and transmitting it?

3.

Implement a Risk Management Program10

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Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with §164.306(a).

•

Do current safeguards ensure the confidentiality, integrity, and availability of all EPHI?

Do current safeguards protect against reasonably

9 The risks that must be assessed are the risks of noncompliance with the requirements of Section 164.306(a) (General Rules) of the HIPAA Security Rule. 17 10 See Section 164.306 of the HIPAA Security Rule.

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Portability and Accountability Act (HIPAA) Security Rule

Kev Activities Description

Sample Questions

Implementation Specification (Required) anticipated uses or disclosures of EPHI that are not permitted by the Privacy Rule?

Has the covered entity protected against all reasonably anticipated threats or hazards to the security and integrity of EPHI?

Has the covered entity assured compliance with all policies and procedures by its workforce?

4.

Acquire IT Systems and Services11, 12

Although the HIPAA Security Rule does not require purchasing any particular technology, additional hardware, software, or services may be needed to adequately protect information. Considerations for their selection should include the following:

Applicability of the IT solution to the intended environment;

The sensitivity of the data;

The organization's security policies, procedures, and standards; and

Other requirements such as resources available for operation, maintenance, and training.

Will new security controls work with the existing IT architecture?

Have the security requirements of the organization been compared with the security features of existing or proposed hardware and software?

Has a cost-benefit analysis been conducted to determine the reasonableness of the investment given the security risks identified?

Has a training strategy been developed?13

5.

Create and Deploy Policies and Procedures14, 15

Implement the decisions concerning the management, operational, and technical controls selected to mitigate identified risks.

Create policies that clearly establish roles and responsibilities and assign ultimate responsibility for the implementation of each control to particular individuals or offices.16

Create procedures to be followed to accomplish particular security-related tasks.

Are policies and procedures in place for security? Is there a formal (documented) system security plan? Is there a formal contingency plan?17 Is there a process for communicating policies and procedures to the affected employees? Are policies and procedures reviewed and updated as needed? 6. **Develop and Implement a Sanction Policy18** Implementation **Specification (Required)** Apply appropriate sanctions against workforce members who fail to comply with the security policies and procedures of the covered entity. Develop policies and procedures for imposing appropriate sanctions (e.g., reprimand, termination) for noncompliance with the organization's security policies. Implement sanction policy as cases arise. Is there a formal process in place to address system misuse, abuse, and fraudulent activity? Have employees been made aware of policies concerning sanctions for inappropriate access, use, and disclosure of EPHI? Has the need and appropriateness of a tiered structure of sanctions that accounts for the magnitude of harm and 11 See Section 164.306(b) of the HIPAA Security Rule. 12 See Key Activity 4.1.3, Implement a Risk Management Program. This activity and all associated bullets in the Description and Sample Questions are part of the process of addressing the risk management implementation specification. 13 See Section 4.5, HIPAA Standard: Security Awareness and Training. 14 See Section 4.21, HIPAA Standard: Policies and Procedures. 15 See Key Activity 4.1.3, Implement a Risk Management Program. This activity and all associated bullets in the Description and Sample Ouestions are part of the process of addressing the risk management implementation specification. 16 See Section 4.21, HIPAA Standard: Policies and Procedures and Section 4.22, **HIPAA Standard: Documentation. 18**

17 See Section 4.7, HIPAA Standard: Contingency Plan.

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19

Sample Questions possible types of inappropriate disclosures been considered? •

How will managers and employees be notified regarding suspect activity?

7.

Develop and Deploy the Information System Activity Review Process Implementation Specification (Required)

Implement procedures to regularly review records of information system activity,

such as audit logs, access reports, and security incident tracking reports.

Who is responsible for the overall process and results?19

How often will reviews take place?

How often will review results be analyzed?

What is the organization's sanction policy for employee violations?

Where will audit information reside (e.g., separate server)? 8.

Develop Appropriate Standard Operating Procedures20

•

Determine the types of audit trail data and monitoring procedures that will be needed to derive exception reports.

•

How will exception reports or logs be reviewed?

Where will monitoring reports be filed and maintained?

9.

Implement the Information System Activity Review and Audit Process21

Activate the necessary review process.

Begin auditing and logging activity.

•

What mechanisms will be implemented to assess the effectiveness of the review process (measures)?

•

What is the plan to revise the review process when needed?

18 See Section 164.306 of the HIPAA Security Rule.

19 See Section 4.2, HIPAA Standard: Assigned Security Responsibility.

20 See Key Activity 4.1.7, Develop and Deploy the Information System Activity Review Process. This activity and all associated bullets in the Description and Sample Questions are part of the process of addressing the information system activity review implementation specification. 21 See Key Activity 4.1.7, Develop and Deploy the Information System Activity Review Process. This activity and all associated bullets in the Description and Sample Questions are part of the process of addressing the information system activity review implementation specification. An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule 4.2.

Assigned Security Responsibility (§ 164.308(a)(2))

HIPAA Standard: Identify the security official who is responsible for the development and implementation of the policies and procedures required by this subpart for the entity. **Key Activities** Description **Sample Questions** 1. Select a Security Official To Be Assigned Responsibility for HIPAA Security Identify the individual who has final responsibility for security. Select an individual who is able to assess effective security and to serve as the point of contact for security policy, implementation, and monitoring. Who in the organization— Oversees the development and communication of security policies and procedures? Is responsible for conducting the risk assessment? Handles the results of periodic security evaluations and continuous monitoring? **Directs IT security purchasing and investment?** A Ensures that security concerns have been addressed in system implementation? Who in the organization is authorized to accept risk from information systems on behalf of the organization? 2. Assign and Document the Individual's Responsibility Document the assignment to one individual's responsibilities in a job description.22 Communicate this assigned role to the entire organization. Is there a complete job description that accurately reflects assigned security duties and responsibilities? Have the staff members in the organization been notified as to whom to call in the event of a security problem?23 22 See Standard 4.22, Standard: Documentation. 2023 See Standard 4.5, Security Awareness and Training, and 4.6, Security Incident **Procedures.** An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule 4.3. Workforce Security (§ 164.308(a)(3)) HIPAA Standard: Implement policies and procedures to ensure that all members of its workforce have appropriate access to electronic protected health information, as provided under paragraph (a)(4) of this section, and to prevent those workforce

members who do not have access under paragraph (a)(4) of this section from obtaining access to electronic protected health information. **Key Activities** Description **Sample Questions** 1. **Implement Procedures for Authorization and/or Supervision Implementation Specification (Addressable)** Implement procedures for the authorization and/or supervision of workforce members who work with EPHI or in locations where it might be accessed. Have chains of command and lines of authority been established? Have staff members been made aware of the identity and roles of their supervisors? 2. **Establish Clear Job Descriptions and Responsibilities24** Define roles and responsibilities for all job functions. Assign appropriate levels of security oversight, training, and access. Identify in writing who has the business need-and who has been granted permission-to view, alter, retrieve, and store EPHI, and at what times, under what circumstances, and for what purposes.25 Are there written job descriptions that are correlated with appropriate levels of access? Have staff members been provided copies of their job descriptions, informed of the access granted to them, as well as the conditions by which this access can be used? 3. Establish Criteria and Procedures for Hiring and Assigning Tasks26 Ensure that staff members have the necessary knowledge, skills, and abilities to fulfill particular roles, e.g., positions involving access to and use of sensitive information. Ensure that these requirements are included as part of the personnel hiring process. Have the qualifications of candidates for specific positions been checked against the job description? Have determinations been made that candidates for specific positions are able to perform the tasks of those positions? 4. **Establish a Workforce Clearance Procedure Implementation Specification (Addressable)** Implement procedures to determine that the access of a workforce member to EPHI is appropriate.

Implement appropriate screening of persons who will have access to EPHI.

Implement a procedure for obtaining clearance from appropriate offices or individuals where access is provided or terminated.

Is there an implementation strategy that supports the designated access authorities? •

Are applicants' employment and educational references checked, if reasonable and appropriate?

Have background checks been completed, if reasonable and appropriate?

Do procedures exist for obtaining appropriate sign-offs to grant or terminate access to EPHI?

5.

Establish Termination Procedures Implementation Specification

Implement procedures for terminating access to EPHI when the employment of a workforce member ends or as required by determinations made as specified in •

Are there separate procedures for voluntary termination (retirement, promotion, transfer, change of employment) vs. involuntary termination (termination for cause, 24 See Key Activity 4.3.1, Implement Procedures for Authorization and/or Supervision. This activity and all associated bullets in the Description and Sample Questions are part of the procedures for authorization and/or supervision. 25 See Section 4.22, HIPAA Standard: Documentation. 26 See Key Activity 4.3.1, Implement Procedures for Authorization and/or Supervision. This activity and all associated bullets in the Description and Sample Questions are part of the procedures for authorization and/or supervision.

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Key Activities

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(Addressable) §164.308(a)(3)(ii)(B). • Develop a standard set of procedures that should be followed to recover access control devices (Identification [ID] badges, keys, access cards, etc.) when employment ends.

•

Deactivate computer access accounts (e.g., disable user IDs and passwords). See the Access Controls Standard. reduction in force, involuntary transfer, and criminal or disciplinary actions), if reasonable and appropriate?

٠

Is there a standard checklist for all action items that should be completed when an employee leaves (return of all access devices, deactivation of logon accounts [including remote access], and delivery of any needed data solely under the employee's control)?

22

An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule 4.4. Information Access Management (§ 164.308(a)(4))27 HIPAA Standard: Implement policies and procedures for authorizing access to electronic protected health information that are consistent with the applicable requirements of subpart E of this part. **Kev Activities** Description **Sample Questions** 1. **Isolate Healthcare Clearinghouse Functions28 Implementation Specification (Required)** If a healthcare clearinghouse is part of a larger organization, the clearinghouse must implement policies and procedures that protect the EPHI of the clearinghouse from unauthorized access by the larger organization. Determine if a component of the covered entity constitutes a healthcare clearinghouse under the HIPAA Security Rule. If no clearinghouse functions exist, document this finding. If a clearinghouse exists within the organization, implement procedures for access consistent with the HIPAA Privacy Rule. Does the healthcare clearinghouse share hardware or software with a larger organization of which it is a part? Does the healthcare clearinghouse share staff or physical space with staff from a larger organization? Has a separate network or subsystem been established for the healthcare clearinghouse, if reasonable and appropriate? Has staff of the healthcare clearinghouse been trained to safeguard EPHI from disclosure to the larger organization, if required for compliance with the HIPAA **Privacy Rule?** 2. **Implement Policies and Procedures for Authorizing Access Implementation Specification (Addressable)** Implement policies and procedures for granting access to EPHI, for example, through access to a workstation, transaction, program, process, or other mechanism. Decide how access will be granted to workforce members within the organization. Select the basis for restricting access.

Select an access control method (e.g., identity-based, role-based, or other reasonable and appropriate means of access.)

•

Determine if direct access to EPHI will ever be appropriate for individuals external to the organization (e.g., business partners or patients seeking access to their own EPHI).

•

Do the organization's IT systems have the capacity to set access controls?29 •

Are there documented job descriptions that accurately reflect assigned duties and responsibilities and enforce segregation of duties?30

Does the organization grant remote access to EPHI?

•

What method(s) of access control is (are) used (e.g., identity-based, role-based, location-based, or a combination)?

3.

Implement Policies and Procedures for Access Establishment and Modification Implementation Specification (Addressable)

•

Implement policies and procedures that, based upon the entity's access authorization policies, establish, document, review, and modify a user's right of access to a workstation, transaction, program, or process.

Establish standards for granting access.

•

Provide formal authorization from the appropriate authority before granting access to sensitive information.

•

Are duties separated such that only the minimum necessary EPHI is made available to each staff member based on their job requirements?

27 Note: See also Section 4.10, HIPAA Standard: Facility Access Controls and Section 4.14, HIPAA Standard: Access Controls.

28 Note: Where the healthcare clearinghouse is a separate legal entity, it is subject to the Security Rule whether or not the larger organization is a covered entity.

29 See Section 4.14, HIPAA Standard: Access Controls.

23

30 See Section 4.3, HIPAA Standard: Workforce Security.

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ample Questions 4. Evaluate Existing Security Measures Related to Access Controls31 • Evaluate the security features of access controls already in place, or those of any planned for implementation, as appropriate.

•

Determine if these security features involve alignment with other existing management, operational, and technical controls, such as policy standards and personnel procedures, maintenance and review of audit trails, identification and authentication of users, and physical access controls. • Are there policies and procedures related to the security of access controls?32 If so, are they updated regularly?

Are authentication mechanisms used to verify the identity of those accessing systems protected from inappropriate manipulation?33

Does management regularly review the list of access authorizations, including remote access authorizations, to verify that the list is accurate and has not been inappropriately altered? 34

31 See Key Activity 4.4.3, Implement Policies and Procedures for Access Establishment and Modification. This activity and all associated bullets in the Description and Sample Questions are part of the access establishment and modification implementation specification.

32 See Section 4.22, HIPAA Section: Documentation.

33 See Section 4.17, HIPAA Standard: Person or Entity Authentication. 24

34 See Section 4.3, HIPAA Standard: Workforce Security.

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4.5.

Security Awareness and Training (§ 164.308(a)(5))35

HIPAA Standard: Implement a security awareness and training program for all members of its workforce (including management).

Key Activities

Description

Sample Questions

1.

Conduct a Training Needs Assessment

•

Determine the training needs of the organization.

•

Interview and involve key personnel in assessing security training needs.

•

What awareness, training, and education programs are needed? Which are required?

•

What is the current status regarding how these needs are being addressed (e.g., how well are current efforts working)?

•

Where are the gaps between the needs and what is being done (e.g., what more needs to be done)?

•

What are the training priorities in terms of content and audience?

2.

Develop and Approve a Training Strategy and a Plan

Address the specific HIPAA policies that require security awareness and training in the security awareness and training program.

Outline in the security awareness and training program the scope of the awareness and training program; the goals; the target audiences; the learning objectives; the
deployment methods, evaluation, and measurement techniques; and the frequency of training.

Is there a procedure in place to ensure that everyone in the organization receives security awareness training?

What type of security training is needed to address specific technical topics based on job responsibility?

•

When should training be scheduled to ensure that compliance deadlines are met? •

Has the organization considered the training needs of non-employees (e.g., contractors, interns)?

3.

Protection from Malicious Software; Log-in Monitoring; and Password Management

Implementation Specifications (All Addressable)

•

As reasonable and appropriate, train employees regarding procedures for:

Guarding against, detecting, and reporting malicious software;

0

Monitoring log-in attempts and reporting discrepancies; and

0

Creating changing, and safeguarding passwords.

•

Incorporate information concerning staff members' roles and responsibilities in implementing these implementation specifications into training and awareness efforts.

•

Do employees know the importance of timely application of system patches to protect against malicious software and exploitation of vulnerabilities?

•

Are employees aware that log-in attempts may be monitored?

•

Do employees that monitor log-in attempts know to whom to report discrepancies? •

Do employees understand their roles and responsibilities in selecting a password of appropriate strength, changing the password periodically (if required), and safeguarding their password?

4.

Develop Appropriate Awareness and Training Content, Materials, and Methods •

Select topics that may need to be included in the training materials.

•

Incorporate new information from email advisories, online IT security daily news Web sites, and periodicals, as is reasonable and appropriate.

Consider using a variety of media and avenues according to what is appropriate for the organization based on workforce

Have employees received a copy of, and do they have ready access to, the organization's security procedures and policies?36

Do employees know whom to contact and how to handle a security incident?37 •

Do employees understand the consequences of

35 Note: See also Section 4.10, HIPAA Standard: Facility Access Controls and Section 4.14, HIPAA Standard: Access Controls.

36 See Section 4.22, HIPAA Standard: Documentation.

25

37 See Section 4.6, HIPAA Standard: Security Incident Procedures.

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Key Activities

Description

Sample Questions size, location, level of education, etc. noncompliance with the stated security policies?38

•

Do employees who travel know how to handle physical laptop security issues and information security issues?39

•

Has the covered entity researched available training resources?

•

Is dedicated training staff available for delivery of security training? If not, who will deliver the training?

•

What is the security training budget?

5.

Implement the Training

•

Schedule and conduct the training outlined in the strategy and plan.

•

Implement any reasonable technique to disseminate the security messages in an organization, including newsletters, screensavers, videotapes, email messages, teleconferencing sessions, staff meetings, and computer-based training.

Have all employees received adequate training to fulfill their security responsibilities?

•

Are there sanctions if employees do not complete required training?

6.

Implement Security Reminders

Implementation Specification (Addressable)

•

Implement periodic security updates.

•

Provide periodic security updates to staff, business associates, and contractors.

What methods are available or already in use to make or keep employees aware of security, e.g., posters or booklets?

Is security refresher training performed on a periodic basis (e.g., annually)?

Is security awareness discussed with all new hires?

Are security topics reinforced during routine staff meetings?

Monitor and Evaluate Training Plan 40

Keep the security awareness and training program current.

•

7.

Conduct training whenever changes occur in the technology and practices as appropriate.

•

Monitor the training program implementation to ensure that all employees participate.

•

Implement corrective actions when problems arise.41

•

Are employee training and professional development programs documented and monitored, if reasonable and appropriate?

•

How are new employees trained on security?

•

Are new non-employees (e.g., contractors, interns) trained on security? 38 See Section 4.1, HIPAA Standard: Security Management Process.

39 See Section 4.13, HIPAA Standard: Security Wanagement Process **39** See Section 4.13, HIPAA Standard: Device and Media Controls.

39 See Section 4.15, HIPAA Standard: Device and Media Controls.

40 Also required under the HIPAA Security Rule § 164.306, General Requirements, Subsection (e), Maintenance. See also Section 4.8, HIPAA Standard: Evaluation.

26

41 See Section 4.1, HIPAA Standard: Security Management Process.

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4.6.

Security Incident Procedures (§ 164.308(a)(6))42

HIPAA Standard: Implement policies and procedures to address security incidents. Key Activities

Description

Sample Questions

1.

Determine Goals of Incident Response

•

Gain an understanding as to what constitutes a true security incident. Under the HIPAA Security Rule, a security incident is the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system. (45 CFR § 164.304)

Determine how the organization will respond to a security incident.

Establish a reporting mechanism and a process to coordinate responses to the security incident.

Provide direct technical assistance, advise vendors to address product-related problems, and provide liaisons to legal and criminal investigative groups as needed.

Has the HIPAA-required security risk assessment resulted in a list of potential physical or technological events that could result in a breach of security?

Is there a procedure in place for reporting and handling incidents?

Has an analysis been conducted that relates reasonably anticipated threats and hazards to the organization that could result in a security incident to the methods that would be used for mitigation?

Have the key functions of the organization been prioritized to determine what would need to be restored first in the event of a disruption?43

2.

Develop and Deploy an Incident Response Team or Other Reasonable and Appropriate Response Mechanism

•

Determine if the size, scope, mission, and other aspects of the organization justify the reasonableness and appropriateness of maintaining a standing incident response team.

•

Identify appropriate individuals to be a part of a formal incident response team, if the organization has determined that implementing an incident response team is reasonable and appropriate.

Do members of the team have adequate knowledge of the organization's hardware and software?

•

Do members of the team have the authority to speak for the organization to the media, law enforcement, and clients or business partners?

•

Has the incident response team received appropriate training in incident response activities?

3.

Develop and Implement Procedures to Respond to and Report Security Incidents Implementation Specification (Required)

•

Identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents that are known to the covered entity; and document security incidents and their outcomes.

•

Document incident response procedures that can provide a single point of reference to guide the day-to-day operations of the incident response team.

Review incident response procedures with staff with roles and responsibilities related to incident response, solicit suggestions for improvements, and make changes to reflect input if reasonable and appropriate.

Update the procedures as required based on changing

Has the organization determined that maintaining a staffed security incident hotline would be reasonable and appropriate?

Has the organization determined reasonable and appropriate mitigation options for security incidents?

•

Has the organization determined that standard incident report templates to ensure that all necessary information related to the incident is documented and investigated are reasonable and appropriate?

•

Has the organization determined under what conditions information related to a security breach will be disclosed to the media?

•

Have appropriate (internal and external) persons who

42 Note: See also Section 4.10, HIPAA Standard: Facility Access Controls and Section 4.14, HIPAA Standard: Access Controls. 27

43 See Section 4.7, HIPAA Standard: Contingency Plan.

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Sample Questions organizational needs.44 should be informed of a security breach been identified and a contact information list prepared?

•

Has a written incident response plan been developed and provided to the incident response team?

4.

Incorporate Post-Incident Analysis into Updates and Revisions

•

Measure effectiveness and update security incident response procedures to reflect lessons learned, and identify actions to take that will improve security controls after a security incident.

•

Does the incident response team keep adequate documentation of security incidents and their outcomes, which may include what weaknesses were exploited and how access to information was gained?

•

Do records reflect new contacts and resources identified for responding to an incident?

•

Does the organization consider whether current procedures were adequate for responding to a particular security incident?

28

44 See Section 4.22, HIPAA Standard: Documentation.

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29

4.7.

Contingency Plan (§ 164.308(a)(7))45

HIPAA Standard: Establish (and implement as needed) policies and procedures for responding to an emergency or other occurrence (for example, fire, vandalism,

system failure, and natural disaster) that damages systems that contain electronic protected health information.

Kev Activities Description **Sample Questions** 1. **Develop Contingency Planning Policy** Define the organization's overall contingency objectives. Establish the organizational framework, roles, and responsibilities for this area. Address scope, resource requirements, training, testing, plan maintenance, and backup requirements. A contingency planning methodology, based on NIST SP 800-34, is included in Appendix F of this document. What critical services must be provided within specified timeframes? Patient treatment, for example, may need to be performed without disruption. By contrast, claims processing may be delayed during an emergency with no longterm damage to the organization. Have cross-functional dependencies been identified so as to determine how the failure in one system may negatively impact another one? 2. **Conduct an Applications and Data Criticality Analysis46 Implementation Specification (Addressable)** Assess the relative criticality of specific applications and data in support of other **Contingency Plan components.** Identify the activities and material involving EPHI that are critical to business operations. Identify the critical services or operations, and the manual and automated processes that support them, involving EPHI. Determine the amount of time the organization can tolerate disruptions to these operations, material, or services (e.g., due to power outages). Establish cost-effective strategies for recovering these critical services or processes. What hardware, software, and personnel are critical to daily operations? What is the impact on desired service levels if these critical assets are not available? What, if any, support is provided by external providers (Internet service providers [ISPs], utilities, or contractors)?

•

What is the nature and degree of impact on the operation if any of the critical resources are not available?

3.

Identify Preventive Measures47

Identify preventive measures for each defined scenario that could result in loss of a critical service operation involving the use of EPHI.

Ensure that identified preventive measures are practical and feasible in terms of their applicability in a given environment.

•

What alternatives for continuing operations of the organization are available in case of loss of any critical function/resource?

What is the cost associated with the preventive measures that may be considered? •

Are the preventive measures feasible (affordable and practical for the environment)?

•

What plans, procedures, or agreements need to be initiated to enable implementation of the preventive measures, if they are necessary? 45 Note: See also Section 4.10, HIPAA Standard: Facility Access Controls and Section 4.14, HIPAA Standard: Access Controls.

46 This activity may be conducted as part of a larger analysis, sometimes called an impact analysis, that considers all material, services, systems, processes, and activities, including those do not involve EPHI and other elements of an organization not covered by the HIPAA Security Rule. 47 See Key Activities 4.7.5, Data Backup Plan and Disaster Recovery Plan and 4.7.6, Develop and Implement an Emergency Mode Operation Plan. This activity and all associated bullets in the Description and Sample Questions are part of the data backup plan, disaster recovery plan and the emergency mode operation plan implementation specifications.

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y Activities D

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ample Questions 4. Develop Recovery Strategy48 • Finalize the set of contingency procedures that should be invoked for all identified impacts, including emergency mode operation. The strategy must be adaptable to the existing operating environment and address allowable outage times and associated priorities identified in step 2.

•

Ensure, if part of the strategy depends on external organizations for support, that formal agreements are in place with specific requirements stated. • Have procedures related to recovery from emergency or disastrous events been documented?

Has a coordinator who manages, maintains, and updates the plan been designated?

•

Has an emergency call list been distributed to all employees? Have recovery procedures been documented?

Has a determination been made regarding when the plan needs to be activated (anticipated duration of outage, tolerances for outage or loss of capability, impact on service delivery, etc.)?

5.

Data Backup Plan and Disaster Recovery Plan Implementation Specifications (Both Required)

•

Establish and implement procedures to create and maintain retrievable exact copies of EPHI.

•

Establish (and implement as needed) procedures to restore any loss of data.

Is there a formal, written contingency plan?49

Does it address disaster recovery and data backup? 50

•

Do data backup procedures exist?

•

Are responsibilities assigned to conduct backup activities?

Are data backup procedures documented and available to other staff? 6.

Develop and Implement an Emergency Mode Operation Plan Implementation Specification (Required)

•

Establish (and implement as needed) procedures to enable continuation of critical business processes for protection of the security of EPHI while operating in emergency mode.

•

"Emergency mode" operation involves only those critical business processes that must occur to protect the security of EPHI during and immediately after a crisis situation.

•

Have procedures been developed to continue the critical functions identified in Key Activity?

•

If so, have those critical functions that also involve the use of EPHI been identified? •

Would different staff, facilities, or systems be needed to perform those functions?

Has the security of that EPHI in that alternative mode of operation been assured? 7.

Testing and Revision Procedure

Implementation Specification (Addressable)

Implement procedures for periodic testing and revision of contingency plans.

•

Test the contingency plan on a predefined cycle (stated in the policy developed under Key Activity), if reasonable and appropriate.

Train those with defined plan responsibilities on their roles.

If possible, involve external entities (vendors, alternative site/service providers) in testing exercises.

Make key decisions regarding how the testing is to occur ("tabletop" exercise versus staging a real operational scenario including actual loss of capability).

Decide how to segment the type of testing based on the assessment of business impact and acceptability of sustained loss of service. Consider cost.

•

How is the plan to be tested?

•

Does testing lend itself to a phased approach?

Is it feasible to actually take down functions/services for the purposes of testing? •

Can testing be done during normal business hours or must it take place during off hours?

•

If full testing is infeasible, has a "tabletop" scenario (e.g., a classroom-like exercise) been considered?

•

How frequently is the plan to be tested (e.g., annually)?

•

When should the plan be revised?

48 See Key Activities 4.7.5, Data Backup Plan and Disaster Recovery Plan and 4.7.6, Develop and Implement an Emergency Mode Operation Plan. This activity and all associated bullets in the Description and Sample Questions are part of the data backup plan, disaster recovery plan and the emergency mode operation plan implementation specifications.

49 See Key Activity 4.7.1, Develop Contingency Planning Policy.30

50 See Key Activity 4.7.1, Develop Contingency Planning Policy.

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Evaluation (§ 164.308(a)(8))51

HIPAA Standard: Perform a periodic technical and nontechnical evaluation, based initially upon the standards implemented under this rule and subsequently, in response to environmental or operational changes affecting the security of electronic protected health information, which establishes the extent to which an entity's security policies and procedures meet the requirements of this subpart. Key Activities Description Sample Questions 1.

Determine Whether Internal or External Evaluation Is Most Appropriate

•

Decide whether the evaluation will be conducted with internal staff resources or external consultants.

Engage external expertise to assist the internal evaluation team where additional skills and expertise is determined to be reasonable and appropriate.

Use internal resources to supplement an external source of help, because these internal resources can provide the best institutional knowledge and history of internal policies and practices.

•

Which staff has the technical experience and expertise to evaluate the systems? •

How much training will staff need on security-related technical and nontechnical issues?

•

If an outside vendor is used, what factors should be considered when selecting the vendor, such as credentials and experience?

•

What is the budget for internal resources to assist with an evaluation?

•

What is the budget for external services to assist with an evaluation? 2.

Develop Standards and Measurements for Reviewing All Standards and Implementation Specifications of the Security Rule52

•

Use an evaluation strategy and tool that considers all elements of the HIPAA Security Rule and can be tracked, such as a questionnaire or checklist.

•

Implement tools that can provide reports on the level of compliance, integration, or maturity of a particular security safeguard deployed to protect EPHI.

•

If available, consider engaging corporate, legal, or regulatory compliance staff when conducting the analysis.

•

Leverage any existing reports or documentation that may already be prepared by the organization addressing compliance, integration, or maturity of a particular security safeguard deployed to protect EPHI.

•

Have management, operational, and technical issues been considered?

•

Do the elements of each evaluation procedure (questions, statements, or other components) address individual, measurable security safeguards for EPHI?

Has the organization determined that the procedure must be tested in a few areas or systems?

•

Does the evaluation tool consider all standards and implementation specifications of the HIPAA Security Rule?

3.

Conduct Evaluation

Determine, in advance, what departments and/or staff will participate in the evaluation.

Secure management support for the evaluation process to ensure participation. •

Collect and document all needed information. Collection methods may include the use of interviews, surveys, and outputs of automated tools, such as access control auditing tools, system logs, and results of penetration testing.

Conduct penetration testing (where trusted insiders attempt

•

If available, have staff members with knowledge of IT security been consulted and included in the evaluation team?

•

If penetration testing has been determined to be reasonable and appropriate, has specifically worded, written approval from senior management been received for any planned penetration testing?

•

Has the process been formally communicated to those who have been assigned roles and responsibilities in the

51 Note: See also Section 4.10, HIPAA Standard: Facility Access Controls and Section 4.14, HIPAA Standard: Access Controls. 31

52 Organizations may wish to review and employ, where reasonable and appropriate, security control assessment procedures found in NIST SP 800-53A, Guide for Assessing the Security Controls in Federal Information Systems. An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule Key Activities

Description

S

a

mple Questions to compromise system security for the sole purpose of testing the effectiveness of security controls), if reasonable and appropriate. evaluation process? • Has the organization explored the use of automated tools to support the evaluation process?

•

Has the organization employed automated tools to support the evaluation process? 4.

Document Results53

•

Document each evaluation finding, remediation options and recommendations, and remediation decisions.

Document known gaps between identified risks and mitigating security controls, and any acceptance of risk, including justification.

•

Develop security program priorities and establish targets for continuous improvement.

Does the process support development of security recommendations?

In determining how best to display evaluation results, have written reports that highlight key findings and recommendations been considered?

If a written final report is to be circulated among key staff, have steps been taken to ensure that it is made available only to those persons designated to receive it? 5.

Repeat Evaluations Periodically

Establish the frequency of evaluations, taking into account the sensitivity of the EPHI controlled by the organization, its size, complexity, and environmental and/or operational changes (e.g., other relevant laws or accreditation requirements).

In addition to periodic reevaluations, consider repeating evaluations when environmental and operational changes are made to the organization that affects the security of EPHI (e.g., if new technology is adopted or if there are newly recognized risks to the security of the information).

•

Do security policies specify that evaluations will be repeated when environmental and operational changes are made that affect the security of EPHI?

Do policies on frequency of security evaluations reflect any and all relevant federal or state laws which bear on environmental or operational changes affecting the security of EPHI?

•

Has the organization explored the use of automated tools to support periodic evaluations?

•

Has the organization employed automated tools to support periodic evaluations? 32

53 See Section 4.22, HIPAA Standard: Documentation.

An In

troductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule 4.9. Business Associate Contracts and Other Arrangements (§ 164.308(b)(1))

54

HIPAA Standard: A covered entity, in accordance with § 164.306, may permit a business associate to create, receive, maintain, or transmit electronic protected health information on the covered entity's behalf only if the covered entity obtains satisfactory assurances, in accordance with § 164.314(a), that the business associate will appropriately safeguard the information.55, 56

Key Activities

Description

Sample Questions

1.

Identify Entities that Are Business Associates under the HIPAA Security Rule •

Identify the individual or department who will be responsible for coordinating the execution of business associate agreements or other arrangements.

Reevaluate the list of business associates to determine who has access to EPHI in order to assess whether the list is complete and current.

Identify systems covered by the contract/agreement.

Do the business associate agreements written and executed contain sufficient language to ensure that required information types will be protected?

Are there any new organizations or vendors that now provide a service or function on behalf of the organization? Such services may include the following:

O **Claims processing or billing Data analysis Utilization review** 0 **Quality assurance Benefit management Practice management Re-pricing** Hardware maintenance A All other HIPAA-regulated functions Have outsourced functions involving the use of EPHI been considered, such as the following: 0 **Actuarial services Data aggregation** 0 Administrative services Accreditation 0 **Financial services?** 2. Written Contract or Other Arrangement57 **Implementation Specification (Required)** Document the satisfactory assurances required by this standard through a written contract or other arrangement with the business associate that meets the applicable requirements of §164.314(a).58

٠

Execute new or update existing agreements or arrangements as appropriate.

Identify roles and responsibilities.

Who is responsible for coordinating and preparing the final agreement or arrangement?

•

Does the agreement or arrangement specify how information is to be transmitted to and from the business associate?

Have security controls been specified for the business associate? 54 See Section 4.19, HIPAA Standard: Business Associate Contracts and Other Arrangements.

55 (2) This standard does not apply with respect to (i) the transmission by a covered entity of EPHI to a healthcare provider concerning the treatment of an individual; (ii) the transmission of EPHI by a group health plan or an HMO or health insurance issuer on behalf of a group health plan to a plan sponsor, to the extent that the requirements of \$164.314(b) and \$164.504(f) apply and are met; or (iii) the transmission of EPHI from or to other agencies providing the services at \$164.502(e)(1)(ii)(C), when the covered entity is a health plan that is a government program providing public benefits, if the requirements of \$164.502(e)(1)(ii)(C) are met. 56 (3) A covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the standards, implementation specifications, and requirements of this paragraph and \$164.314(a).

An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule

D

escription • Include security requirements in business associate contracts/agreements to address confidentiality, integrity, and availability of EPHI. •

Specify any training requirements associated with the contract/agreement or arrangement, if reasonable and appropriate.

3.

Establish Process for Measuring Contract Performance and Terminating the Contract if Security Requirements Are Not Being Met59

•

Maintain clear lines of communication.

•

Conduct periodic security reviews.

•

Establish criteria for measuring contract performance.

•

If the business associate is a governmental entity, update the memorandum of understanding or other arrangement when required by law or regulation or when reasonable and appropriate.

•

What is the service being performed?

•

What is the outcome expected?

Is there a process for reporting security incidents related to the agreement?

•

Is there a process in place to periodically evaluate the effectiveness of business associate security controls?

•

Is there a process in place for terminating the contract if requirements are not being met and has the business associate been advised what conditions would warrant termination?

4.

Implement An Arrangement Other than a Business Associate Contract if Reasonable and Appropriate

•

If the covered entity and its business associate are both governmental entities, use a memorandum of understanding or reliance on law or regulation that requires equivalent actions on the part of the business associate.

•

Document the law, regulation, memorandum, or other document that assures that the governmental entity business associate will implement all required safeguards for EPHI involved in transactions between the parties.

•

Is the covered entity's business associate a federal, state, or local governmental entity?

Is there a usual procedure for creating memoranda of understanding between the parties?

•

Has the covered entity researched and reviewed all law and regulation governing the use of EPHI by the governmental entity business associate?

57 See also Key Activity 4.9.4, Implement an Arrangement Other than a Business Associate Contract if Reasonable and Appropriate.

58 See Section 4.19, HIPAA Standard: Business Associate Contracts and Other Arrangements.

3459 See Section 4.19, HIPAA Standard: Business Associate Contracts and Other Arrangements.

An Introductory Resource Guide for Implementing the HIPAA Security Rule Physical Safeguards

4.10.

Facility Access Controls (§ 164.310(a)(1))60

HIPAA Standard: Implement policies and procedures to limit physical access to its electronic information systems and the facility or facilities in which they are housed, while ensuring that properly authorized access is allowed.

Key Activities

Description

Sample Questions

1.

Conduct an Analysis of Existing Physical Security Vulnerabilities61, 62

•

Inventory facilities and identify shortfalls and/or vulnerabilities in current physical security capabilities.

Assign degrees of significance to each vulnerability identified and ensure that proper access is allowed.

Determine which types of facilities require access controls to safeguard EPHI, such as: 0 **Data Centers Peripheral equipment locations IT staff offices** Workstation locations. If reasonable and appropriate, do nonpublic areas have locks and cameras? Are workstations protected from public access or viewing?63 Are entrances and exits that lead to locations with EPHI secured? Do policies and procedures already exist regarding access to and use of facilities and equipment? Are there possible natural or man-made disasters that could happen in our environment?64 Do normal physical protections exist (locks on doors, windows, etc., and other means of preventing unauthorized access)? 2. **Identify Corrective Measures65, 66** Identify and assign responsibility for the measures and activities necessary to correct deficiencies and ensure that proper access is allowed. Develop and deploy policies and procedures to ensure that repairs, upgrades, and /or modifications are made to the appropriate physical areas of the facility while ensuring that proper access is allowed. Who is responsible for security?67 Is a workforce member other than the security official responsible for facility/physical security?

Are facility access control policies and procedures already in place? Do they need to be revised?

•

What training will be needed for employees to understand the policies and procedures?68

•

How will we document the decisions and actions?69

Are we dependent on a landlord to make physical changes to meet the requirements?

60 Note: See also Section 4.10, HIPAA Standard: Facility Access Controls and Section 4.14, HIPAA Standard: Access Controls.

61 This key activity may be performed as part of the risk analysis implementation specification. See Section 4.1, HIPAA Standard: Security Management Process. 62 See Key Activity 4.10.3, Develop a Facility Security Plan. This activity and all associated bullets in the Description and Sample Questions are part of the facility security plan implementation specification.

63 See Section 4.11, HIPAA Standard: Workstation Use.

64 See Section 4.7, HIPAA Standard: Contingency Plan.

65 This key activity may be performed as part of the risk management implementation specification. See Section 4.1, HIPAA Standard: Security Management Process.

66 See Key Activity 4.10.3, Develop a Facility Security Plan. This activity and all associated bullets in the Description and Sample Questions are part of the facility security plan implementation specification.

67 See Section 4.2, HIPAA Standard: Assigned Security Responsibility.

68 See Section 4.5, HIPAA Standard: Security Awareness and Training. 35 An Introductory Resource Guide for Implementing the HIPAA Security Rule Ke

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ample Questions 3. Develop a Facility Security Plan

Implementation Specification (Addressable) • Implement policies and procedures to safeguard the facility and the equipment therein from unauthorized physical access, tampering, and theft.

•

Implement appropriate measures to provide physical security protection for EPHI in a covered entity's possession.

•

Include documentation of the facility inventory, as well as information regarding the physical maintenance records and the history of changes, upgrades, and other modifications.

•

Identify points of access to the facility and existing security controls.

• Is there an inventory of facilities and existing security practices?

•

What are the current procedures for securing the facilities (exterior, interior, equipment, access controls, maintenance records, etc.)?

•

Is a workforce member other than the security official responsible for the facility plan?

Is there a contingency plan already in place, under revision, or under development?70

4.

Develop Access Control and Validation Procedures Implementation Specification (Addressable) Implement procedures to control and validate a person's access to facilities based on their role or function, including visitor control, and control of access to software programs for testing and revision.

Implement procedures to provide facility access to authorized personnel and visitors, and exclude unauthorized persons.

What are the policies and procedures in place for controlling access by staff, contractors, visitors, and probationary employees?

•

How many access points exist in each facility? Is there an inventory?

Is monitoring equipment necessary?

5.

Establish Contingency Operations Procedures Implementation Specification (Addressable)

•

Establish (and implement as needed) procedures that allow facility access in support of restoration of lost data under the Disaster Recovery Plan and Emergency Mode Operations Plan in the event of an emergency.

•

Who needs access to EPHI in the event of a disaster?

•

What is the backup plan for access to the facility and/or EPHI?

Who is responsible for the contingency plan for access to EPHI?

•

Who is responsible for implementing the contingency plan for access to EPHI in each department, unit, etc.?

•

Will the contingency plan be appropriate in the event of all types of potential disasters (fire, flood, earthquake, etc.)?

6.

Maintain Maintenance Records

Implementation Specification (Addressable)

Implement policies and procedures to document repairs and modifications to the physical components of a facility which are related to security (for example, hardware, walls, doors and locks).

•

Are records of repairs to hardware, walls, doors, and locks maintained? •

Has responsibility for maintaining these records been assigned?

69 See Section 4.22, HIPAA Standard: Documentation.

70 See Section 4.7, HIPAA Standard: Contingency Plan. 36

An Introductory Resource Guide for Implementing the HIPAA Security Rule 4.11.

Workstation Use (§ 164.310(b))

HIPAA Standard: Implement policies and procedures that specify the proper functions to be performed, the manner in which those functions are to be performed, and the physical attributes of the surroundings of a specific workstation or class of workstation that can access electronic protected health information. **Kev Activities** Description **Sample Questions** 1. **Identify Workstation Types and Functions or Uses** Inventory workstations and devices. Develop policies and procedures for each type of workstation and workstation device, identifying and accommodating their unique issues. Classify workstations based on the capabilities, connections, and allowable activities for each workstation used. Do we have an inventory of workstation types and locations in my organization? Who is responsible for this inventory and its maintenance? What tasks are commonly performed on a given workstation or type of workstation? Are all types of computing devices used as workstations identified along with the use of these workstations? 2. **Identify Expected Performance of Each Type of Workstation** Develop and document policies and procedures related to the proper use and performance of workstations. How are workstations used in day-to-day operations? What are key operational risks that could result in a breach of security? 3. **Analyze Physical Surroundings for Physical Attributes71** Ensure that any risks associated with a workstation's surroundings are known and analyzed for possible negative impacts. Develop policies and procedures that will prevent or preclude unauthorized access of unattended workstations, limit the ability of unauthorized persons to view sensitive information, and dispose of sensitive information as needed. Where are workstations located? Is viewing by unauthorized individuals restricted or limited at these workstations?

Do changes need to be made in the space configuration?

Do employees understand the security requirements for the data they use in their day-to-day jobs?

71 See Section 4.5, HIPAA Standard: Security Awareness and Training. This key activity should be performed during security training or awareness activities. 37

An Introductory Resource Guide for Implementing the HIPAA Security Rule 4.12.

Workstation Security (§ 164.310(c))

HIPAA Standard: Implement physical safeguards for all workstations that access electronic protected health information, to restrict access to authorized users. Key Activities

Description

Sample Questions

1.

Identify All Methods of Physical Access to Workstations

•

Document the different ways workstations are accessed by employees and nonemployees.

•

Is there an inventory of all current workstation locations?

•

Are any workstations located in public areas?

•

Are laptops used as workstations?

2.

Analyze the Risk Associated with Each Type of Access72

Determine which type of access holds the greatest threat to security.

•

Are any workstations in areas that are more vulnerable to unauthorized use, theft, or viewing of the data they contain?

•

What are the options for making modifications to the current access configuration? 3.

Identify and Implement Physical Safeguards for Workstations

Implement physical safeguards and other security measures to minimize the possibility of inappropriate access to EPHI through workstations.

•

What safeguards are in place, i.e., locked doors, screen barriers, cameras, guards?73

•

Do any workstations need to be relocated to enhance physical security?

Have employees been trained on security?74

72 This key activity may be conducted pursuant to the risk analysis and risk management implementation specifications of the security management process standard. See Section 4.1, HIPAA Standard: Security Management Process. 73 See Section 4.1, HIPAA Standard: Security Management Process. 74 See Section 4.5, HIPAA Standard: Security Awareness and Training. 38 An Introductory Resource Guide for Implementing the HIPAA Security Rule 4.13. Device and Media Controls (§ 164.310(d)(1)) HIPAA Standard: Implement policies and procedures that govern the receipt and removal of hardware and electronic media that contain electronic protected health information into and out of a facility, and the movement of these items within the facility. **Key Activities** Description **Sample Questions** 1. **Implement Methods for Final Disposal of EPHI Implementation Specification (Required)** Implement policies and procedures to address the final disposition of EPHI and/or the hardware or electronic media on which it is stored. Determine and document the appropriate methods to dispose of hardware, software, and the data itself. Assure that EPHI is properly destroyed and cannot be recreated. What data is maintained by the organization, and where? Is data on removable, reusable media such as tapes and CDs? Is there a process for destroying data on hard drives and file servers? What are the options for disposing of data on hardware? What are the costs? 2. **Develop and Implement Procedures for Reuse of Electronic Media Implementation Specification (Required)** Implement procedures for removal of EPHI from electronic media before the media are made available for reuse. Ensure that EPHI previously stored on electronic media cannot be accessed and reused. Identify removable media and their use. Ensure that EPHI is removed from reusable media before they are used to record new information. Do policies and procedures already exist regarding reuse of electronic media (hardware and software)? Is one individual and/or department responsible for coordinating the disposal of data and the reuse of the hardware and software?

Are employees appropriately trained on security and risks to EPHI when reusing software and hardware?75

3.

Maintain Accountability for Hardware and Electronic Media Implementation Specification (Addressable)

Maintain a record of the movements of hardware and electronic media and any person responsible therefore.

Ensure that EPHI is not inadvertently released or shared with any unauthorized party.

Ensure that an individual is responsible for, and records the receipt and removal of, hardware and software with EPHI.

Where is data stored (what type of media)?

•

What procedures already exist regarding tracking of hardware and software within the company?

•

If workforce members are allowed to remove electronic media that contain or may be used to access EPHI, do procedures exist to track the media externally?

•

Who is responsible for maintaining records of hardware and software? 4.

Develop Data Backup and Storage Procedures Implementation Specification (Addressable)

Create a retrievable exact copy of EPHI, when needed, before movement of equipment.

•

Ensure that an exact retrievable copy of the data is retained and protected to protect the integrity of EPHI during equipment relocation.

•

Are backup files maintained offsite to assure data availability in the event data is lost while transporting or moving electronic media containing EPHI?

If data were to be unavailable while media are transported or moved for a period of time, what would the business impact be?

75 See Section 4.5, HIPAA Standard: Security Awareness and Training. 39 An Introductory Resource Guide for Implementing the HIPAA Security Rule Technical Safeguards

4.14.

Access Control (§ 164.312(a)(1))

HIPAA Standard: Implement technical policies and procedures for electronic information systems that maintain electronic protected health information to allow access only to those persons or software programs that have been granted access rights as specified in § 164.308(a)(4).76

Key Activities Description Sample Questions

1.

Analyze Workloads and Operations To Identify the Access Needs of All Users77

Identify an approach for access control.

Consider all applications and systems containing EPHI that should be available only to authorized users.

Integrate these activities into the access granting and management process.78 •

Have all applications/systems with EPHI been identified?

What user roles are defined for those applications/systems?

•

Where is the EPHI supporting those applications/systems currently housed (e.g., stand-alone PC, network)?

•

Are data and/or systems being accessed remotely?

2.

Identify Technical Access Control Capabilities

•

Determine the access control capability of all information systems with EPHI.

How are the systems accessed (viewing data, modifying data, creating data)? 3.

Ensure that All System Users Have Been Assigned a Unique Identifier Implementation Specification (Required)

•

Assign a unique name and/or number for identifying and tracking user identity. •

Ensure that system activity can be traced to a specific user.

•

Ensure that the necessary data is available in the system logs to support audit and other related business functions.79

•

How should the identifier be established (length and content)?

•

Should the identifier be self-selected or randomly generated?

4.

Develop Access Control Policy80

•

Establish a formal policy for access control that will guide the development of procedures.81

•

Specify requirements for access control that are both feasible and cost-effective for implementation.82

•

Have rules of behavior been established and communicated to system users?

•

How will rules of behavior be enforced?

5.

Implement Access Control Procedures Using Selected Hardware and Software

Implement the policy and procedures using existing or additional hardware/software solution(s).

Who will manage the access controls procedures?

Are current users trained in access control management?83

Will user training be needed to implement access control procedures?

76 Note: This HIPAA standard supports the standards at Section 4.4, Information Access Management and Section 4.10, Facility Access Controls.

77 See Section 4.4, HIPAA Standard: Information Access Management. This activity and all associated bullets in the Description and Sample Questions should be conducted as part of the access granting and access establishment process detailed in the Information Access Management standard.

78 See Section 4.4, HIPAA Standard: Information Access Management.

79 See Section 4.15, HIPAA Standard: Audit Control.

80 See Section 4.4, HIPAA Standard: Information Access Management.

81 See Section 4.4, HIPAA Standard: Information Access Management.

82 See Section 4.1, HIPAA Standard: Security Management Process. 40

An Introductory Resource Guide for Implementing the HIPAA Security Rule 41

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ample Questions 6. Review and Update User Access • Enforce policy and procedures as a matter of ongoing operations.84

•

Determine if any changes are needed for access control mechanisms.

•

Establish procedures for updating access when users require the following:85

0

Initial access

0

Increased access

0

Access to different systems or applications than those they currently have • Have new employees/users been given proper instructions for protecting data and systems?86

•

What are the procedures for new employee/user access to data and systems?87 •

Are there procedures for reviewing and, if appropriate, modifying access authorizations for existing users?88

7.

Establish an Emergency Access Procedure Implementation Specification (Required)

•

Establish (and implement as needed) procedures for obtaining necessary electronic protected health information during an emergency.

•

Identify a method of supporting continuity of operations should the normal access procedures be disabled or unavailable due to system problems.

When should the emergency access procedure be activated?

Who is authorized to make the decision?89

Who has assigned roles in the process?90

•

Will systems automatically default to settings and functionalities that will enable the emergency access procedure or will the mode be activated by the system administrator or other authorized individual?

8.

Automatic Logoff and Encryption and Decryption Implementation Specifications (Both Addressable)

•

Consider whether the addressable implementation specifications of this standard are reasonable and appropriate:

0

Implement electronic procedures that terminate an electronic session after a predetermined time of inactivity.

0

Implement a mechanism to encrypt and decrypt EPHI.

• Are automatic logoff features available for any of the covered entity's operating

systems or other major applications?

•

If applications have been created or developed in-house, is it reasonable and appropriate to modify them to feature automatic logoff capability?

•

What period of inactivity prior to automatic logoff is reasonable and appropriate for the covered entity?

•

What encryption systems are available for the covered entity's EPHI?

Is encryption appropriate for storing and maintaining EPHI ("at rest"), as well as while it is transmitted?

9.

Terminate Access if it is No Longer Required91

•

Ensure that access to EPHI is terminated if the access is no longer authorized. •

Are rules being enforced to remove access by staff members who no longer have a need to know because they have changed assignments or have stopped working for the organization?

83 See Section 4.5, HIPAA Standard: Security Awareness and Training.

84 See Section 4.4, HIPAA Standard: Information Access Management.

85 See Section 4.4, HIPAA Standard: Information Access Management.

86 See Section 4.5, HIPAA Standard: Security Awareness and Training.

87 See Section 4.4, HIPAA Standard: Information Access Management.

88 See Section 4.4, HIPAA Standard: Information Access Management. 89 See Section 4.7, HIPAA Standard: Contingency Plan. 90 See Section 4.7, HIPAA Standard: Contingency Plan. 91 See Section 4.3, HIPAA Standard: Workforce Security. An Introductory Resource Guide for Implementing the HIPAA Security Rule 4.15. Audit Controls (§ 164.312(b)) HIPAA Standard: Implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information. **Key Activities** Description **Sample Questions** 1. Determine the Activities that Will Be Tracked or Audited Determine the appropriate scope of audit controls that will be necessary in information systems that contain or use EPHI based on the covered entity's risk assessment and other organizational factors.92 Determine what data needs to be captured. Where is EPHI at risk in the organization?93 What systems, applications, or processes make data vulnerable to unauthorized or inappropriate tampering, uses, or disclosures?94 What activities will be monitored (e.g., creation, reading, updating, and/or deleting of files or records containing EPHI)? What should the audit record include (e.g., user ID, event type/date/time)? 2. Select the Tools that Will Be Deployed for Auditing and System Activity Reviews Evaluate existing system capabilities and determine if any changes or upgrades are necessary. What tools are in place? What are the most appropriate monitoring tools for the organization (third party, freeware, or operating system-provided)? Are changes/upgrades to information systems reasonable and appropriate? 3. **Develop and Deploy the Information System Activity Review/Audit Policy** Document and communicate to the workforce the facts about the organization's decisions on audits and reviews. Who is responsible for the overall audit process and results?

How often will audits take place?

How often will audit results be analyzed?

What is the organization's sanction policy for employee violations?95

Where will audit information reside (i.e., separate server)?

4.

Develop Appropriate Standard Operating Procedures96

•

Determine the types of audit trail data and monitoring procedures that will be needed to derive exception reports.

•

How will exception reports or logs be reviewed?

Where will monitoring reports be filed and maintained?

•

Is there a formal process in place to address system misuse, abuse, and fraudulent activity?97

•

How will managers and employees be notified, when appropriate, regarding suspect activity?

92 See Section 4.1, HIPAA Standard: Security Management Process and Key Activity 4.1.7, Develop and Deploy the Information System Activity Review Process.
93 See Section 4.1, HIPAA Standard: Security Management Process and Key Activity 4.1.2, Conduct Risk Assessment.

94 See Section 4.1, HIPAA Standard: Security Management Process and Key Activity 4.1.2, Conduct Risk Assessment.

95 See Section 4.1, HIPAA Standard: Security Management Process and Key Activity 4.1.6, Develop and Implement a Sanction Policy.

96 See Section 4.1, HIPAA Standard: Security Management Process and Key Activity 4.1.7, Develop and Deploy the Information system Activity Review Process..
97 See Section 4.1, HIPAA Standard: Security Management Process and Key Activity 4.1.6, Develop and Implement a Sanction Policy.

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ample Questions 5. Implement the Audit/System Activity Review Process98 • Activate the necessary audit system.

Begin logging and auditing procedures. • What mechanisms will be implemented to assess the effectiveness of the audit process (metrics)?

•

What is the plan to revise the audit process when needed?

98 See Section 4.1, HIPAA Standard: Security Management Process and Key Activity 4.1.9, Implement the Information System Activity Review and Audit Process. 43

An Introductory Resource Guide for Implementing the HIPAA Security Rule 4.16.

Integrity (§ 164.312(c)(1))

HIPAA Standard: Implement policies and procedures to protect electronic protected health information from improper alteration or destruction.

Key Activities Description

Sample Ouestions

1.

Identify All Users Who Have Been Authorized to Access EPHI99

Identify all approved users with the ability to alter or destroy data, if reasonable and appropriate.

Address this Key Activity in conjunction with the identification of unauthorized sources in Key Activity 2, below.

•

How are users authorized to access the information?100

•

Is there a sound basis established as to why they need the access?101

Have they been trained on how to use the information?102

•

Is there an audit trail established for all accesses to the information?103 2.

Identify Any Possible Unauthorized Sources that May Be Able to Intercept the Information and Modify It

•

Identify scenarios that may result in modification to the EPHI by unauthorized sources (e.g., hackers, disgruntled employees, business competitors).104

Conduct this activity as part of your risk analysis.105

•

What are likely sources that could jeopardize information integrity?106

What can be done to protect the integrity of the information when it is residing in a system (at rest)?

•

What procedures and policies can be established to decrease or eliminate alteration of the information during transmission (e.g., encryption)?107

3.

Develop the Integrity Policy and Requirements

•

Establish a formal (written) set of integrity requirements based on the results of the analysis completed in the previous steps.

•

Have the requirements been discussed and agreed to by identified key personnel involved in the processes that are affected?

Have the requirements been documented?

Has a written policy been developed and communicated to system users? 4.

Implement Procedures to Address These Requirements

Identify and implement methods that will be used to protect the information from modification.

Identify and implement tools and techniques to be developed or procured that support the assurance of integrity.

Are current audit, logging, and access control techniques sufficient to address the integrity of the information?

•

If not, what additional techniques can we apply to check information integrity (e.g., quality control process, transaction and output reconstruction)?

99 See Section 4.3, HIPAA Standard: Workforce Security, Section 4.3, HIPAA Standard: Access Control, and Section 4.21, HIPAA Standard: Policies and Procedures.

100 See Section 4.3, HIPAA Standard: Workforce Security and Section 4.3, HIPAA Standard: Access Control.

101 See Section 4.3, HIPAA Standard: Workforce Security.

102 See Section 4.5, HIPAA Standard: Security Awareness and Training.

103 See Section 4.15, HIPAA Standard: Audit Controls.

104 See Section 4.1, HIPAA Standard: Security Management Process.

105 See Section 4.1, HIPAA Standard: Security Management Process.

106 See Section 4.1, HIPAA Standard: Security Management Process.

107 See Section 4.1, HIPAA Standard: Security Management Process. 44

An Introductory Resource Guide for Implementing the HIPAA Security Rule Ke

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ample Questions • Can additional training of users decrease instances attributable to human errors? 5. Implement a Mechanism to Authenticate EPHI Implementation Specification (Addressable) • Implement electronic mechanisms to corroborate that EPHI has not been altered or destroyed in an unauthorized manner.

•

Consider possible electronic mechanisms for authentication such as:

0

Error-correcting memory

0

Magnetic disk storage

0

Digital signatures

0

Check sum technology.

•

Are the uses of both electronic and nonelectronic mechanisms necessary for the protection of EPHI?

Are appropriate electronic authentication tools available?

Are available electronic authentication tools interoperable with other applications and system components?

6.

Establish a Monitoring Process To Assess How the Implemented Process Is Working

Review existing processes to determine if objectives are being addressed.108 •

Reassess integrity processes continually as technology and operational environments change to determine if they need to be revised.109

•

Are there reported instances of information integrity problems and have they decreased since integrity procedures have been implemented?110

•

Does the process, as implemented, provide a higher level of assurance that information integrity is being maintained?

108 See Section 4.8, HIPAA Standard: Evaluation.

109 See Section 4.8, HIPAA Standard: Evaluation.

110 See Section 4.6, HIPAA Standard: Security Incident Procedures. 45

An Introductory Resource Guide for Implementing the HIPAA Security Rule 4.17.

Person or Entity Authentication (§ 164.312(d))111

HIPAA Standard: Implement procedures to verify that a person or entity seeking access to electronic protected health information is the one claimed.

Key Activities

Description

Sample Questions

1. Determine Authentication Applicability to Current Systems/Applications

Identify methods available for authentication. Under the HIPAA Security Rule, authentication is the corroboration that a person is the one claimed. (45 CFR § 164.304).

•

Authentication requires establishing the validity of a transmission source and/or verifying an individual's claim that he or she has been authorized for specific access privileges to information and information systems.

•

What authentication methods are available?

What are the advantages and disadvantages of each method?

•

What will it cost to implement the available methods in our environment?

•

Do we have trained staff who can maintain the system or do we need to consider outsourcing some of the support?

Are passwords being used?

•

If so, are they unique by individual?

2. Evaluate Authentication Options Available

Weigh the relative advantages and disadvantages of commonly used authentication approaches.

There are four commonly used authentication approaches available:

0

Something a person knows, such as a password,

0

Something a person has or is in possession of, such as a token (smart card, ATM card, etc.),

0

Some type of biometric identification a person provides, such as a fingerprint, or o

A combination of two or more of the above approaches.

•

What are the strengths and weaknesses of each available option?

•

Which can be best supported with assigned resources (budget/staffing)?

•

What level of authentication is appropriate based on our assessment of risk to the information/systems?

•

Do we need to acquire outside vendor support to implement the process?

3. Select and Implement Authentication Option

Consider the results of the analysis conducted under Key Activity 2, above, and select appropriate authentication methods.

•

Implement the methods selected into your operations and activities.

Has necessary user and support staff training been completed?

Have formal authentication policy and procedures been established and communicated?

•

Has necessary testing been completed to ensure that the authentication system is working as prescribed?

•

Do the procedures include ongoing system maintenance and updates? •

Is the process implemented in such a way that it does not compromise the authentication information (password file encryption, etc.)?

111 See also Section 4.14, HIPAA Standard: Access Control and Section 4.15, HIPAA Standard: Audit Controls.

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An Introductory Resource Guide for Implementing the HIPAA Security Rule 4.18.

Transmission Security (§ 164.312(e)(1))

HIPAA Standard: Implement technical security measures to guard against unauthorized access to electronic protected health information that is being transmitted over an electronic communications network. **Key Activities** Description **Sample Questions** 1. Identify Any Possible Unauthorized Sources that May Be Able to Intercept and/or **Modify the Information** Identify scenarios that may result in modification of the EPHI by unauthorized sources during transmission (e.g., hackers, disgruntled employees, business competitors).112 What measures exist to protect EPHI in transmission? Is there an auditing process in place to verify that EPHI has been protected against unauthorized access during transmission?113 Are there trained staff members to monitor transmissions? 2. **Develop and Implement Transmission Security Policy and Procedures** Establish a formal (written) set of requirements for transmitting EPHI. Identify methods of transmission that will be used to safeguard EPHI. Identify tools and techniques that will be used to support the transmission security policy. Implement procedures for transmitting EPHI using hardware and/or software, if needed. Have the requirements been discussed and agreed to by identified key personnel involved in transmitting EPHI? Has a written policy been developed and communicated to system users? 3. **Implement Integrity Controls Implementation Specification (Addressable)** Implement security measures to ensure that electronically transmitted EPHI is not improperly modified without detection until disposed of. What measures are planned to protect EPHI in transmission? Is there assurance that information is not altered during transmission? 4. **Implement Encryption Implementation Specification (Addressable)**

Implement a mechanism to encrypt EPHI whenever deemed appropriate.

Is encryption reasonable and appropriate for EPHI in transmission?

Is encryption needed to effectively protect the information?

Is encryption feasible and cost-effective in this environment?

What encryption algorithms and mechanisms are available?

•

Does the covered entity have the appropriate staff to maintain a process for encrypting EPHI during transmission?

Are staff members skilled in the use of encryption?

112 See Section 4.7, HIPAA Standard: Contingency Plan and Section 4.1, HIPAA Standard: Security Management Process.

113 See Section 4.1, HIPAA Standard: Security Management Process. 47 An Introductory Resource Guide for Implementing the HIPAA Security Rule Organizational Requirements

4.19.

Business Associate Contracts or Other Arrangements (§ 164.314(a)(1))

HIPAA Standard: (i) The contract or other arrangement between the covered entity and its business associate required by § 164.308(b) must meet the requirements of paragraph (a)(2)(i) or (a)(2)(ii) of this section, as applicable. (ii) A covered entity is not in compliance with the standards in § 164.502(e) and paragraph (a) of this section if the covered entity knew of a pattern of an activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful—(A) Terminated the contract or arrangement, if feasible; or (B) If termination is not feasible, reported the problem to the Secretary.

Kev Activities

Description

Sample Questions

1. Contract Must Provide that Business Associates Adequately Protect EPHI114 Implementation Specification (Required)

Contracts between covered entities and business associates must provide that business associates will implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the EPHI that the business associate creates, receives, maintains, or transmits on behalf of the covered entity.

May consider asking the business associate to conduct a risk assessment that addresses administrative, technical, and physical risks, if reasonable and appropriate.

•

Does the written agreement between the covered entity and the business associate address the applicable functions related to creating, receiving, maintaining, and transmitting EPHI that the business associate is to perform on behalf of the covered entity?

2. Contract Must Provide that Business Associate's Agents Adequately Protect EPHI

Implementation Specification (Required)

Contracts between covered entities and business associates must provide that any agent, including a subcontractor, to whom the business associate provides such information agrees to implement reasonable and appropriate safeguards to protect it;

Does the written agreement address the issue of EPHI access by subcontractors and other agents of the business associate?

3. Contract Must Provide that Business Associates will Report Security Incidents Implementation Specification (Required)

•

Contracts between covered entities and business associates must provide that business associates will report to the covered entity any security incident of which it becomes aware.

•

Establish a reporting mechanism and a process for the business associate to use in the event of a security incident.

•

Is there a procedure in place for reporting of incidents by business associates? •

Have key business associate staff that would be the point of contact in the event of a security incident been identified?

114 Note that business associate contracts must also comply with provisions of the HIPAA Privacy Rule. See 45 CFR, Part 164 — Security and Privacy § 164.504(e) (Standard: Business associate contracts).

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An Introductory Resource Guide for Implementing the HIPAA Security Rule Key Activities

D

escription

S

ample Questions

4. Contract Must Provide that Business Associate Will Authorize Termination of the Contract if it has been Materially Breached

Implementation Specification (Required) • Contracts between covered entities and business associates must provide that the business associate will authorize termination of the contract by the covered entity if the covered entity determines that the business associate has violated a material term of the contract.

Establish in the written agreement with business associates the circumstances under which a violation of agreements relating to the security of EPHI constitutes a material breach of the contract.

Terminate the contract if:

0

the covered entity learns that the business associate has violated the contract or materially breached it, and

0

It is not possible to take reasonable steps to cure the breach or end the violation, as applicable.

•

If terminating the contract is not feasible, report the problem to the Secretary of HHS. • Have standards and thresholds for termination of the contract been included in the contract?

5. Government Entities May Satisfy Business Associate Contract Requirements through Other Arrangements

Implementation Specification (Required)

•

If the covered entity and business associate are both governmental entities, consult § 164.314 (a)(2)(ii) of the Security Rule.

•

If both entities are governmental entities, the covered entity is in compliance with § 164.314 (a)(1) if:

0

It executes a Memorandum of Understanding (MOU) with the business associate that contains terms that accomplish the objectives of § 164.314(a)(2)(i), or

0

Other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of § 164.314(a)(2)(i).

•

Do the arrangements provide protections for EPHI equivalent to those provided by the organization's business associate contracts?

•

If termination of the MOU is not possible due to the nature of the relationship between the covered entity and the business associate, are other mechanisms for enforcement available, reasonable, and appropriate?

6. Other Arrangements for Covered Entities and Business Associates. Implementation Specification (Required)

•

If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of business associate as specified in 6160.103 to a covered entity, the covered entity may permit the business associate to create, receive, maintain, or transmit electronic protected health information on its behalf to the extent necessary to comply with the legal mandate without meeting the requirements of 6164.314(a)(2)(i), provided that the covered entity attempts in good faith to obtain satisfactory assurances as required by 8164.314(a)(2)(ii)(A), and documents the attempt and the reasons that these assurances cannot be obtained.

•

Has the covered entity made a good faith attempt to obtain satisfactory assurances that the security standards required by this section are met?

Are attempts to obtain satisfactory assurances and the reasons assurances cannot be obtained documented?

Does the covered entity or its business associate have statutory obligations which require removal of the authorization of termination requirement? 49

An Introductory Resource Guide for Implementing the HIPAA Security Rule Key Activities

D

escription • The covered entity may omit from its other arrangements authorization of the termination of the contract by the covered entity, as required by § 164.314(a)(2)(i)(D), if such authorization is inconsistent with the statutory obligations of the covered entity or its business associate. 50

An Introductory Resource Guide for Implementing the HIPAA Security Rule 4.20.

Requirements for Group Health Plans (§ 164.314(b)(1))

HIPAA Standard: Except when the only electronic protected health information disclosed to a plan sponsor is disclosed pursuant to § 164.504(f)(1)(ii) or (iii), or as authorized under § 164.508, a group health plan must ensure that its plan documents provide that the plan sponsor will reasonably and appropriately safeguard electronic protected health information created, received, maintained, or transmitted to or by the plan sponsor on behalf of the group health plan.

Key Activities

Description

Sample Questions

1. Amend Plan Documents of Group Health Plan to Address Plan Sponsor's Security of EPHI

Implementation Specification (Required)

•

Amend plan documents to incorporate provisions to require the plan sponsor (e.g., an entity that sponsors a health plan) to implement administrative, technical, and physical safeguards that will reasonably and appropriately protect the confidentiality, integrity, and availability of EPHI that it creates, receives, maintains, or transmits on behalf of the group health plan.

Does the plan sponsor fall under the exception described in the standard? •

Do the plan documents require the plan sponsor to reasonably and appropriately safeguard EPHI?

2. Amend Plan Documents of Group Health Plan to Address Adequate Separation Implementation Specification (Required)

Amend plan documents to ensure that the adequate separation between the group health plan and plan sponsor required by \$164.504(f)(2)(iii) is supported by reasonable and appropriate security measures.

Do plan documents address the obligation to keep EPHI secure with respect to the plan sponsor's employees, classes of employees, or other persons who will be given access to EPHI?

3. Amend Plan Documents of Group Health Plan to Address Security of EPHI Supplied to Plan Sponsors' Agents and Subcontractors Implementation Specification (Required)
Amend plan documents to incorporate provisions to require the plan sponsor to ensure that any agent, including a subcontractor, to whom it provides EPHI agrees to implement reasonable and appropriate security measures to protect the EPHI.

Do the plan documents of the group health plan address the issue of subcontractors and other agents of the plan sponsor implementing reasonable and appropriate security measures?

4. Amend Plan Documents of Group Health Plans to Address Reporting of Security Incidents

Implementation Specification (Required)

•

Amend plan documents to incorporate provisions to require the plan sponsor to report to the group health plan any security incident of which it becomes aware.

Establish specific policy for security incident reporting.115

•

Establish a reporting mechanism and a process for the plan sponsor to use in the event of a security incident.

•

Is there a procedure in place for security incident reporting?

Are procedures in place for responding to security incidents?

115 See Section 4.6, HIPAA Standard: Security Incident Procedures.

51

An Introductory Resource Guide for Implementing the HIPAA Security Rule 52

Policies and Procedures and Documentation Requirements

4.21.

Policies and Procedures (§ 164.316(a))

HIPAA Standard: Implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications, or other requirements of this subpart, taking into account those factors specified in § 164.306(b)(2)(i), (ii), (iii), and (iv). This standard is not to be construed to permit or excuse an action that violates any other standard, implementation specification, or other requirements of this subpart. A covered entity may change its policies and procedures at any time, provided that the changes are documented and are implemented in accordance with this subpart.

Key Activities

Description

Sample Questions

1. Create and Deploy Policies and Procedures

•

Implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications, and other requirements of the HIPAA Security Rule.

•

Periodically evaluate written policies and procedures to verify that:116

Policies and procedures are sufficient to address the standards, implementation specifications, and other requirements of the HIPAA Security Rule.

0

Policies and procedures accurately reflect the actual activities and practices exhibited by the covered entity, its staff, its systems, and its business associates.

Are reasonable and appropriate policies and procedures to comply with the standards, implementation specifications, and other requirements of the HIPAA Security Rule in place?

Are policies and procedures reasonable and appropriate given:

0

the size, complexity, and capabilities of the covered entity;

0

the covered entity's technical infrastructure, hardware, and software security capabilities;

0

the costs for security measures; and

0

the probability and criticality of potential risks to EPHI?

0

Do procedures exist for periodically reevaluating the policies and procedures, updating them as necessary?117

2. Update Documentation of Policy and Procedures

•

Change policies and procedures as is reasonable and appropriate, at any time, provided that the changes are documented and implemented in accordance with the requirements of the HIPAA Security Rule.

Should HIPAA documentation be updated in response to periodic evaluations, following security incidents, and/or after acquisitions of new technology or new procedures? As policies and procedures are changed, are new versions made available and are workforce members appropriately trained?118

116 See Section 4.8, HIPAA Standard: Evaluation.

117 See Section 4.8, HIPAA Standard: Evaluation.

118 See Section 4.22, HIPAA Standard: Documentation and Section 4.5, HIPAA Standard: Security Awareness and Training.

An Introductory Resource Guide for Implementing the HIPAA Security Rule 4.22.

Documentation (§ 164.316(b)(1))

HIPAA Standard: (i) Maintain the policies and procedures implemented to comply with this subpart in written (which may be electronic) form; and (ii) if an action, activity or assessment is required by this subpart to be documented, maintain a written (which may be electronic) record of the action, activity, or assessment.

Key Activities

Description

Sample Questions

1.

Draft, Maintain and Update Required Documentation

•

Document the decisions concerning the management, operational, and technical controls selected to mitigate identified risks.

Written documentation may be incorporated into existing manuals, policies, and other documents, or may be created specifically for the purpose of demonstrating compliance with the HIPAA Security Rule.

Are all required policies and procedures documented?

Should HIPAA Security Rule documentation be maintained by the individual responsible for HIPAA Security implementation?

Should HIPAA Security documentation updated in response to periodic evaluations, following security incidents, and/or after acquisitions of new technology or new procedures?

2.

Retain Documentation for at Least Six Years Implementation Specifications (Required)

•

Retain required documentation of policies, procedures, actions, activities or assessments required by the HIPAA Security Rule for six years from the date of its creation or the date when it last was in effect, whichever is later.

•

Have documentation retention requirements under HIPAA been aligned with the organization's other data retention policies?

3.

Assure that Documentation is Available to those Responsible for Implementation Implementation Specification (Required)

Make documentation available to those persons responsible for implementing the procedures to which the documentation pertains.

•

Is the location of documentation known to all staff that needs to access it?

•

Is availability of the documentation made known as part of education, training and awareness activities?119

4.

Update Documentation as Required

Implementation Specification (Required)

•

Review documentation periodically, and update as needed, in response to environmental or operational changes affecting the security of the EPHI.

Is there a version control procedure that allows verification of the timeliness of policies and procedures, if reasonable and appropriate?

•

Is there a process for soliciting input into updates of policies and procedures from staff, if reasonable and appropriate?

119 See Section 4.5, HIPAA Standard: Security Awareness and Training. 53 Appendix A: Glossary

This appendix provides definitions for those terms used within this document that are defined specifically in the HIPAA Security Rule. Definitions for basic security terms used frequently in NIST publications, including this document, are centrally located in NIST Interagency Report 7298, Glossary of Key Information Security Terms. This glossary is available on http://csrc.nist.gov.

Administrative Safeguards [45 Code of Federal Regulations (C.F.R.) Sec. 164.304] Administrative actions, and policies and procedures, to manage the selection, development, implementation, and maintenance of security measures to protect electronic protected health information and to manage the conduct of the covered entity's workforce in relation to the protection of that information. Addressable [45 C.F.R. Sec. 164.306(d)(3)]

Describing 21 of the HIPAA Security Rule's 42 implementation specifications. To meet the addressable implementation specifications, a covered entity must (i) assess whether each implementation specification is a reasonable and appropriate safeguard in its environment, when analyzed with reference to the likely contribution to protecting the entity's electronic protected health information; and (ii) as applicable to the entity - (A) Implement the implementation specification if reasonable and appropriate; or (B) if implementing the implementation specification is not reasonable and appropriate—(1) document why it would not be reasonable and appropriate to implement the implementation specification; and (2) implement an equivalent alternative measure if reasonable and appropriate. Affiliated Covered Entities [45 C.F.R. Sec. 164.105(b)]

Legally separate covered entities that are under common ownership or control and that have all designated themselves as a single affiliated covered entity for the purposes of the Privacy and Security Rule (more precisely, those parts of the Rules appearing at 45 CFR, Part 160, Subparts C and E).

Agency

[FIPS 200; 44 U.S.C, Sec. 3502]

Any executive department, military department, government corporation, government-controlled corporation, or other establishment in the executive branch of the government (including the Executive Office of the President) or any independent regulatory agency, but does not include: 1) the General Accounting Office; 2) the Federal Election Commission; 3) the governments of the District of Columbia and of the territories and possessions of the United States and their various subdivisions; or 4) government-owned, contractor-operated facilities, including laboratories engaged in national defense research and production activities. Also referred to as Federal Agency.

Authentication

The corroboration that a person is the one claimed.

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[45 C.F.R. Sec. 164.304]

Availability [45 C.F.R. Sec. 164.304]

The property that data or information is accessible and usable upon demand by an authorized person.

Business Associate [45 C.F.R. Sec. 160.103]

(1) Except as provided in paragraph (2) of this definition, "business associate" means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized healthcare arrangement (as defined at 45 C.F.R. Sec. 164.501) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:

(A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis,

processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or

(B) Any other function or activity regulated by this subchapter; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in Sec. 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized healthcare arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity participating in an organized healthcare arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized healthcare arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized healthcare arrangement, does not, simply through the performance of such function or activity or the provision of such service, become a business associate of other covered entities participating in such organized healthcare arrangement.

(3) A covered entity may be a business associate of another covered entity. Confidentiality [45 C.F.R. Sec. 164.304]

The property that data or information is not made available or disclosed to unauthorized persons or processes.

Covered Entities [45 C.F.R. Sec.160.103]

Covered entity means: (1) A health plan. (2) A healthcare clearinghouse. (3) A healthcare provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter. (4) Medicare A-2

Prescription Drug Card Sponsors.

Electronic Protected Health Information (electronic PHI, or EPHI) [45 C.F.R. Sec.160.103]

Information that comes within paragraphs (1)(i) or (1)(ii) of the definition of protected health information (see "protected health information").

Healthcare Clearinghouse [45 C.F.R. Sec.160.103]

A public or private entity, including a billing service, repricing company, community health management information system or community health information system, and "value-added" networks and switches, that does either of the following functions:

(1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.

(2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

Healthcare Provider [45 C.F.R. Sec. 160.103]

A provider of services (as defined in section 1861(u) of the Social Security Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Social Security Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for healthcare in the normal course of business.

Health Information [45 C.F.R. Sec. 160.103]

Any information, whether oral or recorded in any form or medium, that:

(1) Is created or received by a healthcare provider, health plan, public health authority, employer, life insurer, school or university, or healthcare clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual.

Health Plan [45 C.F.R. Sec.160.103]

(1) Health plan includes the following, singly or in combination:

(i) A group health plan, as defined in this section.

(ii) A health insurance issuer, as defined in this section.

(iii) An HMO, as defined in this section. (iv) Part A or Part B of the Medicare program under title XVIII of the Social Security Act.

(v) The Medicaid program under title XIX of the Social Security Act, 42 U.S.C. 1396, et seq.

(vi) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Social Security Act, 42 U.S.C.

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1395ss(g)(1)).

(vii) An issuer of a long-term care policy, excluding a nursing home fixed-indemnity policy.

(viii) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(ix) The healthcare program for active military personnel under title 10 of the United States Code.

(x) The veterans' healthcare program under 38 U.S.C. chapter 17.

(xi) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) (as defined in 10 U.S.C. 1072(4)).

(xii) The Indian Health Service program under the Indian Healthcare Improvement Act, 25 U.S.C. 1601, et seq.

(xiii) The Federal Employees Health Benefits Program under 5 U.S.C. 8902, et seq.
(xiv) An approved State child health plan under title XXI of the Social Security Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Social Security Act, 42 U.S.C. 1397, et seq.

(xv) The Medicare + Choice program under Part C of title XVIII of the Social Security Act, 42 U.S.C. 1395w-21 through 1395w-28.

(xvi) A high-risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals.

(xvii) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Social Security Act, 42 U.S.C. 300gg-91(a)(2)).

(2) Health plan excludes:

(i) Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg-

91(c)(1); and

(ii) A government-funded program (other than one listed in paragraph (1)(i)-(xvi) of this definition):

(A) Whose principal purpose is other than providing, or paying the cost of, healthcare; or

(B) Whose principal activity is:

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(1) The direct provision of healthcare to persons; or

(2) The making of grants to fund the direct provision of healthcare to persons.

Hybrid Entity [45 C.F.R. Sec.164.103]

A single legal entity:

(1) That is a covered entity;

(2) Whose business activities include both covered and non-covered functions; and

(3) That designates healthcare components in accordance with paragraph § 164.105(a)(2)(iii)(C).

Implementation Specification [45 C.F.R. Sec. 160.103]

Specific requirements or instructions for implementing a standard.

Individually Identifiable Health Information (IIHI) [45 C.F.R. Sec. 160.103] Information that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a healthcare provider, health plan, employer, or healthcare clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Information System [45 C.F.R. Sec. 164.304]

An interconnected set of information resources under the same direct management control that shares common functionality. A system normally includes hardware,

software, information, data, applications, communications, and people.120 Integrity [45 C.F.R. Sec. 164.304]

The property that data or information have not been altered or destroyed in an unauthorized manner.

Medicare Prescription Drug Card Sponsors

[Pub. L. 108-173]

A nongovernmental entity that offers an endorsed discount drug program under the Medicare Modernization Act.

Physical Safeguards [45 C.F.R. Sec. 164.304]

Physical measures, policies, and procedures to protect a covered entity's electronic information systems and related buildings and equipment from natural and environmental hazards, and unauthorized intrusion.

Protected Health Information (PHI)

Individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that

120 FISMA defines "information system" as "a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information." 44 U.S.C., Sec. 3502.

[45 C.F.R., Sec. 160.103]

is:

(i) Transmitted by electronic media;

(ii) Maintained in electronic media; or

(iii) Transmitted or maintained in any other form or medium. (2) Protected health information excludes individually identifiable health information in:

(i) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;

(ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and

(iii) Employment records held by a covered entity in its role as employer.

Required [45 C.F.R. Sec. 164.306(d)(2]

As applied to an implementation specification (see implementation specification, above], indicating an implementation specification that a covered entity must implement. All implementation specifications are either required or addressable (see "addressable" above).

Security [44 U.S.C., Sec. 3542]

Protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide—

(A) integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;
(B) confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

(C) availability, which means ensuring timely and reliable access to and use of information.

Standard [45 C.F.R., Sec. 160.103]

A rule, condition, or requirement: (1) Describing the following information for products, systems, services or practices: (i) Classification of components. (ii) Specification of materials, performance, or operations; or (iii) Delineation of procedures; or (2) With respect to the privacy of individually identifiable health information.

Technical Safeguards [45 C.F.R., Sec. 164.304]

The technology and the policy and procedures for its use that protect electronic protected health information and control access to it.

User [45 C.F.R., Sec. 164.304]

A person or entity with authorized access.

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Appendix B: Acronyms

The appendix lists acronyms used within this document.

AC

Access Control (NIST SP 800-53 security control family)

AT

Awareness and Training (NIST SP 800-53 security control family)

AU

Audit and Accountability (NIST SP 800-53 security control family)

BAC

Business Associate Contract

CA

Certification, Accreditation, and Security Assessments (NIST SP 800-53 security control family)

C&A

Certification and Accreditation

CFR

Code of Federal Regulations

CIO

Chief Information Officer

CM **Configuration Management (NIST SP 800-53 security control family)** CMS **Centers for Medicare and Medicaid Services** CP Contingency Planning (NIST SP 800-53 security control family) CSD **Computer Security Division** DHHS **Department of Health and Human Services** EPHI **Electronic Protected Health Information FISMA Federal Information Security Management Act** FIPS **Federal Information Processing Standard** HHS **Department of Health and Human Services** HIPAA Health Insurance Portability and Accountability Act IA Identification and Authentication (NIST SP 800-53 security control family) ID Identification IR Incident Response (NIST SP 800-53 security control family) ISP **Internet Service Provider** IT **Information Technology** ITL **Information Technology Laboratory** LAN Local Area Network MA Maintenance (NIST SP 800-53 security control family) MOU Memorandum of Understanding MP Media Protection (NIST SP 800-53 security control family) NIST National Institute of Standards and Technology **NISTIR NIST Interagency Report OESS Office of E-Health Standards and Services** OIG **Office of the Inspector General** OMB **Office of Management and Budget** PE

Physical and Environmental Protection (NIST SP 800-53 security control family) PHI **Protected Health Information** PKI **Public Key Infrastructure** PL Planning (NIST SP 800-53 security control family) PS Personnel Security (NIST SP 800-53 security control family) RA Risk Assessment (NIST SP 800-53 security control family) SA System and Services Acquisition (NIST SP 800-53 security control family) SC System and Communications Protection (NIST SP 800-53 security control family) SI System and Information Integrity (NIST SP 800-53 security control family) SP **Special Publication US-CERT United States Computer Emergency Response Team** US **United States Appendix C: References Public Laws** Public Law 107-347, E-Government Act of 2002 (Title III: Federal Information Security Management Act [FISMA] of 2002), December 17, 2002. Public Law 104-191, Health Insurance Portability and Accountability Act (HIPAA) of 1996, August 21, 1996. **Federal Regulations** Health Insurance Reform: Security Standards; Final Rule ("The HIPAA Security Rule"), 68 FR 8334, February 20, 2003. Federal Information Processing Standards (FIPS) Publications FIPS 140-2, Security Requirements for Cryptographic Modules, June 2001. FIPS 199, Standards for Security Categorization of Federal Information and Information Systems, February 2004. FIPS 200, Minimum Security Requirements for Federal Information and Information Systems, March 2006. FIPS 201-1, Personal Identity Verification (PIV) of Federal Employees and **Contractors, March 2006. NIST Special Publications (SPs)** NIST SP 800-12, An Introduction to Computer Security: The NIST Handbook, October 1995. NIST SP 800-14, Generally Accepted Principles and Practices for Securing Information Technology Systems, September 1996. NIST SP 800-16, Information Technology Security Training Requirements: A Role-And Performance-Based Model, April 1998. NIST SP 800-18 Revision 1, Guide for Developing Security Plans for Information Technology Systems, February 2006. NIST SP 800-21, Guideline for Implementing Cryptography in the Federal Government, December 2005.

NIST SP 800-30, Risk Management Guide for Information Technology Systems, January 2002.

NIST SP 800-34, Contingency Planning Guide for Information Technology Systems, June 2002.

NIST SP 800-35, Guide to Information Technology Security Services, October 2003. NIST 800-37, DRAFT Guide for Security Authorization of Federal Information

Systems: A Security Lifecycle Approach, August 2008.

NIST SP 800-39, DRAFT Managing Risk from Information Systems: An Organizational Perspective, April 2008.

NIST SP 800-41, Guidelines on Firewalls and Firewall Policy, January 2002.

NIST SP 800-42, Guideline on Network Security Testing, October 2003.

NIST SP 800-45, Version 2, Guidelines on Electronic Mail Security, February 2007. C-1

NIST SP 800-46, Security for Telecommuting and Broadband Communications, August 2002.

NIST SP 800-47, Security Guide for Interconnecting Information Technology Systems, September 2002.

NSIT SP 800-48, Revision 1, Guide to Securing Legacy IEEE 802.11 Wireless Networks, July 2008.

NIST SP 800-50, Building an Information Technology Security Awareness and Training Program, October 2003.

NIST SP 800-52, Guidelines for the Selection and Use of Transport Layer Security (TLS) Implementations, June 2005.

NIST SP 800-53, Revision 2, Recommended Security Controls for Federal Information Systems, December 2007.

NIST SP 800-53A, Guide for Assessing the Security Controls in Federal Information Systems, June 2008.

NIST SP 800-55, Revision 1, Performance Measurement Guide for Information Security, July 2008.

NIST SP 800-58, Security Considerations for Voice Over IP Systems, January 2005. NIST SP 800-60, Revision 1, Guide for Mapping Types of Information and

Information Systems to Security Categories, July 2008. NIST SP 800-61, Revision 1, Computer Security Incident Handling Guide, March

2008.

NIST SP 800-63-1, DRAFT Electronic Authentication Guide, February 2008.

NIST SP 800-64 Revision 2, Security Considerations in the Information Systems Development Life Cycle, October 2008.

NIST SP 800-77, Guide to IPsec VPNs, December 2005.

NIST SP 800-81, Secure Domain Name System (DNS) Deployment Guide, May 2006.

NIST SP 800-83, Guide to Malware Incident Prevention and Handling, November 2005.

NIST SP 800-84, Guide to Test, Training, and Exercise Programs for IT Plans and Capabilities, September 2006.

NIST SP 800-86, Guide to Integrating Forensic Techniques into Incident Response, August 2006.

NIST SP 800-88, Guidelines for Media Sanitization, September 2006.

NIST SP 800-92, Guide to Computer Security Log Management, September 2006. NIST SP 800-94, Guide to Intrusion Detection and Prevention Systems (IDPS), February 2007. NIST SP 800-100, Information Security Handbook: A Guide for Managers, October 2006.

NIST SP 800-106, DRAFT Randomized Hashing Digital Signatures, July 2008.

NIST SP 800-107, DRAFT Recommendation for Using Approved Hash Algorithms, July 2008.

NIST SP 800-111, Guide to Storage Encryption Technologies for End User Devices, November 2007.

NIST SP 800-113, Guide to SSL VPNs, July 2008.

C-2

C-3

NIST SP 800-114, User's Guide to Securing External Devices for Telework and Remote Access, November 2007.

NIST SP 800-115, Technical Guide to Information Security Testing, November 2007.

NIST SP 800-124, DRAFT Guidelines on Cell Phone and PDA Security, July 2008. NIST Interagency Reports (NISTIRs)

NISTIR 7298, Glossary of Key Information Security Terms, April 2006.

CMS HIPAA Security Series Publications

Security 101 for Covered Entities, March 2007.

Security Standards Administrative Safeguards, March 2007.

Security Standards Physical Safeguards, March 2007.

Security Standards Technical Safeguards, March 2007.

Security Standards Organizational Policies, March 2007.

Basics of Risk Analysis and Risk Management, March 2007.

HIPAA Security Guidance for Remote Use of and Access to Electronic Protected

Health Information, December 2006

Web sites and Other Resources

NIST: Computer Security Resource Center (CSRC): http://csrc.nist.gov/

NIST: National Vulnerability Database (NVD): http://nvd.nist.gov/

Guide to NIST Information Security Documents:

http://csrc.nist.gov/publications/CSD_DocsGuide.pdf

Department of Health and Human Services (DHHS), Centers for Medicare and

Medicaid Services (CMS), HIPAA Resources:

http://www.cms.hhs.gov/hipaa/hipaa2.

Workgroup for Electronic Data Interchange (WEDI): http://www.wedi.org Appendix D: Security Rule Standards and Implementation Specifications Crosswalk

Appendix D provides a catalog (see Table 4) of the HIPAA Security Rule standards and implementation specifications within the Administrative, Physical, and Technical Safeguards sections of the Security Rule. Additionally, this catalog crosswalks, or maps, those Security Rule standards and implementation specifications to NIST publications relevant to each Security Rule standard, and to applicable security controls detailed in NIST SP 800-53, Recommended Security Controls for Federal Information Systems. Readers may draw upon these NIST publications and security controls for consideration in implementing the Security

Rule.

The catalog is organized according to the categorization of standards within each of the safeguards sections in the Security Rule. Table 3 provides an overview of the catalog content.

Table 3. Overview of Catalog ContentColumn Headers

Description

Section of HIPAA Security Rule

Indicates the regulatory citation to the appropriate section of the Security Rule where the standard and implementation specification can be found.

Standards

Lists the Security Rule Standards.

Implementation Specifications

Lists the implementation specifications associated with the standard, if any exist, and designates the specification as required or addressable. (R = Required, A = Addressable)

NIST SP 800-53 Security Controls Mapping

Provides a listing of NIST SP 800-53 security controls that may provide value when implementing the particular standards and implementation specifications. For full security control specifications, refer to NIST SP 800-53, which can be found online at http://csrc.nist.gov.

NIST Publications Crosswalk

Provides a listing of NIST publications that support each particular standard. Publications are listed by publication number. For the full publication title, refer to Appendix C: References within this document, or to the Guide to NIST Information Security Documents located on the NIST Computer Security Resource Center (CSRC) Web site at http://csrc.nist.gov.

The mapping of SP 800-53 security controls to Security Rule standards and implementation specifications is of particular importance because it allows for the traceability of legislative and regulatory directives, such as HIPAA and FISMA, to underlying technical security configurations. This mapping can also enable standards-based measurement and monitoring of technical security safeguards and computer security configurations; facilitate compliance management by automating portions of D-1

D-2

compliance demonstration and reporting; and reduce the chance of misinterpretation between auditors and operations teams.

To accomplish this automation, NIST has defined, and maintains, the Security Content Automation Protocol (SCAP),121 a suite of selected and integrated open standards that enable standards-based communication of vulnerability data, customizing and managing configuration baselines for various IT products, assessing information systems and reporting compliance status, using standard measures to weigh and aggregate potential vulnerability impact, and remediating identified vulnerabilities.

121 More information on the Security Content Automation Protocol (SCAP) is available on the National Vulnerability Web site, http://nvd.nist.gov.

Table 4. HIPAA Standards and Implementation Specifications Catalog

Section of HIPAA Security Rule

HIPAA Security Rule Standards

Implementation Specifications

NIST SP 800-53 Security Controls Mapping

NIST Publications Crosswalk

Administrative Safeguards

164.308(a)(1)(i)

Security Management Process: Implement policies and procedures to prevent, detect, contain, and correct security violations.

RA-1

164.308(a)(1)(ii)(A)

Risk Analysis (R): Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity.

RA-2, RA-3, RA-4

164.308(a)(1)(ii)(B)

Risk Management (R): Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with Section 164.306(a).

RA-2, RA-3, RA-4, PL-6

164.308(a)(1)(ii)(C)

Sanction Policy (R): Apply appropriate sanctions against workforce members who fail to comply with the security policies and procedures of the covered entity. **PS-8**

164.308(a)(1)(ii)(D)

Information System Activity Review (R): Implement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports.

AU-6, AU-7, CA-7, IR-5, IR-6, SI-4

FIPS 199

NIST SP 800-14 NIST SP 800-18 NIST SP 800-30 NIST SP 800-37 NIST Draft SP 800-39 **NIST SP 800-42 NIST SP 800-53 NIST SP 800-55 NIST SP 800-60 NIST SP 800-84 NIST SP 800-92 NIST SP 800-100**

164.308(a)(2)

Assigned Security Responsibility: Identify the security official who is responsible for the development and implementation of the policies and procedures required by this subpart for the entity.

CA-4, CA-6

NIST SP 800-12 NIST SP 800-14 NIST SP 800-37 NIST SP 800-53 **NIST SP 800-53A NIST SP 800-100**

D-3

HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping

164.308(a)(3)(i)

Workforce Security: Implement policies and procedures to ensure that all members of its workforce have appropriate access to electronic protected health information, as provided under paragraph (a)(4) of this section, and to prevent those workforce

members who do not have access under paragraph (a)(4) of this section from obtaining access to electronic protected health information.

AC-1, AC-5, AC-6

164.308(a)(3)(ii)(A)

Authorization and/or Supervision (A): Implement procedures for the authorization and/or supervision of workforce members who work with electronic protected health information or in locations where it might be accessed.

AC-1, AC-3, AC-4, AC-13, MA-5, MP-2, PS-1, PS-6, PS-7 164.308(a)(3)(ii)(B)

Workforce Clearance Procedure (A): Implement procedures to determine that the access of a workforce member to electronic protected health information is

appropriate. AC-2, PS-1, PS-2, PS-3, PS-6

164.308(a)(3)(ii)(C)

Termination Procedure (A): Implement procedures for terminating access to electronic protected health information when the employment of a workforce member ends or as required by determinations made as specified in paragraph (a)(3)(ii)(B) of this section.

PS-1, PS-4, PS-5

NIST SP 800-12

NIST SP 800-14

NIST SP 800-53

164.308(a)(4)(i)

Information Access Management: Implement policies and procedures for authorizing access to electronic protected health information that are consistent with the applicable requirements of subpart E of this part.

AC-1, AC-2, AC-5, AC-6, AC-13

NIST SP 800-12 NIST SP 800-14 NIST SP 800-18 NIST SP 800-53 NIST SP 800-63

D-4

HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r503ls NISTC rPoussbwliacalkti ons Rule Mapping

164.308(a)(4)(ii)(A)

Isolating Healthcare Clearinghouse Functions (R): If a healthcare clearinghouse is part of a larger organization, the clearinghouse must implement policies and procedures that protect the electronic protected health information of the clearinghouse from unauthorized access by the larger organization.

AC-5, AC-6

164.308(a)(4)(ii)(B)

Access Authorization (A): Implement policies and procedures for granting access to electronic protected health information, for example, through access to a workstation, transaction, program, process, or other mechanism.

AC-1, AC-2, AC-3, AC-4, AC-13, PS-6, PS-7

164.308(a)(4)(ii)(C)

Access Establishment and Modification (A): Implement policies and procedures that, based upon the entity's access authorization policies, establish, document,

review, and modify a user's right of access to a workstation, transaction, program, or process. AC-1, AC-2, AC-3 NIST SP 800-100 164.308(a)(5)(i) Security Awareness and Training: Implement a security awareness and training program for all members of its workforce (including management). AT-1, AT-2, AT-3, AT-4, AT-5 164.308(a)(5)(ii)(A) Security Reminders (A): Periodic security updates. AT-2, AT-5, SI-5 164.308(a)(5)(ii)(B) Protection from Malicious Software (A): Procedures for guarding against, detecting, and reporting malicious software. AT-2, SI-3, SI-4, SI-8 164.308(a)(5)(ii)(C) Log-in Monitoring (A): Procedures for monitoring log-in attempts and reporting discrepancies. AC-2, AC-13, AU-2, AU-6 164.308(a)(5)(ii)(D) Password Management (A): Procedures for creating, changing, and safeguarding passwords. IA-2, IA-4, IA-5, IA-6, IA-7 NIST SP 800-12 **NIST SP 800-14 NIST SP 800-16 NIST SP 800-50** NIST SP 800-61 **NIST SP 800-83 D-5** HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping 164.308(a)(6)(i) Security Incident Procedures: Implement policies and procedures to address security incidents. IR-1, IR-2, IR-3 164.308(a)(6)(ii) Response and Reporting (R): Identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents that are known to the covered entity; and document security incidents and their outcomes. IR-4, IR-5, IR-6, IR-7 **NIST SP 800-12 NIST SP 800-14**

NIST SP 800-61 NIST SP 800-83 NIST SP 800-86 NIST SP 800-94 164.308(a)(7)(i) Contingency Plan: Establish (and implement as needed) policies and procedures for responding to an emergency or other occurrence (for example, fire, vandalism, system failure, and natural disaster) that damages systems that contain electronic protected health information. **CP-1** 164.308(a)(7)(ii)(A) Data Backup Plan (R): Establish and implement procedures to create and maintain retrievable exact copies of electronic protected health information. **CP-9** 164.308(a)(7)(ii)(B) Disaster Recovery Plan (R): Establish (and implement as needed) procedures to restore any loss of data. CP-2, CP-6, CP-7, CP-8, CP-9, CP-10 164.308(a)(7)(ii)(C) Emergency Mode Operation Plan (R): Establish (and implement as needed) procedures to enable continuation of critical business processes for protection of the security of electronic protected health information while operating in emergency mode. **CP-2, CP-10 FIPS 199 NIST SP 800-12 NIST SP 800-14 NIST SP 800-18 NIST SP 800-30 NIST SP 800-34 NIST SP 800-60 NIST SP 800-84 D-6** HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSvP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping 164.308(a)(7)(ii)(D) Testing and Revision Procedure (A): Implement procedures for periodic testing and revision of contingency plans. CP-3, CP-4, CP-5 164.308(a)(7)(ii)(E) Applications and Data Criticality Analysis (A): Assess the relative criticality of specific applications and data in support of other contingency plan components. **RA-2, CP-2** 164.308(a)(8) Evaluation: Perform a periodic technical and nontechnical evaluation, based initially upon the standards implemented under this rule and subsequently, in response to environmental or operational changes affecting the security of electronic protected health information that establishes the extent to which an entity's security policies and procedures meet the requirements of this subpart. CA-1, CA-2, CA-4, CA-6, CA-7 **NIST SP 800-12 NIST SP 800-14 NIST SP 800-37** NIST SP 800-42 **NIST SP 800-53A**

NIST SP 800-55 NIST SP 800-84 NIST SP 800-115 164.308(b)(1)

Business Associate Contracts and Other Arrangements: A covered entity, in accordance with § 164.306, may permit a business associate to create, receive, maintain, or transmit electronic protected health information on the covered entity's behalf only if the covered entity obtains satisfactory assurances, in accordance with Sec. 164.314(a), that the business associate will appropriately safeguard the information.

CA-3, PS-7, SA-9 NIST SP 800-12 NIST SP 800-14 NIST SP 800-37 NIST SP 800-47 NIST SP 800-100

D-7

HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping

164.308(b)(4)

Written Contract or Other Arrangement (R): Document the satisfactory assurances required by paragraph (b)(1) of this section through a written contract or other arrangement with the business associate that meets the applicable requirements of § 164.314(a).

CA-3, SA-9

Physical Safeguards

164.310(a)(1)

Facility Access Controls: Implement policies and procedures to limit physical access to its electronic information systems and the facility or facilities in which they are housed, while ensuring that properly authorized access is allowed.

PE-1, PE-2, PE-3, PE-4, PE-5

164.310(a)(2)(i)

Contingency Operations (A): Establish (and implement as needed) procedures that allow facility access in support of restoration of lost data under the disaster recovery plan and emergency mode operations plan in the event of an emergency.

CP-2, CP-6, CP-7, PE-17

164.310(a)(2)(ii)

Facility Security Plan (A): Implement policies and procedures to safeguard the facility and the equipment therein from unauthorized physical access, tampering, and theft.

PE-1, PL-2, PL-6

164.310(a)(2)(iii)

Access Control and Validation Procedures (A): Implement procedures to control and validate a person's access to facilities based on their role or function, including visitor control, and control of access to software programs for testing and revision. AC-3, PE-1, PE-2, PE-3, PE-6, PE-7, PE-8

NIST SP 800-12 NIST SP 800-14 NIST SP 800-18

NIST SP 800-30

NIST SP 800-34 NIST SP 800-53 D-8 HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping 164.310(a)(2)(iv) Maintenance Records (A): Implement policies and procedures to document repairs and modifications to the physical components of a facility which are related to security (for example, hardware, walls, doors, and locks). MA-1122, MA-2, MA-6 164.310(b) Workstation Use: Implement policies and procedures that specify the proper functions to be performed, the manner in which those functions are to be performed, and the physical attributes of the surroundings of a specific workstation or class of workstation that can access electronic protected health information. AC-3, AC-4, AC-11, AC-12, AC-15, AC-16, AC-17, AC-19, PE-3, PE-5, PS-6 **NIST SP 800-12 NIST SP 800-14 NIST SP 800-53** 164.310(c) Workstation Security: Implement physical safeguards for all workstations that access electronic protected health information to restrict access to authorized users. MP-2, MP-3, MP-4, PE-3, PE-4, PE-5, PE-18 **NIST SP 800-12 NIST SP 800-14 NIST SP 800-53** 164.310(d)(1) Device and Media Controls: Implement policies and procedures that govern the receipt and removal of hardware and electronic media that contain electronic protected health information into and out of a facility, and the movement of these items within the facility. CM-8, MP-1, MP-2, MP-3, MP-4, MP-5, MP-6 **NIST SP 800-12 NIST SP 800-14 NIST SP 800-34 NIST SP 800-53 NIST SP 800-88** 122 In NIST SP 800-53, the Maintenance security control family discusses maintenance activities relating to information systems. The same principles, however, can be applied to facility maintenance. **D-9** HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSvP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping 164.310(d)(2)(i) Disposal (R): Implement policies and procedures to address the final disposition of electronic protected health information and/or the hardware or electronic media on which it is stored. **MP-6** 164.310(d)(2)(ii)

Media Reuse (R): Implement procedures for removal of electronic protected health information from electronic media before the media are made available for reuse. **MP-6** 164.310(d)(2)(iii) Accountability (A): Maintain a record of the movements of hardware and electronic media and any person responsible therefore. CM-8, MP-5, PS-6 164.310(d)(2)(iv) Data Backup and Storage (A): Create a retrievable exact copy of electronic protected health information, when needed, before movement of equipment. **CP-9**, **MP-4 Technical Safeguards** 164.312(a)(1) Access Control: Implement technical policies and procedures for electronic information systems that maintain electronic protected health information to allow access only to those persons or software programs that have been granted access rights as specified in § 164.308(a)(4). AC-1, AC-3, AC-5, AC-6 164.312(a)(2)(i) Unique User Identification (R): Assign a unique name and/or number for identifying and tracking user identity. AC-2, AC-3, IA-2, IA-3, IA-4 164.312(a)(2)(ii) **Emergency Access Procedure (R): Establish (and implement as needed) procedures** for obtaining necessary electronic protected health information during an emergency. AC-2, AC-3, CP-2 **NIST SP 800-12 NIST SP 800-14 NIST SP 800-21 NIST SP 800-34 NIST SP 800-53 NIST SP 800-63 FIPS 140-2 D-10** HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSvP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping 164.312(a)(2)(iii) Automatic Logoff (A): Implement electronic procedures that terminate an electronic session after a predetermined time of inactivity. AC-11, AC-12 164.312(a)(2)(iv) Encryption and Decryption (A): Implement a mechanism to encrypt and decrypt electronic protected health information. AC-3, SC-13 164.312(b) Audit Controls: Implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information. AU-1, AU-2, AU-3, AU-4, AU-6, AU-7

NIST SP 800-12 NIST SP 800-14 NIST SP 800-42 NIST SP 800-53 NIST SP 800-53A NIST SP 800-55 NIST SP 800-92 NIST SP 800-115 164.312(c)(1)Integrity: Implement policies and procedures to protect electronic protected health information from improper alteration or destruction. CP-9, MP-2, MP-5, SC-8, SI-1, SI-7 164.312(c)(2)Mechanism to Authenticate Electronic Protected Health Information (A): Implement electronic mechanisms to corroborate that electronic protected health information has not been altered or destroyed in an unauthorized manner. SC-8, SI-7 **NIST SP 800-12 NIST SP 800-14 NIST SP 800-53 NIST Draft SP 800-106 NIST Draft SP 800-107** 164.312(d) Person or Entity Authentication: Implement procedures to verify that a person or entity seeking access to electronic protected health information is the one claimed. IA-2. IA-3. IA-4 **FIPS 201 NIST SP 800-12 NIST SP 800-14 NIST SP 800-53 NIST SP 800-63 D-11** HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSvP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping 164.312(e)(1) Transmission Security: Implement technical security measures to guard against unauthorized access to electronic protected health information that is being transmitted over an electronic communications network. **SC-9** 164.312(e)(2)(i) Integrity Controls (A): Implement security measures to ensure that electronically transmitted electronic protected health information is not improperly modified without detection until disposed of. SC-8, SI-7 164.312(e)(2)(ii) Encryption (A): Implement a mechanism to encrypt electronic protected health information whenever deemed appropriate. SC-9, SC-12, SC-13 **FIPS 140-2 NIST SP 800-12**

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NIST SP 800-14
NIST SP 800-21
NIST SP 800-24
NIST SP 800-41
NIST SP 800-42
NIST SP 800-45
NIST SP 800-46
NIST SP 800-48 NIST SP 800-52
NIST SP 800-53
NIST SP 800-58
NIST SP 800-63
NIST SP 800-77
NIST SP 800-81
NIST SP 800-113
Organizational
D-12
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HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r503ls NISTC rPoussbwliacalkti ons Rule

Mapping

164.314(a)(1)

Business Associate Contracts or Other Arrangements: (i) The contract or other arrangement between the covered entity and its business associate required by § 164.308(b) must meet the requirements of paragraph (a)(2)(i) or (a)(2)(ii) of this section, as applicable. (ii) A covered entity is not in compliance with the standards in § 164.502(e) and paragraph (a) of this section if the covered entity knew of a pattern of an activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful—(A) Terminated the contract or arrangement, if feasible; or (B) If termination is not feasible, reported the problem to the Secretary.

PS-6, PS-7, SA-9 NIST SP 800-35 NIST Draft SP 800-39 NIST SP 800-47 NIST SP 800-64 NIST SP 800-100 D-13

HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping

164.314(a)(2)(i)

Business Associate Contracts (R): The contract between a covered entity and a business associate must provide that the business associate will-- (A) Implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits on behalf of the covered entity as required by this subpart; (B) Ensure that any agent, including a subcontractor, to whom it provides such information agrees to implement reasonable and appropriate safeguards to protect it; (C) Report to the covered entity any security incident of which it becomes aware; (D) Authorize termination of the contract by the covered entity if the covered entity determines that the business associate has violated a material term of the contract.

IR-6, PS-6, PS-7, SA-4, SA-9

164.314(a)(2)(ii)

Other Arrangements: When a covered entity and its business associate are both governmental entities, the covered entity is in compliance with paragraph (a)(1) of this section, if-- (1) It enters into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of paragraph (a)(2)(i) of this section; or (2) Other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of paragraph (a)(2)(i) of that accomplish the objectives of paragraph (a)(2)(i) of this section.

CA-3, PS-6, PS-7, SA-9

D-14

HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping

164.314(b)(1)

Requirements for Group Health Plans: Except when the only electronic protected health information disclosed to a plan sponsor is disclosed pursuant to § 164.504(f)(1)(ii) or (iii), or as authorized under § 164.508, a group health plan must ensure that its plan documents provide that the plan sponsor will reasonably and appropriately safeguard electronic protected health information created, received, maintained, or transmitted to or by the plan sponsor on behalf of the group health plan.

Does not map

164.314(b)(2)(i)

Group Heath Plan Implementation Specification (R): The plan documents of the group health plan must be amended to incorporate provisions to require the plan sponsor to-- (i) Implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits on behalf of the group health plan.

Does not map

164.314(b)(2)(ii)

Group Heath Plan Implementation Specification (R): The plan documents of the group health plan must be amended to incorporate provisions to require the plan sponsor to-- (ii) Ensure that the adequate separation required by § 164.504(f)(2)(iii) is supported by reasonable and appropriate security measures.

Does not map NIST SP 800-35 NIST Draft SP 800-39 NIST SP 800-47 NIST SP 800-61 NIST SP 800-64 NIST SP 800-100 D-15 HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping 164.314(b)(2)(iii) Group Heath Plan Implementation Specification (R): The plan documents of the group health plan must be amended to incorporate provisions to require the plan sponsor to-- (iii) Ensure that any agent, including a subcontractor, to whom it provides this information, agrees to implement reasonable and appropriate security measures to protect the information.

Does not map

164.314(b)(2)(iv)

Group Heath Plan Implementation Specification (R): The plan documents of the group health plan must be amended to incorporate provisions to require the plan sponsor to-- (iv) Report to the group health plan any security incident of which it becomes aware.

Does not map

Policies and Procedure and Documentation Requirements 164.316(a) Policies and Procedures: Implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications, or other requirements of this subpart, taking into account those factors specified in § 164.306(b)(2)(i), (ii), (iii), and (iv). This standard is not to be construed to permit or excuse an action that violates any other standard, implementation specification, or other requirements of this subpart. A covered entity may change its policies and procedures at any time, provided that the changes are documented and are implemented in accordance with this subpart. PL-1, PL-2, PL-3, RA-1, RA-3 NIST SP 800-12 **NIST SP 800-14 NIST SP 800-100 D-16 D-17** Section of **HIPAA Security** Rule **HIPAA Security Rule Standards Implementation Specifications** NIST SP 800-53 **Security Controls** Mapping **NIST Publications** Crosswalk 164.316(b)(1) **Documentation:** (i) Maintain the policies and procedures implemented to comply with this subpart in written (which may be electronic) form; and (ii) If an action, activity or assessment is required by this subpart to be documented, maintain a written (which may be electronic) record of the action, activity, or assessment. **PL-2** 164.316(b)(2)(i) Time Limit (R): Retain the documentation required by paragraph (b)(1) of this section for six years from the date of its creation or the date when it last was in effect, whichever is later. **Does not map**

164.316(b)(2)(ii)

Availability (R): Make documentation available to those persons responsible for implementing the procedures to which the documentation pertains.

Does not map

164.316(b)(2)(iii)

Updates (R): Review documentation periodically, and update as needed, in response to environmental or operational changes affecting the security of the electronic protected health information.

PL-3

NIST SP 800-18

NIST SP 800-53

NIST SP 800-53A

Appendix E: Risk Assessment Guidelines

This appendix incorporates risk assessment concepts and processes described in NIST SP 800-30 Revision 1, Effective Use of Risk Assessments in Managing Enterprise Risk, the NIST Risk Management Framework, and the HIPAA Security Series: Basics of Risk Analysis and Risk Management. It is intended to assist covered entities in identifying and mitigating risks to acceptable levels.

The purpose of a risk assessment is to identify conditions where EPHI could be disclosed without proper authorization, improperly modified, or made unavailable when needed. This information is then used to make risk management decisions on whether the HIPAA-required implementation specifications are sufficient or what additional addressable implementation specifications are needed to reduce risk to an acceptable level.

Key Terms Defined

When talking about risk, it is important that terminology be defined and clearly understood. This section defines important terms associated with risk assessment and management.

•

Risk is the potential impact that a threat can have on the confidentiality, integrity, and availability on EPHI by exploiting a vulnerability.

•

Threats are anything that can have a negative impact on EPHI. Threats are:

0

Intentional (e.g., malicious intent); or

0

Unintentional (e.g., misconfigured server, data entry error).

•

Threat sources are:

0

Natural (e.g., floods, earthquakes, storms, tornados);

0

Human (e.g., intentional such as identity thieves, hackers, spyware authors; unintentional such as data entry error, accidental deletions); or

0

Environmental (e.g., power surges and spikes, hazmat contamination, environmental pollution).

•

Vulnerabilities are a flaw or weakness in a system security procedure, design, implementation, or control that could be intentionally or unintentionally exercised by a threat.

Impact is a negative quantitative and/or qualitative assessment of a vulnerability being exercised on the confidentiality, integrity, and availability of EPHI. It can be easy to confuse vulnerabilities and threats. An organization may be vulnerable to damage from power spikes. The threats that could exploit this vulnerability may be overloaded circuits, faulty building wiring, dirty street power, or too much load on the local grid. It is important to separate these two terms in order to assist in proper security control selection. In this example, security controls could range from installing UPS systems, additional fuse boxes, or standby generators, or rewiring the office. These E-1

additional security controls may help to mitigate the vulnerability but not necessarily for each threat.

HIPAA Risk Assessment Requirements

Standard 164.308(a)(1)(i), Security Management Process, requires covered entities to:

Implement policies and procedures to prevent, detect, contain, and correct security violations.

The Security Management Process standard includes four required implementation specifications. Two of these specifications deal directly with risk analysis and risk management.

1.

Risk Analysis (R123) – 164.308(a)(1)(ii)(A): Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity.

2.

Risk Management (R) - 163.308(a)(1)(ii)(B): Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with Section 164.306(a).

How to Conduct the Risk Assessment:

Risk assessments can be conducted using many different methodologies. There is no single methodology that will work for all organizations and all situations. The following steps represent key elements in a comprehensive risk assessment program, and provide an example of the risk assessment methodology described in NIST SP 800-30. It is expected that these steps will be customized to most effectively identify risk for an organization based on its own uniqueness. Even though these items are listed as steps, they are not prescriptive in the order that they should be conducted. Some steps can be conducted simultaneously rather than sequentially. 1.

Scope the Assessment. The first step in assessing risk is to define the scope of the effort, resulting in a general characterization of the information system, its operating environment, and its boundary. To do this, it is necessary to identify where EPHI is created, received, maintained, processed, or transmitted. The scope of a risk assessment should include both the physical boundaries of a covered entity's location as well as a logical boundary covering the media containing EPHI, regardless of its location. Ensure that the risk assessment scope takes into consideration the remote work force and telecommuters, and removable media and portable computing devices (e.g., laptops, removable media, and backup media). 2.

Gather Information. During this step, the covered entity should identify:

The conditions under which EPHI is created, received, maintained, processed, or transmitted by the covered entity; and

123 "R" indicates a required implementation specification. E-2

The security controls currently being used to protect the EPHI.

This step is essential to ensure that vulnerabilities and threats are correctly identified. For example, an invalidated belief that a policy is being followed can miss a potential vulnerability, and not knowing about portable media containing EPHI can miss a threat to that environment. The level of effort needed to gather the necessary information depends heavily on the scope of the assessment and the size of the covered entity.

3.

Identify Realistic Threats. Often performed simultaneously with step 4, Identify Potential Vulnerabilities, the goal of this step is to identify the potential threat sources and compile a threat statement listing potential threat-sources that are applicable to the covered entity and its operating environment. The listing of threat sources should include realistic and probable human and natural incidents that can have a negative impact on an organizations ability to protect EPHI. Threats can be easily identified by examining the environments where EPHI is being used. Many external sources can be used for threat identification. Internet searches, vendor information, insurance data, and crime statistics are all viable sources of threat data. Examples of some common threat sources are listed in Table 5 below. Table 5. Common Threat Sources

Type

Examples

Natural

Floods, earthquakes, tornados, landslides, avalanches, electrical storms, and other such events

Human

Events that are either enabled by or caused by human beings, such as unintentional acts (inadvertent data entry) or deliberate actions (network-based attacks, malicious software upload, and unauthorized access to confidential information) Environmental

Long-term power failure, pollution, chemicals, liquid leak 4.

Identify Potential Vulnerabilities. Often performed simultaneously with step 3, Identify Realistic Threats, the goal of this step is to develop a list of vulnerabilities (flaws or weaknesses) that could be exploited by potential threat sources. This list should focus on realistic technical and nontechnical areas where EPHI can be disclosed without proper authorization, improperly modified, or made unavailable when needed.

Covered entities should use internal and external sources to identify potential vulnerabilities. Internal sources may include previous risk assessments, vulnerability scan and system security test results, and audit reports. External sources may include Internet searches, vendor information, insurance data, and vulnerability databases such as the National Vulnerability Database (http://nvd.nist.gov). At the end of this appendix, a suggested (but not all-inclusive) source list is provided that organizations may wish to use to help in vulnerability identification.

E-3

5.

Assess Current Security Controls. Often performed simultaneously with step 2, Gather Information, the purpose of this step is to determine if the implemented or planned security controls will minimize or eliminate risks to EPHI. A thorough understanding of the actual security controls in place for a covered entity will reduce the list of vulnerabilities, as well as the realistic probability, of a threat attacking (intentionally or unintentionally) EPHI.

Covered entities should evaluate technical and nontechnical security controls at all places where EPHI is created, received, maintained, processed, or transmitted. This evaluation should determine whether the security measures implemented or planned are adequate to protect EPHI, and whether those measures required by the Security Rule are in place, configured, and used properly. The appropriateness and adequacy of security measures may vary depending on the structure, size, and geographical dispersion of the covered entity.

6.

Determine the Likelihood and the Impact of a Threat Exercising a Vulnerability. The next major step in measuring the level of risk is to determine the likelihood and the adverse impact resulting from a threat successfully exploiting a vulnerability. This information can be obtained from existing organizational documentation, such as business impact and asset criticality assessments. A business impact assessment prioritizes the impact levels associated with the compromise of an organization's information assets based on a qualitative or quantitative assessment of the sensitivity and criticality of those assets. An asset criticality assessment identifies and prioritizes the sensitive and critical organization information assets (e.g., hardware, software, systems, services, and related technology assets) that support the organization's critical missions.

If these organizational documents do not exist, the system and data sensitivity can be determined based on the level of protection required to maintain the EPHI's confidentiality, integrity, and availability. The adverse impact of a security event can be described in terms of loss or degradation of any, or a combination of any, of the following three security objectives: integrity, availability, and confidentiality. Table 6 provides a brief description of each security objective and the consequence (or impact) of its not being met.

Table 6. Security Objectives and Impacts

Security Objective

Impacts

Loss of Confidentiality

System and data confidentiality refers to the protection of information from unauthorized disclosure. The impact of unauthorized disclosure of confidential information can range from the jeopardizing of national security to the disclosure of Privacy Act data. Unauthorized, unanticipated, or unintentional disclosure could result in loss of public confidence, embarrassment, or legal action against the organization.

E-4

Security Objective Impacts

Loss of Integrity

System and data integrity refers to the requirement that information be protected from improper modification. Integrity is lost if unauthorized changes are made to the data or IT system by either intentional or accidental acts. If the loss of system or data integrity is not corrected, continued use of the contaminated system or corrupted data could result in inaccuracy, fraud, or erroneous decisions. Also, violation of integrity may be the first step in a successful attack against system availability or confidentiality. For all these reasons, loss of integrity reduces the assurance of an IT system.

Loss of Availability

If a mission-critical IT system is unavailable to its end users, the organization's mission may be affected. Loss of system functionality and operational effectiveness, for example, may result in loss of productive time, thus impeding the end users' performance of their functions in supporting the organization's mission. Some tangible impacts can be measured quantitatively in terms of lost revenue, the cost of repairing the system, or the level of effort required to correct problems caused by a successful threat action. Other impacts, such as the loss of public confidence, the loss of credibility, or damage to an organization's interest, cannot be measured in specific units but can be qualified or described in terms of high, medium, and low impacts. Qualitative and quantitative methods can be used to measure the impact of a threat occurring 7.

Determine the Level of Risk. The purpose of this step is to assess the level of risk to the IT system. The determination of risk takes into account the information gathered and determinations made during the previous steps. The level of risk is determined by analyzing the values assigned to the likelihood of threat occurrence and resulting impact of threat occurrence. The risk-level determination may be performed by assigning a risk level based on the average of the assigned likelihood and impact levels. A risk-level matrix, such as the sample depicted in Table 7, can be used to assist in determining risk levels.

Table 7. Sample Risk-Level Matrix Impact **Threat Likelihood** Low **Moderate** High High Low **Moderate** High **Moderate** Low Moderate **Moderate** Low Low Low Low E-5 8.

Recommend Security Controls. During this step, security controls that could mitigate the identified risks, as appropriate to the organization's operations, are recommended. The goal of the recommended controls is to reduce the level of risk to the IT system and its data to an acceptable level. Security control recommendations provide input to the risk mitigation process, during which the recommended security controls are evaluated, prioritized, and implemented. It should be noted that not all possible recommended security controls can be

implemented to reduce loss. To determine which ones are required and appropriate

for a specific organization, a cost-benefit analysis should be conducted for the proposed recommended controls, to demonstrate that the costs of implementing the controls can be justified by the reduction in the level of risk. In addition to cost, organizations should consider the operational impact and feasibility of introducing the recommended security controls into the operating environment. 9.

Document the Risk Assessment Results.

Once the risk assessment has been completed (threat sources and vulnerabilities identified, risks assessed, and security controls recommended), the results of each step in the risk assessment should be documented. NIST SP 800-30 provides a sample risk assessment report outline that may prove useful to covered entities. Risk Assessment Results Affect Risk Management

The results of a risk assessment play a significant role in executing an organization's risk management strategy. In the context of the HIPAA Security Rule, the security control baseline, which consists of the standards and required implementation specifications, should be viewed as the foundation or starting point in the selection of adequate security controls necessary to protect EPHI. In many cases, additional security controls or control enhancements will be needed to protect EPHI or to satisfy the requirements of applicable laws, policies, standards, or regulations. The risk assessment provides important inputs to determine the sufficiency of the security control baseline. The risk assessment results, coupled with the security control baseline, should be used to identify which addressable implementation specifications should be implemented to adequately mitigate identified risks. Risk Assessment Resources

The following resources may provide useful information to assist covered entities in performing risk assessment, analysis, and management activities, and demonstrate compliance with the Security Management Process standard and related implementation specifications:

•

HIPAA Security Series, Basics of Risk Analysis and Risk Management, 6/2005: rev. 3/2007;

http://www.cms.hhs.gov/EducationMaterials/Downloads/BasicsofRiskAnalysisandRiskManagement.pdf E-6

E-7

NIST SP 800-30, Risk Management Guide for Information Technology Systems; http://csrc.nist.gov/publications/nistpubs/800-30/sp800-30.pdf

Department of Homeland Security (DHS) National Infrastructure Protection Plan; http://www.dhs.gov/xprevprot/programs/editorial_0827.shtm

•

NIST National Vulnerability Database (NVD); http://nvd.nist.gov/

US-CERT; http://www.us-cert.gov/index.html

•

Carnegie Mellon CERT Coordination Center; http://www.cert.org/insider_threat/ Appendix F: Contingency Planning Guidelines

Information technology (IT) and automated information systems are vital elements in most business processes. Because these IT resources are so essential to an organization's success, it is critical that the services provided by these systems are able to operate effectively without excessive interruption. Contingency planning supports this requirement by establishing thorough plans and procedures and technical measures that can enable a system to be recovered quickly and effectively following a service disruption or disaster. Interim measures may include the relocation of IT systems and operations to an alternate site, the recovery of IT functions using alternate equipment, or the performance of IT functions using manual methods.

IT systems are vulnerable to a variety of disruptions, ranging from mild (e.g., shortterm power outage, disk drive failure) to severe (e.g., equipment destruction, fire). Vulnerabilities may be minimized or eliminated through technical, management, or operational solutions as part of the organization's risk management effort. However, it is virtually impossible to completely eliminate all risks. Contingency planning is designed to mitigate the risk of system and service unavailability by focusing efficient and effective recovery solutions.

Within the context of HIPAA, the goal of contingency planning is to adequately protect EPHI during a contingency event, and to ensure that organizations have their EPHI available when it is needed.

This appendix, Contingency Planning Guidelines, will identify fundamental planning principles and practices to help personnel develop and maintain effective information system contingency plans. This section will be based on NIST Special Publication 800-34, Contingency Planning Guide for Information Technology Systems.

Contingency Planning Defined

IT contingency planning refers to a coordinated strategy involving plans, procedures, and technical measures that enable the recovery of IT systems, operations, and data after a disruption. Contingency planning generally includes one or more of the approaches to restore disrupted IT services:

Restoring IT operations at an alternate location;

•

Recovering IT operations using alternate equipment; and

F-1

•

Performing some or all of the affected business processes using non-IT (manual) means (typically acceptable for only short-term disruptions).

Types of Contingency-Related Plans

IT contingency planning represents a broad scope of activities designed to sustain and recover critical IT services following an emergency. IT contingency planning fits into a much broader emergency preparedness environment that includes organizational and business process continuity and recovery planning. Ultimately, an organization would use a suite of plans to properly prepare response, recovery, and continuity activities for disruptions affecting the organization's IT systems, business processes, and the facility. Because there is an inherent relationship between an IT system and the business process it supports, there should be coordination between each plan during development and updates to ensure that recovery strategies and supporting resources neither negate each other nor duplicate efforts. Table & Types of Contingency Plans

Table 8. Types of Contingency Plans Type of Plan Description Scope Contingency Plan (CP) Management policy and procedures designed to maintain or restore business operations, including computer operations, possibly at an alternate location, in the event of emergencies, system failures, or disaster.

Addresses IT system disruptions; not typically business process-focused Continuity of Operations Plan (COOP)

A predetermined set of instructions or procedures that describe how an organization's essential functions will be sustained for up to 30 days as a result of a disaster event before returning to normal operations.

Addresses the subset of an organization's missions that are deemed most critical; not typically IT-focused

Disaster Recovery Plan (DRP)

A written plan for processing critical applications in the event of a major hardware or software failure or destruction of facilities.

Limited to major disruptions with long-term effects; typically IT-focused HIPAA Contingency Planning Requirements

Standard 164.308(a)(7), Contingency Plan, requires covered entities to:

Establish (and implement as needed) policies and procedures for responding to an emergency or other occurrence (for example, fire, vandalism, system failure, and natural disaster) that damages systems that contain electronic protected health information

The Contingency Plan standard includes five implementation specifications. F-2

1.

Data Backup Plan (R) - 164.308(a)(7)(ii)(A): Establish and implement procedures to create and maintain retrievable exact copies of electronic protected health information.

2.

Disaster Recovery Plan (R) - 164.308(a)(7)(ii)(B): Establish (and implement as needed) procedures to restore any loss of data.

3.

Emergency Mode Operation Plan (R) - 164.308(a)(7)(ii)(C): Establish (and implement as needed) procedures to enable continuation of critical business processes for protection of the security of electronic protected health information while operating in emergency mode.

4.

Testing and Revision Procedures (A) - 164.308(a)(7)(ii)(D): Implement procedures for periodic testing and revision of contingency plans.

5.

Applications and Data Criticality Analysis (A) - 164.308(a)(7)(ii)(E): Assess the relative criticality of specific applications and data in support of other contingency plan components.

IT Contingency Planning Process

To develop and maintain an effective IT contingency plan, organizations should consider using the approach discussed in NIST SP 800-34, Contingency Planning Guide for Information Technology Systems, which proposes a step-by-step contingency planning process, and provides an in-depth discussion of technical contingency planning considerations for specific types of information technology systems. A summary of this process is detailed below. 1.

Develop the Contingency Planning Policy Statement. To be effective and to ensure that personnel fully understand the agency's contingency planning requirements, the contingency plan must be based on a clearly defined policy supported by organizational leadership. The contingency planning policy statement should define the organization's overall contingency objectives and establish the organizational framework and responsibilities for IT contingency planning. Key policy elements include:

•

Roles and responsibilities

•

Scope as applies to the type(s) of platform(s) and organization functions subject to contingency planning

•

Resource requirements

•

Training requirements

•

Exercise and testing, and plan maintenance schedules

•

Frequency of backups and storage of backup media.

2.

Conduct the Business Impact Analysis (BIA). The BIA is a key step in the contingency planning process. The BIA enables the organization to fully characterize information system requirements, processes, and interdependencies and use this information to determine contingency requirements and priorities. F-3

The purpose of the BIA is to correlate specific system components with the critical services that they provide and, based on that information, to characterize the consequences of a disruption to the system components. Key steps include identifying critical IT resources, disruption impacts and allowable outage times, and developing recovery priorities. Results from the BIA should be appropriately incorporated into the analysis and strategy development efforts for the organization's other continuity and recovery plans, including disaster recovery and emergency mode operations plans.

3.

Identify Preventive Controls. In some cases, the outage impacts identified in the BIA may be mitigated or eliminated through preventive measures that deter, detect, and/or reduce impacts to the system. Where feasible and cost-effective, preventive methods are preferable to actions that may be necessary to recover the system after a disruption. Preventive controls should be documented in the contingency plan, and personnel associated with the system should be trained on how and when to use the controls.

A variety of preventive controls are available, depending on system type and configuration; however, some common measures are listed below:

Appropriately sized uninterruptible power supplies (UPS) to provide short-term backup power to all system components (including environmental and safety controls)

•

Gasoline- or diesel-powered generators to provide long-term backup power •

Air-conditioning systems with adequate excess capacity to permit failure of certain components, such as a compressor

Fire suppression systems

Fire and smoke detectors

Water sensors in the computer room ceiling and floor

Plastic tarps that may be unrolled over IT equipment to protect it from water damage

Heat-resistant and waterproof containers for backup media and vital nonelectronic records

Emergency master system shutdown switch

Offsite storage of backup media, nonelectronic records, and system documentation

Technical security controls, such as cryptographic key management and leastprivilege access controls

Frequent scheduled backups.

F-4 4.

Develop Recovery Strategies. Recovery strategies provide a means to restore IT operations quickly and effectively following a service disruption. Strategies should address disruption impacts and allowable outage times identified in the BIA. Several alternatives should be considered when developing the strategy, including cost, allowable outage time, security, and integration with larger organization-level contingency plans.

The selected recovery strategy should address the potential impacts identified in the BIA and should be integrated into the system architecture during the design and implementation phases of the system life cycle.

The strategy should include a combination of methods that complement one another to provide recovery capability over the full spectrum of incidents, ranging from minor service disruption to a partial or total loss of primary system operations requiring operational resumption at another location. A wide variety of recovery approaches may be considered; the appropriate choice depends on the incident, type of system, and its operational requirements, including retention requirements. Specific recovery methods may include commercial contracts with cold, warm, or hot site vendors, mobile sites, mirrored sites, reciprocal agreements with internal or external organizations, and service-level agreements (SLAs) with the equipment vendors. In addition, high-availability technologies such as Redundant Arrays of Independent Disks (RAID), automatic fail-over, uninterruptible power supply (UPS), mirrored systems, and multisite data archiving systems should be considered when developing a system recovery strategy.

5.

Develop an IT Contingency Plan. IT contingency plan development is a critical step in the process of implementing a comprehensive contingency planning program. The plan contains detailed roles, responsibilities, teams, and procedures associated with restoring an IT system following a disruption. The contingency plan should document technical capabilities designed to support contingency operations. Plans

need to balance detail with flexibility; usually the more detailed the plan, the less scalable and versatile the approach.

Following the approach described in NIST SP 800-34, the contingency plan comprises five main components: Supporting Information, Notification and Activation, Recovery, Reconstitution, and Plan Appendices. The first and last components provide essential information to ensure a comprehensive plan. The Notification and Activation, Recovery, and Reconstitution phases address specific actions that the organization should take following a system disruption or emergency.

The Supporting Information component includes an introduction and concept of operations section that provides essential background or contextual information that makes the contingency plan easier to understand, implement, and maintain. These details aid in understanding the applicability of the guidance, in making decisions on how to use the plan, and in providing information on where associated plans and information outside the scope of the plan may be found. F-5

•

The Notification and Activation Phase defines the initial actions taken once a system disruption or emergency has been detected or appears to be imminent. This phase includes activities to notify recovery personnel, assess system damage, and implement the plan. At the completion of the Notification and Activation Phase, recovery staff will be prepared to perform contingency measures to restore system functions on a temporary basis.

•

The Recovery Phase begins after the contingency plan has been activated, damage assessment has been completed (if possible), personnel have been notified, and appropriate teams have been mobilized. Recovery phase activities focus on contingency measures to execute temporary IT processing capabilities, repair damage to the original system, and restore operational capabilities at the original or new facility. At the completion of the Recovery Phase, the IT system will be operational and performing the functions designated in the plan. Depending on the recovery strategies defined in the plan, these functions could include temporary manual processing, recovery and operation at an alternate system, or relocation and recovery at an alternate site. Teams with recovery responsibilities should understand and be able to perform these recovery strategies well enough that if the paper plan is unavailable during the initial stages of the event, they can still perform the necessary activities.

• In the Reconstitution Phase, recovery activities are terminated, and normal operations are transferred back to the organization's facility. If the original facility is unrecoverable, the activities in this phase can also be applied to preparing a new facility to support system processing requirements. Until the primary system is restored and tested, the contingency system should continue to be operated. The Reconstitution Phase should specify teams responsible for restoring or replacing both the site and the information system.

Contingency Plan Appendices should provide key details not contained in the main body of the plan. The appendices should reflect the specific technical, operational, and management contingency requirements of the information system and the larger organization. Appendices can include, but are not limited to, contact information for contingency planning team personnel; vendor contact information, including offsite storage and alternate site points of contact; standard operating procedures and checklists for system recovery or processes; equipment and system requirements lists of the hardware, software, firmware, and other resources required to support system operations; vendor agreements, reciprocal agreements with other organizations, and other vital records; description of, and directions to, the alternate site; and the BIA.

Plans should be formatted to provide quick and clear direction in the event those personnel unfamiliar with the plan or the systems are called on to perform recovery operations. Plans should be clear, concise, and easy to implement in an emergency. Where possible, checklists and step-by-step procedures should be F-6

used. A concise and well-formatted plan reduces the likelihood of creating an overly complex or confusing plan.

6.

Plan Testing, Training, and Exercises. Plan testing is a critical element of a viable contingency capability. Testing enables plan deficiencies to be identified and addressed. Testing also helps evaluate the ability of the recovery staff to implement the plan quickly and effectively. Each IT contingency plan element should be tested to confirm the accuracy of individual recovery procedures and the overall effectiveness of the plan. The following areas should be addressed in a contingency test:

•

System recovery on an alternate platform from backup media

Coordination among recovery teams

•

Internal and external connectivity

•

System performance using alternate equipment

•

Restoration of normal operations

•

Notification procedures.

Training for personnel with contingency plan responsibilities should complement testing. Training should be provided at least annually; new hires with plan responsibilities should receive training shortly after they are hired. Ultimately, contingency plan personnel should be trained to the extent that that they are able to execute their respective recovery procedures without aid of the actual document. This is an important goal in the event that paper or electronic versions of the plan are unavailable for the first few hours resulting from the extent of the disaster. Recovery personnel should be trained on the following plan elements:

Purpose of the plan

Cross-team coordination and communication

•

Reporting procedures

Security requirements

•
Team-specific processes (Notification/Activation, Recovery, and Reconstitution Phases)

Individual responsibilities (Notification/ Activation, Recovery, and Reconstitution Phases).

7.

Maintain the plan. To be effective, the plan must be maintained in a ready state that accurately reflects system requirements, procedures, organizational structure, and policies. IT systems undergo frequent changes because of shifting business needs, technology upgrades, or new internal or external policies. Therefore, it is essential that the contingency plan be reviewed and updated regularly, as part of the organization's change management process, to ensure that new information is documented and contingency measures are revised if required. As a general rule, F-7

F-8

Contingency Planning Resources

The following resources may provide useful information to assist covered entities in developing contingency planning strategies to adequately protect and recover access to EPHI during a contingency event, and demonstrate compliance with the Contingency Plan standard and implementation specifications:

NIST Special Publication 800-34, Contingency Planning Guide for Information Technology Systems, http://csrc.nist.gov/publications/nistpubs/800-34/sp800-34.pdf •

HIPAA Security Series, Security Standards: Administrative Safeguards; http://www.cms.hhs.gov/EducationMaterials/Downloads/SecurityStandardsAdminis trativeSafeguards.pdf

STANDARD

Appendix G: Sample Contingency Plan Template

This sample format provides a template for preparing an information technology (IT) contingency plan. The template is intended to be used as a guide and should be modified as necessary to meet the system's contingency requirements and comply with internal policies. Where practical, the guide provides instructions for completing specific sections. Text is added in certain sections; however, this information is intended only to suggest the type of information that may be found in that section. The text is not comprehensive and should be modified to meet specific organization and system considerations.

1. INTRODUCTION

1.1 PURPOSE

This {system name} Contingency Plan establishes procedures to recover the {system name} system following a disruption. The following objectives have been established for this plan:

•

Maximize the effectiveness of contingency operations through an established plan that consists of the following phases:

- Notification/Activation phase to detect and assess damage and to activate the plan;

- Recovery phase to restore temporary IT operations and recover damage done to the original system; and

- Reconstitution phase to restore IT system processing capabilities to normal operations.

•

Identify the activities, resources, and procedures needed to carry out {system name} processing requirements during prolonged interruptions to normal operations.

Assign responsibilities to designated {Organization name} personnel and provide guidance for recovering {system name} during prolonged periods of interruption to normal operations.

Ensure coordination with other {Organization name} staff who will participate in the contingency planning strategies. Ensure coordination with external points of contact and vendors who will participate in the contingency planning strategies. 1.2 APPLICABILITY

The {system name} Contingency Plan applies to the functions, operations, and resources necessary to restore and resume {Organization name}'s {system name} operations as it is installed at its primary location: {Name, City, State}. The {system name} Contingency Plan applies to {Organization name} and all other persons associated with {system name} as identified under Section 2.3, Responsibilities. G-1

1.3 SCOPE

1.3.1 Planning Principles

Various scenarios were considered to form a basis for the plan, and multiple assumptions were made. The applicability of the plan is predicated on two key principles:

•

The {Organization name}'s facility in {City, State}, is inaccessible; therefore, {Organization name} is unable to perform {system name} processing for the organization.

•

A valid contract exists with the alternate site that designates that site in {City, State}, as {Organization name}'s alternate operating facility.

- {Organization name} will use the alternate site building and IT resources to recover {system name} functionality during an emergency situation that prevents access to the original facility.

- The designated computer system at the alternate site has been configured to begin processing {system name} information.

- The alternate site will be used to continue {system name} recovery and processing throughout the period of disruption, until the return to normal operations. 1.3.2 Assumptions

Based on these principles, the following assumptions were used when developing the IT Contingency Plan:

•

The {system name} is inoperable at the {Organization name} computer center and cannot be recovered within {XX} hours.

Key {system name} personnel have been identified and trained in their emergency response and recovery roles; they are available to activate the {system name} Contingency Plan.

•

Preventive controls (e.g., generators, environmental controls, waterproof tarps, sprinkler systems, fire extinguishers, and fire department assistance) are fully operational at the time of the contingency event.

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Computer center equipment, including components supporting {system name}, are connected to an uninterruptible power supply (UPS) that provides {XX} minutes/hours of electricity during a power failure.

{System name} hardware and software at the {Organization name} original site are unavailable for at least {XX} hours.

Current backups of the application software and data are intact and available at the offsite storage facility.

The equipment, connections, and capabilities required to operate {system name} are available at the alternate site in {City, State}.

G-2

Service agreements are maintained with {system name} hardware, software, and communications providers to support the system recovery.

The {system name} Contingency Plan does not apply to the following situations: •

Overall recovery and continuity of business operations. The Business Resumption Plan (BRP) and Continuity of Operations Plan (COOP) are appended to the plan.

Emergency evacuation of personnel. The Occupant Evacuation Plan (OEP) is appended to the plan.

•

Any additional constraints should be added to this list.

1.4 REFERENCES/REQUIREMENTS

This {system name} Contingency Plan complies with the {Organization name}'s IT contingency planning policy as follows:

{Insert organization's contingency planning policy statement}

The {system name} Contingency Plan also complies with the following policies: •

Federal Information Security Management Act (FISMA) of 2002

•

Health Insurance Portability and Accountability Act (HIPAA), 1996

•

OMB Circular A-130, Management of Federal Information Resources, Appendix III, November 2000

•

Federal Preparedness Circular (FPC) 65, Federal Executive Branch Continuity of Operations, July 1999

•

PDD 63, Critical Infrastructure Protection, May 1998

•

Federal Emergency Management Agency (FEMA), The Federal Response Plan (FRP), April 1999

• {Insert other applicable policies} 1.5 RECORD OF CHANGES Modifications made to this plan are as follows: Record of Changes Page No. Change Comment Date of Change Signature 2. CONCEPT OF OPERATIONS

2.1 SYSTEM DESCRIPTION AND ARCHITECTURE G-3

Provide a general description of system architecture and functionality. Indicate the operating environment, physical location, general location of users, and partnerships with external organizations/systems. Include information regarding any other technical considerations that are important for recovery purposes, such as backup procedures. Provide a diagram of the architecture, including security controls and telecommunications connections.

2.2 LINE OF SUCCESSION

The {organization name} sets forth an order of succession to ensure that decisionmaking authority for the {system name} Contingency Plan is uninterrupted. The Chief Information Officer (CIO), {organization name} is responsible for ensuring the safety of personnel and the execution of procedures documented within this {system name} Contingency Plan. If the CIO is unable to function as the overall authority or chooses to delegate this responsibility to a successor, the Deputy CIO shall function as that authority. Identify and describe line of succession as applicable.

2.3 RESPONSIBILITIES

The following teams have been developed and trained to respond to a contingency event affecting the IT system.

The Contingency Plan establishes several teams assigned to participate in recovering {system name} operations. Examples of teams that may be included are management team, application recovery team, operating system team, network operations team, site restoration/salvage team, procurement team, damage assessment team, and communications team. The system environment and the scope of the recovery effort will dictate which teams will be necessary to execute the plan.

{Team name}

0

{Describe each team, their responsibilities, leadership, and coordination with other applicable teams during a recovery operation. Do not detail specific procedures that will be used to execute these responsibilities. These procedures will be itemized in the appropriate phase sections.}

The relationships of the teams involved in system recovery are illustrated in Figure {XX} below.

{Insert hierarchical diagram of recovery teams. Show team names and leaders; do not include actual names of personnel.}

3. NOTIFICATION AND ACTIVATION PHASE

This phase addresses the initial actions taken to detect and assess damage inflicted by a disruption to {system name}. Based on the assessment of the event, the plan may be activated by the Contingency Planning Coordinator.

In an emergency, the {Organization name}'s top priority is to preserve the health and safety of its staff before proceeding to the Notification and Activation procedures. G-4

Notification

Contact information for key personnel is located in Appendix A. The notification sequence is listed below:

The first responder is to notify the Contingency Planning Coordinator. All known information must be relayed to the Contingency Planning Coordinator.

{Insert further notification sequences specific to the organization and the system.} Upon notification, the following procedures are to be performed by their respective teams:

Damage Assessment Procedures:

{Detailed procedures should be outlined to include activities to determine the cause of the disruption; potential for additional disruption or damage; affected physical area and status of physical infrastructure; status of IT equipment functionality and inventory, including items that will need to be replaced; and estimated time to repair services to normal operations.}

•

{team name}

- Team Damage Assessment Procedures

•

{Insert additional team names and procedures as necessary} Activation

The Contingency Plan is to be activated if one or more of the following criteria are met:

1. {System name} will be unavailable for more than {XX} hours.

2. Facility is damaged and will be unavailable for more than {XX} hours.

3. Other criteria, as appropriate:

•

If the plan is to be activated, the Contingency Planning Coordinator is to notify all Team Leaders and inform them of the details of the event and if relocation is required.

•

Upon notification from the Contingency Planning Coordinator, Team Leaders are to notify their respective teams. Team members are to be informed of all applicable information and prepared to respond and relocate if necessary.

•

The Contingency Planning Coordinator is to notify the offsite storage facility that a contingency event has been declared and to ship the necessary materials (as determined by damage assessment) to the alternate site.

The Contingency Planning Coordinator is to notify the alternate site that a contingency event has been declared and to prepare the facility for the organization's arrival.

•

The Contingency Planning Coordinator is to notify remaining personnel (via notification procedures) on the general status of the incident. G-5

4. RECOVERY OPERATIONS

This section provides procedures for recovering the application at the alternate site, whereas other efforts are directed to repair damage to the original system and capabilities.

The following procedures are for recovering the {system name} at the alternate site. Procedures are outlined per team required. Each procedure should be executed in the sequence it is presented to maintain efficient operations. Recovery Goal. State the first recovery objective as determined by the Business Impact Assessment (BIA). For each team responsible for executing a function to meet this objective, state the team names and list their respective procedures.

{team name}

- Team Recovery Procedures

•

{Insert additional team names and procedures as necessary}

Recovery Goal. State the remaining recovery objectives as determined by the BIA. For each team responsible for executing a function to meet this objective, state the team names and list their respective procedures.

{team name}

- Team Recovery Procedures

•

{Insert additional team names and procedures as necessary}

5. RETURN TO NORMAL OPERATIONS

This section discusses activities necessary for restoring {system name} operations at the {Organization name}'s original or a new site. When the computer center at the original or the new site has been restored, {system name} operations at the alternate site must be transitioned back. The goal is to provide a seamless transition of operations from the alternate site to the computer center.

Original or New Site Restoration

Procedures should be outlined, per necessary team, to restore or replace the original site so that normal operations may be transferred. IT equipment and telecommunications connections should be tested.

•

{team name}

- Team Resumption Procedures

•

{Insert additional team names and procedures as necessary}

5.1 CONCURRENT PROCESSING

Procedures should be outlined, per necessary team, to operate the system in coordination with the system at the original or the new site. These procedures should include testing the original or new system until it is functioning properly and ensuring that the contingency system is shut down gracefully.

• {team name}

G-6

G-7

- Team Concurrent Processing Procedures

•

{Insert additional team names and procedures as necessary}

5.2 PLAN DEACTIVATION

Procedures should be outlined, per necessary team, to clean the alternate site of any equipment or other materials belonging to the organization, with a focus on handling sensitive information. Materials, equipment, and backup media should be properly packaged, labeled, and shipped to the appropriate location(s). Team members should be instructed to return to the original or the new site.

{team name}

- Team Deactivation Procedures

{Insert additional team names and procedures as necessary}

6. PLAN APPENDICES

The appendices included should be based on system and plan requirements.

Personnel Contact List

-Vendor Contact List

•

Equipment and Specifications

•

Service-Level Agreements and Memorandums of Understanding

IT Standard Operating Procedures

Business Impact Analysis

Related Contingency Plans

•

Emergency Management Plan

•

Occupant Evacuation Plan

•

Continuity of Operations Plan.

Appendix H: Resources for Secure Remote Use and Access

The HIPAA Security Rule requires all covered entities to protect the EPHI that they use or disclose to business associates, trading partners, or other entities. New technologies, such as remote access and removable media technologies, have significantly simplified the way in which data is transmitted throughout the healthcare industry and created tremendous opportunities for improvements and greater efficiency in the healthcare space. However, these technologies have also increased the risk of loss and unauthorized use and disclosure of this sensitive information. Sensitive information that is accessed by, stored on, or transmitted to or from a remote device needs to be protected so that malicious parties cannot access or alter it. An unauthorized release of sensitive information could damage the trust in an organization, jeopardize its mission, or harm individuals if their personal information has been released.

In December 2006, CMS issued a HIPAA security guidance document, Remote Use of and Access to Electronic Protected Health Information, to reinforce some of the ways a covered entity may protect EPHI when it is accessed or used outside of the organization's physical purview. It sets forth some strategies that may be reasonable and appropriate under the HIPAA Security Rule, for covered entities to follow (based upon their individual technological capabilities and operational needs), for offsite use of, or access to, EPHI. This guidance also places significant emphasis on the importance of risk analysis and risk management strategies, policies and procedures, and security awareness and training on the policies and procedures for safeguarding EPHI during its remote access, storage, and transmission. NIST publications on remote access, storage, and transmission security technologies can be valuable resources to support secure remote use solutions. These publications seek to assist organizations in understanding particular technologies and to provide security considerations and practical, real-world recommendations for implementing and securing these technologies within an organization. Special Publication 800-114, User's Guide to Securing External Devices for Telework and Remote Access, was developed to help teleworkers secure the external devices they use for telework, such as personally owned and third-party privately owned desktop and laptop computers and consumer devices (e.g., cell phones, personal digital assistants). The document focuses specifically on security for telework involving remote access to organizations' nonpublic computing resources by providing:

Recommendations for securing telework computers' operating systems and applications, as well as home networks that the computers use;

Basic recommendations for securing consumer devices used for telework; •

Advice on protecting the information stored on telework computers and removable media; and

•

Tips on considering the security of a device owned by a third party before deciding whether it should be used for telework.

H-1

Special Publication 800-113, Guide to SSL VPNs, assists organizations in understanding SSL VPN technologies and in designing, implementing, configuring, securing, monitoring, and maintaining SSL VPN solutions. This publication intends to help organizations determine how best to deploy SSL VPNs within their specific network environments by:

Describing SSL and how it fits within the context of layered network security; •

Presenting a phased approach to SSL VPN planning and implementation that can help in achieving successful SSL VPN deployments; and

•

Comparing SSL VPN technology with IPsec VPNs and other VPN solutions. Special Publication 800-77, Guide to IPsec VPNs, assists organizations in mitigating the risks associated with the transmission of sensitive information across networks by providing practical guidelines on implementing security services based on Internet Protocol Security (IPsec). This publication intends to help organizations determine how best to deploy IPsec VPNs within their specific network environments by:

•

Discussing the need for, and types of, network layer security services and how IPsec addresses these services;

•

Providing a phased approach to IPsec planning and implementation that can help in achieving successful IPsec deployments;

•

Providing specific recommendations relating to configuring cryptography for IPsec; •

Using a case-based approach to show how IPsec can be used to solve common network security issues; and

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Discussing alternatives to IPsec and under what circumstances each may be appropriate.

Special Publication 800-52, Guidelines for the Selection and Use of Transport Layer Security (TLS), provides guidelines on the selection and implementation of the TLS protocol while making effective use of Federal Information Processing Standards (FIPS)-approved cryptographic algorithms. TLS provides a mechanism to protect sensitive data during electronic dissemination across the Internet. This guideline:

Describes the placement of security in each layer of the communications protocol stack, as defined by the OSI Seven Layer Model;

Provides criteria for developing specific recommendations when selecting, installing and using transport layer security; and

٠

Discusses client implementation, server, and operational considerations. Special Publication 800-111, Guide to Storage Encryption Technologies for End User Devices, assists organizations in understanding storage encryption technologies for end user devices and in planning, implementing, and maintaining storage encryption solutions. The types of end user devices addressed in this document are personal computers (desktops and laptops), consumer devices (e.g., personal digital assistants,

H-2

H-3

smart phones), and removable storage media (e.g., USB flash drives, memory cards, external hard drives, writeable CDs and DVDs). This publication:

Provides an overview of the basic concepts of storage encryption for end user devices;

•

Provides guidelines on commonly used categories of storage encryption techniques (i.e., full disk, volume and virtual disk, and file/folder), and explains the types of protection they provide;

•

Discusses important security elements of a storage encryption deployment, including cryptographic key management and authentication; and

Examines several use cases which illustrate multiple ways to meet most storage encryption needs.

Draft Special Publication 800-124, Guidelines on Cell Phone and PDA Security, provides an overview of cell phone and personal digital assistant (PDA) devices in use today and offers insights for making informed information technology security decisions regarding their treatment. This publication:

Presents an overview of handheld devices and discusses associated security threats and technology risks;

•

Examines the security concerns associated with handheld devices; and

Discusses user- and organization-oriented measures and safeguards available for mitigating the risks and threats.

All NIST publications are accessible on the public Computer Security Resource Center (CSRC) Web site at http://csrc.nist.gov.

Appendix I: Telework Security Considerations

Many people telework, which is the ability for an organization's employees and contractors to conduct work from locations other than the organization's facilities. Teleworkers use various devices, such as desktop and laptop computers, cell phones, and personal digital assistants (PDAs), to read and send email, access Web sites, review and edit documents, and perform many other tasks. Most teleworkers use remote access, which is the ability of an organization's users to access its nonpublic computing resources from locations other than the organization's facilities. Organizations have many options for providing remote access, including virtual private networks, remote system control, and individual application access (e.g., Web-based email).

This appendix provides considerations and tips for securing external devices used for telework and remote access. More detailed information on this topic is available in NIST SP 800-114, User's Guide to Securing External Devices for Telework and Remote Access.

Before teleworking, users should understand their organization's policies and requirements, as well as appropriate ways of protecting the organization's information that they may access.

Teleworkers should consult their organization's policies and requirements to provide adequate security to protect the organization's information. Sensitive information that is stored on, or sent to or from, external telework devices needs to be protected so that malicious parties can neither access nor alter it. An unauthorized release of sensitive information could damage the public's trust in an organization, jeopardize the mission of an organization, or harm individuals if their personal information has been released.

Teleworkers should ensure that all the devices on their wired and wireless home networks are properly secured, as well as the home networks themselves. An important part of telework and remote access security is applying security measures to the personal computers (PCs) and consumer devices using the same wired and wireless home networks to which the telework device normally connects. If any of these other devices become infected with malware or are otherwise compromised, they could attack the telework device or eavesdrop on its communications. Teleworkers should also be cautious about allowing others to place devices on the teleworkers' home networks, in case one of these devices is compromised.

Teleworkers should apply security measures to the home networks to which their telework devices normally connect. One example of a security measure is using a broadband router or firewall appliance to prevent computers outside the home network from initiating communications with telework devices on the home network. Another example is ensuring that sensitive information transmitted over a wireless home network is adequately protected through strong encryption. Teleworkers should consider the security state of a third-party device before using it for telework.

I-1

Teleworkers often want to perform remote access from third-party devices, such as checking email from a kiosk computer at a conference. However, teleworkers typically do not know if such devices have been secured properly or if they have been compromised. Consequently, a teleworker could use a third-party device infected with malware that steals information from users (e.g., passwords or email messages). Many organizations either forbid third-party devices to be used for remote access or permit only limited use, such as for Web-based email. Teleworkers should consider who is responsible for securing a third-party device and who can access the device before deciding whether or not to use it. Whenever possible, teleworkers should not use publicly accessible third-party devices for telework, and teleworkers should avoid using any third-party devices for performing sensitive functions or accessing sensitive information.

Secure a Telework PC

Teleworkers who use their own desktop or laptop PCs for telework should secure their operating systems and primary applications.

Use a combination of security software, such as antivirus and antispyware software, personal firewalls, spam and Web content filtering, and popup blocking, to stop most attacks, particularly malware;

Restrict who can use the PC by having a separate standard user account for each person, assigning a password to each user account, using the standard user accounts for daily use, and protecting user sessions from unauthorized physical access;

Ensure that updates and patches are regularly applied to the operating system and primary applications, such as Web browsers, email clients, instant messaging clients, and security software;

•

Disable unneeded networking features on the PC and configure wireless networking securely;

Configure primary applications to filter content and stop other activity that is likely to be malicious;

•

Install and use only known and trusted software;

•

Configure remote access software based on the organization's requirements and recommendations; and

•

Maintain the PC's security on an ongoing basis, such as changing passwords regularly and checking the status of security software periodically. Secure consumer devices used for telework, such as cell phones, PDAs, and video game systems

A wide variety of consumer devices exists, and security features available for these devices also vary widely. Some devices offer only a few basic features, whereas others offer sophisticated features similar to those offered by PCs. This does not necessarily imply that more security features are better; in fact, many devices offer more security features because the capabilities they provide (e.g., wireless networking, instant

I-2

messaging) make them more susceptible to attack than devices without these capabilities. General recommendations for securing telework devices are as follows: •

Limit access to the device, such as setting a personal identification number (PIN) or password and automatically locking a device after an idle period;

Disable networking capabilities, such as Bluetooth, except when they are needed;

Use additional security software, such as antivirus software and personal firewalls, if appropriate;

Ensure that security updates, if available, are acquired and installed at least monthly, or more frequently; and

Configure applications to support security (e.g., blocking activity that is likely to be malicious).

Secure Information

•

Use physical security controls for telework devices and removable media. For example, an organization might require that laptops be physically secured using cable locks when used in hotels, conferences, and other locations where third parties could easily gain physical access to the devices. Organizations may also have physical security requirements for papers and other non-computer media that contain sensitive information and are taken outside the organization's facilities.

Encrypt files stored on telework devices and removable media such as CDs and flash drives. This prevents attackers from readily gaining access to information in the files. Many options exist for protecting files, including encrypting individual files or folders, volumes, and hard drives. Generally, using an encryption method to protect files also requires the use of an authentication mechanism (e.g., password) to decrypt the files when needed.

Ensure that information stored on telework devices is backed up. If something adverse happens to a device, such as a hardware, software, or power failure or a natural disaster, the information on the device will be lost unless it has been backed up to another device or removable media. Some organizations permit teleworkers to back up their local files to a centralized system (e.g., through VPN remote access), whereas other organizations recommend that their teleworkers perform local backups (e.g., burning CDs, copying files onto removable media). Teleworkers should perform backups, following their organizations' guidelines, and verify that the backups are valid and complete. It is important that backups on removable media be secured at least as well as the device that they backed up. For example, if a computer is stored in a locked room, then the media also should be in a secured location; if a computer stores its data encrypted, then the backups of that data should also be encrypted.

•

Ensure that information is destroyed when it is no longer needed. For example, the organization's files should be removed from a computer scheduled to be retired or from a third-party computer that is temporarily used for remote access. Some remote access methods perform basic information cleanup, such as clearing I-3

I-4

Web browser caches that might inadvertently hold sensitive information, but more extensive cleanup typically requires using a special utility, such as a disk-scrubbing program specifically designed to remove all traces of information from a device. Another example of information destruction is shredding telework papers containing sensitive information once the papers are no longer needed. Erase information from missing cell phones and PDAs. If a cell phone or PDA is lost or stolen, occasionally its contents can be erased remotely. This prevents an attacker from obtaining any information from the device. The availability of this service depends on the capabilities of the product and the company providing network services for the product.

Adequately protect remote access-specific authenticators

Teleworkers need to ensure that they adequately protect their remote access-specific authenticators, such as passwords, personal identification numbers (PINs), and hardware tokens. Such authenticators should not be stored with the telework computer, nor should multiple authenticators be stored with each other (e.g., a password or PIN should not be written on the back of a hardware token). Social Engineering

•

Teleworkers should be aware of how to handle threats involving social engineering, which is a general term for attackers trying to trick people into revealing sensitive information or performing certain actions, such as downloading and executing files that appear to be benign but are actually malicious. For example, an attacker might approach a teleworker in a coffee shop and ask to use the computer for a minute or offer to help the teleworker with using the computer.

•

Teleworkers should be wary of any requests they receive that could lead to a security breach or to the theft of a telework device. Handling a Security Breach

•

If a teleworker suspects that a security breach (including loss or theft of materials) has occurred involving a telework device, remote access communications, removable media, or other telework components, the teleworker should immediately follow the organization's policy and procedures for reporting the possible breach. This is particularly important if any of the affected telework components contain sensitive information such as EPHI, so that the potential impact of a security breach is minimized.

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Security Rule

Reports on Information Systems Technology

The Information Technology Laboratory (ITL) at the National Institute of Standards and Technology (NIST) promotes the U.S. economy and public welfare by providing technical leadership for the nation's measurement and standards infrastructure. ITL develops tests, test methods, reference data, proof of concept implementations, and technical analyses to advance the development and productive use of information technology. ITL's responsibilities include the development of management, administrative, technical, and physical standards and guidelines for the cost-effective security and privacy of other than national security-related information in federal information systems. The Special Publication 800-series reports on ITL's research, guidelines, and outreach efforts in information system security, and its collaborative activities with industry, government, and academic organizations.

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Authority

This document has been developed by the National Institute of Standards and Technology (NIST) to further its statutory responsibilities under the Federal Information Security Management Act (FISMA) of 2002, P.L. 107-347. NIST is responsible for developing standards and guidelines, including minimum requirements, for providing adequate information security for all agency operations and assets, but such standards and guidelines shall not apply to national security systems. This guideline is consistent with the requirements of the Office of Management and Budget (OMB) Circular A-130, Section 8b(3), Securing Agency Information Systems, as analyzed in A-130, Appendix IV: Analysis of Key Sections. Supplemental information is provided in A-130, Appendix III.

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There are references in this publication to documents currently under development by NIST in accordance with responsibilities assigned to NIST under the Federal Information Security Management Act of 2002. The methodologies in this document may be used even before the completion of such companion documents. Thus, until such time as each document is completed, current requirements, guidelines, and procedures (where they exist) remain operative. For planning and transition purposes, agencies may wish to closely follow the development of these new documents by NIST. Individuals are also encouraged to review the public draft documents and offer their comments to NIST. All NIST documents mentioned in this publication, other than the ones noted above, are available at http://csrc.nist.gov/publications.

Certain commercial entities, equipment, or materials may be identified in this document in order to describe an experimental procedure or concept adequately. Such identification is not intended to imply recommendation or endorsement by the National Institute of Standards and Technology, nor is it intended to imply that the entities, materials, or equipment are necessarily the best available for the purpose. iii

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This publication is intended as general guidance only for federal organizations, and is not intended to be, nor should it be construed or relied upon as legal advice or guidance to non federal entities or persons. This document does not modify the Health Insurance Portability and Accountability Act of 1996 (HIPAA) or any other federal law or regulation. The participation of other federal organizations with the National Institute of Standards and Technology (NIST) and NIST workgroups in the development of this special publication does not, and shall not be deemed to, constitute the endorsement, recommendation, or approval by those organizations of its contents.

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Executive Summary
Some federal agencies, in addition to being subject to the Federal Information
Security Management Act of 2002 (FISMA), are also subject to similar
requirements of the Health Insurance Portability and Accountability Act of 1996
(HIPAA) Security Rule (the Security Rule), if the agency is a covered entity as
defined by the rules implementing HIPAA.
The HIPAA Security Rule specifically focuses on the safeguarding of electronic
protected health information (EPHI). Although FISMA applies to all federal
agencies and all information types, only a subset of agencies are subject to the
HIPAA Security Rule based on their functions and use of EPHI. All HIPAA covered
entities, which include some federal agencies, must comply with the Security Rule,
which specifically focuses on protecting the confidentiality, integrity, and
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availability of EPHI, as defined in the Security Rule. The EPHI that a covered entity creates, receives, maintains, or transmits must be protected against reasonably anticipated threats, hazards, and impermissible uses and/or disclosures. In general, the requirements, standards, and implementation specifications of the Security Rule apply to the following covered entities:

Covered Healthcare Providers—Any provider of medical or other health services, or supplies, who transmits any health information in electronic form in connection with a transaction for which the Department of Health and Human Services (DHHS) has adopted a standard.

Health Plans—Any individual or group plan that provides, or pays the cost of, medical care, including certain specifically listed governmental programs (e.g., a health insurance issuer and the Medicare and Medicaid programs).

Healthcare Clearinghouses—A public or private entity that processes another entity's healthcare transactions from a standard format to a nonstandard format, or vice versa.

Medicare Prescription Drug Card Sponsors –A nongovernmental entity that offered an endorsed discount drug program under the Medicare Modernization Act. This fourth category of "covered entity" remained in effect until the drug card program ended in 2006.

NIST publications, many of which are required for federal agencies, can serve as voluntary guidelines and best practices for state, local, and tribal governments and the private sector, and may provide enough depth and breadth to help organizations of many sizes select the type of implementation that best fits their unique circumstances. NIST security standards and guidelines (Federal Information Processing Standards [FIPS], Special Publications in the 800 series), which can be used to support the requirements of both HIPAA and FISMA, may be used by organizations to help provide a structured, yet flexible framework for selecting, specifying, employing, and evaluating the security controls in information systems. This Special Publication (SP), which discusses security considerations and resources that may provide value when implementing the requirements of the HIPAA Security Rule, was written to:

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Help to educate readers about information security terms used in the HIPAA Security Rule and to improve understanding of the meaning of the security standards set out in the Security Rule;

Direct readers to helpful information in other NIST publications on individual topics addressed by the HIPAA Security Rule; and

Aid readers in understanding the security concepts discussed in the HIPAA Security Rule. This publication does not supplement, replace, or supersede the HIPAA Security Rule itself. An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule

1.

Introduction

The National Institute of Standards and Technology (NIST) is responsible for developing standards and guidelines, including minimum requirements, used by federal agencies in providing adequate information security for the protection of agency operations and assets. Pursuant to this mission, NIST's Information Technology Laboratory (ITL) has developed guidelines to improve the efficiency and effectiveness of information technology (IT) planning, implementation, management, and operation.

NIST publishes a wide variety of publications on information security. These publications serve as a valuable resource for federal agencies, as well as public, nonfederal agencies and private organizations, seeking to address existing and new federal information security requirements. One such set of federal information security requirements are the security standards adopted by the Secretary of Health and Human Services (HHS) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA, Public Law 104-191). HIPAA required the Secretary to adopt, among other standards, security standards for certain health information. These standards, known as the HIPAA Security Rule (the Security Rule), were published on February 20, 2003. In the preamble to the Security Rule, several NIST publications were cited as potentially valuable resources for readers with specific questions and concerns about IT security.

Congress enacted the Administrative Simplification (part of Title II) provisions of HIPAA to, among other things, promote efficiency in the healthcare industry through the use of standardized electronic transactions, while protecting the privacy and security of health information. Pursuant to the Administrative Simplification provisions of HIPAA, the Secretary of HHS adopted standards relating to:

Electronic healthcare transactions and code sets;

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Privacy of protected health information;

Security of electronic protected health information (EPHI); and

Unique health identifiers.

This Special Publication summarizes the HIPAA security standards and explains some of the structure and organization of the Security Rule. The publication helps to educate readers about information security terms used in the HIPAA Security Rule and to improve understanding of the meaning of the security standards set out in the Security Rule. It is also designed to direct readers to helpful information in other NIST publications on individual topics addressed by the HIPAA Security Rule. Readers can draw upon these publications for consideration in implementing the Security Rule. This publication is intended as an aid to understanding security concepts discussed in the HIPAA Security Rule, and does not supplement, replace, or supersede the HIPAA Security Rule itself. While the Centers for Medicare and Medicaid Services (CMS) mentioned several NIST publications in the preamble to the HIPAA Security Rule, CMS does not require their use in complying with the Security Rule.1 1 The HIPAA Security Rule mentions NIST documents as potentially helpful guidance but not mandatory for compliance, at 68 Federal Register pages 8346, 8350, 8352, and 8355 (February 20, 2003).

1

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This document addresses only the security standards of the Security Rule and not other provisions adopted or raised by the Rule, such as 45 CFR § 164.105.

Figure 1 shows all the components of HIPAA and illustrates that the focus of this document is on the security provisions of the statute and the regulatory rule.

Figure 1. HIPAA Components

Readers should refer to the CMS Web site,

http://www.cms.hhs.gov/HIPAAGenInfo/, for more detailed information about the passage of HIPAA by Congress, specific provisions of HIPAA, determination of the entities covered under the law, the complete text of the HIPAA Security Rule, the deadline for compliance with the Rule, and enforcement information.

1.1.

Purpose and Scope

The purpose of this publication is to help educate readers about the security standards included in the HIPAA Security Rule. It provides a brief overview of the HIPAA Security Rule, directs the reader to additional NIST publications on information security, and identifies typical activities an agency should consider in implementing an information security program. 2

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This publication is intended as an aid to understand security concepts discussed in the HIPAA Security Rule and does not supplement, replace, modify, or supersede the Security Rule itself. Anyone seeking clarifications of the HIPAA Security Rule should contact the Office of E-Health Standards and Services (OESS) at CMS. For general HIPAA Security Rule information, visit the CMS HIPAA Web site at: http://www.cms.hhs.gov/SecurityStandard/.

The NIST publications available as of the publication date of SP 800-66 Revision 1 were used in preparing this document. NIST frequently publishes new standards and guidelines, or updates existing publications that may also serve as useful references. To remain current with the latest available list of NIST security publications, the reader should periodically review the NIST Computer Security Resource Center (CSRC) Web site at http://csrc.nist.gov.

1.2.

Applicability

The guidelines provided in this publication are applicable to all federal information systems,2 other than those systems designated as national security systems as defined in 44 United States Code (U.S.C.), Section 3542.3 The guidelines included in this publication have been broadly developed from a technical perspective so as to be complementary to similar guidelines issued by agencies and offices operating or exercising control over national security systems. State, local, and tribal governments, as well as private sector organizations composing the critical health infrastructure of the United States are encouraged to consider using these guidelines, as appropriate.

NIST publications may be useful to any agency seeking to understand the security issues raised by the HIPAA Security Rule regardless of that agency's size, structure, or distribution of security responsibilities. Specific agency missions, resources, and organizational structures, however, vary greatly, and agencies' approaches to implementing the HIPAA Security Rule may diverge significantly. Federal agencies use different titles to identify roles that have security-related responsibilities and may also assign particular responsibilities for implementing information security controls (those required by HIPAA and others) differently. NIST SP 800-66 assists all agencies seeking further information on the security safeguards discussed in the HIPAA Security Rule, regardless of the particular structures, methodologies, and approaches used to address its requirements.

2 A federal information system is an information system used or operated by an executive agency, by a contractor of an executive agency, or by another organization on behalf of an executive agency.

3 A national security system is any information system (including any telecommunications system) used or operated by an agency or by a contractor of an agency, or other organization on behalf of an agency—(i) the function, operation, or use of which: involves intelligence activities, involves cryptographic activities related to national security; involves command and control of military forces; involves equipment that is an integral part of a weapon or weapons system; or is critical to the direct fulfillment of military or intelligence missions (excluding a system that is to be used for routine administrative and business applications); or (ii) is protected at all times by procedures established for information that have been specifically authorized under criteria established by an Executive Order or an Act of Congress to be kept classified in the interest of national defense or foreign policy. Agencies should consult NIST Special Publication 800-59, Guide for Identifying an Information System as a National Security System, for guidance on determining the status of their information systems.

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The preamble of the Security Rule states that HHS does not rate or endorse the use of industry-developed guidelines and/or models. Organizations that are not required to use this NIST special publication (by other regulation, law, or requirement) yet choose to use it, must determine the value of its content for implementing the Security Rule standards in their environments. The use of this publication or any other NIST publication does not ensure or guarantee that an organization will be compliant with the Security Rule.

1.3.

Audience

This publication is intended to serve a diverse audience of individuals with HIPAA Security Rule implementation, management, and oversight responsibilities and organizations, federal and nonfederal, considered to be a "Covered Entity" under 45 C.F.R. Sec.160.103.

1.4.

Document Organization

The remaining sections and appendices of this publication include the following:

Section 2 - Background explains the key concepts included in the HIPAA Security Rule and provides an overview of NIST's role in information security, as well as descriptions of its various information security publications.

Section 3 – Risk Management Framework introduces a structured, flexible, extensible, and repeatable process for managing organizational risk and achieving risk-based protection related to the operation and use of information systems, and the protection of EPHI.

Section 4 –Considerations When Applying the HIPAA Security Rule highlights key activities a covered entity may wish to consider when implementing the Security Rule.

Appendix A – Glossary defines terms used in this document.

Appendix B – Acronyms identifies and defines acronyms used within this document.

Appendix C – References provides references and related source material.

Appendix D – Security Rule Standards and Implementation Specifications

Crosswalk provides a catalog of the HIPAA Security Rule standards and implementation specifications, and crosswalks each to relevant NIST publications and security controls detailed in NIST SP 800-53, Recommended Security Controls for Federal Information Systems.

Appendix E – Risk Assessment Guidelines provides a methodology for conducting a risk assessment, the results of which will enable covered entities to identify appropriate security controls for reducing risk to the organization and its data and information systems.

Appendix F – Contingency Planning Guidelines identifies fundamental planning principles and practices to help covered entities develop and maintain effective information system contingency plans.

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Appendix G – Sample Contingency Plan Template provides a template for preparing an information technology (IT) contingency plan.

Appendix H – Resources for Secure Remote Use and Access provides an overview of NIST publications discussing security technologies that may provide value for organizations facing challenges in securing remotely accessible, stored, or transmitted EPHI.

Appendix I – Telework Security Considerations provides considerations and tips for securing external devices used for telework and remote access.

1.5.

How and Why to Use This Document

Users are encouraged to use this document as a resource that provides concepts and tools to assist covered entities, including federal agencies, to comply with the HIPAA Security Rule.

NIST publications, many of which are required for federal agencies, can serve as guidelines and best practices for state, local, and tribal governments, and the private sector, and may provide enough depth and breadth to help organizations of many sizes select the type of implementation that best fits their unique circumstances. This document can support the compliance efforts of covered entities in many ways, including: Ensuring that each organization is selecting methods and controls which adequately and appropriately protect EPHI of which they are the steward;

Informing the development of compliance strategies that are in concert with the size and structure of the entity;

Providing guidelines on best practices for developing and implementing a Risk Management Program; and

Creating appropriate documentation that demonstrates effective compliance with the HIPAA Security Rule.

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2.

Background

2.1.

HIPAA Security Rule

The HIPAA Security Rule specifically focuses on the safeguarding of EPHI. Although FISMA applies to all federal agencies and all information types, only a subset of agencies is subject to the HIPAA Security Rule based on their functions and use of EPHI. All HIPAA covered entities, which includes some federal agencies, must comply with the Security Rule. The Security Rule specifically focuses on protecting the confidentiality, integrity, and availability of EPHI, as defined in the Security Rule. The EPHI that a covered entity creates, receives, maintains, or transmits must be protected against reasonably anticipated threats, hazards, and impermissible uses and/or disclosures. In general, the requirements, standards, and implementation specifications of the Security Rule apply to the following covered entities:

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Covered Healthcare Providers— Any provider of medical or other health services, or supplies, who transmits any health information in electronic form in connection with a transaction for which HHS has adopted a standard.

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Health Plans— Any individual or group plan that provides or pays the cost of medical care (e.g., a health insurance issuer and the Medicare and Medicaid programs).

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Healthcare Clearinghouses— A public or private entity that processes another entity's healthcare transactions from a standard format to a nonstandard format, or vice versa.

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Medicare Prescription Drug Card Sponsors – A nongovernmental entity that offers an endorsed discount drug program under the Medicare Modernization Act. This section identifies the main goals, explains some of the structure and organization, and identifies the purpose of the sections of the Security Rule. 2.1.1.

Security Rule Goals and Objectives

As required by the "Security standards: General rules"4 section of the HIPAA Security Rule, each covered entity must:

Ensure the confidentiality, integrity, and availability of EPHI that it creates, receives, maintains, or transmits;

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Protect against any reasonably anticipated threats and hazards to the security or integrity of EPHI; and

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Protect against reasonably anticipated uses or disclosures of such information that are not permitted by the Privacy Rule.

4 See 45 C.F.R. § 164.306(a).

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In complying with this section of the Security Rule, covered entities must be aware of the definitions provided for confidentiality, integrity, and availability as given by § 164.304:

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Confidentiality is "the property that data or information is not made available or disclosed to unauthorized persons or processes."

Integrity is "the property that data or information have not been altered or destroyed in an unauthorized manner."

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Availability is "the property that data or information is accessible and useable upon demand by an authorized person."

2.1.2.

Security Rule Organization

To understand the requirements of the HIPAA Security Rule, it is helpful to be familiar with the basic security terminology it uses to describe the security standards. By understanding the requirements and the terminology in the HIPAA Security Rule, it becomes easier to see which NIST publications may be appropriate reference resources and where to find more information. The Security Rule is separated into six main sections that each include several standards and implementation specifications that a covered entity must address.5 The six sections are listed below.

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Security standards: General Rules - includes the general requirements all covered entities must meet; establishes flexibility of approach; identifies standards and implementation specifications (both required and addressable); outlines decisions a covered entity must make regarding addressable implementation specifications; and requires maintenance of security measures to continue reasonable and appropriate protection of electronic protected health information.

Administrative Safeguards - are defined in the Security Rule as the "administrative actions and policies, and procedures to manage the selection, development, implementation, and maintenance of security measures to protect electronic protected health information and to manage the conduct of the covered entity's workforce in relation to the protection of that information."

Physical Safeguards - are defined as the "physical measures, policies, and procedures to protect a covered entity's electronic information systems and related

buildings and equipment, from natural and environmental hazards, and unauthorized intrusion."

Technical Safeguards - are defined as the "the technology and the policy and procedures for its use that protect electronic protected health information and control access to it."

5 Sections of the HIPAA regulations that are included in the Security Rule and therefore addressed in this document but do not have their own modules are Part 160 — General Administrative Requirements § 160.103, Definitions; Part 164 — Security and Privacy §§ 164.103, Definitions; 164.104, Applicability; 164.105, Organizational requirements (discussed in section 4 of this document), 164.302 Applicability; 164.304, Definitions; 164.306, Security standards: General rules (discussed in section 3.1 of this document), and 164.318, Compliance dates for the initial implementation of the security standards. 7

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Organizational Requirements - includes standards for business associate contracts and other arrangements, including memoranda of understanding between a covered entity and a business associate when both entities are government organizations; and requirements for group health plans.

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Policies and Procedures and Documentation Requirements - requires implementation of reasonable and appropriate policies and procedures to comply with the standards, implementation specifications and other requirements of the Security Rule; maintenance of written (which may be electronic) documentation and/or records that includes policies, procedures, actions, activities, or assessments required by the Security Rule; and retention, availability, and update requirements related to the documentation.

Within the Security Rule sections are standards and implementation specifications. Each HIPAA Security Rule standard is required. A covered entity is required to comply with all standards of the Security Rule with respect to all EPHI. Many of the standards contain implementation specifications. An implementation specification is a more detailed description of the method or approach covered entities can use to meet a particular standard.6 Implementation specifications are either required or addressable. However, regardless of whether a standard includes implementation specifications, covered entities must comply with each standard.

A required implementation specification is similar to a standard, in that a covered entity must comply with it.

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For addressable implementation specifications, covered entities must perform an assessment to determine whether the implementation specification is a reasonable and appropriate safeguard for implementation in the covered entity's environment. In general, after performing the assessment, a covered entity decides if it will implement the addressable implementation specification; implement an equivalent alternative measure that allows the entity to comply with the standard; or not implement the addressable specification or any alternative measures, if equivalent measures are not reasonable and appropriate within its environment. Covered

entities are required to document these assessments and all decisions. For federal agencies, however, all of the HIPAA Security Rule's addressable implementation specifications will most likely be reasonable and appropriate safeguards for implementation, given their sizes, missions, and resources.

Where there are no implementation specifications identified in the Security Rule for a particular standard, such as for the "Assigned Security Responsibility" and "Evaluation" standards, compliance with the standard itself is required.

Appendix D of this document provides a crosswalk of the HIPAA Security Rule standards and implementation specifications to relevant NIST publications and security controls detailed in NIST SP 800-53.

6 For more information on the required analysis used to determine the manner of implementation of an implementation specification, see § 164.306(d) of the HIPAA Security Rule (Security standards — General rules: Flexibility of approach). 8 An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA)

Security Rule

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For general HIPAA Security Rule information, visit the CMS HIPAA Web site at http://www.cms.hhs.gov/SecurityStandard/.

2.2.

NIST and its Role in Information Security

Founded in 1901, NIST is a non-regulatory federal agency within the U.S. Department of Commerce. NIST's mission is to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life. NIST is composed of several laboratories that conduct research in a wide variety of physical and engineering sciences. Lab researchers respond to industry needs for measurement methods, tools, data, and technology, and collaborate with colleagues in industry, academic institutions, and other government agencies.

The Computer Security Division (CSD), a component within NIST's Information Technology Laboratory (ITL), provides standards and technology to protect information systems against threats to the confidentiality of information, the integrity of information and processes, and the availability of information and services in order to build trust and confidence in IT systems.

CSD develops and issues standards, guidelines, and other publications to assist federal agencies in implementing the requirements of FISMA and in managing costeffective security programs to protect their information and information systems. Table 1 identifies and describes the types of NIST publications.

 Table 1: NIST Publication Types

Publication Type

Description

Federal Information Processing Standards (FIPS)

Developed by NIST in accordance with FISMA. They are approved by the Secretary of Commerce and are compulsory and binding for federal agencies. Since FISMA requires that federal agencies comply with these standards, agencies may not waive their use. FIPS may be used voluntarily by nonfederal organizations (e.g.,

state/local/tribal governments, industry).

Special Publication (SP) 800-series

Reports on ITL's research, guidelines, and outreach efforts in information system security and its collaborative activities with industry, government, and academia. Office of Management and Budget (OMB) policies state that for other than national

security programs and systems, federal agencies must follow NIST guidelines. SPs may be used voluntarily by nonfederal organizations.

Other Security Publications

Other publications including interagency reports (NISTIRs) and ITL bulletins that provide technical and other information about NIST's activities.

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Portability and Accountability Act (HIPAA)

Security Rule

3.

A Framework for Managing Risk

The HIPAA Security Rule is all about implementing effective risk management to adequately and effectively protect EPHI. The assessment, analysis, and management of risk provides the foundation of a covered entity's Security Rule compliance efforts, serving as tools to develop and maintain a covered entity's strategy to protect the confidentiality, integrity, and availability of EPHI.

All EPHI created, received, maintained, or transmitted by a covered entity is subject to the Security Rule. Covered entities are required to implement reasonable and appropriate security measures to protect against reasonably anticipated threats or vulnerabilities to the security of EPHI. Under the Security Rule, covered entities are required to evaluate risks and vulnerabilities in their environments and to implement security controls to address those risks and vulnerabilities. The selection and specification of security controls can be accomplished as part of

an organization-wide information security program that involves the management of organizational risk - that is, the risk to information, individuals, and the organization as a whole. The management of risk is a key element in the organization's information security program and provides an effective framework for selecting the appropriate security controls for an information system - the security controls necessary to protect individuals and the operations and assets of the organization.

This section describes a process of managing risk to organizational missions and business functions that arise from the operation and use of information systems by discussing each phase of the NIST Risk Management Framework7 and providing a mapping of this framework to complementary requirements of the HIPAA Security Rule.

3.1.

NIST Risk Management Framework (RMF)

The NIST RMF, illustrated in Figure 2, provides the covered entity with a disciplined, structured, extensible, and repeatable process for achieving risk-based protection related to the operation and use of information systems and the protection of EPHI. It represents an information security life cycle that facilitates continuous monitoring and improvement in the security state of the information systems within the organization.

The activities that compose the NIST RMF are paramount to an effective information security program and can be applied to both new and legacy information systems within the context of a system development life cycle. A riskbased approach to security control selection and specification considers effectiveness, efficiency, and constraints due to applicable laws, directives, Executive Orders, policies, standards, or regulations.

The flexible nature of the NIST RMF allows other communities of interest (e.g., state, local, and tribal governments and private sector entities) to use the framework voluntarily either with the NIST security standards and guidelines or with industry-

specific standards and guidelines. The RMF provides organizations with the flexibility needed to apply the right security controls to the right information systems at the right time to adequately

7 NIST Special Publication 800-39, Managing Risk from Information Systems: An Organizational Perspective, (Second Public Draft), April 2008.

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protect the critical and sensitive information, missions, and business functions of the organization.

Figure 2. NIST Risk Management Framework

3.2.

The NIST RMF and Links to the Security Rule

The NIST RMF consists of six steps that are paramount to the effective management of risk resulting from the operation and use of information systems. Many Security Rule standards and implementation specifications correspond to the steps of the NIST RMF. Using these corresponding requirements in an integrated fashion can provide a methodical, repeatable, risk-based approach for selecting, specifying, and implementing security controls to adequately protect EPHI. Table 2 describes each step in the NIST RMF as well as the related standards and implementation specifications found in the Security Rule.

Repeat as necessary RISK MANAGEMENT FRAMEWORK **Security Life Cycle** Step 1 **CATEGORIZE Information Systems** FIPS 199 / SP 800-60 Step 6 **MONITOR Security State** SP 800-37 / 800-53A Step 3 **IMPLEMENT Security Controls** SP 800-70 Step 2 **SELECT Security Controls** FIPS 200 / SP 800-53 **Security Plan** Step 5 **AUTHORIZE Information Systems** An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule Table 2: Linking the NIST RMF and the Security Rule

RMF Phase RMF Step Description Security Rule Link

Categorize Information Systems

Security categorization, the first and arguably the most important step in the RMF, employs FIPS 199 and NIST SP 800-60 to determine the criticality and sensitivity of the information system and the information being processed, stored, and transmitted by the system. This exercise aids in determining priorities for organizational information systems and subsequently applying appropriate measures to adequately protect the organizational missions and business functions supported by those missions. The security controls applied to a particular information system should be commensurate with the potential impact on organizational operations and assets, individuals, or other organizations should there be a loss of confidentiality, integrity, or availability.

Identify assets and information systems that create, receive, transmit, or maintain EPHI.

Related Standards and Implementation Specifications:

164.308(a)(1)(i) - Security Management Process

Select Security Controls

Security control selection, the second step in the RMF, employs FIPS 200 and NIST SP 800-53 to identify and specify appropriate security controls for the information system. The selection of security controls for an organization's mission/business processes and the information systems supporting those processes is a risk mitigation activity. The security control selection process consists of three activities:

Selection of baseline security controls for each information system from NIST SP 800-53 in accordance with FIPS 199 impact levels determined during the security categorization process;

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Application of security control tailoring guidance for the information systems to allow organizations to adjust the initial security control baselines with respect to specific mission and business processes,

Select the standards and required implementation specifications as the initial security control set. These required security controls establish the baseline from which to assess risk to EPHI.

Once the baseline is established, perform a risk assessment and analysis to evaluate whether the standards and required implementation specifications alone are reasonable and appropriate to provide adequate protection against reasonably anticipated threats or hazards to the confidentiality, integrity, or availability of EPHI. The results of this risk assessment and analysis will drive the selection of addressable implementation specifications to adequately supplement the baseline. Supplement the initial set of standards and required implementation specifications (baseline) with addressable implementation specifications. The decisions to supplement

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RMF Step Description organizational requirements, and environments of operations; and

Supplementation of tailored baseline security controls with additional controls based on an assessment of risk and local conditions including specific and credible threat information, organization-specific security requirements, cost-benefit analyses, and special circumstances.

Key to this process is documenting the selection and specification of security controls. A documented security plan provides an overview of the security requirements for the information systems within the organization and describes the security controls in place or planned for meeting those requirements. Additionally, the security plans for organizational information systems describe how individual security controls are implemented within specific operational environments. It is important for organizations to document the decisions taken during the security control selection process, providing a sound rationale for those decisions. The resulting set of security controls along with the supporting rationale for security control selection decisions and any information system use restrictions are documented in the security plans for the information system. This provides a clear description of the risk mitigation deemed necessary in order to adequately ensure mission accomplishment and success of business functions potentially impacted by the operation and use of the systems.

the security control baseline should be based on an assessment of risk and local conditions including organization-specific security requirements, specific threat information, cost-benefit analyses, or special circumstances.

The agreed-upon set of security controls will consist of the standards, required implementation specifications, and the risk-based selection of addressable implementation specifications.

Each covered entity must document the security controls determined to be reasonable and appropriate, including analysis, decisions, and rationale for decisions made to refine or adjust the security controls

Related Standards and Implementation Specifications:

164.308(a)(1)(i) – Security Management Process

164.308(a)(1)(ii)(A) - Risk Analysis

164.308(a)(1)(ii)(B) - Risk Management

164.316(b)(1) – Documentation

164.316(b)(2)(ii) – Updates

Implement Security Controls

Security control implementation, the third step in the RMF, employs enterprise architectures, the System Development Lifecycle (SDLC), and various NIST publications to guide the implementation of security controls in organizational information systems.

Implement the security controls that have been determined to be reasonable and appropriate for the organization.

Related Standards and Implementation Specifications:

164.308(a)(1)(ii)(B) – Risk Management

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RMF Phase RMF Step Description Security Rule Link

Assess Security Controls

Security Controls Assessment, the fourth step in the RMF, employs NIST SP 800-53A to evaluate the information system security controls for effectiveness using appropriate methods and procedures to determine the extent to which the controls are implemented correctly, operating as intended, and producing the desired outcome with respect to meeting the security objectives and requirements for the system.

Evaluate the implemented specifications using assessment methods and procedures to determine the extent to which the controls are implemented correctly and operating as intended with respect to protecting EPHI.

Related Standards and Implementation Specifications:

164.308(a)(8) - Evaluation

Authorize Information System

Authorize information system operation (with implemented security controls) based upon a determination of the risk to organizational operations, organizational assets, individuals, and other organizations, and an explicit decision to accept this risk. Inherent in any risk management process is the acceptance of those identified risks that are deemed acceptable to the organization.

Related Standards and Implementation Specifications:

164.308(a)(1)(ii)(B) - Risk Management

Monitor Security State

Threats and vulnerabilities to an operating environment, as well as safeguards designed to combat them, can change frequently. The assessment and evaluation of security controls on a continuous basis provides oversight and monitoring of the security controls to ensure that they continue to operate effectively and as intended. Monitor and assess selected security controls in the information system on a continuous basis including documenting changes to the system, conducting security impact analyses of the changes, and reporting the system security status to appropriate organizational officials on a regular basis.

A covered entity must periodically review and update its security measures and documentation in response to environmental and operational changes that affect security of its EPHI.

Related Standards and Implementation Specifications:

164.308(a)(8) – Evaluation

164.308(a)(1)(ii)(D) – Information System Activity Review

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4.

Considerations when Applying the HIPAA Security Rule

In this section, security measures from NIST publications that are relevant to each section of the Security Rule are presented. Each standard is presented in a consistent tabular format.

The following tables, organized by HIPAA Security Rule standard, are designed to initiate the thought process for implementing the requirements of the Security Rule. These tables highlight information a covered entity may wish to consider when implementing the Security Rule; they are not meant to be prescriptive. The tables may also not be considered all-inclusive of the information available in NIST publications.

In addition to the HIPAA Security Rule standard name and description, each table includes the following information:

•

Key Activities - The Key Activities column suggests, for each HIPAA Security Rule standard, actions that are usually associated with the security function or functions suggested by that standard. Some of these key activities are also the implementation specifications for that particular standard. Each key activity that is also an implementation specification has been identified as such in the table (in italics in the Description section of the table), along with a note as to whether the implementation specification is required or addressable. Other key activities would normally be performed as part of one or more of the related implementation specifications under the standard, but are listed separately for clarity of presentation. Where such a relationship exists, it is indicated in an accompanying footnote.

Other key activities are not implementation specifications. These activities are not specifically discussed or required by the HIPAA Security Rule, and their inclusion here is in no way meant to expand upon the intent or requirements of the Security Rule. Many of these activities, however, are usually included in a robust security process, and many will be required of federal entities under other federal laws, regulations, or procedures that may or may not be discussed within this document. The tables address all HIPAA Security Rule standards and all associated implementation specifications, both required and addressable. Seven of the standards include all the necessary instructions for implementation and have no associated implementation specifications.8 However, as noted earlier in this document, even if there are no implementation specifications outlined in the Security Rule, such as with Assigned Security Responsibility and Evaluation, compliance with the standard itself is still required.

The key activities are illustrative and not all-inclusive. There may be many additional activities an organization will need to consider, specific to its own operations, which are not included in the key activities of the tables. Each entity will need to identify what activities beyond those listed in the tables are necessary and appropriate in its environment, implement those activities, and document them. 8 Standards that do not contain implementation specifications—that "themselves also serve as the implementation specification," as stated in the preamble to the HIPAA Security Rule—are those described in Sections 4.2 (HIPAA Standard: Assigned Security Responsibility); 4.8 (HIPAA Standard: Evaluation); 4.11 (HIPAA Standard: Workstation Use); 4.12 (HIPAA Standard: Workstation Security), 4.15 (HIPAA Standard: Audit Controls); 4.17 (HIPAA Standard: Person or Entity Authentication); and 4.21 (HIPAA Standard: Policies and Procedures). 15 An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule 16

The tables are meant to serve as only a general introduction to the security topics raised by the HIPAA Security Rule. For more detailed information about the key activities, consult one or more NIST publications referenced for the subject HIPAA standard.

•

Description - The Description column in each table includes an expanded explanation about the key activities. The descriptions include types of activities an organization may pursue in addressing a specific security function. These are abbreviated explanations designed to help get an organization started in addressing the HIPAA Security Rule. The first description bullet of each key activity that is also an implementation specification includes the Security Rule implementation specification text in italics. When relationships exist between description bullets and other Security Rule standards or implementation specifications, it is indicated in an accompanying footnote. Sample Questions - The Sample Questions column includes some questions to determine whether or not the elements described have actually been considered or completed. These sample questions are not exhaustive but merely indicative of relevant questions that could be asked. Affirmative answers to these questions do not imply that an organization is meeting all of the requirements of the HIPAA security standards. Negative answers to these questions should prompt the covered entity to consider whether it needs to take further action in order to comply with the standards. In fact, it is expected that many organizations with existing information security infrastructure already in place will have considered most of the Sample Ouestions. The questions an organization asks in assessing and developing its security program should be tailored to fit the unique circumstances of each entity. This document does not discuss Section 164.105 of the HIPAA Security Rule, Organizational Requirements, in detail as they do not set out general security principles. HIPAA covered entities are encouraged to review this section of the HIPAA Security Rule in full and seek further guidance. An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule **Administrative Safeguards** 4.1. Security Management Process (§ 164.308(a)(1)) HIPAA Standard: Implement policies and procedures to prevent, detect, contain, and correct security violations. **Key Activities** Description **Sample Ouestions** 1. **Identify Relevant Information Systems** Identify all information systems that house EPHI. Include all hardware and software that are used to collect, store, process, or transmit EPHI. Analyze business functions and verify ownership and control of information system elements as necessary. Are all hardware and software for which the organization is responsible periodically inventoried? Have hardware and software that maintains or transmits EPHI been identified? Does this inventory include removable media and remote access devices? Is the current information system configuration documented, including connections to other systems?

Have the types of information and uses of that information been identified and the sensitivity of each type of information been evaluated? (See FIPS 199 and SP 800-60 for more on categorization of sensitivity levels.)

2.

Conduct Risk Assessment9

Implementation Specification (Required)

Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of EPHI held by the covered entity.

A risk assessment methodology, based on NIST SP 800-30, is included in Appendix E of this document.

Are there any prior risk assessments, audit comments, security requirements, and/or security test results?

Is there intelligence available from agencies, the Office of the Inspector General (OIG), the US-CERT, virus alerts, and/or vendors?

What are the current and planned controls?

Is the facility located in a region prone to any natural disasters, such as earthquakes, floods, or fires?

•

Has responsibility been assigned to check all hardware and software, including hardware and software used for remote access, to determine whether selected security settings are enabled?

•

Is there an analysis of current safeguards and their effectiveness relative to the identified risks?

•

Have all processes involving EPHI been considered, including creating, receiving, maintaining, and transmitting it?

3.

Implement a Risk Management Program10

•

Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with §164.306(a).

•

Do current safeguards ensure the confidentiality, integrity, and availability of all EPHI?

•

Do current safeguards protect against reasonably

9 The risks that must be assessed are the risks of noncompliance with the requirements of Section 164.306(a) (General Rules) of the HIPAA Security Rule. 17 10 See Section 164.306 of the HIPAA Security Rule.

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Key Activities Description

Sample Questions

Implementation Specification (Required) anticipated uses or disclosures of EPHI that are not permitted by the Privacy Rule?

Has the covered entity protected against all reasonably anticipated threats or hazards to the security and integrity of EPHI?

Has the covered entity assured compliance with all policies and procedures by its workforce?

4.

Acquire IT Systems and Services11, 12

•

Although the HIPAA Security Rule does not require purchasing any particular technology, additional hardware, software, or services may be needed to adequately protect information. Considerations for their selection should include the following: 0

Applicability of the IT solution to the intended environment;

0

The sensitivity of the data;

0

The organization's security policies, procedures, and standards; and

0

Other requirements such as resources available for operation, maintenance, and training.

•

Will new security controls work with the existing IT architecture?

•

Have the security requirements of the organization been compared with the security features of existing or proposed hardware and software?

•

Has a cost-benefit analysis been conducted to determine the reasonableness of the investment given the security risks identified?

•

Has a training strategy been developed?13

5.

Create and Deploy Policies and Procedures14, 15

•

Implement the decisions concerning the management, operational, and technical controls selected to mitigate identified risks.

•

Create policies that clearly establish roles and responsibilities and assign ultimate responsibility for the implementation of each control to particular individuals or offices.16

•

Create procedures to be followed to accomplish particular security-related tasks.

Are policies and procedures in place for security?

•

Is there a formal (documented) system security plan?

Is there a formal contingency plan?17

•

Is there a process for communicating policies and procedures to the affected employees?

Are policies and procedures reviewed and updated as needed?

6.

Develop and Implement a Sanction Policy18

Apply appropriate sanctions against workforce members who fail to comply with the security policies and procedures of the covered entity.

Develop policies and procedures for imposing appropriate sanctions (e.g., reprimand, termination) for noncompliance with the organization's security policies.

Implement sanction policy as cases arise.

•

Is there a formal process in place to address system misuse, abuse, and fraudulent activity?

•

Have employees been made aware of policies concerning sanctions for inappropriate access, use, and disclosure of EPHI?

•

Has the need and appropriateness of a tiered structure of sanctions that accounts for the magnitude of harm and

11 See Section 164.306(b) of the HIPAA Security Rule.

12 See Key Activity 4.1.3, Implement a Risk Management Program. This activity and all associated bullets in the Description and Sample Questions are part of the process of addressing the risk management implementation specification.

13 See Section 4.5, HIPAA Standard: Security Awareness and Training.

14 See Section 4.21, HIPAA Standard: Policies and Procedures.

15 See Key Activity 4.1.3, Implement a Risk Management Program. This activity and all associated bullets in the Description and Sample Questions are part of the process of addressing the risk management implementation specification.

16 See Section 4.21, HIPAA Standard: Policies and Procedures and Section 4.22, HIPAA Standard: Documentation. 18

17 See Section 4.7, HIPAA Standard: Contingency Plan.

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19

Sample Questions possible types of inappropriate disclosures been considered? •

How will managers and employees be notified regarding suspect activity? 7.

Develop and Deploy the Information System Activity Review Process Implementation Specification (Required)

•

Implement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports.

Who is responsible for the overall process and results?19

•

How often will reviews take place?

How often will review results be analyzed?

•

What is the organization's sanction policy for employee violations?

Where will audit information reside (e.g., separate server)? 8.

Develop Appropriate Standard Operating Procedures20

Determine the types of audit trail data and monitoring procedures that will be needed to derive exception reports.

•

How will exception reports or logs be reviewed?

Where will monitoring reports be filed and maintained?

9.

Implement the Information System Activity Review and Audit Process21

Activate the necessary review process.

•

Begin auditing and logging activity.

•

What mechanisms will be implemented to assess the effectiveness of the review process (measures)?

•

What is the plan to revise the review process when needed?

18 See Section 164.306 of the HIPAA Security Rule.

19 See Section 4.2, HIPAA Standard: Assigned Security Responsibility.

20 See Key Activity 4.1.7, Develop and Deploy the Information System Activity Review Process. This activity and all associated bullets in the Description and Sample Questions are part of the process of addressing the information system activity review implementation specification. 21 See Key Activity 4.1.7, Develop and Deploy the Information System Activity Review Process. This activity and all associated bullets in the Description and Sample Questions are part of the process of addressing the information system activity review implementation specification. An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule 4.2.

Assigned Security Responsibility (§ 164.308(a)(2))

HIPAA Standard: Identify the security official who is responsible for the development and implementation of the policies and procedures required by this subpart for the entity.

Key Activities

Description

Sample Questions

1.

Select a Security Official To Be Assigned Responsibility for HIPAA Security •

Identify the individual who has final responsibility for security.

•

Select an individual who is able to assess effective security and to serve as the point of contact for security policy, implementation, and monitoring.

Who in the organization—
0

Oversees the development and communication of security policies and procedures?

0

Is responsible for conducting the risk assessment?

0

Handles the results of periodic security evaluations and continuous monitoring? o

Directs IT security purchasing and investment?

0

Ensures that security concerns have been addressed in system implementation? •

Who in the organization is authorized to accept risk from information systems on behalf of the organization?

2.

Assign and Document the Individual's Responsibility

Document the assignment to one individual's responsibilities in a job description.22 •

Communicate this assigned role to the entire organization.

•

Is there a complete job description that accurately reflects assigned security duties and responsibilities?

•

Have the staff members in the organization been notified as to whom to call in the event of a security problem?23

22 See Standard 4.22, Standard: Documentation.

2023 See Standard 4.5, Security Awareness and Training, and 4.6, Security Incident Procedures.

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4.3.

Workforce Security (§ 164.308(a)(3))

HIPAA Standard: Implement policies and procedures to ensure that all members of its workforce have appropriate access to electronic protected health information, as provided under paragraph (a)(4) of this section, and to prevent those workforce members who do not have access under paragraph (a)(4) of this section from obtaining access to electronic protected health information.

Key Activities

Description

Sample Questions

1.

Implement Procedures for Authorization and/or Supervision Implementation Specification (Addressable)

•

Implement procedures for the authorization and/or supervision of workforce members who work with EPHI or in locations where it might be accessed.

•

Have chains of command and lines of authority been established?

•

Have staff members been made aware of the identity and roles of their supervisors? 2. Establish Clear Job Descriptions and Responsibilities24

Define roles and responsibilities for all job functions.

Assign appropriate levels of security oversight, training, and access.

Identify in writing who has the business need—and who has been granted permission—to view, alter, retrieve, and store EPHI, and at what times, under what circumstances, and for what purposes.25

Are there written job descriptions that are correlated with appropriate levels of access?

•

Have staff members been provided copies of their job descriptions, informed of the access granted to them, as well as the conditions by which this access can be used? 3.

Establish Criteria and Procedures for Hiring and Assigning Tasks26 •

Ensure that staff members have the necessary knowledge, skills, and abilities to fulfill particular roles, e.g., positions involving access to and use of sensitive information.

•

Ensure that these requirements are included as part of the personnel hiring process. •

Have the qualifications of candidates for specific positions been checked against the job description?

Have determinations been made that candidates for specific positions are able to perform the tasks of those positions?

4.

Establish a Workforce Clearance Procedure Implementation Specification (Addressable)

Implement procedures to determine that the access of a workforce member to EPHI is appropriate.

Implement appropriate screening of persons who will have access to EPHI.

Implement a procedure for obtaining clearance from appropriate offices or individuals where access is provided or terminated.

•

Is there an implementation strategy that supports the designated access authorities? $\ensuremath{\cdot}$

Are applicants' employment and educational references checked, if reasonable and appropriate?

•

Have background checks been completed, if reasonable and appropriate?

Do procedures exist for obtaining appropriate sign-offs to grant or terminate access to EPHI?

5.

Establish Termination Procedures Implementation Specification

Implement procedures for terminating access to EPHI when the employment of a workforce member ends or as required by determinations made as specified in

Are there separate procedures for voluntary termination (retirement, promotion, transfer, change of employment) vs. involuntary termination (termination for cause, 24 See Key Activity 4.3.1, Implement Procedures for Authorization and/or Supervision. This activity and all associated bullets in the Description and Sample Questions are part of the procedures for authorization and/or supervision. 25 See Section 4.22, HIPAA Standard: Documentation. 26 See Key Activity 4.3.1, Implement Procedures for Authorization and/or Supervision. This activity and all associated bullets in the Description and Sample Questions are part of the procedures for authorization and/or supervision.

An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule Key Activities

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Sample Questions

(Addressable) §164.308(a)(3)(ii)(B). • Develop a standard set of procedures that should be followed to recover access control devices (Identification [ID] badges, keys, access cards, etc.) when employment ends.

• Deact

Deactivate computer access accounts (e.g., disable user IDs and passwords). See the Access Controls Standard. reduction in force, involuntary transfer, and criminal or disciplinary actions), if reasonable and appropriate?

٠

Is there a standard checklist for all action items that should be completed when an employee leaves (return of all access devices, deactivation of logon accounts [including remote access], and delivery of any needed data solely under the employee's control)?

22

An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule 4.4.

Information Access Management (§ 164.308(a)(4))27

HIPAA Standard: Implement policies and procedures for authorizing access to electronic protected health information that are consistent with the applicable requirements of subpart E of this part.

Key Activities

Description

Sample Questions

1.

Isolate Healthcare Clearinghouse Functions28 Implementation Specification (Required)

•

If a healthcare clearinghouse is part of a larger organization, the clearinghouse must implement policies and procedures that protect the EPHI of the clearinghouse from unauthorized access by the larger organization.

Determine if a component of the covered entity constitutes a healthcare clearinghouse under the HIPAA Security Rule.

If no clearinghouse functions exist, document this finding.

If a clearinghouse exists within the organization, implement procedures for access consistent with the HIPAA Privacy Rule.

•

Does the healthcare clearinghouse share hardware or software with a larger organization of which it is a part?

Does the healthcare clearinghouse share staff or physical space with staff from a larger organization?

•

Has a separate network or subsystem been established for the healthcare clearinghouse, if reasonable and appropriate?

•

Has staff of the healthcare clearinghouse been trained to safeguard EPHI from disclosure to the larger organization, if required for compliance with the HIPAA Privacy Rule?

2.

Implement Policies and Procedures for Authorizing Access Implementation Specification (Addressable)

•

Implement policies and procedures for granting access to EPHI, for example, through access to a workstation, transaction, program, process, or other mechanism.

•

Decide how access will be granted to workforce members within the organization.

•

Select the basis for restricting access.

•

Select an access control method (e.g., identity-based, role-based, or other reasonable and appropriate means of access.)

•

Determine if direct access to EPHI will ever be appropriate for individuals external to the organization (e.g., business partners or patients seeking access to their own EPHI).

•

Do the organization's IT systems have the capacity to set access controls?29

Are there documented job descriptions that accurately reflect assigned duties and responsibilities and enforce segregation of duties?30

•

Does the organization grant remote access to EPHI?

•

What method(s) of access control is (are) used (e.g., identity-based, role-based, location-based, or a combination)?

3.

Implement Policies and Procedures for Access Establishment and Modification Implementation Specification (Addressable)

•

Implement policies and procedures that, based upon the entity's access authorization policies, establish, document, review, and modify a user's right of access to a workstation, transaction, program, or process.

•

Establish standards for granting access.

•

Provide formal authorization from the appropriate authority before granting access to sensitive information.

•

Are duties separated such that only the minimum necessary EPHI is made available to each staff member based on their job requirements?

27 Note: See also Section 4.10, HIPAA Standard: Facility Access Controls and Section 4.14, HIPAA Standard: Access Controls.

28 Note: Where the healthcare clearinghouse is a separate legal entity, it is subject to the Security Rule whether or not the larger organization is a covered entity. 29 See Section 4.14, HIPAA Standard: Access Controls.

23

30 See Section 4.3, HIPAA Standard: Workforce Security.

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Ke

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S

ample Questions 4. Evaluate Existing Security Measures Related to Access Controls31 • Evaluate the security features of access controls already in place, or those of any planned for implementation, as appropriate.

•

Determine if these security features involve alignment with other existing management, operational, and technical controls, such as policy standards and personnel procedures, maintenance and review of audit trails, identification and authentication of users, and physical access controls. • Are there policies and procedures related to the security of access controls?32 If so, are they updated regularly?

•

Are authentication mechanisms used to verify the identity of those accessing systems protected from inappropriate manipulation?33

•

Does management regularly review the list of access authorizations, including remote access authorizations, to verify that the list is accurate and has not been inappropriately altered? 34

31 See Key Activity 4.4.3, Implement Policies and Procedures for Access Establishment and Modification. This activity and all associated bullets in the Description and Sample Questions are part of the access establishment and modification implementation specification.

32 See Section 4.22, HIPAA Section: Documentation.

33 See Section 4.17, HIPAA Standard: Person or Entity Authentication. 24 34 See Section 4.3. HIPAA Standard: Workforce Security. An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule 4.5. Security Awareness and Training (§ 164.308(a)(5))35 HIPAA Standard: Implement a security awareness and training program for all members of its workforce (including management). **Key Activities** Description **Sample Questions** 1. **Conduct a Training Needs Assessment** Determine the training needs of the organization. Interview and involve key personnel in assessing security training needs. What awareness, training, and education programs are needed? Which are required? What is the current status regarding how these needs are being addressed (e.g., how well are current efforts working)? Where are the gaps between the needs and what is being done (e.g., what more needs to be done)? What are the training priorities in terms of content and audience? 2. **Develop and Approve a Training Strategy and a Plan** Address the specific HIPAA policies that require security awareness and training in the security awareness and training program. Outline in the security awareness and training program the scope of the awareness and training program; the goals; the target audiences; the learning objectives; the deployment methods, evaluation, and measurement techniques; and the frequency of training. Is there a procedure in place to ensure that everyone in the organization receives security awareness training? What type of security training is needed to address specific technical topics based on job responsibility? When should training be scheduled to ensure that compliance deadlines are met? Has the organization considered the training needs of non-employees (e.g.,

```
contractors, interns)?
```

3.

Protection from Malicious Software; Log-in Monitoring; and Password Management

Implementation Specifications (All Addressable)

As reasonable and appropriate, train employees regarding procedures for:

Guarding against, detecting, and reporting malicious software;

0

Monitoring log-in attempts and reporting discrepancies; and

0

Creating changing, and safeguarding passwords.

•

Incorporate information concerning staff members' roles and responsibilities in implementing these implementation specifications into training and awareness efforts.

•

Do employees know the importance of timely application of system patches to protect against malicious software and exploitation of vulnerabilities?

Are employees aware that log-in attempts may be monitored?

Do employees that monitor log-in attempts know to whom to report discrepancies? •

Do employees understand their roles and responsibilities in selecting a password of appropriate strength, changing the password periodically (if required), and safeguarding their password?

4.

Develop Appropriate Awareness and Training Content, Materials, and Methods •

Select topics that may need to be included in the training materials.

•

Incorporate new information from email advisories, online IT security daily news Web sites, and periodicals, as is reasonable and appropriate.

• Cond

Consider using a variety of media and avenues according to what is appropriate for the organization based on workforce

•

Have employees received a copy of, and do they have ready access to, the organization's security procedures and policies?36

•

Do employees know whom to contact and how to handle a security incident?37 •

Do employees understand the consequences of

35 Note: See also Section 4.10, HIPAA Standard: Facility Access Controls and Section 4.14, HIPAA Standard: Access Controls.

36 See Section 4.22, HIPAA Standard: Documentation.

25

37 See Section 4.6, HIPAA Standard: Security Incident Procedures.

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Key Activities

Description

Sample Questions size, location, level of education, etc. noncompliance with the stated security policies?38

•

Do employees who travel know how to handle physical laptop security issues and information security issues?39

Has the covered entity researched available training resources?

Is dedicated training staff available for delivery of security training? If not, who will deliver the training?

What is the security training budget?

5.

Implement the Training

•

Schedule and conduct the training outlined in the strategy and plan.

Implement any reasonable technique to disseminate the security messages in an organization, including newsletters, screensavers, videotapes, email messages, teleconferencing sessions, staff meetings, and computer-based training.

•

Have all employees received adequate training to fulfill their security responsibilities?

•

Are there sanctions if employees do not complete required training?

6.

Implement Security Reminders

Implementation Specification (Addressable)

•

Implement periodic security updates.

•

Provide periodic security updates to staff, business associates, and contractors.

•

What methods are available or already in use to make or keep employees aware of security, e.g., posters or booklets?

•

Is security refresher training performed on a periodic basis (e.g., annually)?

Is security awareness discussed with all new hires?

•

Are security topics reinforced during routine staff meetings?

7.

Monitor and Evaluate Training Plan 40

•

Keep the security awareness and training program current.

Conduct training whenever changes occur in the technology and practices as appropriate.

Monitor the training program implementation to ensure that all employees participate.

Implement corrective actions when problems arise.41

Are employee training and professional development programs documented and monitored, if reasonable and appropriate?

How are new employees trained on security?

•

Are new non-employees (e.g., contractors, interns) trained on security?

38 See Section 4.1, HIPAA Standard: Security Management Process.

39 See Section 4.13, HIPAA Standard: Device and Media Controls.

40 Also required under the HIPAA Security Rule § 164.306, General Requirements, Subsection (e), Maintenance. See also Section 4.8, HIPAA Standard: Evaluation.

26

41 See Section 4.1, HIPAA Standard: Security Management Process.

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4.6.

Security Incident Procedures (§ 164.308(a)(6))42

HIPAA Standard: Implement policies and procedures to address security incidents.

Key Activities Description

Sample Questions

1.

Determine Goals of Incident Response

•

Gain an understanding as to what constitutes a true security incident. Under the HIPAA Security Rule, a security incident is the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system. (45 CFR § 164.304)

Determine how the organization will respond to a security incident.

•

Establish a reporting mechanism and a process to coordinate responses to the security incident.

•

Provide direct technical assistance, advise vendors to address product-related problems, and provide liaisons to legal and criminal investigative groups as needed.

Has the HIPAA-required security risk assessment resulted in a list of potential physical or technological events that could result in a breach of security?

Is there a procedure in place for reporting and handling incidents?

•

Has an analysis been conducted that relates reasonably anticipated threats and hazards to the organization that could result in a security incident to the methods that would be used for mitigation?

Have the key functions of the organization been prioritized to determine what would need to be restored first in the event of a disruption?43

2.

Develop and Deploy an Incident Response Team or Other Reasonable and Appropriate Response Mechanism

Determine if the size, scope, mission, and other aspects of the organization justify the reasonableness and appropriateness of maintaining a standing incident response team.

Identify appropriate individuals to be a part of a formal incident response team, if the organization has determined that implementing an incident response team is reasonable and appropriate.

Do members of the team have adequate knowledge of the organization's hardware and software?

•

Do members of the team have the authority to speak for the organization to the media, law enforcement, and clients or business partners?

•

Has the incident response team received appropriate training in incident response activities?

3.

Develop and Implement Procedures to Respond to and Report Security Incidents Implementation Specification (Required)

•

Identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents that are known to the covered entity; and document security incidents and their outcomes.

•

Document incident response procedures that can provide a single point of reference to guide the day-to-day operations of the incident response team.

•

Review incident response procedures with staff with roles and responsibilities related to incident response, solicit suggestions for improvements, and make changes to reflect input if reasonable and appropriate.

Update the procedures as required based on changing

Has the organization determined that maintaining a staffed security incident hotline would be reasonable and appropriate?

•

Has the organization determined reasonable and appropriate mitigation options for security incidents?

Has the organization determined that standard incident report templates to ensure that all necessary information related to the incident is documented and investigated are reasonable and appropriate?

Has the organization determined under what conditions information related to a security breach will be disclosed to the media?

•

Have appropriate (internal and external) persons who

42 Note: See also Section 4.10, HIPAA Standard: Facility Access Controls and Section 4.14. HIPAA Standard: Access Controls. 27

43 See Section 4.7, HIPAA Standard: Contingency Plan.

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Key Activities

Desc

Sample Questions organizational needs.44 should be informed of a security breach been identified and a contact information list prepared?

•

Has a written incident response plan been developed and provided to the incident response team?

4.

Incorporate Post-Incident Analysis into Updates and Revisions

•

Measure effectiveness and update security incident response procedures to reflect lessons learned, and identify actions to take that will improve security controls after a security incident.

•

Does the incident response team keep adequate documentation of security incidents and their outcomes, which may include what weaknesses were exploited and how access to information was gained?

•

Do records reflect new contacts and resources identified for responding to an incident?

•

Does the organization consider whether current procedures were adequate for responding to a particular security incident?

28

44 See Section 4.22, HIPAA Standard: Documentation.

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29

4.7.

Contingency Plan (§ 164.308(a)(7))45

HIPAA Standard: Establish (and implement as needed) policies and procedures for responding to an emergency or other occurrence (for example, fire, vandalism, system failure, and natural disaster) that damages systems that contain electronic protected health information.

Key Activities

Description

Sample Questions

1.

Develop Contingency Planning Policy

•

Define the organization's overall contingency objectives.

•

Establish the organizational framework, roles, and responsibilities for this area.

•

Address scope, resource requirements, training, testing, plan maintenance, and backup requirements.

A contingency planning methodology, based on NIST SP 800-34, is included in Appendix F of this document.

What critical services must be provided within specified timeframes?

Patient treatment, for example, may need to be performed without disruption. o

By contrast, claims processing may be delayed during an emergency with no longterm damage to the organization.

•

Have cross-functional dependencies been identified so as to determine how the failure in one system may negatively impact another one?

2.

Conduct an Applications and Data Criticality Analysis46 Implementation Specification (Addressable)

•

Assess the relative criticality of specific applications and data in support of other Contingency Plan components.

•

Identify the activities and material involving EPHI that are critical to business operations.

•

Identify the critical services or operations, and the manual and automated processes that support them, involving EPHI.

•

Determine the amount of time the organization can tolerate disruptions to these operations, material, or services (e.g., due to power outages).

Establish cost-effective strategies for recovering these critical services or processes.

What hardware, software, and personnel are critical to daily operations?

•

What is the impact on desired service levels if these critical assets are not available? •

What, if any, support is provided by external providers (Internet service providers [ISPs], utilities, or contractors)?

What is the nature and degree of impact on the operation if any of the critical resources are not available?

3.

Identify Preventive Measures47

•

Identify preventive measures for each defined scenario that could result in loss of a critical service operation involving the use of EPHI.

Ensure that identified preventive measures are practical and feasible in terms of their applicability in a given environment.

What alternatives for continuing operations of the organization are available in case of loss of any critical function/resource?

•

What is the cost associated with the preventive measures that may be considered? •

Are the preventive measures feasible (affordable and practical for the environment)?

•

What plans, procedures, or agreements need to be initiated to enable implementation of the preventive measures, if they are necessary? 45 Note: See also Section 4.10, HIPAA Standard: Facility Access Controls and Section 4.14, HIPAA Standard: Access Controls.

46 This activity may be conducted as part of a larger analysis, sometimes called an impact analysis, that considers all material, services, systems, processes, and activities, including those do not involve EPHI and other elements of an organization not covered by the HIPAA Security Rule. 47 See Key Activities 4.7.5, Data Backup Plan and Disaster Recovery Plan and 4.7.6, Develop and Implement an Emergency Mode Operation Plan. This activity and all associated bullets in the Description and Sample Questions are part of the data backup plan, disaster recovery plan and the emergency mode operation plan implementation specifications.

An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule

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ample Questions 4. Develop Recovery Strategy48 • Finalize the set of contingency procedures that should be invoked for all identified impacts, including emergency mode operation. The strategy must be adaptable to the existing operating environment and address allowable outage times and associated priorities identified in step 2.

•

Ensure, if part of the strategy depends on external organizations for support, that formal agreements are in place with specific requirements stated. • Have procedures related to recovery from emergency or disastrous events been documented?

Has a coordinator who manages, maintains, and updates the plan been designated? •

Has an emergency call list been distributed to all employees? Have recovery procedures been documented?

•

Has a determination been made regarding when the plan needs to be activated (anticipated duration of outage, tolerances for outage or loss of capability, impact on service delivery, etc.)?

5.

Data Backup Plan and Disaster Recovery Plan Implementation Specifications (Both Required) Establish and implement procedures to create and maintain retrievable exact copies of EPHI.

Establish (and implement as needed) procedures to restore any loss of data.

Is there a formal, written contingency plan?49

Does it address disaster recovery and data backup? 50

Do data backup procedures exist?

Are responsibilities assigned to conduct backup activities?

Are data backup procedures documented and available to other staff? 6.

Develop and Implement an Emergency Mode Operation Plan Implementation Specification (Required)

•

Establish (and implement as needed) procedures to enable continuation of critical business processes for protection of the security of EPHI while operating in emergency mode.

•

"Emergency mode" operation involves only those critical business processes that must occur to protect the security of EPHI during and immediately after a crisis situation.

Have procedures been developed to continue the critical functions identified in Key Activity?

•

If so, have those critical functions that also involve the use of EPHI been identified? •

Would different staff, facilities, or systems be needed to perform those functions?

Has the security of that EPHI in that alternative mode of operation been assured? 7.

Testing and Revision Procedure

Implementation Specification (Addressable)

Implement procedures for periodic testing and revision of contingency plans.

Test the contingency plan on a predefined cycle (stated in the policy developed under Key Activity), if reasonable and appropriate.

Train those with defined plan responsibilities on their roles.

If possible, involve external entities (vendors, alternative site/service providers) in testing exercises.

Make key decisions regarding how the testing is to occur ("tabletop" exercise versus staging a real operational scenario including actual loss of capability).

Decide how to segment the type of testing based on the assessment of business impact and acceptability of sustained loss of service. Consider cost.

How is the plan to be tested?

•

Does testing lend itself to a phased approach?

•

Is it feasible to actually take down functions/services for the purposes of testing?

Can testing be done during normal business hours or must it take place during off hours?

•

If full testing is infeasible, has a "tabletop" scenario (e.g., a classroom-like exercise) been considered?

•

How frequently is the plan to be tested (e.g., annually)?

•

When should the plan be revised?

48 See Key Activities 4.7.5, Data Backup Plan and Disaster Recovery Plan and 4.7.6, Develop and Implement an Emergency Mode Operation Plan. This activity and all associated bullets in the Description and Sample Questions are part of the data backup plan, disaster recovery plan and the emergency mode operation plan implementation specifications.

49 See Key Activity **4.7.1**, Develop Contingency Planning Policy. **30**

50 See Key Activity 4.7.1, Develop Contingency Planning Policy.

An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule 4.8.

Evaluation (§ 164.308(a)(8))51

HIPAA Standard: Perform a periodic technical and nontechnical evaluation, based initially upon the standards implemented under this rule and subsequently, in response to environmental or operational changes affecting the security of electronic protected health information, which establishes the extent to which an entity's security policies and procedures meet the requirements of this subpart.

Key Activities

Description

Sample Questions

1.

Determine Whether Internal or External Evaluation Is Most Appropriate

•

Decide whether the evaluation will be conducted with internal staff resources or external consultants.

Engage external expertise to assist the internal evaluation team where additional skills and expertise is determined to be reasonable and appropriate.

Use internal resources to supplement an external source of help, because these internal resources can provide the best institutional knowledge and history of internal policies and practices.

Which staff has the technical experience and expertise to evaluate the systems?

How much training will staff need on security-related technical and nontechnical issues?

If an outside vendor is used, what factors should be considered when selecting the vendor, such as credentials and experience?

What is the budget for internal resources to assist with an evaluation?

What is the budget for external services to assist with an evaluation? 2.

Develop Standards and Measurements for Reviewing All Standards and Implementation Specifications of the Security Rule52

•

Use an evaluation strategy and tool that considers all elements of the HIPAA Security Rule and can be tracked, such as a questionnaire or checklist.

•

Implement tools that can provide reports on the level of compliance, integration, or maturity of a particular security safeguard deployed to protect EPHI.

If available, consider engaging corporate, legal, or regulatory compliance staff when conducting the analysis.

•

Leverage any existing reports or documentation that may already be prepared by the organization addressing compliance, integration, or maturity of a particular security safeguard deployed to protect EPHI.

•

Have management, operational, and technical issues been considered?

•

Do the elements of each evaluation procedure (questions, statements, or other components) address individual, measurable security safeguards for EPHI?

Has the organization determined that the procedure must be tested in a few areas or systems?

Does the evaluation tool consider all standards and implementation specifications of the HIPAA Security Rule?

3.

Conduct Evaluation

•

Determine, in advance, what departments and/or staff will participate in the evaluation.

•

Secure management support for the evaluation process to ensure participation.

Collect and document all needed information. Collection methods may include the use of interviews, surveys, and outputs of automated tools, such as access control auditing tools, system logs, and results of penetration testing.

Conduct penetration testing (where trusted insiders attempt

•

If available, have staff members with knowledge of IT security been consulted and included in the evaluation team?

•

If penetration testing has been determined to be reasonable and appropriate, has specifically worded, written approval from senior management been received for any planned penetration testing?

•

Has the process been formally communicated to those who have been assigned roles and responsibilities in the

51 Note: See also Section 4.10, HIPAA Standard: Facility Access Controls and Section 4.14, HIPAA Standard: Access Controls. 31

52 Organizations may wish to review and employ, where reasonable and appropriate, security control assessment procedures found in NIST SP 800-53A, Guide for Assessing the Security Controls in Federal Information Systems. An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule

Key Activities Description

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mple Questions to compromise system security for the sole purpose of testing the effectiveness of security controls), if reasonable and appropriate. evaluation process? • Has the organization explored the use of automated tools to support the evaluation process?

•

Has the organization employed automated tools to support the evaluation process? 4.

Document Results53

•

Document each evaluation finding, remediation options and recommendations, and remediation decisions.

•

Document known gaps between identified risks and mitigating security controls, and any acceptance of risk, including justification.

Develop security program priorities and establish targets for continuous improvement.

•

Does the process support development of security recommendations?

•

In determining how best to display evaluation results, have written reports that highlight key findings and recommendations been considered?

•

If a written final report is to be circulated among key staff, have steps been taken to ensure that it is made available only to those persons designated to receive it? 5.

Repeat Evaluations Periodically

•

Establish the frequency of evaluations, taking into account the sensitivity of the EPHI controlled by the organization, its size, complexity, and environmental and/or operational changes (e.g., other relevant laws or accreditation requirements).

In addition to periodic reevaluations, consider repeating evaluations when environmental and operational changes are made to the organization that affects the security of EPHI (e.g., if new technology is adopted or if there are newly recognized risks to the security of the information).

Do security policies specify that evaluations will be repeated when environmental and operational changes are made that affect the security of EPHI?

Do policies on frequency of security evaluations reflect any and all relevant federal or state laws which bear on environmental or operational changes affecting the security of EPHI?

•

Has the organization explored the use of automated tools to support periodic evaluations?

•

Has the organization employed automated tools to support periodic evaluations? 32

53 See Section 4.22, HIPAA Standard: Documentation.

An In

troductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule 4.9. Business Associate Contracts and Other Arrangements (§ 164.308(b)(1))

54

HIPAA Standard: A covered entity, in accordance with § 164.306, may permit a business associate to create, receive, maintain, or transmit electronic protected health information on the covered entity's behalf only if the covered entity obtains satisfactory assurances, in accordance with § 164.314(a), that the business associate will appropriately safeguard the information.55, 56

Key Activities

Description

Sample Questions

1.

Identify Entities that Are Business Associates under the HIPAA Security Rule •

Identify the individual or department who will be responsible for coordinating the execution of business associate agreements or other arrangements.

•

Reevaluate the list of business associates to determine who has access to EPHI in order to assess whether the list is complete and current.

Identify systems covered by the contract/agreement.

•

Do the business associate agreements written and executed contain sufficient language to ensure that required information types will be protected?

٠

Are there any new organizations or vendors that now provide a service or function on behalf of the organization? Such services may include the following:

0 **Claims processing or billing Data analysis Utilization review Quality assurance Benefit management** 0 **Practice management Re-pricing** Hardware maintenance All other HIPAA-regulated functions Have outsourced functions involving the use of EPHI been considered, such as the following: A **Actuarial services** A **Data aggregation** Administrative services 0 Accreditation 0 **Financial services?** 2. Written Contract or Other Arrangement57 **Implementation Specification (Required)** Document the satisfactory assurances required by this standard through a written contract or other arrangement with the business associate that meets the applicable requirements of §164.314(a).58 Execute new or update existing agreements or arrangements as appropriate. Identify roles and responsibilities. Who is responsible for coordinating and preparing the final agreement or arrangement? Does the agreement or arrangement specify how information is to be transmitted to

and from the business associate?

Have security controls been specified for the business associate?

54 See Section 4.19, HIPAA Standard: Business Associate Contracts and Other Arrangements.

55 (2) This standard does not apply with respect to (i) the transmission by a covered entity of EPHI to a healthcare provider concerning the treatment of an individual; (ii) the transmission of EPHI by a group health plan or an HMO or health insurance issuer on behalf of a group health plan to a plan sponsor, to the extent that the requirements of 164.314(b) and 164.504(f) apply and are met; or (iii) the transmission of EPHI from or to other agencies providing the services at 164.502(e)(1)(ii)(C), when the covered entity is a health plan that is a government program providing public benefits, if the requirements of 164.502(e)(1)(ii)(C) are met. 56 (3) A covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the standards, implementation specifications, and requirements of this paragraph and 164.314(a).

An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule D

escription • Include security requirements in business associate contracts/agreements to address confidentiality, integrity, and availability of EPHI.

•

Specify any training requirements associated with the contract/agreement or arrangement, if reasonable and appropriate.

3.

Establish Process for Measuring Contract Performance and Terminating the Contract if Security Requirements Are Not Being Met59

•

Maintain clear lines of communication.

•

Conduct periodic security reviews.

Establish criteria for measuring contract performance.

•

If the business associate is a governmental entity, update the memorandum of understanding or other arrangement when required by law or regulation or when reasonable and appropriate.

What is the service being performed?

•

What is the outcome expected?

•

Is there a process for reporting security incidents related to the agreement? •

Is there a process in place to periodically evaluate the effectiveness of business associate security controls?

Is there a process in place for terminating the contract if requirements are not being met and has the business associate been advised what conditions would warrant termination?

4.

Implement An Arrangement Other than a Business Associate Contract if Reasonable and Appropriate If the covered entity and its business associate are both governmental entities, use a memorandum of understanding or reliance on law or regulation that requires equivalent actions on the part of the business associate.

•

Document the law, regulation, memorandum, or other document that assures that the governmental entity business associate will implement all required safeguards for EPHI involved in transactions between the parties.

Is the covered entity's business associate a federal, state, or local governmental entity?

•

Is there a usual procedure for creating memoranda of understanding between the parties?

•

Has the covered entity researched and reviewed all law and regulation governing the use of EPHI by the governmental entity business associate?

57 See also Key Activity 4.9.4, Implement an Arrangement Other than a Business Associate Contract if Reasonable and Appropriate.

58 See Section 4.19, HIPAA Standard: Business Associate Contracts and Other Arrangements.

3459 See Section 4.19, HIPAA Standard: Business Associate Contracts and Other Arrangements.

An Introductory Resource Guide for Implementing the HIPAA Security Rule Physical Safeguards

4.10.

Facility Access Controls (§ 164.310(a)(1))60

HIPAA Standard: Implement policies and procedures to limit physical access to its electronic information systems and the facility or facilities in which they are housed, while ensuring that properly authorized access is allowed.

Key Activities

Description

Sample Questions

1.

Conduct an Analysis of Existing Physical Security Vulnerabilities61, 62

Inventory facilities and identify shortfalls and/or vulnerabilities in current physical security capabilities.

•

Assign degrees of significance to each vulnerability identified and ensure that proper access is allowed.

•

Determine which types of facilities require access controls to safeguard EPHI, such as:

```
o
Data Centers
o
Peripheral equipment locations
o
IT staff offices
o
```

Workstation locations.

If reasonable and appropriate, do nonpublic areas have locks and cameras?

Are workstations protected from public access or viewing?63

Are entrances and exits that lead to locations with EPHI secured?

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Do policies and procedures already exist regarding access to and use of facilities and equipment?

•

Are there possible natural or man-made disasters that could happen in our environment?64

•

Do normal physical protections exist (locks on doors, windows, etc., and other means of preventing unauthorized access)?

2.

Identify Corrective Measures65, 66

•

Identify and assign responsibility for the measures and activities necessary to correct deficiencies and ensure that proper access is allowed.

•

Develop and deploy policies and procedures to ensure that repairs, upgrades, and /or modifications are made to the appropriate physical areas of the facility while ensuring that proper access is allowed.

Who is responsible for security?67

•

Is a workforce member other than the security official responsible for facility/physical security?

•

Are facility access control policies and procedures already in place? Do they need to be revised?

•

What training will be needed for employees to understand the policies and procedures?68

•

How will we document the decisions and actions?69

Are we dependent on a landlord to make physical changes to meet the requirements?

60 Note: See also Section 4.10, HIPAA Standard: Facility Access Controls and Section 4.14, HIPAA Standard: Access Controls.

61 This key activity may be performed as part of the risk analysis implementation specification. See Section 4.1, HIPAA Standard: Security Management Process. 62 See Key Activity 4.10.3, Develop a Facility Security Plan. This activity and all associated bullets in the Description and Sample Questions are part of the facility security plan implementation specification.

63 See Section 4.11, HIPAA Standard: Workstation Use.

64 See Section 4.7, HIPAA Standard: Contingency Plan.

65 This key activity may be performed as part of the risk management implementation specification. See Section 4.1, HIPAA Standard: Security Management Process.

66 See Key Activity 4.10.3, Develop a Facility Security Plan. This activity and all associated bullets in the Description and Sample Questions are part of the facility security plan implementation specification.

67 See Section 4.2, HIPAA Standard: Assigned Security Responsibility.

68 See Section 4.5, HIPAA Standard: Security Awareness and Training. 35 An Introductory Resource Guide for Implementing the HIPAA Security Rule Ke

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ample Questions 3. Develop a Facility Security Plan

Implementation Specification (Addressable) • Implement policies and procedures to safeguard the facility and the equipment therein from unauthorized physical access, tampering, and theft.

•

Implement appropriate measures to provide physical security protection for EPHI in a covered entity's possession.

•

Include documentation of the facility inventory, as well as information regarding the physical maintenance records and the history of changes, upgrades, and other modifications.

•

Identify points of access to the facility and existing security controls.

• Is there an inventory of facilities and existing security practices?

•

What are the current procedures for securing the facilities (exterior, interior, equipment, access controls, maintenance records, etc.)?

•

Is a workforce member other than the security official responsible for the facility plan?

•

Is there a contingency plan already in place, under revision, or under development?70

4.

Develop Access Control and Validation Procedures Implementation Specification (Addressable)

•

Implement procedures to control and validate a person's access to facilities based on their role or function, including visitor control, and control of access to software programs for testing and revision.

•

Implement procedures to provide facility access to authorized personnel and visitors, and exclude unauthorized persons.

What are the policies and procedures in place for controlling access by staff, contractors, visitors, and probationary employees?

How many access points exist in each facility? Is there an inventory?

Is monitoring equipment necessary?

5.

Establish Contingency Operations Procedures Implementation Specification (Addressable)

Establish (and implement as needed) procedures that allow facility access in support of restoration of lost data under the Disaster Recovery Plan and Emergency Mode Operations Plan in the event of an emergency.

•

Who needs access to EPHI in the event of a disaster?

What is the backup plan for access to the facility and/or EPHI?

•

Who is responsible for the contingency plan for access to EPHI?

•

Who is responsible for implementing the contingency plan for access to EPHI in each department, unit, etc.?

•

Will the contingency plan be appropriate in the event of all types of potential disasters (fire, flood, earthquake, etc.)?

6.

Maintain Maintenance Records

Implementation Specification (Addressable)

•

Implement policies and procedures to document repairs and modifications to the physical components of a facility which are related to security (for example, hardware, walls, doors and locks).

•

Are records of repairs to hardware, walls, doors, and locks maintained? •

Has responsibility for maintaining these records been assigned?

69 See Section 4.22, HIPAA Standard: Documentation.

70 See Section 4.7, HIPAA Standard: Contingency Plan. 36

An Introductory Resource Guide for Implementing the HIPAA Security Rule 4.11.

Workstation Use (§ 164.310(b))

HIPAA Standard: Implement policies and procedures that specify the proper functions to be performed, the manner in which those functions are to be performed, and the physical attributes of the surroundings of a specific workstation or class of workstation that can access electronic protected health information. Key Activities

Description

Sample Questions

1.

Identify Workstation Types and Functions or Uses

Inventory workstations and devices.

•

Develop policies and procedures for each type of workstation and workstation device, identifying and accommodating their unique issues.

Classify workstations based on the capabilities, connections, and allowable activities for each workstation used.

Do we have an inventory of workstation types and locations in my organization? •

Who is responsible for this inventory and its maintenance?

What tasks are commonly performed on a given workstation or type of workstation?

•

Are all types of computing devices used as workstations identified along with the use of these workstations?

2.

Identify Expected Performance of Each Type of Workstation

Develop and document policies and procedures related to the proper use and performance of workstations.

•

How are workstations used in day-to-day operations?

•

What are key operational risks that could result in a breach of security?

3.

Analyze Physical Surroundings for Physical Attributes71

•

Ensure that any risks associated with a workstation's surroundings are known and analyzed for possible negative impacts.

•

Develop policies and procedures that will prevent or preclude unauthorized access of unattended workstations, limit the ability of unauthorized persons to view sensitive information, and dispose of sensitive information as needed.

Where are workstations located?

Is viewing by unauthorized individuals restricted or limited at these workstations? •

Do changes need to be made in the space configuration?

Do employees understand the security requirements for the data they use in their day-to-day jobs?

71 See Section 4.5, HIPAA Standard: Security Awareness and Training. This key activity should be performed during security training or awareness activities. 37

An Introductory Resource Guide for Implementing the HIPAA Security Rule 4.12.

Workstation Security (§ 164.310(c))

HIPAA Standard: Implement physical safeguards for all workstations that access electronic protected health information, to restrict access to authorized users. Key Activities Description **Sample Questions** 1. **Identify All Methods of Physical Access to Workstations** Document the different ways workstations are accessed by employees and nonemployees. Is there an inventory of all current workstation locations? Are any workstations located in public areas? Are laptops used as workstations? 2. Analyze the Risk Associated with Each Type of Access72 Determine which type of access holds the greatest threat to security. Are any workstations in areas that are more vulnerable to unauthorized use, theft, or viewing of the data they contain? What are the options for making modifications to the current access configuration? 3. **Identify and Implement Physical Safeguards for Workstations** Implement physical safeguards and other security measures to minimize the possibility of inappropriate access to EPHI through workstations. What safeguards are in place, i.e., locked doors, screen barriers, cameras, guards?73 Do any workstations need to be relocated to enhance physical security? Have employees been trained on security?74 72 This key activity may be conducted pursuant to the risk analysis and risk management implementation specifications of the security management process standard. See Section 4.1, HIPAA Standard: Security Management Process. 73 See Section 4.1, HIPAA Standard: Security Management Process. 74 See Section 4.5, HIPAA Standard: Security Awareness and Training. 38 An Introductory Resource Guide for Implementing the HIPAA Security Rule 4.13. Device and Media Controls (§ 164.310(d)(1)) HIPAA Standard: Implement policies and procedures that govern the receipt and removal of hardware and electronic media that contain electronic protected health information into and out of a facility, and the movement of these items within the facility. **Kev Activities** Description **Sample Questions** 1. **Implement Methods for Final Disposal of EPHI**

Implementation Specification (Required)

Implement policies and procedures to address the final disposition of EPHI and/or the hardware or electronic media on which it is stored.

Determine and document the appropriate methods to dispose of hardware, software, and the data itself.

Assure that EPHI is properly destroyed and cannot be recreated.

What data is maintained by the organization, and where?

Is data on removable, reusable media such as tapes and CDs?

Is there a process for destroying data on hard drives and file servers?

What are the options for disposing of data on hardware? What are the costs? 2.

Develop and Implement Procedures for Reuse of Electronic Media Implementation Specification (Required)

Implement procedures for removal of EPHI from electronic media before the media are made available for reuse.

Ensure that EPHI previously stored on electronic media cannot be accessed and reused.

Identify removable media and their use.

Ensure that EPHI is removed from reusable media before they are used to record new information.

Do policies and procedures already exist regarding reuse of electronic media (hardware and software)?

Is one individual and/or department responsible for coordinating the disposal of data and the reuse of the hardware and software?

Are employees appropriately trained on security and risks to EPHI when reusing software and hardware?75

3.

Maintain Accountability for Hardware and Electronic Media **Implementation Specification (Addressable)**

Maintain a record of the movements of hardware and electronic media and any person responsible therefore.

Ensure that EPHI is not inadvertently released or shared with any unauthorized party.

Ensure that an individual is responsible for, and records the receipt and removal of, hardware and software with EPHI.

Where is data stored (what type of media)?

What procedures already exist regarding tracking of hardware and software within the company?

If workforce members are allowed to remove electronic media that contain or may be used to access EPHI, do procedures exist to track the media externally?

Who is responsible for maintaining records of hardware and software? 4.

Develop Data Backup and Storage Procedures Implementation Specification (Addressable)

•

Create a retrievable exact copy of EPHI, when needed, before movement of equipment.

•

Ensure that an exact retrievable copy of the data is retained and protected to protect the integrity of EPHI during equipment relocation.

•

Are backup files maintained offsite to assure data availability in the event data is lost while transporting or moving electronic media containing EPHI?

•

If data were to be unavailable while media are transported or moved for a period of time, what would the business impact be?

75 See Section 4.5, HIPAA Standard: Security Awareness and Training. 39 An Introductory Resource Guide for Implementing the HIPAA Security Rule Technical Safeguards

4.14.

Access Control (§ 164.312(a)(1))

HIPAA Standard: Implement technical policies and procedures for electronic information systems that maintain electronic protected health information to allow access only to those persons or software programs that have been granted access rights as specified in § 164.308(a)(4).76

Key Activities

Description

Sample Questions

1.

Analyze Workloads and Operations To Identify the Access Needs of All Users77

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Identify an approach for access control.

•

Consider all applications and systems containing EPHI that should be available only to authorized users.

•

Integrate these activities into the access granting and management process.78

Have all applications/systems with EPHI been identified?

•

What user roles are defined for those applications/systems?

Where is the EPHI supporting those applications/systems currently housed (e.g., stand-alone PC, network)?

Are data and/or systems being accessed remotely?

2.

Identify Technical Access Control Capabilities

Determine the access control capability of all information systems with EPHI.

How are the systems accessed (viewing data, modifying data, creating data)? 3.

Ensure that All System Users Have Been Assigned a Unique Identifier Implementation Specification (Required)

•

Assign a unique name and/or number for identifying and tracking user identity.

Ensure that system activity can be traced to a specific user.

•

Ensure that the necessary data is available in the system logs to support audit and other related business functions.79

•

How should the identifier be established (length and content)?

Should the identifier be self-selected or randomly generated?

4.

Develop Access Control Policy80

•

Establish a formal policy for access control that will guide the development of procedures.81

•

Specify requirements for access control that are both feasible and cost-effective for implementation.82

•

Have rules of behavior been established and communicated to system users?

How will rules of behavior be enforced?

5.

Implement Access Control Procedures Using Selected Hardware and Software

Implement the policy and procedures using existing or additional hardware/software solution(s).

Who will manage the access controls procedures?

•

Are current users trained in access control management?83

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Will user training be needed to implement access control procedures? 76 Note: This HIPAA standard supports the standards at Section 4.4, Information Access Management and Section 4.10, Facility Access Controls. 77 See Section 4.4, HIPAA Standard: Information Access Management. This activity and all associated bullets in the Description and Sample Questions should be conducted as part of the access granting and access establishment process detailed in the Information Access Management standard. 78 See Section 4.4, HIPAA Standard: Information Access Management. 79 See Section 4.15, HIPAA Standard: Audit Control. 80 See Section 4.4, HIPAA Standard: Information Access Management. 81 See Section 4.4, HIPAA Standard: Information Access Management. 82 See Section 4.1, HIPAA Standard: Security Management Process. 40 An Introductory Resource Guide for Implementing the HIPAA Security Rule 41 Ke y Activities D escription S ample Questions 6. Review and Update User Access • Enforce policy and procedures as a matter of ongoing operations.84 Determine if any changes are needed for access control mechanisms. Establish procedures for updating access when users require the following:85 **Initial access** 0 **Increased access** 0 Access to different systems or applications than those they currently have • Have new employees/users been given proper instructions for protecting data and systems?86 What are the procedures for new employee/user access to data and systems?87 Are there procedures for reviewing and, if appropriate, modifying access authorizations for existing users?88 7. **Establish an Emergency Access Procedure Implementation Specification (Required)** Establish (and implement as needed) procedures for obtaining necessary electronic protected health information during an emergency. Identify a method of supporting continuity of operations should the normal access procedures be disabled or unavailable due to system problems. When should the emergency access procedure be activated? Who is authorized to make the decision?89 Who has assigned roles in the process?90

Will systems automatically default to settings and functionalities that will enable the emergency access procedure or will the mode be activated by the system administrator or other authorized individual? 8. Automatic Logoff and Encryption and Decryption **Implementation Specifications (Both Addressable)** Consider whether the addressable implementation specifications of this standard are reasonable and appropriate: 0 Implement electronic procedures that terminate an electronic session after a predetermined time of inactivity. Implement a mechanism to encrypt and decrypt EPHI. Are automatic logoff features available for any of the covered entity's operating systems or other major applications? If applications have been created or developed in-house, is it reasonable and appropriate to modify them to feature automatic logoff capability? What period of inactivity prior to automatic logoff is reasonable and appropriate for the covered entity? What encryption systems are available for the covered entity's EPHI? Is encryption appropriate for storing and maintaining EPHI ("at rest"), as well as while it is transmitted? 9. **Terminate Access if it is No Longer Required91** Ensure that access to EPHI is terminated if the access is no longer authorized. Are rules being enforced to remove access by staff members who no longer have a need to know because they have changed assignments or have stopped working for the organization? 83 See Section 4.5, HIPAA Standard: Security Awareness and Training. 84 See Section 4.4, HIPAA Standard: Information Access Management. 85 See Section 4.4, HIPAA Standard: Information Access Management. 86 See Section 4.5, HIPAA Standard: Security Awareness and Training. 87 See Section 4.4. HIPAA Standard: Information Access Management. 88 See Section 4.4, HIPAA Standard: Information Access Management. 89 See Section 4.7, HIPAA Standard: Contingency Plan. 90 See Section 4.7, HIPAA Standard: Contingency Plan. 91 See Section 4.3, HIPAA Standard: Workforce Security. An Introductory Resource Guide for Implementing the HIPAA Security Rule 4.15. Audit Controls (§ 164.312(b)) HIPAA Standard: Implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use

electronic protected health information.

Key Activities Description **Sample Questions** 1. Determine the Activities that Will Be Tracked or Audited Determine the appropriate scope of audit controls that will be necessary in information systems that contain or use EPHI based on the covered entity's risk assessment and other organizational factors.92 Determine what data needs to be captured. Where is EPHI at risk in the organization?93 What systems, applications, or processes make data vulnerable to unauthorized or inappropriate tampering, uses, or disclosures?94 What activities will be monitored (e.g., creation, reading, updating, and/or deleting of files or records containing EPHI)? What should the audit record include (e.g., user ID, event type/date/time)? 2. Select the Tools that Will Be Deployed for Auditing and System Activity Reviews Evaluate existing system capabilities and determine if any changes or upgrades are necessary. What tools are in place? What are the most appropriate monitoring tools for the organization (third party, freeware, or operating system-provided)? Are changes/upgrades to information systems reasonable and appropriate? **Develop and Deploy the Information System Activity Review/Audit Policy** Document and communicate to the workforce the facts about the organization's decisions on audits and reviews. Who is responsible for the overall audit process and results? How often will audits take place? How often will audit results be analyzed? What is the organization's sanction policy for employee violations?95 Where will audit information reside (i.e., separate server)? 4. **Develop Appropriate Standard Operating Procedures96**

Determine the types of audit trail data and monitoring procedures that will be needed to derive exception reports.

How will exception reports or logs be reviewed?

Where will monitoring reports be filed and maintained?

•

Is there a formal process in place to address system misuse, abuse, and fraudulent activity?97

•

How will managers and employees be notified, when appropriate, regarding suspect activity?

92 See Section 4.1, HIPAA Standard: Security Management Process and Key Activity 4.1.7, Develop and Deploy the Information System Activity Review Process.
93 See Section 4.1, HIPAA Standard: Security Management Process and Key Activity 4.1.2, Conduct Risk Assessment.

94 See Section 4.1, HIPAA Standard: Security Management Process and Key Activity 4.1.2, Conduct Risk Assessment.

95 See Section 4.1, HIPAA Standard: Security Management Process and Key Activity 4.1.6, Develop and Implement a Sanction Policy.

96 See Section 4.1, HIPAA Standard: Security Management Process and Key Activity 4.1.7, Develop and Deploy the Information system Activity Review Process..
97 See Section 4.1, HIPAA Standard: Security Management Process and Key Activity 4.1.6, Develop and Implement a Sanction Policy.

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An Introductory Resource Guide for Implementing the HIPAA Security Rule Ke

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ample Questions 5. Implement the Audit/System Activity Review Process98 • Activate the necessary audit system.

•

Begin logging and auditing procedures. • What mechanisms will be implemented to assess the effectiveness of the audit process (metrics)?

•

What is the plan to revise the audit process when needed?

98 See Section 4.1, HIPAA Standard: Security Management Process and Key Activity 4.1.9, Implement the Information System Activity Review and Audit Process. 43

An Introductory Resource Guide for Implementing the HIPAA Security Rule 4.16.

Integrity (§ 164.312(c)(1))

HIPAA Standard: Implement policies and procedures to protect electronic protected health information from improper alteration or destruction. Key Activities Description Sample Questions 1.

Identify All Users Who Have Been Authorized to Access EPHI99

•

Identify all approved users with the ability to alter or destroy data, if reasonable and appropriate.

Address this Key Activity in conjunction with the identification of unauthorized sources in Key Activity 2, below.

How are users authorized to access the information?100

•

Is there a sound basis established as to why they need the access?101

Have they been trained on how to use the information?102

Is there an audit trail established for all accesses to the information?103 2.

Identify Any Possible Unauthorized Sources that May Be Able to Intercept the Information and Modify It

•

Identify scenarios that may result in modification to the EPHI by unauthorized sources (e.g., hackers, disgruntled employees, business competitors).104

Conduct this activity as part of your risk analysis.105

•

What are likely sources that could jeopardize information integrity?106

What can be done to protect the integrity of the information when it is residing in a system (at rest)?

•

What procedures and policies can be established to decrease or eliminate alteration of the information during transmission (e.g., encryption)?107

3.

Develop the Integrity Policy and Requirements

•

Establish a formal (written) set of integrity requirements based on the results of the analysis completed in the previous steps.

Have the requirements been discussed and agreed to by identified key personnel involved in the processes that are affected?

Have the requirements been documented?

•

Has a written policy been developed and communicated to system users? 4.

Implement Procedures to Address These Requirements

Identify and implement methods that will be used to protect the information from modification.

Identify and implement tools and techniques to be developed or procured that support the assurance of integrity.

Are current audit, logging, and access control techniques sufficient to address the integrity of the information?

If not, what additional techniques can we apply to check information integrity (e.g., quality control process, transaction and output reconstruction)?

99 See Section 4.3, HIPAA Standard: Workforce Security, Section 4.3, HIPAA Standard: Access Control, and Section 4.21, HIPAA Standard: Policies and Procedures.

100 See Section 4.3, HIPAA Standard: Workforce Security and Section 4.3, HIPAA Standard: Access Control.

101 See Section 4.3, HIPAA Standard: Workforce Security.

102 See Section 4.5, HIPAA Standard: Security Awareness and Training.

103 See Section 4.15, HIPAA Standard: Audit Controls.

104 See Section 4.1, HIPAA Standard: Security Management Process.

105 See Section 4.1, HIPAA Standard: Security Management Process.

106 See Section 4.1, HIPAA Standard: Security Management Process.

107 See Section 4.1, HIPAA Standard: Security Management Process. 44

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ample Questions • Can additional training of users decrease instances attributable to human errors? 5. Implement a Mechanism to Authenticate EPHI Implementation Specification (Addressable) • Implement electronic mechanisms to corroborate that EPHI has not been altered or destroyed in an unauthorized manner.

•

Consider possible electronic mechanisms for authentication such as:

) 0

Error-correcting memory

0

Magnetic disk storage

0

Digital signatures

0

Check sum technology.

•

Are the uses of both electronic and nonelectronic mechanisms necessary for the protection of EPHI?

•

Are appropriate electronic authentication tools available?

•

Are available electronic authentication tools interoperable with other applications and system components?

6.

Establish a Monitoring Process To Assess How the Implemented Process Is Working

Review existing processes to determine if objectives are being addressed.108

•

Reassess integrity processes continually as technology and operational environments change to determine if they need to be revised.109

Are there reported instances of information integrity problems and have they decreased since integrity procedures have been implemented?110

Does the process, as implemented, provide a higher level of assurance that information integrity is being maintained?

108 See Section 4.8, HIPAA Standard: Evaluation.

109 See Section 4.8, HIPAA Standard: Evaluation.

110 See Section 4.6, HIPAA Standard: Security Incident Procedures. 45

An Introductory Resource Guide for Implementing the HIPAA Security Rule 4.17.

Person or Entity Authentication (§ 164.312(d))111

HIPAA Standard: Implement procedures to verify that a person or entity seeking access to electronic protected health information is the one claimed.

Key Activities

Description

Sample Questions

1. Determine Authentication Applicability to Current Systems/Applications
•

Identify methods available for authentication. Under the HIPAA Security Rule, authentication is the corroboration that a person is the one claimed. (45 CFR § 164.304).

•

Authentication requires establishing the validity of a transmission source and/or verifying an individual's claim that he or she has been authorized for specific access privileges to information and information systems.

What authentication methods are available?

•

What are the advantages and disadvantages of each method?

•

What will it cost to implement the available methods in our environment?

Do we have trained staff who can maintain the system or do we need to consider outsourcing some of the support?

Are passwords being used?

•

If so, are they unique by individual?

2. Evaluate Authentication Options Available

•

Weigh the relative advantages and disadvantages of commonly used authentication approaches.

•

There are four commonly used authentication approaches available:

0

Something a person knows, such as a password,

0
Something a person has or is in possession of, such as a token (smart card, ATM card, etc.),

0

Some type of biometric identification a person provides, such as a fingerprint, or o

A combination of two or more of the above approaches.

•

What are the strengths and weaknesses of each available option?

•

Which can be best supported with assigned resources (budget/staffing)?

•

What level of authentication is appropriate based on our assessment of risk to the information/systems?

•

Do we need to acquire outside vendor support to implement the process? 3. Select and Implement Authentication Option

•

Consider the results of the analysis conducted under Key Activity 2, above, and select appropriate authentication methods.

•

Implement the methods selected into your operations and activities.

•

Has necessary user and support staff training been completed?

•

Have formal authentication policy and procedures been established and communicated?

•

Has necessary testing been completed to ensure that the authentication system is working as prescribed?

•

Do the procedures include ongoing system maintenance and updates? •

Is the process implemented in such a way that it does not compromise the authentication information (password file encryption, etc.)?

111 See also Section 4.14, HIPAA Standard: Access Control and Section 4.15, HIPAA Standard: Audit Controls.

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An Introductory Resource Guide for Implementing the HIPAA Security Rule 4.18.

Transmission Security (§ 164.312(e)(1))

HIPAA Standard: Implement technical security measures to guard against unauthorized access to electronic protected health information that is being transmitted over an electronic communications network.

Key Activities

Description

Sample Questions

1.

Identify Any Possible Unauthorized Sources that May Be Able to Intercept and/or Modify the Information

•

Identify scenarios that may result in modification of the EPHI by unauthorized sources during transmission (e.g., hackers, disgruntled employees, business competitors).112

What measures exist to protect EPHI in transmission?

Is there an auditing process in place to verify that EPHI has been protected against unauthorized access during transmission?113

Are there trained staff members to monitor transmissions?

2.

Develop and Implement Transmission Security Policy and Procedures

Establish a formal (written) set of requirements for transmitting EPHI.

•

Identify methods of transmission that will be used to safeguard EPHI.

•

Identify tools and techniques that will be used to support the transmission security policy.

•

Implement procedures for transmitting EPHI using hardware and/or software, if needed.

•

Have the requirements been discussed and agreed to by identified key personnel involved in transmitting EPHI?

•

Has a written policy been developed and communicated to system users? 3.

Implement Integrity Controls

Implementation Specification (Addressable)

•

Implement security measures to ensure that electronically transmitted EPHI is not improperly modified without detection until disposed of.

•

What measures are planned to protect EPHI in transmission?

Is there assurance that information is not altered during transmission?

4.

Implement Encryption

Implementation Specification (Addressable)

•

Implement a mechanism to encrypt EPHI whenever deemed appropriate.

• Ta

Is encryption reasonable and appropriate for EPHI in transmission?

Is encryption needed to effectively protect the information?

Is encryption feasible and cost-effective in this environment?

What encryption algorithms and mechanisms are available?

•

Does the covered entity have the appropriate staff to maintain a process for encrypting EPHI during transmission?

Are staff members skilled in the use of encryption?

112 See Section 4.7, HIPAA Standard: Contingency Plan and Section 4.1, HIPAA Standard: Security Management Process.

113 See Section 4.1, HIPAA Standard: Security Management Process. 47

An Introductory Resource Guide for Implementing the HIPAA Security Rule Organizational Requirements

4.19.

Business Associate Contracts or Other Arrangements (§ 164.314(a)(1)) HIPAA Standard: (i) The contract or other arrangement between the covered entity and its business associate required by § 164.308(b) must meet the requirements of paragraph (a)(2)(i) or (a)(2)(ii) of this section, as applicable. (ii) A covered entity is not in compliance with the standards in § 164.502(e) and paragraph (a) of this section if the covered entity knew of a pattern of an activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful—(A) Terminated the contract or arrangement, if feasible; or (B) If termination is not feasible, reported the problem to the Secretary.

Key Activities

Description

Sample Questions

1. Contract Must Provide that Business Associates Adequately Protect EPHI114 Implementation Specification (Required)

•

Contracts between covered entities and business associates must provide that business associates will implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the EPHI that the business associate creates, receives, maintains, or transmits on behalf of the covered entity.

•

May consider asking the business associate to conduct a risk assessment that addresses administrative, technical, and physical risks, if reasonable and appropriate.

•

Does the written agreement between the covered entity and the business associate address the applicable functions related to creating, receiving, maintaining, and transmitting EPHI that the business associate is to perform on behalf of the covered entity?

2. Contract Must Provide that Business Associate's Agents Adequately Protect EPHI

Implementation Specification (Required)

•

Contracts between covered entities and business associates must provide that any agent, including a subcontractor, to whom the business associate provides such information agrees to implement reasonable and appropriate safeguards to protect it;

•

Does the written agreement address the issue of EPHI access by subcontractors and other agents of the business associate?

3. Contract Must Provide that Business Associates will Report Security Incidents Implementation Specification (Required)

Contracts between covered entities and business associates must provide that business associates will report to the covered entity any security incident of which it becomes aware.

•

Establish a reporting mechanism and a process for the business associate to use in the event of a security incident.

•

Is there a procedure in place for reporting of incidents by business associates? •

Have key business associate staff that would be the point of contact in the event of a security incident been identified?

114 Note that business associate contracts must also comply with provisions of the HIPAA Privacy Rule. See 45 CFR, Part 164 — Security and Privacy § 164.504(e) (Standard: Business associate contracts).

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An Introductory Resource Guide for Implementing the HIPAA Security Rule Key Activities

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ample Questions

4. Contract Must Provide that Business Associate Will Authorize Termination of the Contract if it has been Materially Breached

Implementation Specification (Required) • Contracts between covered entities and business associates must provide that the business associate will authorize termination of the contract by the covered entity if the covered entity determines that the business associate has violated a material term of the contract.

Establish in the written agreement with business associates the circumstances under which a violation of agreements relating to the security of EPHI constitutes a material breach of the contract.

•

Terminate the contract if:

0

the covered entity learns that the business associate has violated the contract or materially breached it, and

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It is not possible to take reasonable steps to cure the breach or end the violation, as applicable.

•

If terminating the contract is not feasible, report the problem to the Secretary of HHS. • Have standards and thresholds for termination of the contract been included in the contract?

5. Government Entities May Satisfy Business Associate Contract Requirements through Other Arrangements

Implementation Specification (Required)

If the covered entity and business associate are both governmental entities, consult § 164.314 (a)(2)(ii) of the Security Rule.

•

If both entities are governmental entities, the covered entity is in compliance with § 164.314 (a)(1) if:

0

It executes a Memorandum of Understanding (MOU) with the business associate that contains terms that accomplish the objectives of § 164.314(a)(2)(i), or o

Other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of § 164.314(a)(2)(i).

•

Do the arrangements provide protections for EPHI equivalent to those provided by the organization's business associate contracts?

•

If termination of the MOU is not possible due to the nature of the relationship between the covered entity and the business associate, are other mechanisms for enforcement available, reasonable, and appropriate?

6. Other Arrangements for Covered Entities and Business Associates.

Implementation Specification (Required)

•

If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of business associate as specified in §160.103 to a covered entity, the covered entity may permit the business associate to create, receive, maintain, or transmit electronic protected health information on its behalf to the extent necessary to comply with the legal mandate without meeting the requirements of § 164.314(a)(2)(i), provided that the covered entity attempts in good faith to obtain satisfactory assurances as required by § 164.314(a)(2)(ii)(A), and documents the attempt and the reasons that these assurances cannot be obtained.

•

Has the covered entity made a good faith attempt to obtain satisfactory assurances that the security standards required by this section are met?

•

Are attempts to obtain satisfactory assurances and the reasons assurances cannot be obtained documented?

•

Does the covered entity or its business associate have statutory obligations which require removal of the authorization of termination requirement? 49

An Introductory Resource Guide for Implementing the HIPAA Security Rule Key Activities

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escription • The covered entity may omit from its other arrangements authorization of the termination of the contract by the covered entity, as required by § 164.314(a)(2)(i)(D), if such authorization is inconsistent with the statutory obligations of the covered entity or its business associate.

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An Introductory Resource Guide for Implementing the HIPAA Security Rule 4.20.

Requirements for Group Health Plans (§ 164.314(b)(1))

HIPAA Standard: Except when the only electronic protected health information disclosed to a plan sponsor is disclosed pursuant to § 164.504(f)(1)(ii) or (iii), or as authorized under § 164.508, a group health plan must ensure that its plan documents provide that the plan sponsor will reasonably and appropriately safeguard electronic protected health information created, received, maintained, or transmitted to or by the plan sponsor on behalf of the group health plan. Key Activities Description

Sample Questions

1. Amend Plan Documents of Group Health Plan to Address Plan Sponsor's Security of EPHI

Implementation Specification (Required)

•

Amend plan documents to incorporate provisions to require the plan sponsor (e.g., an entity that sponsors a health plan) to implement administrative, technical, and physical safeguards that will reasonably and appropriately protect the confidentiality, integrity, and availability of EPHI that it creates, receives, maintains, or transmits on behalf of the group health plan.

•

Does the plan sponsor fall under the exception described in the standard? •

Do the plan documents require the plan sponsor to reasonably and appropriately safeguard EPHI?

2. Amend Plan Documents of Group Health Plan to Address Adequate Separation Implementation Specification (Required)

Amend plan documents to ensure that the adequate separation between the group health plan and plan sponsor required by §164.504(f)(2)(iii) is supported by reasonable and appropriate security measures.

•

Do plan documents address the obligation to keep EPHI secure with respect to the plan sponsor's employees, classes of employees, or other persons who will be given access to EPHI?

3. Amend Plan Documents of Group Health Plan to Address Security of EPHI Supplied to Plan Sponsors' Agents and Subcontractors Implementation Specification (Required)

Amend plan documents to incorporate provisions to require the plan sponsor to ensure that any agent, including a subcontractor, to whom it provides EPHI agrees to implement reasonable and appropriate security measures to protect the EPHI.

Do the plan documents of the group health plan address the issue of subcontractors and other agents of the plan sponsor implementing reasonable and appropriate security measures?

4. Amend Plan Documents of Group Health Plans to Address Reporting of Security Incidents

Implementation Specification (Required)

Amend plan documents to incorporate provisions to require the plan sponsor to report to the group health plan any security incident of which it becomes aware.

Establish specific policy for security incident reporting.115

Establish a reporting mechanism and a process for the plan sponsor to use in the event of a security incident.

Is there a procedure in place for security incident reporting?

Are procedures in place for responding to security incidents?

115 See Section 4.6, HIPAA Standard: Security Incident Procedures.

51

An Introductory Resource Guide for Implementing the HIPAA Security Rule 52

Policies and Procedures and Documentation Requirements 4.21.

Policies and Procedures (§ 164.316(a))

HIPAA Standard: Implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications, or other requirements of this subpart, taking into account those factors specified in § 164.306(b)(2)(i), (ii), (iii), and (iv). This standard is not to be construed to permit or excuse an action that violates any other standard, implementation specification, or other requirements of this subpart. A covered entity may change its policies and procedures at any time, provided that the changes are documented and are implemented in accordance with this subpart.

Key Activities

Description

Sample Questions

1. Create and Deploy Policies and Procedures

•

Implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications, and other requirements of the HIPAA Security Rule.

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Periodically evaluate written policies and procedures to verify that:116 o

Policies and procedures are sufficient to address the standards, implementation specifications, and other requirements of the HIPAA Security Rule.

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Policies and procedures accurately reflect the actual activities and practices exhibited by the covered entity, its staff, its systems, and its business associates.

Are reasonable and appropriate policies and procedures to comply with the standards, implementation specifications, and other requirements of the HIPAA Security Rule in place?

•

Are policies and procedures reasonable and appropriate given:

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the size, complexity, and capabilities of the covered entity;

0

the covered entity's technical infrastructure, hardware, and software security capabilities;

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the costs for security measures; and

0 41

the probability and criticality of potential risks to EPHI?

0

Do procedures exist for periodically reevaluating the policies and procedures, updating them as necessary?117

2. Update Documentation of Policy and Procedures

•

Change policies and procedures as is reasonable and appropriate, at any time, provided that the changes are documented and implemented in accordance with the requirements of the HIPAA Security Rule.

•

Should HIPAA documentation be updated in response to periodic evaluations, following security incidents, and/or after acquisitions of new technology or new procedures? As policies and procedures are changed, are new versions made available and are workforce members appropriately trained?118

116 See Section 4.8, HIPAA Standard: Evaluation.

117 See Section 4.8, HIPAA Standard: Evaluation.

118 See Section 4.22, HIPAA Standard: Documentation and Section 4.5, HIPAA Standard: Security Awareness and Training.

An Introductory Resource Guide for Implementing the HIPAA Security Rule 4.22.

Documentation (§ 164.316(b)(1))

HIPAA Standard: (i) Maintain the policies and procedures implemented to comply with this subpart in written (which may be electronic) form; and (ii) if an action, activity or assessment is required by this subpart to be documented, maintain a written (which may be electronic) record of the action, activity, or assessment.

Key Activities

Description

Sample Questions

1.

Draft, Maintain and Update Required Documentation

Document the decisions concerning the management, operational, and technical controls selected to mitigate identified risks.

•

Written documentation may be incorporated into existing manuals, policies, and other documents, or may be created specifically for the purpose of demonstrating compliance with the HIPAA Security Rule.

Are all required policies and procedures documented?

Should HIPAA Security Rule documentation be maintained by the individual responsible for HIPAA Security implementation?

Should HIPAA Security documentation updated in response to periodic evaluations, following security incidents, and/or after acquisitions of new technology or new procedures?

2.

Retain Documentation for at Least Six Years Implementation Specifications (Required)

Retain required documentation of policies, procedures, actions, activities or assessments required by the HIPAA Security Rule for six years from the date of its creation or the date when it last was in effect, whichever is later.

Have documentation retention requirements under HIPAA been aligned with the organization's other data retention policies?

3.

Assure that Documentation is Available to those Responsible for Implementation Implementation Specification (Required)

Make documentation available to those persons responsible for implementing the procedures to which the documentation pertains.

• Ta

Is the location of documentation known to all staff that needs to access it?

Is availability of the documentation made known as part of education, training and awareness activities?119

4.

Update Documentation as Required

Implementation Specification (Required)

•

Review documentation periodically, and update as needed, in response to environmental or operational changes affecting the security of the EPHI. •

Is there a version control procedure that allows verification of the timeliness of policies and procedures, if reasonable and appropriate?

•

Is there a process for soliciting input into updates of policies and procedures from staff, if reasonable and appropriate?

119 See Section 4.5, HIPAA Standard: Security Awareness and Training. 53 Appendix A: Glossary

This appendix provides definitions for those terms used within this document that are defined specifically in the HIPAA Security Rule. Definitions for basic security terms used frequently in NIST publications, including this document, are centrally located in NIST Interagency Report 7298, Glossary of Key Information Security Terms. This glossary is available on http://csrc.nist.gov.

Administrative Safeguards [45 Code of Federal Regulations (C.F.R.) Sec. 164.304] Administrative actions, and policies and procedures, to manage the selection, development, implementation, and maintenance of security measures to protect electronic protected health information and to manage the conduct of the covered entity's workforce in relation to the protection of that information. Addressable [45 C.F.R. Sec. 164.306(d)(3)]

Describing 21 of the HIPAA Security Rule's 42 implementation specifications. To meet the addressable implementation specifications, a covered entity must (i) assess whether each implementation specification is a reasonable and appropriate safeguard in its environment, when analyzed with reference to the likely contribution to protecting the entity's electronic protected health information; and

(ii) as applicable to the entity - (A) Implement the implementation specification if reasonable and appropriate; or (B) if implementing the implementation specification is not reasonable and appropriate—(1) document why it would not be reasonable and appropriate to implement the implementation specification; and (2) implement an equivalent alternative measure if reasonable and appropriate. Affiliated Covered Entities [45 C.F.R. Sec. 164.105(b)]

Legally separate covered entities that are under common ownership or control and that have all designated themselves as a single affiliated covered entity for the purposes of the Privacy and Security Rule (more precisely, those parts of the Rules appearing at 45 CFR, Part 160, Subparts C and E). Agency

[FIPS 200; 44 U.S.C, Sec. 3502]

Any executive department, military department, government corporation, government-controlled corporation, or other establishment in the executive branch of the government (including the Executive Office of the President) or any independent regulatory agency, but does not include: 1) the General Accounting Office; 2) the Federal Election Commission; 3) the governments of the District of Columbia and of the territories and possessions of the United States and their various subdivisions; or 4) government-owned, contractor-operated facilities, including laboratories engaged in national defense research and production activities. Also referred to as Federal Agency.

Authentication

The corroboration that a person is the one claimed.

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[45 C.F.R. Sec. 164.304]

Availability [45 C.F.R. Sec. 164.304]

The property that data or information is accessible and usable upon demand by an authorized person.

Business Associate [45 C.F.R. Sec. 160.103]

(1) Except as provided in paragraph (2) of this definition, "business associate" means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized healthcare arrangement (as defined at 45 C.F.R. Sec. 164.501) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:

(A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or

(B) Any other function or activity regulated by this subchapter; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in Sec. 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized healthcare arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity participating in an organized healthcare arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized healthcare arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized healthcare arrangement, does not, simply through the performance of such function or activity or the provision of such service, become a business associate of other covered entities participating in such organized healthcare arrangement.

(3) A covered entity may be a business associate of another covered entity. Confidentiality [45 C.F.R. Sec. 164.304]

The property that data or information is not made available or disclosed to unauthorized persons or processes.

Covered Entities [45 C.F.R. Sec.160.103]

Covered entity means: (1) A health plan. (2) A healthcare clearinghouse. (3) A healthcare provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter. (4) Medicare A-2

Prescription Drug Card Sponsors.

Electronic Protected Health Information (electronic PHI, or EPHI) [45 C.F.R. Sec.160.103]

Information that comes within paragraphs (1)(i) or (1)(ii) of the definition of protected health information (see "protected health information"). Healthcare Clearinghouse [45 C.F.R. Sec.160.103]

A public or private entity, including a billing service, repricing company, community health management information system or community health information system, and "value-added" networks and switches, that does either of the following functions:

(1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.

(2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

Healthcare Provider [45 C.F.R. Sec. 160.103]

A provider of services (as defined in section 1861(u) of the Social Security Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Social Security Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for healthcare in the normal course of business.

Health Information [45 C.F.R. Sec. 160.103]

Any information, whether oral or recorded in any form or medium, that:

(1) Is created or received by a healthcare provider, health plan, public health authority, employer, life insurer, school or university, or healthcare clearinghouse;

and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual.

Health Plan [45 C.F.R. Sec.160.103]

(1) Health plan includes the following, singly or in combination:

(i) A group health plan, as defined in this section.

(ii) A health insurance issuer, as defined in this section.

(iii) An HMO, as defined in this section. (iv) Part A or Part B of the Medicare program under title XVIII of the Social Security Act.

(v) The Medicaid program under title XIX of the Social Security Act, 42 U.S.C. 1396, et seq.

(vi) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Social Security Act, 42 U.S.C.

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1395ss(g)(1)).

(vii) An issuer of a long-term care policy, excluding a nursing home fixed-indemnity policy.

(viii) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(ix) The healthcare program for active military personnel under title 10 of the United States Code.

(x) The veterans' healthcare program under 38 U.S.C. chapter 17.

(xi) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) (as defined in 10 U.S.C. 1072(4)).

(xii) The Indian Health Service program under the Indian Healthcare Improvement Act, 25 U.S.C. 1601, et seq.

(xiii) The Federal Employees Health Benefits Program under 5 U.S.C. 8902, et seq.
(xiv) An approved State child health plan under title XXI of the Social Security Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Social Security Act, 42 U.S.C. 1397, et seq.

(xv) The Medicare + Choice program under Part C of title XVIII of the Social Security Act, 42 U.S.C. 1395w-21 through 1395w-28.

(xvi) A high-risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals.

(xvii) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Social Security Act, 42 U.S.C. 300gg-91(a)(2)).

(2) Health plan excludes:

(i) Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg-

91(c)(1); and

(ii) A government-funded program (other than one listed in paragraph (1)(i)-(xvi) of this definition):

(A) Whose principal purpose is other than providing, or paying the cost of,

healthcare; or

(B) Whose principal activity is:

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(1) The direct provision of healthcare to persons; or

(2) The making of grants to fund the direct provision of healthcare to persons.

Hybrid Entity [45 C.F.R. Sec.164.103]

A single legal entity:

(1) That is a covered entity;

(2) Whose business activities include both covered and non-covered functions; and

(3) That designates healthcare components in accordance with paragraph § 164.105(a)(2)(iii)(C).

Implementation Specification [45 C.F.R. Sec. 160.103]

Specific requirements or instructions for implementing a standard.

Individually Identifiable Health Information (IIHI) [45 C.F.R. Sec. 160.103]

Information that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a healthcare provider, health plan, employer, or healthcare clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Information System [45 C.F.R. Sec. 164.304]

An interconnected set of information resources under the same direct management control that shares common functionality. A system normally includes hardware, software, information, data, applications, communications, and people.120

Integrity [45 C.F.R. Sec. 164.304]

The property that data or information have not been altered or destroyed in an unauthorized manner.

Medicare Prescription Drug Card Sponsors

[Pub. L. 108-173]

A nongovernmental entity that offers an endorsed discount drug program under the Medicare Modernization Act.

Physical Safeguards [45 C.F.R. Sec. 164.304]

Physical measures, policies, and procedures to protect a covered entity's electronic information systems and related buildings and equipment from natural and environmental hazards, and unauthorized intrusion.

Protected Health Information (PHI)

Individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that

120 FISMA defines "information system" as "a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information." 44 U.S.C., Sec. 3502.

[45 C.F.R., Sec. 160.103]

is:

(i) Transmitted by electronic media;

(ii) Maintained in electronic media; or

(iii) Transmitted or maintained in any other form or medium. (2) Protected health

information excludes individually identifiable health information in:

(i) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;

(ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and

(iii) Employment records held by a covered entity in its role as employer.

Required [45 C.F.R. Sec. 164.306(d)(2]

As applied to an implementation specification (see implementation specification, above], indicating an implementation specification that a covered entity must implement. All implementation specifications are either required or addressable (see "addressable" above).

Security [44 U.S.C., Sec. 3542]

Protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide—

(A) integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;

(B) confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and (C) availability, which means ensuring timely and reliable access to and use of information. Standard [45 C.F.R., Sec. 160.103] A rule, condition, or requirement: (1) Describing the following information for products, systems, services or practices: (i) Classification of components. (ii) Specification of materials, performance, or operations; or (iii) Delineation of procedures; or (2) With respect to the privacy of individually identifiable health information. Technical Safeguards [45 C.F.R., Sec. 164.304] The technology and the policy and procedures for its use that protect electronic protected health information and control access to it. User [45 C.F.R., Sec. 164.304] A person or entity with authorized access. A-6 **B-1 Appendix B: Acronyms** The appendix lists acronyms used within this document. AC Access Control (NIST SP 800-53 security control family) AT Awareness and Training (NIST SP 800-53 security control family) AU Audit and Accountability (NIST SP 800-53 security control family) BAC **Business Associate Contract** CA Certification, Accreditation, and Security Assessments (NIST SP 800-53 security control family) C&A **Certification and Accreditation** CFR **Code of Federal Regulations** CIO **Chief Information Officer** CM **Configuration Management (NIST SP 800-53 security control family)** CMS **Centers for Medicare and Medicaid Services** CP **Contingency Planning (NIST SP 800-53 security control family)** CSD **Computer Security Division** DHHS **Department of Health and Human Services** EPHI **Electronic Protected Health Information FISMA Federal Information Security Management Act**

FIPS **Federal Information Processing Standard** HHS **Department of Health and Human Services HIPAA** Health Insurance Portability and Accountability Act IA Identification and Authentication (NIST SP 800-53 security control family) ID Identification IR Incident Response (NIST SP 800-53 security control family) ISP **Internet Service Provider** IT **Information Technology** ITL **Information Technology Laboratory** LAN **Local Area Network** MA Maintenance (NIST SP 800-53 security control family) MOU **Memorandum of Understanding** MP Media Protection (NIST SP 800-53 security control family) NIST National Institute of Standards and Technology NISTIR **NIST Interagency Report OESS Office of E-Health Standards and Services** OIG **Office of the Inspector General** OMB **Office of Management and Budget** PE Physical and Environmental Protection (NIST SP 800-53 security control family) PHI **Protected Health Information** PKI **Public Key Infrastructure** PL Planning (NIST SP 800-53 security control family) PS Personnel Security (NIST SP 800-53 security control family) RA **Risk Assessment (NIST SP 800-53 security control family)** SA System and Services Acquisition (NIST SP 800-53 security control family) SC

System and Communications Protection (NIST SP 800-53 security control family) SI System and Information Integrity (NIST SP 800-53 security control family) SP **Special Publication US-CERT United States Computer Emergency Response Team** US **United States Appendix C: References Public Laws** Public Law 107-347, E-Government Act of 2002 (Title III: Federal Information Security Management Act [FISMA] of 2002), December 17, 2002. Public Law 104-191, Health Insurance Portability and Accountability Act (HIPAA) of 1996, August 21, 1996. **Federal Regulations** Health Insurance Reform: Security Standards; Final Rule ("The HIPAA Security Rule"), 68 FR 8334, February 20, 2003. Federal Information Processing Standards (FIPS) Publications FIPS 140-2, Security Requirements for Cryptographic Modules, June 2001. FIPS 199, Standards for Security Categorization of Federal Information and Information Systems, February 2004. FIPS 200, Minimum Security Requirements for Federal Information and Information Systems, March 2006. FIPS 201-1, Personal Identity Verification (PIV) of Federal Employees and Contractors, March 2006. **NIST Special Publications (SPs)** NIST SP 800-12, An Introduction to Computer Security: The NIST Handbook, October 1995. NIST SP 800-14, Generally Accepted Principles and Practices for Securing Information Technology Systems, September 1996. NIST SP 800-16, Information Technology Security Training Requirements: A Role-And Performance-Based Model, April 1998. NIST SP 800-18 Revision 1, Guide for Developing Security Plans for Information Technology Systems, February 2006. NIST SP 800-21, Guideline for Implementing Cryptography in the Federal Government, December 2005. NIST SP 800-30, Risk Management Guide for Information Technology Systems, January 2002. NIST SP 800-34, Contingency Planning Guide for Information Technology Systems, June 2002. NIST SP 800-35, Guide to Information Technology Security Services, October 2003. NIST 800-37, DRAFT Guide for Security Authorization of Federal Information Systems: A Security Lifecycle Approach, August 2008. NIST SP 800-39, DRAFT Managing Risk from Information Systems: An **Organizational Perspective, April 2008.** NIST SP 800-41, Guidelines on Firewalls and Firewall Policy, January 2002. NIST SP 800-42, Guideline on Network Security Testing, October 2003. NIST SP 800-45, Version 2, Guidelines on Electronic Mail Security, February 2007. C-1

NIST SP 800-46, Security for Telecommuting and Broadband Communications, August 2002.

NIST SP 800-47, Security Guide for Interconnecting Information Technology Systems, September 2002.

NSIT SP 800-48, Revision 1, Guide to Securing Legacy IEEE 802.11 Wireless Networks, July 2008.

NIST SP 800-50, Building an Information Technology Security Awareness and Training Program, October 2003.

NIST SP 800-52, Guidelines for the Selection and Use of Transport Layer Security (TLS) Implementations, June 2005.

NIST SP 800-53, Revision 2, Recommended Security Controls for Federal Information Systems, December 2007.

NIST SP 800-53A, Guide for Assessing the Security Controls in Federal Information Systems, June 2008.

NIST SP 800-55, Revision 1, Performance Measurement Guide for Information Security, July 2008.

NIST SP 800-58, Security Considerations for Voice Over IP Systems, January 2005. NIST SP 800-60, Revision 1, Guide for Mapping Types of Information and

Information Systems to Security Categories, July 2008.

NIST SP 800-61, Revision 1, Computer Security Incident Handling Guide, March 2008.

NIST SP 800-63-1, DRAFT Electronic Authentication Guide, February 2008.

NIST SP 800-64 Revision 2, Security Considerations in the Information Systems Development Life Cycle, October 2008.

NIST SP 800-77, Guide to IPsec VPNs, December 2005.

NIST SP 800-81, Secure Domain Name System (DNS) Deployment Guide, May 2006.

NIST SP 800-83, Guide to Malware Incident Prevention and Handling, November 2005.

NIST SP 800-84, Guide to Test, Training, and Exercise Programs for IT Plans and Capabilities, September 2006.

NIST SP 800-86, Guide to Integrating Forensic Techniques into Incident Response, August 2006.

NIST SP 800-88, Guidelines for Media Sanitization, September 2006.

NIST SP 800-92, Guide to Computer Security Log Management, September 2006.

NIST SP 800-94, Guide to Intrusion Detection and Prevention Systems (IDPS), February 2007.

NIST SP 800-100, Information Security Handbook: A Guide for Managers, October 2006.

NIST SP 800-106, DRAFT Randomized Hashing Digital Signatures, July 2008.

NIST SP 800-107, DRAFT Recommendation for Using Approved Hash Algorithms, July 2008.

NIST SP 800-111, Guide to Storage Encryption Technologies for End User Devices, November 2007.

NIST SP 800-113, Guide to SSL VPNs, July 2008.

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NIST SP 800-114, User's Guide to Securing External Devices for Telework and Remote Access, November 2007.

NIST SP 800-115, Technical Guide to Information Security Testing, November 2007.

NIST SP 800-124, DRAFT Guidelines on Cell Phone and PDA Security, July 2008. **NIST Interagency Reports (NISTIRs)** NISTIR 7298, Glossary of Key Information Security Terms, April 2006. **CMS HIPAA Security Series Publications** Security 101 for Covered Entities, March 2007. Security Standards Administrative Safeguards, March 2007. Security Standards Physical Safeguards, March 2007. Security Standards Technical Safeguards, March 2007. Security Standards Organizational Policies, March 2007. Basics of Risk Analysis and Risk Management, March 2007. HIPAA Security Guidance for Remote Use of and Access to Electronic Protected Health Information, December 2006 Web sites and Other Resources NIST: Computer Security Resource Center (CSRC): http://csrc.nist.gov/ NIST: National Vulnerability Database (NVD): http://nvd.nist.gov/ **Guide to NIST Information Security Documents:** http://csrc.nist.gov/publications/CSD_DocsGuide.pdf Department of Health and Human Services (DHHS), Centers for Medicare and Medicaid Services (CMS), HIPAA Resources: http://www.cms.hhs.gov/hipaa/hipaa2. Workgroup for Electronic Data Interchange (WEDI): http://www.wedi.org **Appendix D: Security Rule Standards and Implementation Specifications** Crosswalk Appendix D provides a catalog (see Table 4) of the HIPAA Security Rule standards and implementation specifications within the Administrative, Physical, and Technical Safeguards sections of the Security Rule. Additionally, this catalog crosswalks, or maps, those Security Rule standards and implementation specifications to NIST publications relevant to each Security Rule standard, and to applicable security controls detailed in NIST SP 800-53, Recommended Security Controls for Federal Information Systems. Readers may draw upon these NIST publications and security controls for consideration in implementing the Security Rule. The catalog is organized according to the categorization of standards within each of the safeguards sections in the Security Rule. Table 3 provides an overview of the catalog content. **Table 3. Overview of Catalog Content Column Headers** Description Section of HIPAA Security Rule Indicates the regulatory citation to the appropriate section of the Security Rule where the standard and implementation specification can be found. **Standards** Lists the Security Rule Standards. **Implementation Specifications** Lists the implementation specifications associated with the standard, if any exist, and designates the specification as required or addressable. ($\mathbf{R} = \mathbf{Required}, \mathbf{A} =$ Addressable) NIST SP 800-53 Security Controls Mapping Provides a listing of NIST SP 800-53 security controls that may provide value when implementing the particular standards and implementation specifications. For full

security control specifications, refer to NIST SP 800-53, which can be found online at http://csrc.nist.gov.

NIST Publications Crosswalk

Provides a listing of NIST publications that support each particular standard. Publications are listed by publication number. For the full publication title, refer to Appendix C: References within this document, or to the Guide to NIST Information Security Documents located on the NIST Computer Security Resource Center (CSRC) Web site at http://csrc.nist.gov.

The mapping of SP 800-53 security controls to Security Rule standards and implementation specifications is of particular importance because it allows for the traceability of legislative and regulatory directives, such as HIPAA and FISMA, to underlying technical security configurations. This mapping can also enable standards-based measurement and monitoring of technical security safeguards and computer security configurations; facilitate compliance management by automating portions of D-1

D-2

compliance demonstration and reporting; and reduce the chance of misinterpretation between auditors and operations teams.

To accomplish this automation, NIST has defined, and maintains, the Security Content Automation Protocol (SCAP),121 a suite of selected and integrated open standards that enable standards-based communication of vulnerability data, customizing and managing configuration baselines for various IT products, assessing information systems and reporting compliance status, using standard measures to weigh and aggregate potential vulnerability impact, and remediating identified vulnerabilities.

121 More information on the Security Content Automation Protocol (SCAP) is available on the National Vulnerability Web site, http://nvd.nist.gov.

Table 4. HIPAA Standards and Implementation Specifications Catalog

Section of HIPAA Security Rule

HIPAA Security Rule Standards

Implementation Specifications

NIST SP 800-53 Security Controls Mapping

NIST Publications Crosswalk

Administrative Safeguards

164.308(a)(1)(i)

Security Management Process: Implement policies and procedures to prevent, detect, contain, and correct security violations.

RA-1

164.308(a)(1)(ii)(A)

Risk Analysis (R): Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity.

RA-2, RA-3, RA-4

164.308(a)(1)(ii)(B)

Risk Management (R): Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with Section 164.306(a).

RA-2, RA-3, RA-4, PL-6

164.308(a)(1)(ii)(C)

Sanction Policy (R): Apply appropriate sanctions against workforce members who fail to comply with the security policies and procedures of the covered entity.

PS-8

164.308(a)(1)(ii)(D)

Information System Activity Review (R): Implement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports.

AU-6, AU-7, CA-7, IR-5, IR-6, SI-4 FIPS 199 NIST SP 800-14 NIST SP 800-18

NIST SP 800-30 NIST SP 800-37 NIST Draft SP 800-39 NIST SP 800-42 NIST SP 800-53 NIST SP 800-55 NIST SP 800-60 NIST SP 800-84 NIST SP 800-92

NIST SP 800-100 164.308(a)(2)

Assigned Security Responsibility: Identify the security official who is responsible for the development and implementation of the policies and procedures required by this subpart for the entity.

CA-4, CA-6

NIST SP 800-12 NIST SP 800-14 NIST SP 800-37 NIST SP 800-53 NIST SP 800-53A NIST SP 800-100

D-3

HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping

164.308(a)(3)(i)

Workforce Security: Implement policies and procedures to ensure that all members of its workforce have appropriate access to electronic protected health information, as provided under paragraph (a)(4) of this section, and to prevent those workforce members who do not have access under paragraph (a)(4) of this section from obtaining access to electronic protected health information.

AC-1, AC-5, AC-6

164.308(a)(3)(ii)(A)

Authorization and/or Supervision (A): Implement procedures for the authorization and/or supervision of workforce members who work with electronic protected health information or in locations where it might be accessed.

AC-1, AC-3, AC-4, AC-13, MA-5, MP-2, PS-1, PS-6, PS-7

164.308(a)(3)(ii)(B)

Workforce Clearance Procedure (A): Implement procedures to determine that the access of a workforce member to electronic protected health information is appropriate.

AC-2, PS-1, PS-2, PS-3, PS-6

164.308(a)(3)(ii)(C)

Termination Procedure (A): Implement procedures for terminating access to electronic protected health information when the employment of a workforce member ends or as required by determinations made as specified in paragraph (a)(3)(ii)(B) of this section.

PS-1, PS-4, PS-5 NIST SP 800-12 NIST SP 800-14 NIST SP 800-53 164.308(a)(4)(i) Information Access Management: Implement policies and procedures for authorizing access to electronic protected health information that are consistent with the applicable requirements of subpart E of this part. AC-1, AC-2, AC-5, AC-6, AC-13 NIST SP 800-12 **NIST SP 800-14 NIST SP 800-18 NIST SP 800-53 NIST SP 800-63 D-4** HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping 164.308(a)(4)(ii)(A) Isolating Healthcare Clearinghouse Functions (R): If a healthcare clearinghouse is part of a larger organization, the clearinghouse must implement policies and procedures that protect the electronic protected health information of the clearinghouse from unauthorized access by the larger organization. AC-5, AC-6 164.308(a)(4)(ii)(B) Access Authorization (A): Implement policies and procedures for granting access to electronic protected health information, for example, through access to a workstation, transaction, program, process, or other mechanism. AC-1, AC-2, AC-3, AC-4, AC-13, PS-6, PS-7 164.308(a)(4)(ii)(C) Access Establishment and Modification (A): Implement policies and procedures that, based upon the entity's access authorization policies, establish, document, review, and modify a user's right of access to a workstation, transaction, program, or process. AC-1, AC-2, AC-3 **NIST SP 800-100** 164.308(a)(5)(i)Security Awareness and Training: Implement a security awareness and training program for all members of its workforce (including management). AT-1, AT-2, AT-3, AT-4, AT-5 164.308(a)(5)(ii)(A) Security Reminders (A): Periodic security updates. AT-2, AT-5, SI-5 164.308(a)(5)(ii)(B)

Protection from Malicious Software (A): Procedures for guarding against, detecting, and reporting malicious software. AT-2, SI-3, SI-4, SI-8 164.308(a)(5)(ii)(C) Log-in Monitoring (A): Procedures for monitoring log-in attempts and reporting discrepancies. AC-2, AC-13, AU-2, AU-6 164.308(a)(5)(ii)(D) Password Management (A): Procedures for creating, changing, and safeguarding passwords. IA-2, IA-4, IA-5, IA-6, IA-7 NIST SP 800-12 **NIST SP 800-14 NIST SP 800-16 NIST SP 800-50 NIST SP 800-61 NIST SP 800-83 D-5** HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSvP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping 164.308(a)(6)(i) Security Incident Procedures: Implement policies and procedures to address security incidents. **IR-1, IR-2, IR-3** 164.308(a)(6)(ii) Response and Reporting (R): Identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents that are known to the covered entity; and document security incidents and their outcomes. IR-4, IR-5, IR-6, IR-7 **NIST SP 800-12 NIST SP 800-14 NIST SP 800-61 NIST SP 800-83 NIST SP 800-86 NIST SP 800-94** 164.308(a)(7)(i) Contingency Plan: Establish (and implement as needed) policies and procedures for responding to an emergency or other occurrence (for example, fire, vandalism, system failure, and natural disaster) that damages systems that contain electronic protected health information. **CP-1** 164.308(a)(7)(ii)(A) Data Backup Plan (R): Establish and implement procedures to create and maintain retrievable exact copies of electronic protected health information. **CP-9** 164.308(a)(7)(ii)(B) Disaster Recovery Plan (R): Establish (and implement as needed) procedures to restore any loss of data.

CP-2, CP-6, CP-7, CP-8, CP-9, CP-10 164.308(a)(7)(ii)(C) **Emergency Mode Operation Plan (R): Establish (and implement as needed)** procedures to enable continuation of critical business processes for protection of the security of electronic protected health information while operating in emergency mode. **CP-2, CP-10 FIPS 199 NIST SP 800-12 NIST SP 800-14 NIST SP 800-18 NIST SP 800-30 NIST SP 800-34 NIST SP 800-60 NIST SP 800-84 D-6**

HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r503ls NISTC rPoussbwliacalkti ons Rule Mapping

164.308(a)(7)(ii)(D)

Testing and Revision Procedure (A): Implement procedures for periodic testing and revision of contingency plans.

CP-3, CP-4, CP-5

164.308(a)(7)(ii)(E)

Applications and Data Criticality Analysis (A): Assess the relative criticality of specific applications and data in support of other contingency plan components. RA-2, CP-2

164.308(a)(8)

Evaluation: Perform a periodic technical and nontechnical evaluation, based initially upon the standards implemented under this rule and subsequently, in response to environmental or operational changes affecting the security of electronic protected health information that establishes the extent to which an entity's security policies and procedures meet the requirements of this subpart.

CA-1, CA-2, CA-4, CA-6, CA-7

NIST SP 800-12 NIST SP 800-14 NIST SP 800-37 NIST SP 800-42 NIST SP 800-53A NIST SP 800-55 NIST SP 800-84 NIST SP 800-115 164.308(b)(1)

Business Associate Contracts and Other Arrangements: A covered entity, in accordance with § 164.306, may permit a business associate to create, receive, maintain, or transmit electronic protected health information on the covered entity's behalf only if the covered entity obtains satisfactory assurances, in accordance with Sec. 164.314(a), that the business associate will appropriately safeguard the information.

CA-3, PS-7, SA-9 NIST SP 800-12 **NIST SP 800-14 NIST SP 800-37** NIST SP 800-47 **NIST SP 800-100 D-7** HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSvP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping 164.308(b)(4) Written Contract or Other Arrangement (R): Document the satisfactory assurances required by paragraph (b)(1) of this section through a written contract or other arrangement with the business associate that meets the applicable requirements of § 164.314(a). CA-3, SA-9 **Physical Safeguards** 164.310(a)(1) Facility Access Controls: Implement policies and procedures to limit physical access to its electronic information systems and the facility or facilities in which they are housed, while ensuring that properly authorized access is allowed. PE-1, PE-2, PE-3, PE-4, PE-5 164.310(a)(2)(i) Contingency Operations (A): Establish (and implement as needed) procedures that allow facility access in support of restoration of lost data under the disaster recovery plan and emergency mode operations plan in the event of an emergency. CP-2, CP-6, CP-7, PE-17 164.310(a)(2)(ii) Facility Security Plan (A): Implement policies and procedures to safeguard the facility and the equipment therein from unauthorized physical access, tampering, and theft. PE-1, PL-2, PL-6 164.310(a)(2)(iii) Access Control and Validation Procedures (A): Implement procedures to control and validate a person's access to facilities based on their role or function, including visitor control, and control of access to software programs for testing and revision. AC-3, PE-1, PE-2, PE-3, PE-6, PE-7, PE-8 **NIST SP 800-12 NIST SP 800-14 NIST SP 800-18 NIST SP 800-30 NIST SP 800-34 NIST SP 800-53 D-8** HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSvP C 800n0t-r503ls NISTC rPoussbwliacalkti ons Rule Mapping 164.310(a)(2)(iv) Maintenance Records (A): Implement policies and procedures to document repairs and modifications to the physical components of a facility which are related to security (for example, hardware, walls, doors, and locks). MA-1122, MA-2, MA-6 164.310(b)

Workstation Use: Implement policies and procedures that specify the proper functions to be performed, the manner in which those functions are to be performed, and the physical attributes of the surroundings of a specific workstation or class of workstation that can access electronic protected health information. AC-3, AC-4, AC-11, AC-12, AC-15, AC-16, AC-17, AC-19, PE-3, PE-5, PS-6 NIST SP 800-12 **NIST SP 800-14 NIST SP 800-53** 164.310(c) Workstation Security: Implement physical safeguards for all workstations that access electronic protected health information to restrict access to authorized users. MP-2, MP-3, MP-4, PE-3, PE-4, PE-5, PE-18 NIST SP 800-12 **NIST SP 800-14** NIST SP 800-53 164.310(d)(1) Device and Media Controls: Implement policies and procedures that govern the receipt and removal of hardware and electronic media that contain electronic protected health information into and out of a facility, and the movement of these items within the facility. CM-8, MP-1, MP-2, MP-3, MP-4, MP-5, MP-6 NIST SP 800-12 **NIST SP 800-14 NIST SP 800-34** NIST SP 800-53 **NIST SP 800-88** 122 In NIST SP 800-53, the Maintenance security control family discusses maintenance activities relating to information systems. The same principles, however, can be applied to facility maintenance. **D-9** HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping 164.310(d)(2)(i) Disposal (R): Implement policies and procedures to address the final disposition of electronic protected health information and/or the hardware or electronic media on which it is stored. **MP-6** 164.310(d)(2)(ii) Media Reuse (R): Implement procedures for removal of electronic protected health information from electronic media before the media are made available for reuse. **MP-6** 164.310(d)(2)(iii) Accountability (A): Maintain a record of the movements of hardware and electronic media and any person responsible therefore. CM-8, MP-5, PS-6 164.310(d)(2)(iv) Data Backup and Storage (A): Create a retrievable exact copy of electronic protected health information, when needed, before movement of equipment. **CP-9, MP-4 Technical Safeguards**

164.312(a)(1)

Access Control: Implement technical policies and procedures for electronic information systems that maintain electronic protected health information to allow access only to those persons or software programs that have been granted access rights as specified in § 164.308(a)(4). AC-1, AC-3, AC-5, AC-6 164.312(a)(2)(i)Unique User Identification (R): Assign a unique name and/or number for identifying and tracking user identity. AC-2, AC-3, IA-2, IA-3, IA-4 164.312(a)(2)(ii) Emergency Access Procedure (R): Establish (and implement as needed) procedures for obtaining necessary electronic protected health information during an emergency. AC-2, AC-3, CP-2 **NIST SP 800-12 NIST SP 800-14 NIST SP 800-21 NIST SP 800-34 NIST SP 800-53 NIST SP 800-63 FIPS 140-2 D-10** HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping 164.312(a)(2)(iii) Automatic Logoff (A): Implement electronic procedures that terminate an electronic session after a predetermined time of inactivity. AC-11, AC-12 164.312(a)(2)(iv) **Encryption and Decryption (A): Implement a mechanism to encrypt and decrypt** electronic protected health information. AC-3, SC-13 164.312(b) Audit Controls: Implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information. AU-1, AU-2, AU-3, AU-4, AU-6, AU-7 **NIST SP 800-12 NIST SP 800-14 NIST SP 800-42 NIST SP 800-53** NIST SP 800-53A **NIST SP 800-55 NIST SP 800-92 NIST SP 800-115** 164.312(c)(1)Integrity: Implement policies and procedures to protect electronic protected health information from improper alteration or destruction.

CP-9, MP-2, MP-5, SC-8, SI-1, SI-7

164.312(c)(2)

Mechanism to Authenticate Electronic Protected Health Information (A): Implement electronic mechanisms to corroborate that electronic protected health information has not been altered or destroyed in an unauthorized manner. SC-8, SI-7 **NIST SP 800-12 NIST SP 800-14** NIST SP 800-53 NIST Draft SP 800-106 NIST Draft SP 800-107 164.312(d) Person or Entity Authentication: Implement procedures to verify that a person or entity seeking access to electronic protected health information is the one claimed. IA-2. IA-3. IA-4 **FIPS 201 NIST SP 800-12 NIST SP 800-14** NIST SP 800-53 NIST SP 800-63 **D-11** HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping 164.312(e)(1) Transmission Security: Implement technical security measures to guard against unauthorized access to electronic protected health information that is being transmitted over an electronic communications network. **SC-9** 164.312(e)(2)(i) Integrity Controls (A): Implement security measures to ensure that electronically transmitted electronic protected health information is not improperly modified without detection until disposed of. SC-8, SI-7 164.312(e)(2)(ii) **Encryption** (A): Implement a mechanism to encrypt electronic protected health information whenever deemed appropriate. SC-9, SC-12, SC-13 **FIPS 140-2 NIST SP 800-12 NIST SP 800-14** NIST SP 800-21 **NIST SP 800-24** NIST SP 800-41 **NIST SP 800-42** NIST SP 800-45 NIST SP 800-46 NIST SP 800-48 NIST SP 800-52 NIST SP 800-53 **NIST SP 800-58 NIST SP 800-63**

NIST SP 800-77

NIST SP 800-81 NIST SP 800-113 Organizational D-12 HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping 164.314(a)(1) Business Associate Contracts or Other Arrangements: (i) The contract or other arrangement between the covered entity and its business associate required by § 164.308(b) must meet the requirements of paragraph (a)(2)(i) or (a)(2)(ii) of this section, as applicable. (ii) A covered entity is not in compliance with the standards in § 164.502(e) and paragraph (a) of this section if the covered entity knew of a pattern of an activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful—(A) Terminated the contract or arrangement, if feasible; or (B) If termination is not feasible, reported the problem to the Secretary. PS-6, PS-7, SA-9 **NIST SP 800-35** NIST Draft SP 800-39 **NIST SP 800-47 NIST SP 800-64**

NIST SP 800-100

D-13

HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping

164.314(a)(2)(i)

Business Associate Contracts (R): The contract between a covered entity and a business associate must provide that the business associate will-- (A) Implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits on behalf of the covered entity as required by this subpart; (B) Ensure that any agent, including a subcontractor, to whom it provides such information agrees to implement reasonable and appropriate safeguards to protect it; (C) Report to the covered entity any security incident of which it becomes aware; (D) Authorize termination of the contract by the covered entity if the covered entity determines that the business associate has violated a material term of the contract. IR-6, PS-6, PS-7, SA-4, SA-9

164.314(a)(2)(ii)

Other Arrangements: When a covered entity and its business associate are both governmental entities, the covered entity is in compliance with paragraph (a)(1) of this section, if-- (1) It enters into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of paragraph (a)(2)(i) of this section; or (2) Other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of paragraph (a)(2)(i) of that accomplish the objectives of paragraph (a)(2)(i) of this section. CA-3, PS-6, PS-7, SA-9

D-14

HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping

164.314(b)(1)

Requirements for Group Health Plans: Except when the only electronic protected health information disclosed to a plan sponsor is disclosed pursuant to § 164.504(f)(1)(ii) or (iii), or as authorized under § 164.508, a group health plan must ensure that its plan documents provide that the plan sponsor will reasonably and appropriately safeguard electronic protected health information created, received, maintained, or transmitted to or by the plan sponsor on behalf of the group health plan.

Does not map

164.314(b)(2)(i)

Group Heath Plan Implementation Specification (R): The plan documents of the group health plan must be amended to incorporate provisions to require the plan sponsor to-- (i) Implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits on behalf of the group health plan.

Does not map

164.314(b)(2)(ii)

Group Heath Plan Implementation Specification (R): The plan documents of the group health plan must be amended to incorporate provisions to require the plan sponsor to-- (ii) Ensure that the adequate separation required by § 164.504(f)(2)(iii) is supported by reasonable and appropriate security measures.

Does not map NIST SP 800-35 NIST Draft SP 800-39 NIST SP 800-47 NIST SP 800-61 NIST SP 800-64 NIST SP 800-100

D-15

HIPSAecAti oSnec oufr ity HIPAA Security Rule Standards Implementation Specifications SNecIuSrTi tSyP C 800n0t-r5o3ls NISTC rPoussbwliacalkti ons Rule Mapping

164.314(b)(2)(iii)

Group Heath Plan Implementation Specification (R): The plan documents of the group health plan must be amended to incorporate provisions to require the plan sponsor to-- (iii) Ensure that any agent, including a subcontractor, to whom it provides this information, agrees to implement reasonable and appropriate security measures to protect the information.

Does not map

164.314(b)(2)(iv)

Group Heath Plan Implementation Specification (R): The plan documents of the group health plan must be amended to incorporate provisions to require the plan sponsor to-- (iv) Report to the group health plan any security incident of which it becomes aware.

Does not map

Policies and Procedure and Documentation Requirements 164.316(a)

Policies and Procedures: Implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications, or other requirements of this subpart, taking into account those factors specified in § 164.306(b)(2)(i), (ii), (iii), and (iv). This standard is not to be construed to permit or excuse an action that violates any other standard, implementation specification, or other requirements of this subpart. A covered entity may change its policies and procedures at any time, provided that the changes are documented and are implemented in accordance with this subpart.

PL-1, PL-2, PL-3, RA-1, RA-3 **NIST SP 800-12 NIST SP 800-14 NIST SP 800-100 D-16 D-17** Section of **HIPAA Security** Rule **HIPAA Security Rule Standards Implementation Specifications** NIST SP 800-53 **Security Controls** Mapping **NIST Publications** Crosswalk 164.316(b)(1) **Documentation:** (i) Maintain the policies and procedures implemented to comply with this subpart in written (which may be electronic) form; and (ii) If an action, activity or assessment is required by this subpart to be documented, maintain a written (which may be electronic) record of the action, activity, or assessment. **PL-2** 164.316(b)(2)(i) Time Limit (R): Retain the documentation required by paragraph (b)(1) of this section for six years from the date of its creation or the date when it last was in effect, whichever is later. **Does not map** 164.316(b)(2)(ii) Availability (R): Make documentation available to those persons responsible for implementing the procedures to which the documentation pertains. **Does not map** 164.316(b)(2)(iii) Updates (R): Review documentation periodically, and update as needed, in response to environmental or operational changes affecting the security of the electronic protected health information. PL-3 **NIST SP 800-18 NIST SP 800-53** NIST SP 800-53A **Appendix E: Risk Assessment Guidelines** This appendix incorporates risk assessment concepts and processes described in NIST SP 800-30 Revision 1, Effective Use of Risk Assessments in Managing

Enterprise Risk, the NIST Risk Management Framework, and the HIPAA Security Series: Basics of Risk Analysis and Risk Management. It is intended to assist covered entities in identifying and mitigating risks to acceptable levels. The purpose of a risk assessment is to identify conditions where EPHI could be disclosed without proper authorization, improperly modified, or made unavailable when needed. This information is then used to make risk management decisions on whether the HIPAA-required implementation specifications are sufficient or what additional addressable implementation specifications are needed to reduce risk to an acceptable level.

Key Terms Defined

When talking about risk, it is important that terminology be defined and clearly understood. This section defines important terms associated with risk assessment and management.

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Risk is the potential impact that a threat can have on the confidentiality, integrity, and availability on EPHI by exploiting a vulnerability.

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Threats are anything that can have a negative impact on EPHI. Threats are: o

Intentional (e.g., malicious intent); or

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Unintentional (e.g., misconfigured server, data entry error).

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Threat sources are:

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Natural (e.g., floods, earthquakes, storms, tornados);

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Human (e.g., intentional such as identity thieves, hackers, spyware authors; unintentional such as data entry error, accidental deletions); or

0

Environmental (e.g., power surges and spikes, hazmat contamination, environmental pollution).

•

Vulnerabilities are a flaw or weakness in a system security procedure, design, implementation, or control that could be intentionally or unintentionally exercised by a threat.

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Impact is a negative quantitative and/or qualitative assessment of a vulnerability being exercised on the confidentiality, integrity, and availability of EPHI. It can be easy to confuse vulnerabilities and threats. An organization may be vulnerable to damage from power spikes. The threats that could exploit this vulnerability may be overloaded circuits, faulty building wiring, dirty street power, or too much load on the local grid. It is important to separate these two terms in order to assist in proper security control selection. In this example, security controls could range from installing UPS systems, additional fuse boxes, or standby generators, or rewiring the office. These E-1

additional security controls may help to mitigate the vulnerability but not necessarily for each threat.

HIPAA Risk Assessment Requirements

Standard 164.308(a)(1)(i), Security Management Process, requires covered entities to:

Implement policies and procedures to prevent, detect, contain, and correct security violations.

The Security Management Process standard includes four required implementation specifications. Two of these specifications deal directly with risk analysis and risk management.

1.

Risk Analysis (R123) – 164.308(a)(1)(ii)(A): Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity.

2.

Risk Management (R) - 163.308(a)(1)(ii)(B): Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with Section 164.306(a).

How to Conduct the Risk Assessment:

Risk assessments can be conducted using many different methodologies. There is no single methodology that will work for all organizations and all situations. The following steps represent key elements in a comprehensive risk assessment program, and provide an example of the risk assessment methodology described in NIST SP 800-30. It is expected that these steps will be customized to most effectively identify risk for an organization based on its own uniqueness. Even though these items are listed as steps, they are not prescriptive in the order that they should be conducted. Some steps can be conducted simultaneously rather than sequentially. 1.

Scope the Assessment. The first step in assessing risk is to define the scope of the effort, resulting in a general characterization of the information system, its operating environment, and its boundary. To do this, it is necessary to identify where EPHI is created, received, maintained, processed, or transmitted. The scope of a risk assessment should include both the physical boundaries of a covered entity's location as well as a logical boundary covering the media containing EPHI, regardless of its location. Ensure that the risk assessment scope takes into consideration the remote work force and telecommuters, and removable media and portable computing devices (e.g., laptops, removable media, and backup media). 2.

Gather Information. During this step, the covered entity should identify: •

The conditions under which EPHI is created, received, maintained, processed, or transmitted by the covered entity; and

123 "R" indicates a required implementation specification. E-2 •

The security controls currently being used to protect the EPHI.

This step is essential to ensure that vulnerabilities and threats are correctly identified. For example, an invalidated belief that a policy is being followed can miss a potential vulnerability, and not knowing about portable media containing EPHI can miss a threat to that environment. The level of effort needed to gather the necessary information depends heavily on the scope of the assessment and the size of the covered entity.

3.

Identify Realistic Threats. Often performed simultaneously with step 4, Identify Potential Vulnerabilities, the goal of this step is to identify the potential threat sources and compile a threat statement listing potential threat-sources that are applicable to the covered entity and its operating environment. The listing of threat sources should include realistic and probable human and natural incidents that can have a negative impact on an organizations ability to protect EPHI. Threats can be easily identified by examining the environments where EPHI is being used. Many external sources can be used for threat identification. Internet searches, vendor information, insurance data, and crime statistics are all viable sources of threat data. Examples of some common threat sources are listed in Table 5 below. Table 5. Common Threat Sources

Туре

Examples

Natural

Floods, earthquakes, tornados, landslides, avalanches, electrical storms, and other such events

Human

Events that are either enabled by or caused by human beings, such as unintentional acts (inadvertent data entry) or deliberate actions (network-based attacks, malicious software upload, and unauthorized access to confidential information) Environmental

Long-term power failure, pollution, chemicals, liquid leak 4.

Identify Potential Vulnerabilities. Often performed simultaneously with step 3, Identify Realistic Threats, the goal of this step is to develop a list of vulnerabilities (flaws or weaknesses) that could be exploited by potential threat sources. This list should focus on realistic technical and nontechnical areas where EPHI can be disclosed without proper authorization, improperly modified, or made unavailable when needed.

Covered entities should use internal and external sources to identify potential vulnerabilities. Internal sources may include previous risk assessments, vulnerability scan and system security test results, and audit reports. External sources may include Internet searches, vendor information, insurance data, and vulnerability databases such as the National Vulnerability Database (http://nvd.nist.gov). At the end of this appendix, a suggested (but not all-inclusive) source list is provided that organizations may wish to use to help in vulnerability identification.

E-3

5.

Assess Current Security Controls. Often performed simultaneously with step 2, Gather Information, the purpose of this step is to determine if the implemented or planned security controls will minimize or eliminate risks to EPHI. A thorough understanding of the actual security controls in place for a covered entity will reduce the list of vulnerabilities, as well as the realistic probability, of a threat attacking (intentionally or unintentionally) EPHI.

Covered entities should evaluate technical and nontechnical security controls at all places where EPHI is created, received, maintained, processed, or transmitted. This evaluation should determine whether the security measures implemented or planned are adequate to protect EPHI, and whether those measures required by the Security Rule are in place, configured, and used properly. The appropriateness and adequacy of security measures may vary depending on the structure, size, and geographical dispersion of the covered entity.

6.

Determine the Likelihood and the Impact of a Threat Exercising a Vulnerability. The next major step in measuring the level of risk is to determine the likelihood and the adverse impact resulting from a threat successfully exploiting a vulnerability. This information can be obtained from existing organizational documentation, such as business impact and asset criticality assessments. A business impact assessment prioritizes the impact levels associated with the compromise of an organization's information assets based on a qualitative or quantitative assessment of the sensitivity and criticality of those assets. An asset criticality assessment identifies and prioritizes the sensitive and critical organization information assets (e.g., hardware, software, systems, services, and related technology assets) that support the organization's critical missions.

If these organizational documents do not exist, the system and data sensitivity can be determined based on the level of protection required to maintain the EPHI's confidentiality, integrity, and availability. The adverse impact of a security event can be described in terms of loss or degradation of any, or a combination of any, of the following three security objectives: integrity, availability, and confidentiality. Table 6 provides a brief description of each security objective and the consequence (or impact) of its not being met.

Table 6. Security Objectives and Impacts

Security Objective

Impacts

Loss of Confidentiality

System and data confidentiality refers to the protection of information from unauthorized disclosure. The impact of unauthorized disclosure of confidential information can range from the jeopardizing of national security to the disclosure of Privacy Act data. Unauthorized, unanticipated, or unintentional disclosure could result in loss of public confidence, embarrassment, or legal action against the organization.

E-4

Security Objective Impacts

Loss of Integrity

System and data integrity refers to the requirement that information be protected from improper modification. Integrity is lost if unauthorized changes are made to the data or IT system by either intentional or accidental acts. If the loss of system or data integrity is not corrected, continued use of the contaminated system or corrupted data could result in inaccuracy, fraud, or erroneous decisions. Also, violation of integrity may be the first step in a successful attack against system availability or confidentiality. For all these reasons, loss of integrity reduces the assurance of an IT system.

Loss of Availability

If a mission-critical IT system is unavailable to its end users, the organization's mission may be affected. Loss of system functionality and operational effectiveness, for example, may result in loss of productive time, thus impeding the end users' performance of their functions in supporting the organization's mission. Some tangible impacts can be measured quantitatively in terms of lost revenue, the cost of repairing the system, or the level of effort required to correct problems caused by a successful threat action. Other impacts, such as the loss of public confidence, the loss of credibility, or damage to an organization's interest, cannot be

measured in specific units but can be qualified or described in terms of high, medium, and low impacts. Qualitative and quantitative methods can be used to measure the impact of a threat occurring 7.

Determine the Level of Risk. The purpose of this step is to assess the level of risk to the IT system. The determination of risk takes into account the information gathered and determinations made during the previous steps. The level of risk is determined by analyzing the values assigned to the likelihood of threat occurrence and resulting impact of threat occurrence. The risk-level determination may be performed by assigning a risk level based on the average of the assigned likelihood and impact levels. A risk-level matrix, such as the sample depicted in Table 7, can be used to assist in determining risk levels.

Table 7. Sample Risk-Level Matrix Impact **Threat Likelihood** Low **Moderate** High High Low **Moderate** High Moderate Low **Moderate** Moderate Low Low Low Low E-5

8.

Recommend Security Controls. During this step, security controls that could mitigate the identified risks, as appropriate to the organization's operations, are recommended. The goal of the recommended controls is to reduce the level of risk to the IT system and its data to an acceptable level. Security control recommendations provide input to the risk mitigation process, during which the recommended security controls are evaluated, prioritized, and implemented.

It should be noted that not all possible recommended security controls can be implemented to reduce loss. To determine which ones are required and appropriate for a specific organization, a cost-benefit analysis should be conducted for the proposed recommended controls, to demonstrate that the costs of implementing the controls can be justified by the reduction in the level of risk. In addition to cost, organizations should consider the operational impact and feasibility of introducing the recommended security controls into the operating environment. 9.

Document the Risk Assessment Results.

Once the risk assessment has been completed (threat sources and vulnerabilities identified, risks assessed, and security controls recommended), the results of each step in the risk assessment should be documented. NIST SP 800-30 provides a sample risk assessment report outline that may prove useful to covered entities.

Risk Assessment Results Affect Risk Management

The results of a risk assessment play a significant role in executing an organization's risk management strategy. In the context of the HIPAA Security Rule, the security control baseline, which consists of the standards and required implementation specifications, should be viewed as the foundation or starting point in the selection of adequate security controls necessary to protect EPHI. In many cases, additional security controls or control enhancements will be needed to protect EPHI or to satisfy the requirements of applicable laws, policies, standards, or regulations. The risk assessment provides important inputs to determine the sufficiency of the security control baseline. The risk assessment results, coupled with the security control baseline, should be used to identify which addressable implementation specifications should be implemented to adequately mitigate identified risks. Risk Assessment Resources

The following resources may provide useful information to assist covered entities in performing risk assessment, analysis, and management activities, and demonstrate compliance with the Security Management Process standard and related implementation specifications:

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HIPAA Security Series, Basics of Risk Analysis and Risk Management, 6/2005: rev. 3/2007;

http://www.cms.hhs.gov/EducationMaterials/Downloads/BasicsofRiskAnalysisandRiskManagement.pdf E-6

E-7

NIST SP 800-30, Risk Management Guide for Information Technology Systems; http://csrc.nist.gov/publications/nistpubs/800-30/sp800-30.pdf

Department of Homeland Security (DHS) National Infrastructure Protection Plan; http://www.dhs.gov/xprevprot/programs/editorial_0827.shtm

NIST National Vulnerability Database (NVD); http://nvd.nist.gov/

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US-CERT; http://www.us-cert.gov/index.html

Carnegie Mellon CERT Coordination Center; http://www.cert.org/insider_threat/ Appendix F: Contingency Planning Guidelines

Information technology (IT) and automated information systems are vital elements in most business processes. Because these IT resources are so essential to an organization's success, it is critical that the services provided by these systems are able to operate effectively without excessive interruption. Contingency planning supports this requirement by establishing thorough plans and procedures and technical measures that can enable a system to be recovered quickly and effectively following a service disruption or disaster. Interim measures may include the relocation of IT systems and operations to an alternate site, the recovery of IT functions using alternate equipment, or the performance of IT functions using manual methods.

IT systems are vulnerable to a variety of disruptions, ranging from mild (e.g., shortterm power outage, disk drive failure) to severe (e.g., equipment destruction, fire). Vulnerabilities may be minimized or eliminated through technical, management, or operational solutions as part of the organization's risk management effort. However, it is virtually impossible to completely eliminate all risks. Contingency
planning is designed to mitigate the risk of system and service unavailability by focusing efficient and effective recovery solutions.

Within the context of HIPAA, the goal of contingency planning is to adequately protect EPHI during a contingency event, and to ensure that organizations have their EPHI available when it is needed.

This appendix, Contingency Planning Guidelines, will identify fundamental planning principles and practices to help personnel develop and maintain effective information system contingency plans. This section will be based on NIST Special Publication 800-34, Contingency Planning Guide for Information Technology Systems.

Contingency Planning Defined

IT contingency planning refers to a coordinated strategy involving plans, procedures, and technical measures that enable the recovery of IT systems, operations, and data after a disruption. Contingency planning generally includes one or more of the approaches to restore disrupted IT services:

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Restoring IT operations at an alternate location;

Recovering IT operations using alternate equipment; and F-1

•

Performing some or all of the affected business processes using non-IT (manual) means (typically acceptable for only short-term disruptions).

Types of Contingency-Related Plans

IT contingency planning represents a broad scope of activities designed to sustain and recover critical IT services following an emergency. IT contingency planning fits into a much broader emergency preparedness environment that includes organizational and business process continuity and recovery planning. Ultimately, an organization would use a suite of plans to properly prepare response, recovery, and continuity activities for disruptions affecting the organization's IT systems, business processes, and the facility. Because there is an inherent relationship between an IT system and the business process it supports, there should be coordination between each plan during development and updates to ensure that recovery strategies and supporting resources neither negate each other nor duplicate efforts.

 Table 8. Types of Contingency Plans

Type of Plan

Description

Scope

Contingency Plan (CP)

Management policy and procedures designed to maintain or restore business operations, including computer operations, possibly at an alternate location, in the event of emergencies, system failures, or disaster.

Addresses IT system disruptions; not typically business process-focused Continuity of Operations Plan (COOP)

A predetermined set of instructions or procedures that describe how an organization's essential functions will be sustained for up to 30 days as a result of a disaster event before returning to normal operations.

Addresses the subset of an organization's missions that are deemed most critical; not typically IT-focused

Disaster Recovery Plan (DRP)

A written plan for processing critical applications in the event of a major hardware or software failure or destruction of facilities.

Limited to major disruptions with long-term effects; typically IT-focused HIPAA Contingency Planning Requirements

Standard 164.308(a)(7), Contingency Plan, requires covered entities to: Establish (and implement as needed) policies and procedures for responding to an emergency or other occurrence (for example, fire, vandalism, system failure, and natural disaster) that damages systems that contain electronic protected health information

The Contingency Plan standard includes five implementation specifications. F-2

1.

Data Backup Plan (R) - 164.308(a)(7)(ii)(A): Establish and implement procedures to create and maintain retrievable exact copies of electronic protected health information.

2.

Disaster Recovery Plan (R) - 164.308(a)(7)(ii)(B): Establish (and implement as needed) procedures to restore any loss of data.

3.

Emergency Mode Operation Plan (R) - 164.308(a)(7)(ii)(C): Establish (and implement as needed) procedures to enable continuation of critical business processes for protection of the security of electronic protected health information while operating in emergency mode.

4.

Testing and Revision Procedures (A) - 164.308(a)(7)(ii)(D): Implement procedures for periodic testing and revision of contingency plans.

5.

Applications and Data Criticality Analysis (A) - 164.308(a)(7)(ii)(E): Assess the relative criticality of specific applications and data in support of other contingency plan components.

IT Contingency Planning Process

To develop and maintain an effective IT contingency plan, organizations should consider using the approach discussed in NIST SP 800-34, Contingency Planning Guide for Information Technology Systems, which proposes a step-by-step contingency planning process, and provides an in-depth discussion of technical contingency planning considerations for specific types of information technology systems. A summary of this process is detailed below. 1.

Develop the Contingency Planning Policy Statement. To be effective and to ensure that personnel fully understand the agency's contingency planning requirements, the contingency plan must be based on a clearly defined policy supported by organizational leadership. The contingency planning policy statement should define the organization's overall contingency objectives and establish the organizational framework and responsibilities for IT contingency planning. Key policy elements include:

•

Roles and responsibilities

•

Scope as applies to the type(s) of platform(s) and organization functions subject to contingency planning

Resource requirements

Training requirements

•

Exercise and testing, and plan maintenance schedules

٠

Frequency of backups and storage of backup media.

2.

Conduct the Business Impact Analysis (BIA). The BIA is a key step in the contingency planning process. The BIA enables the organization to fully characterize information system requirements, processes, and interdependencies and use this information to determine contingency requirements and priorities. F-3

The purpose of the BIA is to correlate specific system components with the critical services that they provide and, based on that information, to characterize the consequences of a disruption to the system components. Key steps include identifying critical IT resources, disruption impacts and allowable outage times, and developing recovery priorities. Results from the BIA should be appropriately incorporated into the analysis and strategy development efforts for the organization's other continuity and recovery plans, including disaster recovery and emergency mode operations plans.

3.

Identify Preventive Controls. In some cases, the outage impacts identified in the BIA may be mitigated or eliminated through preventive measures that deter, detect, and/or reduce impacts to the system. Where feasible and cost-effective, preventive methods are preferable to actions that may be necessary to recover the system after a disruption. Preventive controls should be documented in the contingency plan, and personnel associated with the system should be trained on how and when to use the controls.

A variety of preventive controls are available, depending on system type and configuration; however, some common measures are listed below:

•

Appropriately sized uninterruptible power supplies (UPS) to provide short-term backup power to all system components (including environmental and safety controls)

Gasoline- or diesel-powered generators to provide long-term backup power •

Air-conditioning systems with adequate excess capacity to permit failure of certain components, such as a compressor

• F

Fire suppression systems

•

Fire and smoke detectors

•

Water sensors in the computer room ceiling and floor

•

Plastic tarps that may be unrolled over IT equipment to protect it from water damage

Heat-resistant and waterproof containers for backup media and vital nonelectronic records

Emergency master system shutdown switch

Offsite storage of backup media, nonelectronic records, and system documentation

Technical security controls, such as cryptographic key management and leastprivilege access controls

Frequent scheduled backups.

F-4

4. Develop Recovery Strategies. Recovery strategies provide a means to restore IT operations quickly and effectively following a service disruption. Strategies should address disruption impacts and allowable outage times identified in the BIA. Several alternatives should be considered when developing the strategy, including cost, allowable outage time, security, and integration with larger organization-level contingency plans.

The selected recovery strategy should address the potential impacts identified in the BIA and should be integrated into the system architecture during the design and implementation phases of the system life cycle.

The strategy should include a combination of methods that complement one another to provide recovery capability over the full spectrum of incidents, ranging from minor service disruption to a partial or total loss of primary system operations requiring operational resumption at another location. A wide variety of recovery approaches may be considered; the appropriate choice depends on the incident, type of system, and its operational requirements, including retention requirements. Specific recovery methods may include commercial contracts with cold, warm, or hot site vendors, mobile sites, mirrored sites, reciprocal agreements with internal or external organizations, and service-level agreements (SLAs) with the equipment vendors. In addition, high-availability technologies such as Redundant Arrays of Independent Disks (RAID), automatic fail-over, uninterruptible power supply (UPS), mirrored systems, and multisite data archiving systems should be considered when developing a system recovery strategy.

5.

Develop an IT Contingency Plan. IT contingency plan development is a critical step in the process of implementing a comprehensive contingency planning program. The plan contains detailed roles, responsibilities, teams, and procedures associated with restoring an IT system following a disruption. The contingency plan should document technical capabilities designed to support contingency operations. Plans need to balance detail with flexibility; usually the more detailed the plan, the less scalable and versatile the approach.

Following the approach described in NIST SP 800-34, the contingency plan comprises five main components: Supporting Information, Notification and Activation, Recovery, Reconstitution, and Plan Appendices. The first and last components provide essential information to ensure a comprehensive plan. The Notification and Activation, Recovery, and Reconstitution phases address specific actions that the organization should take following a system disruption or emergency.

The Supporting Information component includes an introduction and concept of operations section that provides essential background or contextual information that makes the contingency plan easier to understand, implement, and maintain. These details aid in understanding the applicability of the guidance, in making decisions on how to use the plan, and in providing information on where associated plans and information outside the scope of the plan may be found. **F-5**

The Notification and Activation Phase defines the initial actions taken once a system disruption or emergency has been detected or appears to be imminent. This phase includes activities to notify recovery personnel, assess system damage, and implement the plan. At the completion of the Notification and Activation Phase. recovery staff will be prepared to perform contingency measures to restore system functions on a temporary basis.

The Recovery Phase begins after the contingency plan has been activated, damage

assessment has been completed (if possible), personnel have been notified, and appropriate teams have been mobilized. Recovery phase activities focus on contingency measures to execute temporary IT processing capabilities, repair damage to the original system, and restore operational capabilities at the original or new facility. At the completion of the Recovery Phase, the IT system will be operational and performing the functions designated in the plan. Depending on the recovery strategies defined in the plan, these functions could include temporary manual processing, recovery and operation at an alternate system, or relocation and recovery at an alternate site. Teams with recovery responsibilities should understand and be able to perform these recovery strategies well enough that if the paper plan is unavailable during the initial stages of the event, they can still perform the necessary activities.

In the Reconstitution Phase, recovery activities are terminated, and normal operations are transferred back to the organization's facility. If the original facility is unrecoverable, the activities in this phase can also be applied to preparing a new facility to support system processing requirements. Until the primary system is restored and tested, the contingency system should continue to be operated. The Reconstitution Phase should specify teams responsible for restoring or replacing both the site and the information system.

Contingency Plan Appendices should provide key details not contained in the main body of the plan. The appendices should reflect the specific technical, operational, and management contingency requirements of the information system and the larger organization. Appendices can include, but are not limited to, contact information for contingency planning team personnel: vendor contact information. including offsite storage and alternate site points of contact; standard operating procedures and checklists for system recovery or processes; equipment and system requirements lists of the hardware, software, firmware, and other resources required to support system operations; vendor agreements, reciprocal agreements with other organizations, and other vital records; description of, and directions to, the alternate site: and the BIA.

Plans should be formatted to provide quick and clear direction in the event those personnel unfamiliar with the plan or the systems are called on to perform recovery operations. Plans should be clear, concise, and easy to implement in an emergency. Where possible, checklists and step-by-step procedures should be

F-6

used. A concise and well-formatted plan reduces the likelihood of creating an overly complex or confusing plan.

6.

Plan Testing, Training, and Exercises. Plan testing is a critical element of a viable contingency capability. Testing enables plan deficiencies to be identified and addressed. Testing also helps evaluate the ability of the recovery staff to implement the plan quickly and effectively. Each IT contingency plan element should be tested to confirm the accuracy of individual recovery procedures and the overall effectiveness of the plan. The following areas should be addressed in a contingency test:

System recovery on an alternate platform from backup media

Coordination among recovery teams

-Internal and external connectivity

System performance using alternate equipment

•

Restoration of normal operations

•

Notification procedures.

Training for personnel with contingency plan responsibilities should complement testing. Training should be provided at least annually; new hires with plan responsibilities should receive training shortly after they are hired. Ultimately, contingency plan personnel should be trained to the extent that that they are able to execute their respective recovery procedures without aid of the actual document. This is an important goal in the event that paper or electronic versions of the plan are unavailable for the first few hours resulting from the extent of the disaster. Recovery personnel should be trained on the following plan elements:

•

Purpose of the plan

Cross-team coordination and communication

Reporting procedures

•

Security requirements

Team-specific processes (Notification/Activation, Recovery, and Reconstitution Phases)

•

Individual responsibilities (Notification/ Activation, Recovery, and Reconstitution Phases).

7.

Maintain the plan. To be effective, the plan must be maintained in a ready state that accurately reflects system requirements, procedures, organizational structure, and policies. IT systems undergo frequent changes because of shifting business needs, technology upgrades, or new internal or external policies. Therefore, it is essential that the contingency plan be reviewed and updated regularly, as part of the

organization's change management process, to ensure that new information is documented and contingency measures are revised if required. As a general rule, F-7

F-8

Contingency Planning Resources

The following resources may provide useful information to assist covered entities in developing contingency planning strategies to adequately protect and recover access to EPHI during a contingency event, and demonstrate compliance with the Contingency Plan standard and implementation specifications:

•

NIST Special Publication 800-34, Contingency Planning Guide for Information Technology Systems, http://csrc.nist.gov/publications/nistpubs/800-34/sp800-34.pdf

HIPAA Security Series, Security Standards: Administrative Safeguards; http://www.cms.hhs.gov/EducationMaterials/Downloads/SecurityStandardsAdminis trativeSafeguards.pdf

STANDARD

Appendix G: Sample Contingency Plan Template

This sample format provides a template for preparing an information technology (IT) contingency plan. The template is intended to be used as a guide and should be modified as necessary to meet the system's contingency requirements and comply with internal policies. Where practical, the guide provides instructions for completing specific sections. Text is added in certain sections; however, this information is intended only to suggest the type of information that may be found in that section. The text is not comprehensive and should be modified to meet specific organization and system considerations.

1. INTRODUCTION

1.1 PURPOSE

This {system name} Contingency Plan establishes procedures to recover the {system name} system following a disruption. The following objectives have been established for this plan:

•

Maximize the effectiveness of contingency operations through an established plan that consists of the following phases:

- Notification/Activation phase to detect and assess damage and to activate the plan;

- Recovery phase to restore temporary IT operations and recover damage done to the original system; and

- Reconstitution phase to restore IT system processing capabilities to normal operations.

•

Identify the activities, resources, and procedures needed to carry out {system name} processing requirements during prolonged interruptions to normal operations.

Assign responsibilities to designated {Organization name} personnel and provide guidance for recovering {system name} during prolonged periods of interruption to normal operations.

•

Ensure coordination with other {Organization name} staff who will participate in the contingency planning strategies. Ensure coordination with external points of contact and vendors who will participate in the contingency planning strategies. 1.2 APPLICABILITY

The {system name} Contingency Plan applies to the functions, operations, and resources necessary to restore and resume {Organization name}'s {system name} operations as it is installed at its primary location: {Name, City, State}. The {system name} Contingency Plan applies to {Organization name} and all other persons associated with {system name} as identified under Section 2.3, Responsibilities. G-1

1.3 SCOPE

1.3.1 Planning Principles

Various scenarios were considered to form a basis for the plan, and multiple assumptions were made. The applicability of the plan is predicated on two key principles:

•

The {Organization name}'s facility in {City, State}, is inaccessible; therefore, {Organization name} is unable to perform {system name} processing for the organization.

•

A valid contract exists with the alternate site that designates that site in {City, State}, as {Organization name}'s alternate operating facility.

- {Organization name} will use the alternate site building and IT resources to recover {system name} functionality during an emergency situation that prevents access to the original facility.

- The designated computer system at the alternate site has been configured to begin processing {system name} information.

- The alternate site will be used to continue {system name} recovery and processing throughout the period of disruption, until the return to normal operations.

1.3.2 Assumptions

Based on these principles, the following assumptions were used when developing the IT Contingency Plan:

•

The {system name} is inoperable at the {Organization name} computer center and cannot be recovered within {XX} hours.

Key {system name} personnel have been identified and trained in their emergency response and recovery roles; they are available to activate the {system name} Contingency Plan.

Preventive controls (e.g., generators, environmental controls, waterproof tarps, sprinkler systems, fire extinguishers, and fire department assistance) are fully operational at the time of the contingency event.

Computer center equipment, including components supporting {system name}, are connected to an uninterruptible power supply (UPS) that provides {XX} minutes/hours of electricity during a power failure.

{System name} hardware and software at the {Organization name} original site are unavailable for at least {XX} hours.

Current backups of the application software and data are intact and available at the offsite storage facility.

The equipment, connections, and capabilities required to operate {system name} are available at the alternate site in {City, State}. G-2

•

Service agreements are maintained with {system name} hardware, software, and communications providers to support the system recovery.

The {system name} Contingency Plan does not apply to the following situations: •

Overall recovery and continuity of business operations. The Business Resumption Plan (BRP) and Continuity of Operations Plan (COOP) are appended to the plan.

Emergency evacuation of personnel. The Occupant Evacuation Plan (OEP) is appended to the plan.

•

Any additional constraints should be added to this list.

1.4 REFERENCES/REQUIREMENTS

This {system name} Contingency Plan complies with the {Organization name}'s IT contingency planning policy as follows:

{Insert organization's contingency planning policy statement}

The {system name} Contingency Plan also complies with the following policies:

Federal Information Security Management Act (FISMA) of 2002

•

Health Insurance Portability and Accountability Act (HIPAA), 1996

OMB Circular A-130, Management of Federal Information Resources, Appendix III, November 2000

•

Federal Preparedness Circular (FPC) 65, Federal Executive Branch Continuity of Operations, July 1999

PDD 63, Critical Infrastructure Protection, May 1998

•

Federal Emergency Management Agency (FEMA), The Federal Response Plan (FRP), April 1999

{Insert other applicable policies}
1.5 RECORD OF CHANGES
Modifications made to this plan are as follows:
Record of Changes
Page No.
Change Comment
Date of Change
Signature
2. CONCEPT OF OPERATIONS
2.1 SYSTEM DESCRIPTION AND ARCHITECTURE G-3

Provide a general description of system architecture and functionality. Indicate the operating environment, physical location, general location of users, and partnerships with external organizations/systems. Include information regarding any other technical considerations that are important for recovery purposes, such as

backup procedures. Provide a diagram of the architecture, including security controls and telecommunications connections.

2.2 LINE OF SUCCESSION

The {organization name} sets forth an order of succession to ensure that decisionmaking authority for the {system name} Contingency Plan is uninterrupted. The Chief Information Officer (CIO), {organization name} is responsible for ensuring the safety of personnel and the execution of procedures documented within this {system name} Contingency Plan. If the CIO is unable to function as the overall authority or chooses to delegate this responsibility to a successor, the Deputy CIO shall function as that authority. Identify and describe line of succession as applicable.

2.3 RESPONSIBILITIES

The following teams have been developed and trained to respond to a contingency event affecting the IT system.

The Contingency Plan establishes several teams assigned to participate in recovering {system name} operations. Examples of teams that may be included are management team, application recovery team, operating system team, network operations team, site restoration/salvage team, procurement team, damage assessment team, and communications team. The system environment and the scope of the recovery effort will dictate which teams will be necessary to execute the plan.

{Team name}

0

{Describe each team, their responsibilities, leadership, and coordination with other applicable teams during a recovery operation. Do not detail specific procedures that will be used to execute these responsibilities. These procedures will be itemized in the appropriate phase sections.}

The relationships of the teams involved in system recovery are illustrated in Figure {XX} below.

{Insert hierarchical diagram of recovery teams. Show team names and leaders; do not include actual names of personnel.}

3. NOTIFICATION AND ACTIVATION PHASE

This phase addresses the initial actions taken to detect and assess damage inflicted by a disruption to {system name}. Based on the assessment of the event, the plan may be activated by the Contingency Planning Coordinator.

In an emergency, the {Organization name}'s top priority is to preserve the health and safety of its staff before proceeding to the Notification and Activation procedures. G-4

Notification

Contact information for key personnel is located in Appendix A. The notification sequence is listed below:

•

The first responder is to notify the Contingency Planning Coordinator. All known information must be relayed to the Contingency Planning Coordinator.

{Insert further notification sequences specific to the organization and the system.} Upon notification, the following procedures are to be performed by their respective teams:

Damage Assessment Procedures:

{Detailed procedures should be outlined to include activities to determine the cause of the disruption; potential for additional disruption or damage; affected physical

area and status of physical infrastructure; status of IT equipment functionality and inventory, including items that will need to be replaced; and estimated time to repair services to normal operations.}

•

{team name}

- Team Damage Assessment Procedures

•

{Insert additional team names and procedures as necessary}

Activation

The Contingency Plan is to be activated if one or more of the following criteria are met:

1. {System name} will be unavailable for more than {XX} hours.

2. Facility is damaged and will be unavailable for more than {XX} hours.

- 3. Other criteria, as appropriate:
- •

If the plan is to be activated, the Contingency Planning Coordinator is to notify all Team Leaders and inform them of the details of the event and if relocation is required.

•

Upon notification from the Contingency Planning Coordinator, Team Leaders are to notify their respective teams. Team members are to be informed of all applicable information and prepared to respond and relocate if necessary.

•

The Contingency Planning Coordinator is to notify the offsite storage facility that a contingency event has been declared and to ship the necessary materials (as determined by damage assessment) to the alternate site.

The Contingency Planning Coordinator is to notify the alternate site that a contingency event has been declared and to prepare the facility for the organization's arrival.

•

The Contingency Planning Coordinator is to notify remaining personnel (via notification procedures) on the general status of the incident. G-5

4. RECOVERY OPERATIONS

This section provides procedures for recovering the application at the alternate site, whereas other efforts are directed to repair damage to the original system and capabilities.

The following procedures are for recovering the {system name} at the alternate site. Procedures are outlined per team required. Each procedure should be executed in the sequence it is presented to maintain efficient operations.

Recovery Goal. State the first recovery objective as determined by the Business Impact Assessment (BIA). For each team responsible for executing a function to meet this objective, state the team names and list their respective procedures.

•

{team name}

- Team Recovery Procedures

{Insert additional team names and procedures as necessary}

Recovery Goal. State the remaining recovery objectives as determined by the BIA. For each team responsible for executing a function to meet this objective, state the team names and list their respective procedures.

•

{team name}

- Team Recovery Procedures

•

{Insert additional team names and procedures as necessary}

5. RETURN TO NORMAL OPERATIONS

This section discusses activities necessary for restoring {system name} operations at the {Organization name}'s original or a new site. When the computer center at the original or the new site has been restored, {system name} operations at the alternate site must be transitioned back. The goal is to provide a seamless transition of operations from the alternate site to the computer center.

Original or New Site Restoration

Procedures should be outlined, per necessary team, to restore or replace the original site so that normal operations may be transferred. IT equipment and telecommunications connections should be tested.

•

{team name}

- Team Resumption Procedures

•

{Insert additional team names and procedures as necessary}

5.1 CONCURRENT PROCESSING

Procedures should be outlined, per necessary team, to operate the system in coordination with the system at the original or the new site. These procedures should include testing the original or new system until it is functioning properly and ensuring that the contingency system is shut down gracefully.

{team name}

G-6

G-7

- Team Concurrent Processing Procedures

•

{Insert additional team names and procedures as necessary}

5.2 PLAN DEACTIVATION

Procedures should be outlined, per necessary team, to clean the alternate site of any equipment or other materials belonging to the organization, with a focus on handling sensitive information. Materials, equipment, and backup media should be properly packaged, labeled, and shipped to the appropriate location(s). Team members should be instructed to return to the original or the new site.

•

{team name}

- Team Deactivation Procedures

•

{Insert additional team names and procedures as necessary}

6. PLAN APPENDICES

The appendices included should be based on system and plan requirements.

•

Personnel Contact List

•

Vendor Contact List

Equipment and Specifications

Service-Level Agreements and Memorandums of Understanding

IT Standard Operating Procedures

Business Impact Analysis

•

Related Contingency Plans

•

Emergency Management Plan

•

Occupant Evacuation Plan

•

Continuity of Operations Plan.

Appendix H: Resources for Secure Remote Use and Access

The HIPAA Security Rule requires all covered entities to protect the EPHI that they use or disclose to business associates, trading partners, or other entities. New technologies, such as remote access and removable media technologies, have significantly simplified the way in which data is transmitted throughout the healthcare industry and created tremendous opportunities for improvements and greater efficiency in the healthcare space. However, these technologies have also increased the risk of loss and unauthorized use and disclosure of this sensitive information. Sensitive information that is accessed by, stored on, or transmitted to or from a remote device needs to be protected so that malicious parties cannot access or alter it. An unauthorized release of sensitive information could damage the trust in an organization, jeopardize its mission, or harm individuals if their personal information has been released.

In December 2006, CMS issued a HIPAA security guidance document, Remote Use of and Access to Electronic Protected Health Information, to reinforce some of the ways a covered entity may protect EPHI when it is accessed or used outside of the organization's physical purview. It sets forth some strategies that may be reasonable and appropriate under the HIPAA Security Rule, for covered entities to follow (based upon their individual technological capabilities and operational needs), for offsite use of, or access to, EPHI. This guidance also places significant emphasis on the importance of risk analysis and risk management strategies, policies and procedures, and security awareness and training on the policies and procedures for safeguarding EPHI during its remote access, storage, and transmission. NIST publications on remote access, storage, and transmission security technologies can be valuable resources to support secure remote use solutions. These publications seek to assist organizations in understanding particular technologies and to provide security considerations and practical, real-world recommendations for implementing and securing these technologies within an organization. Special Publication 800-114, User's Guide to Securing External Devices for Telework and Remote Access, was developed to help teleworkers secure the external devices they use for telework, such as personally owned and third-party privately owned desktop and laptop computers and consumer devices (e.g., cell phones, personal digital assistants). The document focuses specifically on security for

telework involving remote access to organizations' nonpublic computing resources by providing:

Recommendations for securing telework computers' operating systems and applications, as well as home networks that the computers use;

Basic recommendations for securing consumer devices used for telework; •

Advice on protecting the information stored on telework computers and removable media; and

•

Tips on considering the security of a device owned by a third party before deciding whether it should be used for telework.

H-1

Special Publication 800-113, Guide to SSL VPNs, assists organizations in understanding SSL VPN technologies and in designing, implementing, configuring, securing, monitoring, and maintaining SSL VPN solutions. This publication intends to help organizations determine how best to deploy SSL VPNs within their specific network environments by:

•

Describing SSL and how it fits within the context of layered network security; •

Presenting a phased approach to SSL VPN planning and implementation that can help in achieving successful SSL VPN deployments; and

•

Comparing SSL VPN technology with IPsec VPNs and other VPN solutions. Special Publication 800-77, Guide to IPsec VPNs, assists organizations in mitigating the risks associated with the transmission of sensitive information across networks by providing practical guidelines on implementing security services based on Internet Protocol Security (IPsec). This publication intends to help organizations determine how best to deploy IPsec VPNs within their specific network environments by:

•

Discussing the need for, and types of, network layer security services and how IPsec addresses these services;

Providing a phased approach to IPsec planning and implementation that can help in achieving successful IPsec deployments;

•

Providing specific recommendations relating to configuring cryptography for IPsec; •

Using a case-based approach to show how IPsec can be used to solve common network security issues; and

Discussing alternatives to IPsec and under what circumstances each may be appropriate.

Special Publication 800-52, Guidelines for the Selection and Use of Transport Layer Security (TLS), provides guidelines on the selection and implementation of the TLS protocol while making effective use of Federal Information Processing Standards (FIPS)-approved cryptographic algorithms. TLS provides a mechanism to protect sensitive data during electronic dissemination across the Internet. This guideline: •

Describes the placement of security in each layer of the communications protocol stack, as defined by the OSI Seven Layer Model;

Provides criteria for developing specific recommendations when selecting, installing and using transport layer security; and

Discusses client implementation, server, and operational considerations. Special Publication 800-111, Guide to Storage Encryption Technologies for End User Devices, assists organizations in understanding storage encryption technologies for end user devices and in planning, implementing, and maintaining storage encryption solutions. The types of end user devices addressed in this document are personal computers (desktops and laptops), consumer devices (e.g., personal digital assistants,

H-2

H-3

smart phones), and removable storage media (e.g., USB flash drives, memory cards, external hard drives, writeable CDs and DVDs). This publication:

•

Provides an overview of the basic concepts of storage encryption for end user devices;

•

Provides guidelines on commonly used categories of storage encryption techniques (i.e., full disk, volume and virtual disk, and file/folder), and explains the types of protection they provide;

Discusses important security elements of a storage encryption deployment, including cryptographic key management and authentication; and

•

Examines several use cases which illustrate multiple ways to meet most storage encryption needs.

Draft Special Publication 800-124, Guidelines on Cell Phone and PDA Security, provides an overview of cell phone and personal digital assistant (PDA) devices in use today and offers insights for making informed information technology security decisions regarding their treatment. This publication:

Presents an overview of handheld devices and discusses associated security threats and technology risks;

•

Examines the security concerns associated with handheld devices; and

Discusses user- and organization-oriented measures and safeguards available for mitigating the risks and threats.

All NIST publications are accessible on the public Computer Security Resource Center (CSRC) Web site at http://csrc.nist.gov.

Appendix I: Telework Security Considerations

Many people telework, which is the ability for an organization's employees and contractors to conduct work from locations other than the organization's facilities. Teleworkers use various devices, such as desktop and laptop computers, cell phones, and personal digital assistants (PDAs), to read and send email, access Web sites, review and edit documents, and perform many other tasks. Most teleworkers use remote access, which is the ability of an organization's users to access its nonpublic computing resources from locations other than the organization's facilities. Organizations have many options for providing remote access, including virtual private networks, remote system control, and individual application access (e.g., Web-based email).

This appendix provides considerations and tips for securing external devices used for telework and remote access. More detailed information on this topic is available in NIST SP 800-114, User's Guide to Securing External Devices for Telework and Remote Access.

Before teleworking, users should understand their organization's policies and requirements, as well as appropriate ways of protecting the organization's information that they may access.

Teleworkers should consult their organization's policies and requirements to provide adequate security to protect the organization's information. Sensitive information that is stored on, or sent to or from, external telework devices needs to be protected so that malicious parties can neither access nor alter it. An unauthorized release of sensitive information could damage the public's trust in an organization, jeopardize the mission of an organization, or harm individuals if their personal information has been released.

Teleworkers should ensure that all the devices on their wired and wireless home networks are properly secured, as well as the home networks themselves. An important part of telework and remote access security is applying security measures to the personal computers (PCs) and consumer devices using the same wired and wireless home networks to which the telework device normally connects. If any of these other devices become infected with malware or are otherwise compromised, they could attack the telework device or eavesdrop on its communications. Teleworkers should also be cautious about allowing others to place devices on the teleworkers' home networks, in case one of these devices is compromised.

Teleworkers should apply security measures to the home networks to which their telework devices normally connect. One example of a security measure is using a broadband router or firewall appliance to prevent computers outside the home network from initiating communications with telework devices on the home network. Another example is ensuring that sensitive information transmitted over a wireless home network is adequately protected through strong encryption. Teleworkers should consider the security state of a third-party device before using it for telework.

I-1

Teleworkers often want to perform remote access from third-party devices, such as checking email from a kiosk computer at a conference. However, teleworkers typically do not know if such devices have been secured properly or if they have been compromised. Consequently, a teleworker could use a third-party device infected with malware that steals information from users (e.g., passwords or email messages). Many organizations either forbid third-party devices to be used for remote access or permit only limited use, such as for Web-based email. Teleworkers should consider who is responsible for securing a third-party device and who can access the device before deciding whether or not to use it. Whenever possible, teleworkers should not use publicly accessible third-party devices for telework, and teleworkers should avoid using any third-party devices for performing sensitive functions or accessing sensitive information.

Secure a Telework PC

Teleworkers who use their own desktop or laptop PCs for telework should secure their operating systems and primary applications.

Use a combination of security software, such as antivirus and antispyware software, personal firewalls, spam and Web content filtering, and popup blocking, to stop most attacks, particularly malware;

Restrict who can use the PC by having a separate standard user account for each person, assigning a password to each user account, using the standard user accounts for daily use, and protecting user sessions from unauthorized physical access;

Ensure that updates and patches are regularly applied to the operating system and primary applications, such as Web browsers, email clients, instant messaging clients, and security software;

Disable unneeded networking features on the PC and configure wireless networking securely;

•

Configure primary applications to filter content and stop other activity that is likely to be malicious;

Install and use only known and trusted software;

Configure remote access software based on the organization's requirements and recommendations; and

Maintain the PC's security on an ongoing basis, such as changing passwords regularly and checking the status of security software periodically.

Secure consumer devices used for telework, such as cell phones, PDAs, and video game systems

A wide variety of consumer devices exists, and security features available for these devices also vary widely. Some devices offer only a few basic features, whereas others offer sophisticated features similar to those offered by PCs. This does not necessarily imply that more security features are better; in fact, many devices offer more security features because the capabilities they provide (e.g., wireless networking, instant

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messaging) make them more susceptible to attack than devices without these capabilities. General recommendations for securing telework devices are as follows:

Limit access to the device, such as setting a personal identification number (PIN) or password and automatically locking a device after an idle period;

Disable networking capabilities, such as Bluetooth, except when they are needed; •

Use additional security software, such as antivirus software and personal firewalls, if appropriate;

Ensure that security updates, if available, are acquired and installed at least monthly, or more frequently; and

Configure applications to support security (e.g., blocking activity that is likely to be malicious).

Secure Information

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Use physical security controls for telework devices and removable media. For example, an organization might require that laptops be physically secured using cable locks when used in hotels, conferences, and other locations where third parties could easily gain physical access to the devices. Organizations may also have physical security requirements for papers and other non-computer media that contain sensitive information and are taken outside the organization's facilities.

Encrypt files stored on telework devices and removable media such as CDs and flash drives. This prevents attackers from readily gaining access to information in the files. Many options exist for protecting files, including encrypting individual files or folders, volumes, and hard drives. Generally, using an encryption method to protect files also requires the use of an authentication mechanism (e.g., password) to decrypt the files when needed.

Ensure that information stored on telework devices is backed up. If something adverse happens to a device, such as a hardware, software, or power failure or a natural disaster, the information on the device will be lost unless it has been backed up to another device or removable media. Some organizations permit teleworkers to back up their local files to a centralized system (e.g., through VPN remote access), whereas other organizations recommend that their teleworkers perform local backups (e.g., burning CDs, copying files onto removable media). Teleworkers should perform backups, following their organizations' guidelines, and verify that the backups are valid and complete. It is important that backups on removable media be secured at least as well as the device that they backed up. For example, if a computer is stored in a locked room, then the media also should be in a secured location; if a computer stores its data encrypted, then the backups of that data should also be encrypted.

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Ensure that information is destroyed when it is no longer needed. For example, the organization's files should be removed from a computer scheduled to be retired or from a third-party computer that is temporarily used for remote access. Some remote access methods perform basic information cleanup, such as clearing I-3

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Web browser caches that might inadvertently hold sensitive information, but more extensive cleanup typically requires using a special utility, such as a disk-scrubbing program specifically designed to remove all traces of information from a device. Another example of information destruction is shredding telework papers containing sensitive information once the papers are no longer needed.

Erase information from missing cell phones and PDAs. If a cell phone or PDA is lost or stolen, occasionally its contents can be erased remotely. This prevents an attacker from obtaining any information from the device. The availability of this service depends on the capabilities of the product and the company providing network services for the product.

Adequately protect remote access-specific authenticators

Teleworkers need to ensure that they adequately protect their remote access-specific authenticators, such as passwords, personal identification numbers (PINs), and hardware tokens. Such authenticators should not be stored with the telework computer, nor should multiple authenticators be stored with each other (e.g., a password or PIN should not be written on the back of a hardware token). Social Engineering

Teleworkers should be aware of how to handle threats involving social engineering, which is a general term for attackers trying to trick people into revealing sensitive information or performing certain actions, such as downloading and executing files that appear to be benign but are actually malicious. For example, an attacker might approach a teleworker in a coffee shop and ask to use the computer for a minute or offer to help the teleworker with using the computer.

Teleworkers should be wary of any requests they receive that could lead to a security breach or to the theft of a telework device. Handling a Security Breach

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If a teleworker suspects that a security breach (including loss or theft of materials) has occurred involving a telework device, remote access communications, removable media, or other telework components, the teleworker should immediately follow the organization's policy and procedures for reporting the possible breach. This is particularly important if any of the affected telework components contain sensitive information such as EPHI, so that the potential impact of a security breach is minimized.

Southern Adjustment Services, Inc.

DOCUMENT RETENTION-PROTECTION-DESTRUCTION POLICY

Our policy regarding document retention, protection and destruction is compliant with the following federal laws, Gramm-Leach-Bliley Act (financial data), the Fair and Accurate Credit Transaction Act (Credit Data) and the Health Insurance Portability and Accountability Act (health information).

DOCUMENT RETENTION

List each document you use and how long you retain each document:

•	8.	
I.e. Assignment Form		5 years
Hold Harmless		5 years
Assignment Notes		5 years
		•

DOCUMENT PROTECTION

Documents (hardcopy, online or other media) will be stored in a protected environment area, safe, secure and accessible for the duration of the required document retention period. Storage containers will be secured and accessible only to employees as their duties, position and needs require.

DOCUMENT DESTRUCTION

Hard copies of document will be destroyed by _Record Shred______ after they have been retained for the required document retention period. Online copies will be destroyed by fire or other proven means after they have been retained for the required document retention period.

PROVISION OF DOCUMENTATION FOR INVESTIGATION OR LITIGATION

Documents requested and subpoenaed by legally authorized personnel will be provided within five (5) business days. The designated officer(s) of the corporation must authorize provision. No documents will be concealed, altered or destroyed with the intent to obstruct the investigation or litigation.