



# Modified Stage 2 Eligible Hospitals, CAHs and Dual-Eligible Hospitals Attesting to CMS Security Risk Analysis Tip Sheet: Protect Patient Health Information

Updated: November 2016



Conducting or reviewing a security risk analysis to meet the standards of Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule is included in the meaningful use requirements of the [Medicare and Medicaid EHR Incentive Programs](#).

Eligible hospitals and critical access hospitals (CAHs) must conduct or review a security risk analysis for each EHR reporting period to ensure the privacy and security of their patients' protected health information:

Modified Stage 2 Meaningful Use Requirement: Protect Patient Health Information		
Objective	Measure	Description of HIPAA Requirement
Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical capabilities.	Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including Addressing the security (to include encryption) of ePHI created or maintained in CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary, and correct identified security deficiencies as part of the eligible hospital's or CAH's risk management process.	Under the HIPAA Security Rule, you are required to conduct an accurate and thorough analysis of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information (ePHI) held by the covered entity or business associate. Once you have completed the risk analysis, you must take any additional "reasonable and appropriate" steps to reduce identified risks to reasonable and appropriate levels. (45 CFR 164.308(a)(1)(ii)).

Conducting a security risk analysis is required when certified EHR technology is adopted in the first reporting year. In subsequent reporting years, or when changes to the practice or electronic systems occur, a review must be conducted. It is acceptable for the security risk analysis to be conducted outside the EHR reporting period; however, the analysis must be conducted for the certified EHR technology used during the EHR reporting period and the analysis or review must be conducted on an annual basis prior to the date of attestation. In other words, the provider must conduct a unique analysis or review applicable for the EHR reporting period and the scope of the analysis or review must include the full EHR reporting period. Any security updates and deficiencies that are identified in the review should be included in the provider's risk management process and implemented or corrected as dictated by that process.

This tip sheet<sup>1</sup> provides an overview of the security risk analysis requirement. Meaningful use does not impose new or expanded requirements on the HIPAA Security Rule, nor does it require specific use of every certification and standard that is included in certification of EHR technology. You can also find additional information and resources to assist you in learning more about the HIPAA Security Rule through the U.S. Department of Health

<sup>1</sup> Content adapted from the HHS Office of the National Coordinator on Health Information Technology's [Guide to Privacy and Security of Health Information](#).

and Human Services (HHS) [Office for Civil Rights](#).

## Performing a Security Risk Analysis

Today many patients' protected health information is stored electronically, so the risk of a breach of their ePHI, or electronic protected health information, is very real. To help you conduct a risk analysis that is right for your medical practice, OCR has issued [Guidance on Risk Analysis](#).

There is no single method or "best practice" that guarantees compliance, but most risk analysis and risk management processes have steps in common. Here are some considerations as you conduct your risk analysis<sup>2</sup>:

- Define the scope of the risk analysis and collect data regarding the ePHI pertinent to the defined scope.<sup>3</sup>
- Identify potential threats and vulnerabilities to patient privacy and to the security of your practice's ePHI.
- Assess the effectiveness of implemented security measures in protecting against the identified threats and vulnerabilities.
- Determine the likelihood a particular threat will occur and the impact such an occurrence would have to the confidentiality, integrity and availability of ePHI.
- Determine and assign risk levels based on the likelihood and impact of a threat occurrence.
- Prioritize the remediation or mitigation of identified risks based on the severity of their impact on your patients and practice.
- Document your risk analysis including information from the steps above as well as the risk analysis results.
- Review and update your risk analysis on a periodic basis.

## Creating an Action Plan

Once you have completed these steps, create an action plan to implement appropriate security measures to safeguard the confidentiality, integrity and availability the ePHI and make your practice better at protecting patients' health information.

Your action plan will involve a review of the risks to your practice's ePHI identified in your risk analysis to correct any processes that make your patients' information vulnerable. Make sure your analysis examines risks

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<sup>2</sup> See OCR's [Guidance on Risk Analysis Requirements under the HIPAA Security Rule](#). These steps are consistent with the NIST 800-30 guidance for conducting risk analysis.

<sup>3</sup> Although the scope of the risk analysis for Meaningful Use would be, at a minimum, with respect to e-PHI created, received, maintained, or transmitted by the CEHRT, for a risk analysis to also be compliant with HIPAA Security Rule requirements, risks must be identified and assessed for all of the e-PHI the practice creates, receives, maintains or transmits.

specific to your practice. For example, how do you store patient information—on an EHR system in your office, or on an Internet-based system? Each scenario carries different potential risks.

Your risk analysis may also reveal that you need to update your system software, change the workflow processes or storage methods, review and modify policies and procedures, schedule additional training for your staff, or take other necessary corrective action to eliminate identified security deficiencies.

When creating your action plan, be sure to document the relevant information to ensure the plan is followed. This should include the steps your practice has decided to take to remediate or mitigate the identified risks, the individual responsible for implementing the required changes, and a target date identifying when it is expected the required changes will be implemented.

### Protecting Patients’ Electronic Information

Your security risk analysis will help you measure the impact of threats and vulnerabilities that pose a risk to the confidentiality, integrity and availability to your ePHI. Once you have completed the risk analysis of your practice’s facility and information technology, you will need to develop and implement safeguards to mitigate or lower the risks to your ePHI. For example, if you want to assure continuous access to patient information, you may need to add a power surge protection strip to prevent damage to sensitive equipment from electric power surges, put the computer server in a locked room, and become meticulous about performing information system backups.

The Security Rule requires that you put into place reasonable and appropriate administrative, physical and technical safeguards to protect your patients’ ePHI. The Security Rule allows you to tailor security policies, procedures, and technologies for safeguarding ePHI based on your medical practice’s size, complexity, and capabilities—as well as its technical, hardware, and software infrastructure.

The following table shows examples of some safeguards and processes you might put in place to mitigate security risks to your practice. These are only examples and should not be used as a comprehensive guide for mitigating security risks. You should put into place reasonable and appropriate administrative, physical and technical safeguards that are tailored to the size and complexity of your practice.

Security Areas to Consider		Examples of Potential Security Measures
Physical Safeguards	<ul style="list-style-type: none"> <li>Your facility and other places where patient data is accessed</li> <li>Computer equipment</li> <li>Portable devices</li> </ul>	<ul style="list-style-type: none"> <li>Building alarm systems</li> <li>Locked offices</li> <li>Screens shielded from secondary viewers</li> </ul>
Administrative Safeguards	<ul style="list-style-type: none"> <li>Designated security officer</li> <li>Workforce training and oversight</li> <li>Controlling information access</li> <li>Periodic security reassessment</li> </ul>	<ul style="list-style-type: none"> <li>Staff training</li> <li>Monthly review of user activities</li> <li>Policy enforcement</li> </ul>

Security Areas to Consider		Examples of Potential Security Measures
Technical Safeguards	<ul style="list-style-type: none"> <li>• Controls on access to EHR</li> <li>• Use of audit logs to monitor users and other EHR activities</li> <li>• Measures that keep electronic patient data from improper changes</li> <li>• Secure, authorized electronic exchanges of patient information</li> </ul>	<ul style="list-style-type: none"> <li>• Secure passwords</li> <li>• Backing-up data</li> <li>• Virus checks</li> <li>• Data encryption</li> </ul>
Policies & Procedures	<ul style="list-style-type: none"> <li>• Written policies and procedures to ensure HIPAA security compliance</li> <li>• Documentation of security measures</li> </ul>	<ul style="list-style-type: none"> <li>• Written protocols on authorizing users</li> <li>• Record retention</li> </ul>
Organizational Requirements	<ul style="list-style-type: none"> <li>• Business associate agreements</li> </ul>	<ul style="list-style-type: none"> <li>• Plan for identifying and managing vendors who access, create or store PHI</li> <li>• Agreement review and updates</li> </ul>

## Myths and Facts

The following table addresses common myths about conducting a risk analysis, and provides facts and tips that can help you structure your risk analysis process.

Security Risk Analysis Myths and Facts	
Myth	Fact
The security risk analysis is optional for small providers.	False. All providers who conduct certain electronic transactions, such as billing, are “covered entities” under HIPAA and are required to perform a risk analysis. In addition, all providers who want to receive EHR incentive payments must conduct a risk analysis.
Simply installing a certified EHR fulfills the security risk analysis MU requirement.	False. Even with a certified EHR, you must perform a full security risk analysis. Security requirements address all electronic protected health information you maintain, not just what is in your EHR.
My EHR vendor took care of everything I need to do about privacy and security.	False. Your EHR vendor may be able to provide information, assistance, and training on the privacy and security aspects of the EHR product. However, EHR vendors are not responsible for making their products compliant with HIPAA Privacy and Security Rules. It is solely your responsibility to have a complete risk analysis conducted.
I have to outsource the security risk analysis.	False. It is possible for small practices to do risk analysis themselves using self-help tools. However, doing a thorough and professional risk analysis that will stand up to a compliance review will require expert knowledge that could be obtained through services of an experienced outside professional.
A checklist will suffice for the risk analysis requirement.	False. Checklists can be useful tools, especially when starting a risk analysis, but they fall short of performing a systematic security risk analysis or documenting that one has been performed.

Security Risk Analysis Myths and Facts	
Myth	Fact
There is a specific risk analysis method that I must follow.	False. A risk analysis can be performed in countless ways. OCR has issued <a href="#">several technical assistance documents</a> describing approaches for conducting risk analysis. This guidance assists organizations in identifying and implementing the most effective and appropriate safeguards to secure ePHI.
My security risk analysis only needs to look at my EHR.	False. Review all electronic devices that store, capture, or modify electronic protected health information. Include your EHR hardware and software and devices that can access your EHR data (e.g., your tablet computer, your practice manager’s mobile phone). Remember that <a href="#">copiers also store data</a> . Please see U.S. Department of Health and Human Services (HHS) guidance on <a href="#">remote use</a> .
I only need to do a risk analysis once.	False. To comply with HIPAA, you must continue to review, correct or modify, and update security protections.
Before I attest for an EHR incentive program, I must fully mitigate all risks.	False. The EHR incentive program requires correcting any deficiencies (identified during the risk analysis) according to the timeline established in the provider’s risk management process, not the date the provider chooses to submit meaningful use attestation. The timeline needs to meet the requirements under 45 CFR 164.308(a)(1), including the requirement to “Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with [45 CFR]§164.306(a).”
Each year, I’ll have to completely redo my security risk analysis.	False. Perform the full security risk analysis as you adopt an EHR. Each year or when changes to your practice or electronic systems occur, review and update the prior analysis for changes in risks. Under meaningful use, reviews are required for each EHR reporting period..

For more information, including a ten-step plan for health information privacy and security, [review \*ONC’s Guide to Privacy and Security of Health Information\*](#), or visit [OCR’s webpage](#).