

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-09-53

DATE: August 14, 2009

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Surveying Facilities That Use Electronic Health Records (EHR)

Memorandum Summary

- **EHR Goal:** The Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) are committed to the goal that by 2014, most Americans will have access to health care providers who use EHRs. CMS recognizes the importance of the use of EHRs and their benefits to better patient/resident care and reduced costs.
- **Provider Choice:** Providers/suppliers have the right to use whatever system of medical records they choose as long as that system complies with its Medicare participation requirements.
- **Access to Records by Surveyors:** During the entrance conference, surveyors will verify with the facility the process they will follow in order to have unrestricted access to the medical record. Impeding the survey process by unnecessarily delaying or restricting access to the medical records may lead to termination from Medicare participation.
- **Surveyor Role:** While surveyors are expected to enforce the specific health and safety regulatory requirements for providers/suppliers to protect the confidentiality of medical records, they are not expected to assess EHRs to determine whether they satisfy the requirements of the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules.

Background:

Health information technology (Health IT) allows comprehensive management of medical information and its secure exchange among health care consumers and providers. More and more health care providers are using Health IT; in particular, EHR. The HHS and CMS support the use of EHRs and have committed to a goal that by 2014, most Americans will have access to health care providers who use EHRs. The expected benefits of the EHR include: better patient/resident care, reduced costs to providers, and reduced costs to Medicare and Medicaid.

The expanded use of EHRs will mean that surveyors will increasingly encounter more facilities that no longer have paper-based records. Surveyors must be able to conduct the survey process in a consistent manner in all facilities regardless of whether the facility uses paper-based records and/or EHRs.

Additionally, the expanded use of EHRs also raises issues concerning the scope of responsibility of State Survey Agencies (SAs) in enforcing the various provider or supplier-specific Conditions of Participation (CoPs), Conditions for Coverage or Conditions for Certification (CfCs) concerning confidentiality of patient/resident clinical information stored in an EHR. Surveyors are expected to carry out these requirements as currently enforced and are not expected to evaluate the overall features of the EHR system for compliance with the HIPAA Security and Privacy Rules.

Discussion

Provider/Supplier Responsibilities

Currently there are no regulatory or statutory requirements that Medicare providers use an EHR system or a designated type of EHR system. Providers are allowed to use whatever system of medical records best suits their needs. This includes paper and/or electronic systems. There is not one required electronic system that providers must use.

However, a provider must grant access to any medical record, including access to EHRs, when requested by the surveyor. If access to an EHR is requested by the surveyor, the facility will (a) provide the surveyor with a tutorial on how to use its particular electronic system and (b) designate an individual who will, when requested by the surveyor, access the system, respond to any questions or assist the surveyor as needed in accessing electronic information in a timely fashion. Each surveyor will determine the EHR access method that best meets the need for that survey. During the entrance conference in a facility using EHRs the survey team must request that the facility; provide a terminal(s) where the surveyors may access records. In the case of a hospital or other provider or supplier with terminals at multiple care locations, surveyors must be provided access to a terminal at each care location.

If the facility is unable to provide direct print capability to the surveyor, the provider must make available a printout of any record or part of a record upon request in a timeframe that does not impede the survey process. Undue delays in the production of records are unacceptable. Whenever possible, the facility must provide surveyors electronic access to records in a read-only format or other secure format to avoid any inadvertent changes to the record. The provider is solely responsible for ensuring that all necessary back up of data and security measures are in place.

Generally the provider or supplier-specific CoPs or CfCs include a requirement that the provider or supplier assure the confidentiality of a patient's or resident's clinical record. All providers and suppliers that conduct standard transactions (electronic claims filing, etc.) are "covered entities" and, as such, they must comply with the HIPAA Privacy Rule and the HIPAA Security Rule. These rules are found at 45 CFR Parts 160 and 164.

Surveyor's Responsibilities

Surveyors will cooperate and work with facilities that use EHR. During the entrance conference surveyors will establish with the facility the process they will follow in order to have unrestricted access to the medical record. Electronic access to records will not eliminate the need for a surveyor to print a paper copy or to request a paper copy of certain parts of certain records. However, the surveyor shall make reasonable efforts to avoid, where possible, the printing of entire records. The surveyor should print or request a paper copy of only those parts of records that are needed to support findings of noncompliance, unless protocols for particular types of surveys require otherwise, e.g., copying complete medical records to be submitted for an EMTALA physician review.

Surveyors are not responsible for assessing compliance with the HIPAA Privacy and Security Rules. The Department of Health and Human Services Office of Civil Rights has the primary responsibility for enforcing the HIPAA Privacy Rule. The Office of eHealth Standards and Services within CMS is responsible for enforcing the HIPAA Security Rule. The surveyors' responsibility is to assess compliance with the provider or supplier-specific requirements for maintaining the content and confidentiality of the medical record. This delineation of responsibilities has resulted in questions about how far surveyors are expected to go in assessing EHR systems.

For example, questions have been raised about whether a hospital may share an EHR system with other health care providers/suppliers that share the same ownership without violating the requirement at 42 CFR 482.13(d) requiring confidentiality of the patient's/resident's medical record. CMS actively encourages the development of systems that permit appropriate sharing of clinical information across providers and suppliers, and the development of such systems is fully consistent with the requirement for protecting the confidentiality of the medical record. Surveyors must not cite providers/suppliers for violation of confidentiality requirements simply due to participation in an EHR system that includes multiple providers/suppliers.

Furthermore, surveyors are not trained nor are they expected to review the features of the provider's/supplier's EHR system, such as its rules and procedures for access management or auditing, in order to determine whether a sufficient level of confidentiality is assured. The HIPAA Security Rule has detailed, highly technical requirements that address such issues.

Surveyors are also not trained nor are they expected to review whether the facility has made required disclosures to all patients/residents; entered into all required business associate agreements; provided all required staff training; or fulfilled any other of its obligations as specified in the HIPAA Privacy Rule.

Surveyors instead are to focus on how the EHR system is being used in the facility, and whether that use is consistent with the Medicare CoPs or CfCs. For example, are computer screens showing clinical record information left unattended and readily observable or accessible by other patients/residents or visitors? Are there documents publicly posting passwords, which would be evidence of noncompliance with both confidentiality and medical record authentication requirements? Is there evidence to support a complaint allegation that facility staff shared information obtained from an EHR with unauthorized individuals?

When an SA has concerns that a provider or supplier practice may constitute significant violations of the HIPAA Privacy Rule, the SA has the discretion to file a complaint with the Office of Civil Rights. Information on filing Privacy Rule complaints may be found at: <http://www.hhs.gov/ocr/privacy/hipaa/complaints/index.html>. Likewise, when an SA has concerns that a provider or supplier EHR system may not be in compliance with the HIPAA Security Rule, the SA has the discretion to file a complaint with the CMS Office of eHealth Standards and Services. Information on filing Security Rule complaints may be found at: http://www.cms.hhs.gov/Enforcement/05_HowtoFileaComplaint.asp#TopOfPage. It would not be appropriate to file such complaints as a matter of routine whenever a provider or supplier is cited for noncompliance with CoP or CfC requirements concerning confidentiality or security of medical records.

Conclusion:

Existing requirements allow CMS and others authorized by law to have access to facility records whether those records are paper or electronic record systems. Refusing access to any patient/resident records is a basis for termination of the facility's Medicare agreement. If surveyors request access to EHR, the facility should ensure that data are backed-up and secure, and access does not impede the survey and certification process or the provision of care and services to beneficiaries.

Although there is some overlap between HIPAA and CoP/CfC requirements concerning the confidentiality and security of medical records, surveyors are responsible only for enforcement of the CoP or CfC requirements. SAs have the discretion to file complaints with the agencies that enforce the HIPAA Privacy and Security Rules if they suspect violation by a provider or supplier with those regulatory requirements.

Effective Date: Immediately. Please ensure that all appropriate staff is fully informed within 30 days of the date of this memorandum.

Training: This policy should be shared with all survey and certification staff, their managers and the State/RO training coordinator.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management