Managing Amendments in an HIE Environment

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The era of electronic health information has increased the complexity of managing amended protected health information (PHI) and the designated record set (DRS). Historically, changes had to be made to handwritten and transcribed reports and then corrected copies were mailed or faxed to the appropriate providers. Today, the challenge for covered entities (CE) participating in a health information exchange (HIE) environment is determining who owns the information as part of their medical record and who is responsible for processing amendments and ensuring all necessary parties receive the corrected information. The aim is to ensure data integrity is maintained across the continuum of care with accurate and complete PHI.

This Practice Brief outlines the issues to be addressed by a CE as it puts the necessary policies and processes in place for amending an electronic health record (EHR) that has been shared with other healthcare providers through a HIE. The CE must validate the amendment request, make the changes as determined, test with the HIE to confirm that updated information is readily identifiable, develop a process for alerting providers of the amended information, and meet its obligations as outlined by the HIE's Participant Agreement.

Amendments on the Rise

Amendment requests have increased as healthcare consumers have become more engaged in their care by obtaining, reviewing, and sharing their PHI. The Health Insurance Portability and Accountability Act (HIPAA) 45 CFR §164.526 grants individuals the right to access their PHI contained within a designated record set as well as request to amend that PHI.

HIEs allow information to be shared longitudinally and immediately to a variety of healthcare organizations and providers. If the CE determines that the information will be amended, it is responsible for amending the PHI and is required to notify all necessary parties involved with the care of the patient regarding the amended content. A clearly defined system of notification must be established with the HIE to alert providers of the modifications to PHI. Urgent changes to PHI must also be identified so patient care is not compromised.

HIE Agreements: Outline a Process for Amendments

Healthcare organizations or providers contemplating entering into affiliation with a HIE will need to carefully review any documents outlining both the responsibilities of the participants and of the HIE. The agreement is key to understanding the HIE's structure and its functions.

It is crucial that the CE understand the expectation and responsibility for ensuring that any data provided to the HIE is accurate and complete. Some agreements may have a simple statement that all participants will make reasonable efforts to provide accurate and complete data. Other agreements may impose more concrete requirements about the steps a provider must take to ensure contributed data is accurate and complete. Likewise, the agreement may detail a CE's responsibility for updating inaccurate or incomplete information. Those responsibilities may include complying with a request for an amendment and updating the information within a specified time period.

There are many factors to take into account with respect to amendments that may not be addressed in an agreement (see Appendix A in the online version of this Practice Brief, available in the AHIMA HIM Body of Knowledge at http://bok.ahima.org). The CE should review and discuss the checklist with the HIE to determine how the HIE will respond in these types of situations. It may also be advisable for the CE to request additional language to the agreement to clarify the responsibilities for each organization.

HIE Governance Policies and Procedures

HIPAA designates a CE as the responsible party for acting on an amendment request. In the case where the HIE is operating as a business associate (45 C.F.R. § 164.504(e)(2)(i)(F)) of the CE, the HIE may be required by the business associate contract to perform certain functions related to amendments, including informing others of the amendment. The HIE will also be accountable for compliance with HIPAA and with any state law more restrictive than HIPAA.

As with any policy and procedure, auditing and monitoring of the amendment policies and procedures will need to be facilitated. Specific attention should be given to:

- Compliance with the timeframes for responding to requests
- Documentation and communication of extensions, the reason for the delay, and the new date for a response
- Determination of approval or denial of the amendment request
- Reason for denial, if denied
- Compliance with any requests to include the amendment denial in future disclosures

HIEs will want to have a high degree of integrity with respect to the information for which they are responsible. The HIE should be able to confirm that the information from the source CE is available to other HIE participants in a form that is both accurate and complete. Confirmation should be accomplished through both documentation of data flows and robust testing of the use cases. In other words, test the amendment process. Testing the inclusion of the amendment denial information in future disclosures is an important part of overall testing. Understanding the capabilities of each application between the CE and HIE will allow for a design to be developed and thoroughly tested before implementation.

Policies will also need to address the appropriate timeframe for responding to a patient requesting an amendment of PHI. The policy should detail which entity is responsible for reviewing the request, either granting approval or denying the request, notifying the patient of the decision, and following the appeals process if the patient chooses to appeal a denial of an amendment request. The HIE's policy will need to address the methods by which erroneous information is corrected and disputed denials are documented.[1]

Training for Processing Amendments

Education and training for both HIE staff and CE staff is critical. Ideally, the HIE participation agreement will address the steps the HIE is responsible for and how they communicate with the CE once an amendment request is brought to their attention. The CE will also have its policies and procedures on how to handle a request for amendment. Each entity is responsible for training their staff on how to handle an amendment request.

If they become aware of a request, the HIE will have processes for notifying the CE. The HIE will also have to ensure the process for receiving the updated amendment or notification and ensuring the information is connected to the appropriate record, then notify all CEs that originally received the initial document.

It is vital that all staff understand the full amendment process and know which entity is responsible for each step in the amendment process. Failure to adequately understand the roles of all those involved can result in a breakdown in the amendment process. Such breakdown could compromise patient care due to a significant error that is not corrected in a timely manner and/or a violation of a patient's HIPAA rights if the amendment process is not properly followed.

Amendments Involving the HIE

Generally, the CE that created the documentation in question determines whether to grant the amendment request or deny it. One challenge with an HIE may be identifying the originating provider if the patient directs the request to the HIE or to another provider who obtained the health information through the HIE. It is important that the HIE or the provider who receives the amendment request from the patient have a designated process for identifying the originating provider so that the amendment request may be passed along to that provider. If the identity of the originating provider is not evident by reviewing the PHI in question, the HIE administrator may be called upon for assistance in identifying the originating provider and forwarding the amendment request. The HIPAA Privacy Rule requires all amendment requests be processed within 60 days of the date of the initial request (with 30-day extension). There must be clear processes with time frames for the HIE to notify the originating provider of the amendment request. If the CE grants the amendment request, it must generate the amendment, notify the patient, and relay the changes to all involved parties. In the event the request is denied, the patient must be notified in

writing and following the conclusion of the patient appeal procedure, the CE must append the following information to the PHI that is in question: the amendment request, the CE's denial, the patient's statement of disagreement, and the CE's rebuttal. The appended information, or an accurate summary thereof, must be included with any subsequent disclosures of the PHI related to the amendment request.

CEs must understand the role the HIE plays in updating or correcting any patient data that has been placed with the HIE. Depending upon the design and workflow of the HIE, it may be necessary for HIE employees to manually remove or correct data within the HIE databases that has been sent by the CE. If the information is manually removed, the audit trail must reflect who made the change, the organizations, and the date and time. Alternatively, the CE may choose to have the patient "opted-out" of HIE until the correction can be made. HIE participants need to make sure the HIE has a sufficient number of employees to handle correction needs in a timely manner. CEs may also find that there is a combination approach for which the HIE employees will make certain changes, such as manually removing two pages of Patient A's radiology report which were inadvertently included with Patient B's radiology report, while the provider is tasked with uploading a corrected surgery report that had listed "right hip" rather than "left hip." It is important that the HIE and the participants have clearly delineated which party is responsible for specific actions.

Notification of Amendment

Part of providing accurate and complete information involves updating any other providers who may have relied upon the incorrect information. In order to reach out to those other providers, the originator of the data must be able to determine whether the data has been accessed during the time period after it was sent to the HIE and prior to the data's correction and, if so, by whom. Therefore, it is important to know whether the information system used by the HIE has a robust audit trail. It is also important to know whether a CE can run its own audit trail of the information system or whether the provider must rely on the HIE employees to supply the information.

Once an HIE receives any updated or corrected information, the HIE makes the information available to its participants. If a CE makes updates to the medical record, that updated information will be available to any participant who accesses the information going forward. Most HIEs track where information is distributed. However, there are typically no alerts to notify providers when information has changed. The onus is usually on the provider who must access or request the latest information from the HIE. Data with a corrected status is usually shown with the "old" data to keep the data in context. Newer data is usually appended, not deleted, so the history can be tracked. In the case where data has been applied to the wrong patient, that data is removed to avoid decision errors and possible privacy violations (see AHIMA's Breach Management Toolkit for more details on handling a breach).[2] An audit trail is maintained for legal purposes, but only the updated information is presented to the end user.

There are times when the incorrect information is of such a type that it is vital to correct it immediately in order to ensure patient safety. This could include information about a rare blood disease, a life-threatening allergy to a common medication, or other information that would impact a physician's treatment approach, particularly in an emergency situation. Therefore, CEs considering participation in an HIE should inquire about the escalation process the HIE uses for these types of data corrections.

The HIE may act as the gatekeeper of the amendment process by providing an amendment request form for the patient to complete and then forwarding that amendment request to the originating provider. Alternatively, the HIE may provide the originating provider's contact information to the patient in order for the patient to contact the provider and follow the provider's amendment request process. CEs should ask a few questions of the HIE such as:

- Will the HIE provide the patient with information about any other providers who have accessed the patient's data and possibly viewed the incorrect information?
- How can the patient be assured that the incorrect information has not been disseminated further than the originating provider's record and the HIE?

It would be reasonable to outline the maximum acceptable timeline in the participation agreement in order to ensure HIE accountability. The CE will also need to ensure that the audit trail will provide sufficient information about the other HIE participants who viewed the incorrect information in order to ensure the updated information is provided in a timely manner.

Routine Testing Scenarios and the Testing Process

Managing amendments in the HIE environment requires understanding how to correct and/or amend patient information systematically. Communication between a CE's EHR and an HIE is usually through Health Level Seven (HL7) messages such as observation results (ORUs) and medical document management (MDM) as well as clinical document architecture (CDA) documents. Therefore, it is imperative to understand how these messages and documents can be updated when the need for an amendment arises.

ORUs are typically sent in response to an order and contain test results (e.g., lab, imaging). The ORU^R01 for unsolicited observation messages and ORU^R03 unsolicited update are the most common ORU messages.[3,4] If there is a correction to an ORU message, the ORU^03 message is sent and the receiving system should replace the current patient information/order/test info with the updated information. A status of "C" can be used when sending the corrected message and the date/time changes when the ORU gets updated; thus, the latest message becomes the "official record" at that time.

The MDM message transmits new or updated documents (e.g., progress note, operative report) as well as status information and may or may not be in response to an order. The most commonly used type of MDM message is the MDM^T02 (i.e., original document notification and content) which is similar to an ORU message. Other MDM message types include the MDM^T05 for Document Addendum Notification and the MDM^T06 for Document Addendum Notification with Content. For example, a specification may require a MDM^T10 (i.e., document replacement notification and content) rather than an MDM^T06 (Document Addendum Notification with Content) for amendments so participants will need to be able to send messages based on the specification and understand what message type and format is being used for amended information. In some cases, only the "F" final status is used (no "C" corrected status).

HL7 messages have many segments. One of the required message segments is for patient identification (PID). The PID includes the patient identifier, name, date of birth (DOB), sex, race, address, and other identifying information. Many updates and corrections involve name changes or DOB corrections, so the PID segment is often the segment being updated. The observation (OBX) segment contains document information and contents in the case of MDMs and clinical observation results in the case of ORUs. The format (e.g., plain text, formatted text, or encoded PDFs) is dictated by the receiving system. The contents of the OBX segment is another possible area where corrections/amendments may occur.

Evaluation of CDA conformance should also be a part of the testing process. CDA is a document markup standard used to exchange clinical documents. The CDA specification is very broad; templates are used to limit or "constrain" to specific use cases. Most templates are open and allow for customization of content. The CDA header enables clinical document management and exchange. The CDA standard allows for the function of amending or replacing records via the CDA header but CEs must make sure the end system (e.g., the HIE) can handle these functions as well. The CDA header can be used to identify document revisions and addenda as well. Typically, if there is an error in a CDA document, such as incorrect medications, the originator will resend the entire document which, once sent, becomes the official new record. CDA documents can be distributed via email, HL7 messaging, or Direct messaging, among other options. Documentation for amendments that were not accepted can be included as part of a CDA document or sent as an embedded document in an ORU or MDM message.

There are a number of steps to managing amendments or making corrections of patient information with regards to health information exchange. In general, participants do not correct the already-processed HL7 message or CDA document. Providers correct the information in the EHR or source system, which sends a new message with the corrected information and it is up to the receiving system to update its information based on the new information in the HL7 message or CDA document. Each part of the interface or exchange process must be tested. For example, for ORU or MDM messages, each segment, status, and acknowledgment used should be a part of the testing plan.

Best Practices and Recommendations

The following are best practices and recommendations for CEs to follow with regard to managing amendments in an HIE environment.

Review HIE Agreements. Prior to joining an HIE within the organization, it is recommended that the agreement between the CE and HIE be clearly reviewed and understood. Policies, procedures, and internal processes addressing how EHR

corrections are handled within the provider/HIE communication infrastructure must be addressed and thoroughly tested to ensure that all parties can track and display the request, final decision, actual correction, and current patient information. Additionally, these transactions should be incorporated into the organization's performance improvement processes where audits are routinely conducted to ensure that defined workflow processes are working as designed.

Define Procedures. It is recommended that the organization have clear procedures defined for processing amendment requests and accountability must be transparent within each organization (HIE and/or provider). A designated point person should be assigned responsibility for ensuring that the amendment request has been processed, from initial request through final decision. This includes the process for handling a request that has been denied. These processes must be clearly documented and displayed within the HIE to ensure that the patient request is known to all providers of care.

Monitor Compliance. Healthcare organizations must have a process for monitoring compliance of amendments, notification, and denial of amendments in place. Periodic reviews or audits should be conducted to ensure systems and procedures are working as expected.

Understand the Escalation Process. Escalation processes must be in place when patient safety is at risk. The escalation process could include a 24/7 hotline number, a special email address that is continuously monitored, an instant messaging address, or on-call staff.

Provide a Standard Request Form. State law, in addition to HIPAA, may play a role in the process patients use to request amendments from HIEs. Therefore, it is important to check the applicable state laws for any additional guidance. Some HIEs provide a standard amendment request form which is a good practice to document the request (see Appendix B in the online version of this Practice Brief). In addition, there is the opportunity for the patient to disagree (see Appendix C).

Use an Internal Checklist for EHR Correction Notifications. Many organizations use some kind of internal checklist to track places to check and/or verify when corrections are required. Below are some examples of areas that may need to be notified based on the type of amendment request:

- Internal patient EHR portal
- Billing
- Coding
- Compliance and Privacy Office
- Pro Fee Coding
- Registration
- Enterprise Master Patient Index
- Information Technology
- EHR, clinical, and ancillary systems
- Scanning system
- Sending/legacy systems
- HIE release (opt-in or opt-out)

Following the above best practices and recommendations will help ensure that healthcare organizations manage amendments in a HIE environment in the most effective way possible.

Notes

1. Department of Health and Human Services Office for Civil Rights. "The HIPAA Privacy Rule and Electronic Health Information Exchange in a Networked Environment: Correction." www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/healthit/correction.pdf.
2. AHIMA. "Breach Management Toolkit: A Comprehensive Guide for Compliance." 2014. http://bok.ahima.org/PdfView?oid=300305.
3. Remote Operations. "SecureFlow ProTM HL7 Specifications: ORM, ORU and ACK Message Types." October 17, 2005. http://hl7reference.com/HL7%20Specifications%20ORM-ORU.PDF.
4. Corepoint Health. "HL7 Messages." https://corepointhealth.com/resource-center/hl7-resources/hl7-messages.

Read More
Appendices Available Online

http://bok.ahima.org

Three appendices are available in the online version of this Practice Brief in AHIMA's HIM Body of Knowledge:

Appendix A: Checklist: Questions to Consider Before Participating in an HIE

Appendix B: AHIMA Sample Patient Request to Amend the Health Record

Appendix C: AHIMA Sample Patient Statement of Disagreement

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