Implementing Electronic Signatures - Retired

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Implementing Electronic Signatures (AHIMA Practice Brief)

Editor's note: The following information supplants information contained in the practice brief "Electronic Signatures (Updated)" published in the October 1998 Journal of AHIMA.

Electronic health records may provide the ability to sign (or authenticate) entries electronically. This practice brief provides the reader with insight into the technology used to implement electronic signatures, the regulatory environment, and recommendations on the implementation of such an application. Key issues are addressed relative to the changes necessary in end-user processes, as well as supporting departments such as health information management.

Background

In electronic health records, an "original" document may be created in a variety of ways but ultimately is viewed on a computer screen. Responsible healthcare practitioners then authenticate (or sign) entries in the record. Electronic signatures are created when the user enters a unique code, biometric, or password that verifies the identity of the signer, thus creating an individual "signature" on the record.

Signature lines generated in these media are usually prefaced by a statement such as "Electronically authenticated by John Doe, MD on (date and time)." Other information such as the practitioner's title may also be included in the signature block.

It should be noted that digital and electronic signature systems are not the same as "auto-authentication" or "auto-signature" systems, some of which do not require or allow the healthcare practitioner to review the entry before signature. Some "auto" systems do not require any specific action by the healthcare practitioner to authenticate an entry.

Legal/Regulatory/Accreditation Effects

Accreditation Requirements

The use of electronic signatures is acceptable to the Joint Commission on Accreditation of Healthcare Organizations. According to the proposed 2004 *Comprehensive Accreditation Manual for Hospitals (CAMH),* Standard IM. 6.10, entries may be authenticated "by written signatures or initials, by rubber-stamp, or computer key." In the CAMH, the Joint Commission outlines specific requirements for the use of rubber-stamp and electronic signatures, stating, "The practitioner must sign a statement that he or she alone will use it."[1]

The Joint Commission accepts the use of electronic signatures in other care settings too. The use of electronic signatures is noted to be acceptable in ambulatory care, home care, long-term care, and mental health, subject to the requirements outlined above.[2,3]

Legal and Regulatory Requirements

To participate in the Medicare program, healthcare organizations must comply with federal regulations promulgated by the Centers for Medicare and Medicaid Services (CMS; formerly HCFA), which are commonly referred to as the Medicare Conditions of Participation. The use of electronic signatures is acceptable under the Medicare Conditions of Participation. The *Code of Federal Regulations,* Section 482.24, "Conditions of Participation for Hospitals, Condition of Participation: Medical Record Services (c)(1)(iii)" states, "Authentication may include signatures, written initials, or computer entry." According to CMS's "Hospitals Interpretive Guidelines and Survey Procedures," a list of computer codes and written signatures must be readily available and maintained under appropriate safeguards. Sanctions must be established for improper or unauthorized use of rubber-stamp and electronic signatures. In addition, the organization's governing body must authorize the use of electronic signatures.[4]

Medicare Conditions of Participation for other care settings have requirements that entries be signed, but acceptable methods of authentication are not specified:

- Medicare Conditions of Participation for States and Long-Term Care Facilities (42 CFR Ch. IV, Part 483, Subpart A, Section 483.40) require that physicians "write, sign, and date progress notes at each visit and sign and date all orders."[5]
- Medicare Conditions of Participation for Hospice Care (42 CFR Ch. IV, Subpart C, Section 418.74) require that "entries are made and signed by the person providing the services."[6]
- Medicare Conditions of Participation for Home Health Agencies (42 CFR, Ch. IV, Section 484.48) require "signed and dated clinical and progress notes."[7]
- Medicare Conditions of Participation for Rural Primary Care Hospitals (42 CFR Ch. IV, Section 485.638) require "dated signatures of the doctor of medicine or osteopathy or other health care professional."[8]
- Medicare Conditions of Participation for Comprehensive Outpatient Rehabilitation Facilities (42 CFR Ch. IV, part 485) and Ambulatory Care Surgical Services (42 CFR Ch. IV, art 416) do not address signature requirements for patient record entries.[6]

Public Law 104-191, the Health Insurance Portability and Accountability Act (HIPAA), originally mandated that the secretary of Health and Human Services, in coordination with the secretary of Commerce, should adopt standards specifying procedures for the electronic transmission and authentication of signatures as part of the security rule. The notice of proposed rule making that pertained to electronic signatures was published in August 1998. However, in the final security rule published April 21, 2003, the references to electronic signatures were eliminated. The rule did provide for the secretary of Health and Human Services to evaluate rules for electronic signatures at a later date.[11]

State Laws and Regulations

State laws and regulations on authentication of medical records vary widely. Some are silent on authentication of medical records, whereas others simply require medical records to be maintained according to recognized professional standards. On the other hand, some states are very specific as to how practitioners must authenticate medical record entries, outlining requirements for the use of electronic signatures. States with specific laws or regulations addressing electronic signatures are listed in the Appendix, State-by-State Review of Regulations Pertaining to Electronic Signature."

If your state has not authorized authentication of medical record entries by electronic signature--either by statute or regulation--check with your state licensing authority to see if it permits the use of electronic signature. A few states do not address this issue in their

statutes or regulations but may permit the use of electronic signatures with approval from fiscal intermediaries or state authorities.

Digital Signature Technology

A digital signature is determined by applying an algorithm to an electronic document. This process yields a unique string of characters known as a message digest. The digest uses private key encryption, and the signature is placed on the electronic document.

The receiver of the signed document decrypts the message digest with the sender's public key encryption, applies the same message algorithm, and compares the digest with the transmitted version. This guarantees that the message is unaltered (data integrity) and the signer is who he says he is if they are identical (authentication). Because only the signer can have the private key encryption, nonrepudiation is enforced.

Digitized signatures differ from electronic signatures in that digitized signatures use handwritten signatures on a pen pad. Electronic signatures use a unique personal identification number (PIN), electronic identification, or biometric scans.

The ASTM has developed standards for the use of electronic signatures. Taken into consideration are accountability, nonrepudiation, and data integrity. A copy of the standards may be obtained by calling ASTM customer service at (610) 832-9585. Also, information on how to obtain copies and descriptions of the ASTM standards is available at www. astm. org.

The Human Element of Change

Although technology is an important element of an electronic signature system, it is not the only factor that must be considered. Every technical decision must also be evaluated in terms of the human component. Failure to recognize the needs of various users can mean the difference between a project that is widely embraced and one burdened with complaints.

The implementation of electronic signatures will have a profound effect not only on clinicians, but on HIM department staff as well. The shift away from paper processing requires planning and coordination to bring about an efficient and effective change. The decisions made will affect the users' perceptions of the effectiveness of the process and have the power to increase or decrease the workload of the HIM department.

Recommendations and Considerations

Sponsors

Determine the level and strength of leadership support for the project. Unwavering leadership support is a critical success factor for implementation. Engage executive, HIM and ancillary department, and medical staff sponsors for the project. Sponsors have the responsibility for approving the use of electronic signatures in the organization.

Planning

Careful planning is the key to the success of any project. The table below includes a number of topics that require decisions during the planning process. This list is meant to trigger discussions that are germane to individual environments and lead to decisions that guide implementation. Development of checklists may be extremely helpful in the planning and implementation process.

Item	Issues to Consider
Communication	Medical staff and other end users must be notified of the changing system and implementation. Consider the use of letters, posters, fliers, and presentations at department meetings with a clear message of the change. Be explicit on timelines, target dates, and plans for training. Involve clinicians in making presentations when possible. Strategy for communicating future functional changes and upgrades to end users should be considered so it can be communicated during training. Let users know what the application will bring to them. Try to key into benefits they will realize as a result of the implementation of electronic signature.
Courtesy Copies	Waiting to send copies until after authentication allows for edited documents to be sent. It provides an impetus for signing promptly. However, delays in signing documents may result in phone calls from providers who need the information.
Display/Availability	Displaying information as soon as it is available allows caregivers to see information promptly if there are delays in signing. If an updated copy is displayed once the document has been signed, the previous version must be accessible if required.
Documents Included	There must be a clear list of which documents are available to electronically sign. Documents may include transcribed documents, scanned documents, and laboratory or other reports, depending on the facility. Documents (such as letters) that may continue to require manual signature should be clearly noted

	in training. Policy about whether these documents will be included in the electronic health record should be determined prior to implementation.
Implementation Approach	*Partial or phased implementation* offers the opportunity to test and refine with a pilot group and then move on to other groups. There are fewer users to train at one time, and you can target a few physicians early who want to be trained; they can be advocates for functionality. This approach requires clear accounting of who is signing electronically and who is signing paper. *Full or "big bang" implementation* allows faster implementation that is not drawn out. However, it is critical that all problems be anticipated and dealt with promptly. Depending on the size of the implementation, training and support resources may not be able to adequately support the implementation. Retraining may be a bigger issue than with phased or partial implementation.
Legal Record Definition	Electronic signatures may be part of the overall electronic health record journey of an organization. During implementation of electronic signatures, the organization may have a hybrid definition of the record in place, with some documents stored in hard copy and some stored electronically. Some organizations choose to have each document printed after electronic authentication and filed in a hard copy file that remains the "legal" record.
Medical Staff Bylaws	Bylaws must outline who can and cannot sign documents (per Joint Commission, state, and federal requirements). They should be amended to reflect approval of the use of an electronic signature application.
Printing	Printing must be considered in the context of the overall policy about document printing. Printing outside the HIM department heightens the loss of control of copies of the documents. Protection of protected health information is greatly reduced.
Provider User Group	Going live with *all providers* in a user group (e. g., physicians, ancillary provider group) makes it easy for HIM to track the signing more easily and clarifies training and support needs. Size of the groups is important in making this decision. Going live with *limited groups of providers* (e. g., one department or section) may be a good option. Training and support resources can be available. HIM tracking is more complex. If you expect to implement electronic signatures with residents or with providers where co-signatures are required, be sure the application selected is capable of handling the requirement. In this model, one person (resident) dictates, edits, and signs a document prior to having a second person (attending physician) sign the document. The second signature is the "official" signature and is the one that removes the signature deficiency. If there are documents that require two "official" signatures, it may be necessary to generate two separate documents.
Steering Committee	An oversight or steering committee must be set up to provide leadership and guidance to the project. It is imperative that clinicians, HIM, and information technology be well represented on the committee. Regular reports should be made to project sponsors.

	Responsibilities include: • Seeking approval of the sponsors for use of electronic signatures in the organization • Understanding legal/ regulatory/ accreditation issues • Approving the organization's requirements for the application • Overseeing development of a request for proposal (RFP) • Evaluating the RFP responses • Selecting the vendor • Approving the charter, scope, and project plan • Tracking progress of project according to the plan • Assisting in removing barriers to implementation
Support--Go Live	This is linked with the training strategy. Effectiveness of telephone versus in-person methods of providing support should be considered.
Support--Ongoing	Determine who will provide ongoing support and how users will receive help when they need it. To minimize confusion for clinicians, they should be given *one* number to call for assistance. If possible, use the existing "help desk." Staff familiar with the application can provide a backup to the help desk staff when needed. "Super-users" or staff familiar with the application in departments or on nursing units can be immensely helpful as staff changes over time. If there are centralized areas where electronic signatures may be accessed (such as in the HIM department), staff working in that area should be included in training so they can assist clinicians.
System Functionality	*Sign only* is easier in terms of training, as fewer functions are being used by end users. However, this does not allow clinicians to make corrections to documents before signing. *Edit and sign* allows documents to be complete and accurate before clinicians authenticate them. Skill levels of providers need to be assessed and may add to training time. More functions must be included in training. Known limitations of the software should be discussed during training. *Messaging* is useful to communicate errors in assignment of a deficiency or other issues with document completion. (See also "Implementation-Deficiency Analysis" and "Transcription.") *Notification* is a communication to providers that there are documents waiting for signatures. Training must address how signers will know there are documents needing signature (e. g., inbox, check regularly).
Training Strategy	Classes are most efficient. However, it is often difficult to schedule group classes. Depending on the length of training, consider the use of department meetings to deliver it. One-on-one training can focus at the provider's level of skill but is much more labor intensive. Training should be brief (10 to 30 minutes) and focused on exactly what providers need to know to use the system and understand any work flow and

	policy changes. Trainers should have flexible schedules to allow informal support for a period following going live. Training super-users as trainers and to provide go-live support spreads training and support over a broader base and closer to end users. Checklists can reduce the risk of inconsistency when multiple trainers are used. Use of video, CD-ROM, or Web-based training methods may help, depending on the level of computer literacy of the group(s) being trained, accessibility of computers that can be used for the training, and quality of the training tools to be used. If handouts or guides are needed, they should include screen shots where possible and be available to participants at the time of training. Providers should sign confidentiality agreements as part of the training process. The decision as to where confidentiality agreements will be stored and how training will be documented should be made before starting. If documents are to be signed in one system (e. g., an electronic signature module) and then transferred to another system (e. g., the electronic health record), providers must be clear about where to look for and sign documents electronically. If there are multiple electronic signature applications in the facility and the signing conventions differ, training must address the issue so distinctions in procedure can be pointed out to clinicians.
Use of the System	With *mandatory use* of the application, all users are doing the same thing, which may be easier on the HIM department once implementation is complete. *Optional use* allows users time to "buy in" or use the option they prefer. This capitalizes on those who are 100 percent in favor of the application to be promoters of the new system. The HIM department has to know which providers are and are not using the application at any point in time. When use of the application is optional, the definition of the legal record is more complicated. Optional use of the application means that an organization will take longer in the journey toward a completely electronic health record. The organization may inadvertently send a message that the change is not important if clinicians are allowed to opt in or out of using the application.

Implementation

Work Flow Changes/Policy and Procedures Updates

The table below includes a number of topics that require decisions during the planning process. This list is meant to trigger discussions that are germane to individual environments and may result in changes in policies, procedures, and work flow.

Item	Issues to Consider
Addenda	Each facility must stipulate in policy who has the authority to create an addendum to an existing document.
Amendments and Corrections	Minimizing the need for corrections must be a stated goal. Documents should be complete and accurate before electronic authentication. However, there must be a procedure for corrections to signed documents. Consider creating an addendum rather than an amendment to a signed document. Policy should dictate whether there is any difference when the edits needed are for substantive or minor issues. Limiting the persons authorized to make amendments to signed documents ensures that the correction is appropriate and procedures are followed to preserve the integrity of the legal record.
Confidentiality Statement	Require members of the staff using the electronic signature application to sign a confidentiality statement acknowledging their responsibility and accountability for the use of their electronic signature. The statement should explicitly state that the provider is the only one who has access to and will use his or her specific password. This is optimally done at the time of training.
Contingency Plan	There must be written procedures for staff to follow if the application is unavailable. It is recommended that the procedure be to wait for restoration of the application rather than revert to manual signatures. A decision to revert to paper must not be made lightly. It is nearly impossible for HIM staff to reconcile documents that were signed manually with those waiting for electronic signature, while the application was unavailable. Any difference in procedures depending on the duration of the down time, or if the down time is planned or unplanned, should be clear.
Copy and Paste Policy	The application allows copying of all or portions of documents from one system to another, determine if it allows copying and pasting of electronic signatures between documents. This must be prohibited by policy if the application does not prevent it.
Deficiency Analysis	HIM department should maintain a list of physicians or other healthcare practitioners who are authorized to use electronic signatures. There must be a way to distinguish among documents to be manually signed, those that are electronically signed, and those that do not require any signature. There must be a procedure for assigning a deficiency for a required signature and for changing the assignment when appropriate. A tracking mechanism is needed for monitoring unsigned documents. Information from this tracking may be incorporated into the delinquent records tracking system. It is unlikely that there will be any change in the way that deficiency statistics are calculated, but this should be verified.

	When multiple electronic signature applications exist in an organization, HIM staff must be able to reconcile all the information for deficiency analysis. (See also "Multiple Systems Using Electronic Signatures.") Written procedures must be in place to close deficiencies created when a provider will not be available to electronically sign documents. Often, a department or section chief, chief of staff, or medical record committee chair is authorized to administratively sign such documents.
Document Printing	Printing policy must be made in conjunction with the overall organizational policies for printing the electronic health record.
Filing/Clerical	Based on the organization's legal medical record definition, work flow for the filing area may be affected. Procedures must reflect whether unsigned and/ or signed documents will be filed in the record. Clerical staff must be able to distinguish between documents that are to be filed and those that are not.
Multiple Signatures or Co-signatures	The application allows multiple or co-signatures, clear procedures must guide deficiency analysis. If the application does not allow multiple signatures, consider breaking the document into two documents, each requiring the appropriate signature. If the application does not allow co-signatures, evaluate the pros and cons of implementing with only one signature required on the document for completion.
Multiple Systems Using Electronic Signatures	If multiple systems in the facility include an electronic signature module, there must be an integration point in the HIM department, or staff there will be unable to reconcile deficiencies.
Other HIM Functions	Although it is unlikely that there will be changes to HIM departmental work flow other than those cited above, all areas should be evaluated for changes that may result from the implementation of an electronic signature application.
Release of Information	If the facility has previously allowed unsigned documents to be released, there may be an opportunity to restrict release of information to signed documents only. Otherwise, there will likely be no change in the process.
Transcription	This should be a method for communication between dictators and transcriptionists, prior to signing a document, to facilitate document completion. Policy should dictate who has the responsibility of making corrections to documents.
Version Control	If policy allows signed documents to be edited, all signed versions of documents must be available for medicolegal purposes. There must be a procedure for accessing each version. If documents in the electronic signature application are the legal medical record copy, no signed documents can be deleted permanently from the system. If documents are printed and maintained as part of a hard copy record or are transferred to another system or repository, this is not an issue.

Information Systems

The table below includes a number of topics that require decisions during the planning process. This list is meant to trigger discussions that are germane to individual environments and may result in changes in policies, procedures, and work flow.

Item	Issues to Consider
Access	Determine whether the application will use standard network, terminal emulation, Web-based (intranet/ Internet) access, or a combination.
Access Locations	Decide where clinicians will be able to sign documents. Every location--nursing unit, HIM department, personal office, or home--has unique challenges. However, multiple access points usually add to the success of implementation. The ability to protect confidential information must be considered as part of this strategy. Consider whether the Internet or VPN will enhance usage of the system.
Audit Trails	Determine what is available from the application. Evaluate its usefulness as a monitoring tool to ascertain whether a user viewed, edited, or printed any documents or pages. Assign responsibility for evaluating audit trails or exception reports. Regular reports should be generated for oversight groups.
Change Management	Clear change-management processes must be followed when upgrades or changes are made to the electronic signature application or to any system interfaced to it.
Contingency Plan	Procedures to be followed if systems are down must be written and available to users. How the down time will be communicated to system owners and end users is of utmost importance. Note if procedures differ based on whether the down time is planned or unplanned. Clearly communicate what support will be provided to users during down times.
Data Requirements	Electronic signatures must include the printed name of the signer; the date and time when the signature was executed; any actions taken to create, modify, or delete electronic records (audit trail); and the meaning associated with the signature (e. g., review, approval, responsibility, authorship, authentication). Each of these items must be readable/ viewable as part of the electronic record or printed form of the electronic record.
Passwords	Passwords allow access to the application. Processes for issuing, changing, and terminating passwords are required. Passwords should be "strong," meaning they contain alpha, numeric, and special characters; are case sensitive; and are at least seven characters in length if the application permits. Group or multiple user passwords do not provide adequate security. Every user must have a unique password. Passwords should be changed at specified intervals. If available, "single sign-on" is an advantage for providers besieged with numerous passwords to remember. Single sign-on applications allow the user to employ one set of identifiers that can be synchronized with all the applications the user is authorized to access.
Retention	Documents signed electronically must be retained in conformity with the organization's definition of the legal medical record and retention policy.
Security	The application should include automatic time-outs.

	Security screens covering the face of terminals so only the user directly facing the screen can read what is on the screen should be implemented if feasible.
System Availability	The application should be available at all times. Policies need to address availability while backups are performed or system updates/ upgrades are installed. If the network has routine or extended down times, procedures for notifying users must be clear. Analyze whether access issues of availability are different on-and off-site. Negotiate support agreements that support around-the-clock access.

Skills Required

The list below includes a number of topics that require decisions during the planning process. This list is meant to trigger discussions that are germane to individual environments and may result in new or revised job descriptions.

Role	Required Skills
Champion(s)	Have the respect of peers and ability to convince others Keyboarding skills Understand processes that may change with implementation of electronic signature Know where to get help when needed Learn use of required functions of the system Understand which documents will be electronically signed and which will retain manual signatures
End Users	Keyboarding skills Understand processes that will change with implementation of electronic signature Know how to get help when needed Use required functions, including options available for editing, signing, addenda, which documents will be electronically signed, and which documents will retain manual signatures Know how to obtain or change a password and where to get help if the password is forgotten or lost
Executive Sponsor	Have the respect of clinicians and staff Provide unwavering support for implementation of system as well as policies and enforcement mechanisms Understand processes that may change with implementation of electronic signature

HIM Clerical Staff	Keyboarding skills Understand processes that will change with implementation of electronic signature Know how to get help when needed Use required functions of the system Understand which documents will be electronically signed, remain with manual signatures, and require no signature Know how to obtain or change a password and where to get help if the password is forgotten or lost Know and can perform their role in the contingency plan
HIM Manager	Department-level manager/director with overall responsibility for electronic signature Has a high degree of understanding of application Understands processes that may change with implementation of electronic signature Knows how to get information when needed Understands which documents will be electronically signed and which will retain manual signatures
HIM Transcriptionists	Keyboarding skills Understand transcription processes that will change with implementation of electronic signature Know how to get help when needed Use required functions of the system Understand which documents will be electronically signed, remain with manual signatures, and require no signature Know how to obtain or change a password and where to get help if the password is forgotten or lost Know and can perform their role in the contingency plan.
Project Manager	Deliver positive reinforcement for using the application Capable of garnering trust and confidence of the executives and steering committee Strong organizational skills Ability to manage project along the critical path to implementation Outstanding communication skills

	Ability to work with and gain the trust of clinicians and staffs of widely varying backgrounds and levels of skill Basic project management skills of working with teams, organization, planning, business process re-engineering, implementation, and budget Proficiency with the tools of project management and reporting
System Administrator	Understands entire application and mechanisms in place Responsible for assigning levels of authority and privileges for the application Keyboarding skills Understands processes that may change with implementation of electronic signature Knows how to get help when needed Uses required functions of the application Knows where to obtain or change a password and how to get help if password is forgotten or lost Knows and can perform his or her role in the contingency plan
Trainers	Patience Delivery with positive reinforcement for using the application Outstanding presentation skills for groups and individuals Ability to communicate with and answer questions for providers of all backgrounds and levels Understand "as is" and "to be" work flow if there will be changes Knowledge of application and work flow in order to suggest ways of integrating electronic signatures into the provider's work flow

Maintenance

The table below includes a number of topics that require decisions during the planning and implementation phases for ongoing maintenance of the electronic signature application. This list is meant to trigger discussions that are germane to individual environments and may result in changes in policies, procedures, and work flow.

Item	Issues to Consider
Customer Service	Determine the mechanism whereby user suggestions about the application can be evaluated and forwarded to the vendor as appropriate.
Passwords	Generation of passwords for the electronic signature application should fit with the overall organizational system. There must be a notification process when users leave the organization to facilitate timely deactivation of passwords.

	The organization should maintain a list of the practitioners' passwords using appropriate safeguards.
Software and Hardware Upgrades	Plan for system expansion if appropriate. Require complete testing before implementing any patches or upgrades.
System Maintenance	Assign responsibility for building tables and performing other required system maintenance tasks. Determine who will do troubleshooting when needed. Write policies and procedures requiring periodic reviews. Assign responsibility for communication of changes when software upgrades bring work flow or procedure changes. System monitoring of usage should be in concert with other organizational policies.
Training	Determine the methodology for ongoing training. There should be a system to notify individual users who need review or new training. There must be a method of training all users as new or expanded features and functions become available.

Conclusion

Implementation of electronic signatures can be either a step in the journey toward an electronic health record or a means of aiding in the process of getting signatures on required documents. In the latter scenario, documents can be made available to clinicians more rapidly and allow them to edit or complete documents prior to signing them. In either scenario, many decisions must be made and each one will have an effect on the work flow of those involved.

Critical factors in the success of the implementation are unwavering support for the project for project sponsors and detailed planning. With these two factors covered, participating in an electronic signature project can bring many rewards to those involved and to the organization.

Glossary

Notes

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