5. LEGAL DOCUMENTATION STANDARDS

This section will review the legal documentation standards for entries in and maintaining the medical record. In today's healthcare environment health information is collected in various formats – paper-based, electronic resident records, and computerized resident databases. The legal documentation standards have mainly applied to a paper medical record, however, most are also applicable to documentation in an electronic medical record as well. This section is divided into three topics and will address the following issues:

1. Purpose of the medical record and definition of the legal medical record
2. Legal documentation standards that apply to medical records
3. Proper methods for handling errors, omissions, addendum, and late entries.

1. Purpose and definition of the Legal Medical Record*

A patient's health record plays many important roles:

1. It provides a view of the resident's health history - In other words, it provides, a record of the resident's health status including observations, measurements, history and prognosis, and serves as the legal document describing the health care services provided to the patient. The medical record provides evidence of the quality of resident care by -
   - Describing the services provided to the resident
   - Providing evidence that the care was necessary
   - Documenting the resident's response to the care and changes made to the plan of care
   - Identifying the standards by which care was delivered
2. Documenting adherence to company standards and procedures
3. It provides a method for clinical communication and care planning among the individual healthcare practitioners serving the resident.
4. It provides supporting documentation for the reimbursement of services provided to the resident.
5. It is a source of data for clinical, health services, outcomes research as well as public health purposes.
6. It serves as a major resource for healthcare practitioner education.
7. It serves as the legal business record for a health care organization and is used in support of business decision-making.
8. There is not a one-size-fits-all definition of the legal record since laws and regulations governing the content vary by practice setting and by state. However, there are common principles to be followed in creating a definition. The following table "Guidelines for Defining the Health Record for Legal Purposes" breaks down the health record into four categories to provide guidelines for assisting health care organizations in defining the content of their legal record.

Guidelines for Defining the Health Record for Legal Purposes

LEGAL HEALTH RECORD *The legal business record generated at or for a healthcare organization. This record would be released upon request.*	The legal health record is the documentation of the healthcare services provided to an individual in any aspect of healthcare delivery by a healthcare provider organization. The legal heath record is individually identifiable data, in any medium,

	collected and directly used in and/or documenting health care or health status. The term includes records of care in any health-related setting used by healthcare professionals while providing patient care services, for reviewing patient data or documenting observations, actions, or instructions. Some types of documentation that comprise the 2. legal health record (see examples listed below) may physically exist in separate and multiple paper-based or electronic/computer-based databases. Typically this includes records that are considered part of the active, overflow, and discharge chart. The legal health records EXCLUDES health records that are NOT official business records of a healthcare provider organization (even though copies of the documentation of the healthcare services provided to an individual by a healthcare provider organization are provided to and shared with the individual). Thus, records such as Personal Health Records (PHRs) that are patient controlled, managed, and populated would not be part of the legal health record. Copies of PHRs that are patient owned, managed, and populated by the individual but are provided to a healthcare provider organization(s)1. should be considered part of the legal health record. Such records are then used by healthcare provider organizations to provide patient care services, review patient data or document observations, actions or instructions. This includes patient owned, managed and populated "tracking" records, such as medication tracking records and glucose/insulin tracking records. Examples of documentation found in the legal health record: Records of history and physical examination Multidisciplinary progress notes/documentation Immunization record Problem list Medication profile / Physician Orders and Renewals Consent for treatment forms Consultation reports Physical therapy, Speech therapy, and Occupational therapy records Email containing patient-provider or provider-provider communication Graphic records Intake/output records Nursing and other discipline assessment Care planMinimum data sets Practice guidelines or protocols/clinical pathways that

	imbed patient data Telephone orders Advanced Directives Discharge instructions, plan of care, etc.
PATIENT - IDENTIFIABLESOURCE DATA *An adjunct component of the legal business record as defined by the organization. Often maintained in a separate location or database, these secondary records are provided the same level of confidentiality as the legal business record. The information is usually retrievable upon request.*	Patient-identifiable source data are data from which interpretations, summaries, notes, etc. are derived. Source data should be accorded the same level of confidentiality as the legal health record. These data are increasingly captured in multimedia form. For example, the videotape recording of the encounter would not represent the legal health record but rather would be considered source data. In the absence of documentation, (e.g., interpretations, summarization, etc.), the source data should be considered part of the legal health record. Examples of patient-identifiable source data: Diagnostic films and other diagnostic images from which interpretations are derived Electrocardiogram tracings from which interpretations are derived Audio of dictation Analog and digital patient photographs for identification purposes only Videos of procedure 2.
ADMINISTRATIVE DATA *Provided the same level of confidentiality as the legal health record, however, the data is not considered part of the legal health record (such as in response to a subpoena for the "medical record.")*	Administrative data are patient-identifiable data used for administrative, regulatory, and payment (financial) purposes Examples of administrative data: Authorization forms for release of information Correspondence concerning requests for records Event history/audit trails Protocols/clinical pathways, practice guidelines and other knowledge sources that do not imbed patient data Patient-identifiable claimPatient-identifiable data reviewed for quality assurance or utilization management Death CertificatesPatient identifiers (e.g., medical record number, biometrics)
DERIVED DATA *Provided the same level of confidentiality as the legal health record, however, the data is not considered part of the legal health record (such as in response to a subpoena for the "medical record."*	Derived data are data derived from patient records that are aggregated so that there are no means to identify patients. Examples of derived data: Best practice guidelines created from aggregate patient dataAnonymous patient data for research purposes ORYX report OASIS report MDS report Survey/Accreditation reports Public health records Statistical reports

be on every page including both sides of the pages, every shingled form, computerized print out, etc. When double-sided forms are used, the resident name and number should be on both sides since information is often copied and must be identifiable to the resident. Forms both paper and computer generated with multiple pages must also have the resident name and number on all pages.

3. **Date and Time on Entries**

Every entry in the medical record must include a complete date – month, day and year and have a time associated with it. Time must be included in all types of narrative notes even if it may not seem important to the type of entry -- it is a good legal standard to follow. Charting time as a block (i.e. 7-3) especially for narrative notes is not advised. Narrative documentation should reflect the actual time the entry was made. For certain types of flowsheets such as a treatment record, recording time as a block could be acceptable. For example, a treatment that can be delivered any time during a shift, could have a block of time identified on the treatment record with staff signing that they delivered the treatment during that shift.

For assessment forms where multiple individuals are completing sections, the date and time of completion should be indicated as well as who has completed each section (Exception: MDS).

1. ***Timeliness of Entries***

Entries should be made as soon as possible after an event or observation is made. An entry should never be made in advance. If it is necessary to summarize events that occurred over a period of time (such as a shift), the notation should indicate the actual time the entry was made with the narrative documentation identifying the time events occurred if time is pertinent to the situation.

2. ***Pre-dating and back-dating***

It is both unethical and illegal to pre-date or back-date an entry. Entries must be dated for the date and time the entry is made. (See section on late entries, addendum, and clarifications). If pre-dating or back-dating occurs it is critical that the underlying reason be identified to determine whether there are system failures. The cause must be evaluated and appropriate corrective action implemented.

4. **Authentication of Entries and Methods of Authentication**

Every entry in the medical record must be authenticated by the author – an entry should not be made or signed by someone other than the author. This includes all types of entries such as narrative/progress notes, assessments, flowsheets, orders, etc. whether in paper or electronic format. There are various acceptable methods for authentication of an entry. Each facility must identify the proper and acceptable method of authentication for the type of entry taking into consideration state regulations and payer requirements.

1. ***Signature***

Entries are typically authenticated by a signature. At a minimum the signature should include the first initial, last name and title/credential. A facility can choose a

more stringent standard requiring the author's full name with title/credential to assist in proper identification of the writer. If there are two people with same first initial and last name both must use their full signatures (and/or middle initial if applicable). Facility policies should define the acceptable format for signatures in the medical record.

2. ***Countersignatures***

Countersignatures should be used as required by state law (i.e graduate nurse who is not licensed therapy assistants, etc.). The person who is making the countersignature must be qualified to countersign. For example, licensed nurses who don't have the authority to supervise should not be countersigning an entry for a graduate nurse who is not yet licensed).

Practitioners who are asked to countersign should do so carefully. If there is a procedure involved, there should be some observation (i.e. view treatment or view dressing) to assure that it was done properly.

The federal regulations for long term care facilities do not require countersignatures for nurse practitioners and physician assistants. It is important to know state licensure and professional practice regulations for a NP/PA to determine if countersignatures are required.

3. ***Initials***

Any time a facility chooses to use initials in any part of the record for authentication of an entry there has to be corresponding full identification of the initials on the same form or on a signature legend. Initials can be used to authenticate entries such as flow sheets, medication records or treatment records, but should not be used in such entries as narrative notes or assessments. Initials should never be used where a signature is required by law (for example, on the MDS).

4. ***Fax Signatures***

The acceptance of fax signatures is dependent on state, federal, and reimbursement regulations. Federal regulations for nursing facilities do not prohibit the use of fax signatures. Unless specifically prohibited by state regulations or facility policy, fax signatures are acceptable. When a fax document/signature is included in the medical record, the document with the original signature should be retrievable.

5. ***Electronic/Digital Signatures***

Electronic signatures are acceptable if allowed by state, federal, and reimbursement regulations. The federal regulations for nursing facilities allow for the use of electronic signatures when computerized medical records are maintained rather than a hard copy except for the MDS (HCFA currently requires the facility to retain a hard copy of the MDS signatures). State regulations and payer policies must be reviewed to assure acceptability of electronic signatures when developing facility policies.

If electronic signatures are used in the medical record, the software program/technology should provide assurance that the following standards are met:

- **Message Integrity:** The message sent or entry made by a user is the same as the one received or maintained in the system.
- **Non-Repudiation:** Assurance that the entry or message came from a particular user. It will be difficult for a party to deny the content of an entry or creating it.
- **Authentication:** Confirms the identity of the user and verifies that a person really is who he says he is.

Electronic Signature Standard

6. ***Rubber Stamp Signatures:***

Rubber stamp signatures are acceptable if allowed by state, federal and reimbursement regulations. Federal regulations for nursing facilities allow for the use of rubber stamp signatures by physicians provided that the facility authorizes their use and has a statement on file indicating that the physician is the owner of the stamp and attested that they will be the only one using the signature stamp (F386).

From a reimbursement perspective, some fiscal intermediaries have local policies prohibiting the use of rubber stamp signatures in the medical record even though federal regulation allows for their use. Facility policies should define if rubber stamp signatures are acceptable and define the circumstances for their use after review of state regulations and payer policies.

7. ***Authenticating Documents with Multiple Sections or Completed by Multiple Individuals:***

Some documentation tools particularly assessments are set up to be completed by multiple staff members at different times. As with any entry, there must be a mechanism to determine who completed information on the document. At a minimum, there should be a signature area at the end of the document for staff to sign and date. Staff who have completed sections of the assessment should either indicate the sections they completed at the signature line or initial the sections they completed.

5. **Signature Legends**

A signature legend may be used to identify the author and full signature when initials are used to authenticate entries. Each author who initials an entry must have a corresponding full signature on record. There are three types of acceptable signature legends:

1. Signature Legend on the Original Document: A signature legend can be included on the actual form where the initials are used. The legend would include the authors initials and their full signature and title.
2. One Master Signature Legend per Resident Record: A separate signature legend form can be kept with staff initials and signatures for each resident's record. The legend should include the initials, full signature and title. A process must be implemented to obtain staff signatures with each new admission as well as a process for new staff to sign the signature legends for all current residents.
3. One Facility Master Signature Legend with Copies for Resident Records: Another acceptable method for maintaining a signature legend is to keep one master

for the facility and make copies of the original for the resident's record. During the resident's stay a copy of the legend must be available (for example, posted at station or kept at the front of the medication and treatment book). At the time of discharge, a copy of the signature legend must be incorporated in the record. The discharge record must include a copy of the master signature legends maintained and updated by the facility during the resident's stay. At a minimum the signature legend should contain the initials, full signature and title of staff.

If master signature forms are to be used, there must be systems in place to assure all staff who initial entries sign the legend on an on-going basis. If staff turn over is high new master signature legends should be completed on a regular basis (i.e. once a year). With each update of the master signature legend there should be a date indicating implementation and revision.

6. **Permanency of Entries**

All entries in the medical record regardless of form or format must be permanent (manual or computerized records).

For hard copy/paper records facilities should document in blue or black ink only. No other colored ink should be used in the event that any part of the record needs to be copied. The ink should be permanent (no erasable or water-soluble ink should be used). Never use a pencil to document in the medical record.

1. ***Printers***

When documentation is printed from a computer for entry in the medical record, the print must be permanent. For example, a laser printer would be used rather than an ink jet printer because the ink is water-soluble.

2. ***Fax Copies***

When fax records are maintained in the medical record the assurance must be made that the record will maintain its integrity over time. For example, if thermal paper is used for the receipt of a fax that will become part of the medical record, a copy must be made for filing in the medical record since the print on thermal paper fades over time.

3. ***Photo Copies***

The medical record should contain original documents whenever possible. There are times when it is acceptable to have copies of records and signatures particularly when records are sent from another health care facility or provider.

4. ***Carbon Copy Paper (NCR)***

If there is a question about the permanency of the paper (i.e. NCR, carbon paper) when the carbon paper is the permanent entry it needs to be photocopied. Policy should indicate when items are copied and how the original is disposed. At times carbon copies of documents (i.e. TO's) may be used on a temporary basis and the original will replace the

carbon – this is considered an acceptable practice.

5. ***Use of Labels in the Medical Record***

The use of adhesive labels in the medical record is an accepted practice in the health care industry including long term care. Labels or label paper (adhesive-backed paper) are used for a variety of reasons including, but not limited to, resident demographics, transcription of dictated progress notes, printing of physician orders for telephone orders, medication or treatment records.

There are a number of advantages to using labels: 1) they are often computer generated and usually typed providing a readable record/document such as progress notes; 2) when used in the physician order transcription process within an clinical computer system they can help to reduce or eliminate transcription errors by printing the order in a consistent format for all areas of the record (telephone order, medication/treatment record, physician order sheets); and 3) when demographic labels are used in the record, it is more likely that complete resident identification information will be provided on each page of the record rather than relying on staff to write in the demographic information.

When labels are used in the record, there are a number of issues or concerns that must be considered and addressed before implementation. Facility policies and practices should address how and where labels will be used as well as the following issues:

- If labels are to be used in the medical record, selection of a label vendor and/or type of label requires careful consideration. Because the labels lose their adhesiveness over time, facilities must select a vendor and labels that offer a guarantee on the length of time the labels will retain their adhesiveness. The length of time should be consistent with the average length of stay for residents in the facility plus the retention period for medical records after discharge. A guarantee of 10 years should be adequate for most facilities. The label should also be considered permanently adhesive shortly after being affixed to the backing sheet (some labels do not adhere permanently for 24 hours after placing it on a backing sheet allowing for possible removal).
- Basic resident identification information should be included on each label should it become dislodged from the backing sheet to assure that the label/entry can always be tracked to the proper resident's record. If the label paper is used for documentation such as a progress note or order, the date and signature should also be included on the label.
- If an error was made on a label, another label should never be placed over the original. Proper error correction procedures should be used for the entry.
- Labels must never be placed over other documentation in the medical record. This would be the equivalent of using whiteout or blacking out an entry in the record and is not acceptable.
- Consideration should be given to the type of file folder used to house overflow and discharge records. Although not a

requirement, using a pocket folder could help to contain any labels that may have become dislodged from the backing sheet over time.

- When labels are computer-generated, the printer ink must be permanent (i.e. a laser printer is permanent vs. an ink jet printer which is usually water-soluble).

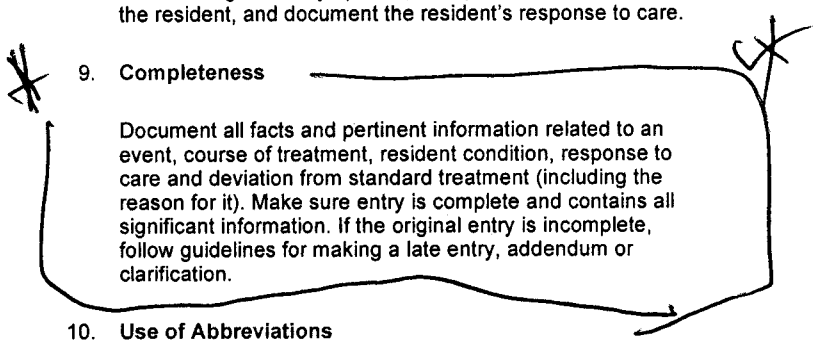
7. **Specificity**

In writing entries use language that is specific rather than vague or generalized. Do not speculate when documenting -- the record should always reflect factual information (what is known vs. what is thought or presumed) and be written using factual statements.

Examples of generalizations/vague words: Resident doing well, appears to be, confused, anxious, status quo, stable, as usual.

8. **Objectivity**

Chart the facts and avoid the use of personal opinions when documenting. By documenting what can be seen, heard, touched and smelled entries will be specific and objective. Describe signs and symptoms, use quotation marks to quote the resident, and document the resident's response to care.



9. **Completeness**

Document all facts and pertinent information related to an event, course of treatment, resident condition, response to care and deviation from standard treatment (including the reason for it). Make sure entry is complete and contains all significant information. If the original entry is incomplete, follow guidelines for making a late entry, addendum or clarification.

10. **Use of Abbreviations**

Every facility should set a standard for acceptable abbreviations to be used in the medical record (develop a facility-specific abbreviation list). Only those abbreviations approved by the facility should be used in the medical record. When there is more than one meaning for an approved abbreviation, facilities chose one meaning or identify the context in which the abbreviation is to be used.

11. **Legibility**

All entries in the medical record must be legible. Illegible documentation can put the resident at risk. Readable documentation assists other caregivers and helps to assure continuation of the resident's plan of care. If entry cannot be read, the author should rewrite the entry on next available line, define what the entry is for referring back to the original documentation and legibly rewrite the entry. *Example: "Clarified entry of (date)" and rewrite entry, date and sign. The entry rewritten must be the same as the original.*

12. **Continuous Entries**

In manual records, document entries on the next available space – do not skip lines or leave blanks. There must be a continuous flow of information without gaps or extra space between documentation. A new form should not be started until all previous lines are filled. If a new sheet was started,

the lines available on the previous page must be crossed off. If an entry is made out of chronological order it should be documented as a late entry.

13. **Completing all Fields**

Some of the questions or fields on documentation tools such as assessments, flow sheets, checklist documents may not be applicable to the resident. All fields should have some entry made whether it applies to the resident or not. If a field is not applicable, an entry like "N/A" should be made to show that the question was reviewed and answered. Fields left blank may be suspect to tampering or back-dating after the document has been completed and authenticated. If the documentation will be reported by exception (e.g. documenting only on shifts where a behavior occurs), there should be a statement on the form indicating how charting will be completed.

14. **Continuity of Entries – Avoiding Contradictions**

All entries should be consistent with the --

- Concurrent entries
- Other parts of the medical record – the assessments, care plan, physician's orders, medication and treatment records, etc.
- Other facility document – incident reports, twenty-four hour reports, nursing service shift reports, etc.

Ongoing treatments and conditions (feeding tube, vent, trach, catheter, etc.) should be noted as continuing. Avoid repetitive (copy cat or parrot) charting. The current entry should document current observations, outcomes/progress.

If an entry is made that contradicts previous documentation, the new entry should elaborate or explain why there is a contradiction or why there has been a change.

15. **Condition Changes**

Every change in a resident's condition or significant resident care issues must be noted and charted until the resident's condition is stabilized or the situation is otherwise resolved. Documentation that provides evidence of follow-through is critical.

16. **Document Informed Consent**

Informed consent should be carefully documented whenever applicable. An informed consent entry should include an explanation of the risks and benefits of a treatment/procedure, alternatives to the treatment/procedure, and evidence that the resident or appropriate legal surrogate understands and consents to undergo the treatment/procedure.

17. **Admission/Discharge Notes**

The resident's initial admission note and discharge summary should fully and accurately describe the resident's condition at the time of admission and discharge, respectively. Documentation should include the method/mode of arrival/discharge, resident's response to admission/discharge and physical assessment. When discharging a resident, take special care in documenting resident education when

applicable including instructions for self-care, and that the resident/responsible party demonstrated an understanding of the self-care regimen.

18. **Notification or Communications**

If notification to the resident's physician or family is required, or a discussion with the resident's family occurs regarding the care of the resident, all such communication (including attempts at notification) should be charted. Include the time and method of all communications or attempts. The entry should include any orders received or responses, the implementation of such orders, if any, and the resident's response. Messages left on answering machines should be limited to a request to return call and does not meet the definition of notification.

19. **Delegation**

The charge nurse is responsible for ensuring that all entries by nursing assistants (CNA, NAR, etc.) are complete and consistent with the remainder of the record. All entries by nursing assistants should be reviewed by the charge nurse at the end of the shift. The charge nurse is responsible for all delegated nursing acts, as allowed by state/federal requirements, including charting of such care in the resident's medical record (i.e. flowsheets).

20. **Incidents**

When an incident occurs, document the facts of the occurrence in the progress notes. Do not chart that an incident report has been completed or refer to the report in charting.

21. **Make and Sign Own Entries**

Authors must always make and sign their own entries (both manual and computerized records). An author should never make an entry or sign an entry for someone else or have someone else make or sign an entry for them.

22. **Appropriateness of Entries – Keep Documentation Relevant to Resident Care**

The medical record should only contain documentation that pertains to the direct care of the resident. Do not let emotions show up in charting. Charting should be free from jousting statements that blame, accuse, or compromise other care givers, the resident, or his/her family. The medical record should be a compilation of factual and objective information about the resident. The record should not be used to voice complaints (about other care givers, departments, physicians or the facility), family fights, fights between disciplines, gripes, staffing issues, vendor issues, etc.

3. LEGAL GUIDELINES FOR HANDLING CORRECTIONS, ERRORS, OMISSIONS, AND OTHER DOCUMENTATION PROBLEMS

There will be times when documentation problems or mistakes occur and changes or clarifications will be necessary. Proper procedures must be followed in handling these situations.

1. **Proper Error Correction Procedure:**

When an error is made in a medical record entry, proper error

correction procedures must be followed.

- Draw line through entry (thin pen line). Make sure that the inaccurate information is still legible.
- Initial and date the entry.
- State the reason for the error (i.e. in the margin or above the note if room).
- Document the correct information. If the error is in a narrative note, it may be necessary to enter the correct information on the next available line/space documenting the current date and time and referring back to the incorrect entry.

Do not obliterate or otherwise alter the original entry by blacking out with marker, using white out, writing over an entry, etc.

Correcting an error in an electronic/computerized medical record systems should follow the same basic principles. The system must have the ability to track corrections or changes to the entry once the entry has been entered or authenticated. When correcting or making a change to an entry in a computerized medical record system, the original entry should be viewable, the current date and time should be entered, the person making the change should be identified, and the reason should be noted. In situations where there is a hard copy printed from the electronic record, the hard copy must also be corrected.

2. **Handling Omissions in Documentation**

At times it will be necessary to make an entry that is late (out of sequence) or provide additional documentation to supplement entries previously written.

1. **Making a Late Entry**

When a pertinent entry was missed or not written in a timely manner, a late entry should be used to record the information in the medical record.

- Identify the new entry as a "late entry"
- Enter the current date and time – do not try to give the appearance that the entry was made on a previous date or an earlier time.
- Identify or refer to the date and incident for which late entry is written
- If the late entry is used to document an omission, validate the source of additional information as much as possible (where did you get information to write late entry). For example, use of supporting documentation on other facility worksheets or forms.
- When using late entries document as soon as possible. There is not a time limit to writing a late entry, however, the more time that passes the less reliable the entry becomes.

1. **Entering an Addendum**

An addendum is another type of late entry that is used to provide additional information in conjunction with a previous entry. With this type of correction, a previous note has been made and the addendum provides additional information to address a specific situation or incident. With an addendum, additional information is provided, but would not be used to document information that was forgotten or written in error.

When making an addendum --

- Document the current date and time.
- Write "addendum" and state the reason for the addendum referring back to the original entry.
- Identify any sources of information used to support the addendum.
- When writing an addendum, complete it as soon after the original note as possible.

2. **Entering a Clarification**

Another type of late entry is the use of a clarification note. A clarification is written to avoid incorrect interpretation of information that has been previously documented. For example, after reading an entry there is a concern that the entry could be misinterpreted. To make a clarification entry –

- Document the current date and time.
- Write "clarification", state the reason and refer back to the entry being clarified.
- Identify any sources of information used to support the clarification.
- When writing a clarification note, complete it as soon after the original entry as possible.

3. **Omissions on Medication, Treatment Records, Graphic and other Flowsheets**

It is considered willful falsification and illegal to go back and complete and/or fill-in signature "holes" on medication and treatment records or other graphic/flow records in the medical record. Facility protocol should establish procedures for documenting a late entry when there is total recall and other supporting information to prove that a medication or treatment was administered. Some states have established time frames in which the omissions can be completed if the practitioner recalls administering the medication and treatmen such as no more than 24 hours should go by in which a practitioner is allowed to complete a medication, treatment, graphic or flow record and only when there is a clear recollection of administering the medication, treatment or information pertinent to a flow/graphic record.

Facilities should use concurrent monitoring (self-monitoring, shift-to-shift review, etc.) to assure that the documentation is complete and timely for all medications and treatments administered. When systemic problems are identified corrective action should be implemented. If an omission is older than 24 hours or the staff member does not have a clear recollection or there is not supporting documentation (i.e. worksheets, narcotic records, drug delivery records, initialed punch cards, etc.), the record should be left blank. At no time should the records be audited after a period of time (i.e. end of month) with the intent of identifying omissions and filling in "holes."

4. **Documenting Care Provided by a Colleague**

Documentation must reflect who performed the action. If it is absolutely necessary to document care given by another person, document factual information. For example, if a call is received from a nurse from the previous shift who indicates that he/she forgot to chart something in the record, enter the

date and time of the telephone call and note: "At 16:00 Louise Jackson, R.N., called to report that at 11:00 this morning, Mr. Smith indicated he had a headache and requested Tylenol. Tylenol 650mg p.o. was given by Ms. Jackson at 11:05am. Ms. Jackson stated that Mr. Smith verbalized he was free of pain at 12:00 noon." (Signed by Penelope E. Olson, RN). Also place initials on the medication record as follows: "PEO for LJ." When Louise returns to work, she should review your note for accuracy and countersign it. She should also place her initials by your entry on the medication record. If there is not adequate room on the medication record, the initials are entered on the medication record and the entry is circled. On the back of the medication record document the above entry.

5. **Resident Amendments to their Record**

LTC facilities should have policies to address how a resident or their legally responsible party can enter amendments into their medical record. A separate entry (progress note, form, typed letter, etc.) can be used for resident amendment documentation. The amendment should refer back to the information questioned, date, and time. The amendment should document the information believed to be inaccurate and the information the resident/responsible party believes to be correct. At no time should the documentation in question be removed from the chart or obliterated in any way. The resident cannot require that the records be removed or deleted.

Under HIPAA, the resident has the right to request an amendment for as long as the record(s) is maintained by the facility. The facility may require a resident to make the request for an amendment in writing and provide a reason to support a requested amendment. The facility must act on the individual's request for an amendment no later than 60 days after receipt (a 30 day extension may be granted if the resident is notified). Once the amendment request has been reviewed, the facility must inform the resident if the amendment was granted in whole or in part. If all or a portion of the amendment request was denied, the facility must provide the resident with a written reason for the denial. The resident has the right to make a written statement of disagreement with the denial that will become part of the medical record. The facility can also document a rebuttal statement. When disclosing information pertaining to the disagreement, the written statement by the resident and the rebuttal by the facility must be included.

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Session 47

Making Your Electronic Record Legal

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2002 ANNUAL HIMSS CONFERENCE & EXHIBITION

INTRODUCTION

About two years ago while attending a conference a professional peer of mine recounted a tale of how the electronic signature function of his organization's long planned and much lauded computerized patient record (CPR) failed to comply with state and federal regulations and professional guidelines. He told me of how the application would allow physicians to batch sign more than one report at a time, that even after the document was signed it could be easily altered, and that documents could be signed without being reviewed. All of these capabilities did not comply with existing federal and state laws and guidelines. His facility was involved in a major rework of the software application to correct the problems. Since that time I have heard many similar stories, all of these accounts involved organizations that overlooked long established principals of health information management supported by laws, regulations, and guidelines and developed over many years. These health information management principals that challenge computerized patient record implementers include:

- document authentication,
- record retention,
- confidentiality,
- content requirements,
- Amendment and correction, and
- Patient control over the content, use, and disclosure of the medical record.

CPR applications have been designed without the means or storage capacity to archive and retain historical medical records. The system designers fail to realize that medical records must, by law, be securely retained for many years. These same designers often under estimate the large volume of medical record information that must be stored. Furthermore, many system designers do not design systems to allow for easy retrieval of stored information.

CPR systems with weak or non-existent access control systems fail to secure protected health information stored in the medical record. Systems with widely known "back door" passwords allow the end user to bypass the access control system, gaining unrestricted access to protected health information.

There are systems that progressed all the way to "go live" only to find that critical pieces of medical record content required by law and healthcare accreditation organizations were absent from the systems data dictionary and had to be added.

Reportedly, CPR systems exist where the captured health information is difficult or impossible to amend or correct. Where functions exist to allow for amendment and correction, the procedure in place often does not conform with generally accepted standards, or federal, and state laws.

Many system designers fail to realize the impact of patient control over their health information. CPR systems don't allow the patient to readily access, track, amend, and correct their personal medical information.

Finally, there are systems, that by design, make it difficult or impossible to quickly and easily disclose health information to individuals and entities beyond the network's primary end users. In studies conducted by the American Health Information Management Association it was determined that on average approximately 150 individuals access the patient's medical record. With so many different individuals and entities accessing the information, one would assume that ease of access and disclosure would be a number one priority for CPR systems. State laws spell out how quickly healthcare facilities must respond to requests for access and disclosure. Yet, CPR systems exist that make access and disclosure slow and difficult.

Laws, regulations, standards, and guidelines address all of these issues. However, lack of awareness often causes them to be overlooked during CPR planning and implementation.

CPR implementers that ignore the key characteristics that govern medical records soon find out that there is more to implementing a computerized patient record than purchasing and installing the most innovative technology. The laws, regulations, guidelines, and standards that have been developed over the years define modern health records. Computer applications that don't comply with the existing health record laws and regulations will ultimately face major rework before they can be implemented.

Careful attention to the key health record characteristics that define the legal medical will ensure that CPR will serve it's intended propose.

DOCUMENT AUTHENTICATION

The use of an individual's signature to validate a business document is strongly supported by common law. The medical record is considered a business document and a signature on a medical record serves the same purpose as a signature on a business document.

The appropriate way to authenticate a medical record entry is mandated in:

- state laws,
- federal regulations,
- accreditation organization standards,
- and industry standards.

The rules of evidence

Statements made outside the court and offered as proof of an occurrence are considered hearsay evidence. Normally, hearsay evidence is considered unreliable. Anyone can make a claim that someone consented to, said, or did something at another time and place. The party wishing to have such records accepted, as evidence must somehow demonstrate the reliability of record.

The most common type of exception is the business record exception. Under this exception records maintained in the regular course of business are considered admissible as evidence. Medical records fall under the business record exception provided that method of record keeping conforms to certain established guidelines.

- The record was made in the regular course of business.
- The entries in the record are made promptly.
- The entries were made by the individual within the enterprise with first-hand knowledge of the acts, events, conditions, and opinions.
- Process controls and checks must exist to ensure the reliability and accuracy of the record.
- Policies and procedures must exist to protect the record from alteration and tampering.
- Policies and procedures must exist to prevent loss of stored data.
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The rules of evidence and the business record rule provide a strong foundation for an enterprise seeking to develop medical record authentication policies and procedures.

In order to ensure the admissibility of the medical record as evidence, the enterprise must first establish policies and procedures that address.

- Author authentication
- Medical record access control
- Medical record archiving and retention
- Medical record security
- Medical record disaster recovery policies and procedures.

By establishing controls over the creation of medical records, enterprises can ensure the non-repudiation of medical record entries made in the normal course of business.

Ultimately, by controlling the how, who, where, and when of creating the medical record the enterprise establishes the methodology for creating a strong defensible medical record

To comply with the rules of evidence guidelines computer applications must have controls in place to ensure that only the author can sign medical record entries. Once an entry is signed the application should prevent the signature and the entry from being altered. Access to the medical record should be controlled and limited to individuals with a need to know.

The Medicare Conditions of Participation

The Conditions of Participation outline the steps required to achieve compliance with the Medicare program mandates.

Section 482.24, c, 1, requires that "All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for