

APPENDIX Q. REGULATIONS FOR MEDICAL RECORDS

This appendix provides excerpts from the Medicare Conditions of Participation (CoP) concerning medical records and plans of care for health care providers. Existing CoP language could be updated to reflect contemporary use of EHR technology and aligned with Meaningful Use criteria. The following sections highlight regulatory requirements and interpretive guidelines surrounding patient medical records to demonstrate where they might align with the EHR Incentive Program and where the language could be updated to reflect current use of EHR technology and aligned with meaningful use criteria.

Regulatory language is provided for: (1) Hospitals, (2) Long-Term Care Facilities, (3) Home Health Agencies, (4) Hospice, (5) Outpatient Rehabilitation, (6) Outpatient Physical Therapy and Speech-Language Pathology, (7) Ambulatory Surgical Centers, (8) End Stage Renal Disease, (9) Psychiatric Hospitals, (10) Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs), and (11) Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID).

A. Federal Regulations -- Hospital Conditions of Participation [Excepts Pertaining to Medical Records]¹

§482.13 Condition of Participation: Patient's Rights

- (d) Standard: Confidentiality of patient records.
- (1) The patient has the right to the confidentiality of his or her clinical records.
 - (2) The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

Interpretive Guidelines §482.13(d)(2)

The patient has the right to easily access his/her medical records. Reasonable cost-based fees may be imposed only to cover the cost of copying, postage, and/or preparing an explanation or summary of patient health information, as outlined in 42 CFR §164.524(c). The cost of

¹ Source: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf.

duplicating a patient's record must not create a barrier to the individual's receiving his or her medical record.

Survey Procedures §482.13(d)(2)

- Does the hospital promote and protect the patient's right to access information contained in his/her clinical record?
- Does the hospital have a procedure for providing records to patients within a reasonable time frame?
- Does the hospital's system frustrate the legitimate efforts of individuals to gain access to their own medical record?
- Does the procedure include the method to identify what documents were not provided and the reason?

§482.23(c)(2)

- (i) If verbal orders are used, they are to be used infrequently.
- (ii) When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with federal and state law.

Interpretive Guidelines §482.23(c)(2)(i)

Verbal orders should be used only to meet the care needs of the patient when it is impossible or impractical for the ordering practitioner to write the order or enter it into a computer (in the case of a hospital with an electronic prescribing system) without delaying treatment.

§482.24 Condition of Participation: Medical Record Services [51 FR 22042, June 17, 1986, as amended at 71 FR 68694, November 27, 2006; 72 FR 66933, November 27, 2007; 77 FR 29074, May 16, 2012]

The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.

Interpretive Guidelines §482.24

The term "**medical records**" includes at least written documents, computerized electronic information, radiology film and scans, laboratory reports and pathology slides, videos, audio recordings, and other forms of information regarding the condition of a patient.

- (a) *Standard: Organization and staffing.* The organization of the medical record service must be appropriate to the scope and complexity of the services

performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

§482.24(b) Standard: Form and Retention of Record

The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

Interpretive Guidelines §482.24(b)

These requirements apply to both manual and electronic medical record systems.

§482.24(b)(1) -- Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.

Interpretive Guidelines §482.24(b)(1)

Medical records are retained in their original or legally reproduced form in hard copy, microfilm, computer memory, or other electronic storage media. The hospital must be able to promptly retrieve the complete medical record of every individual evaluated or treated in any part or location of the hospital within the last 5 years.

Survey Procedures §482.24(b)(1)

- Determine that records are retained for at least 5 years, or more if required by state or local laws.
- Select a sample of patients, both inpatient and outpatient who were patients of the hospital between the previous 48-60 months. Request their medical record. Is it promptly retrieved? Is it complete? Is it in original or in a legally reproduced form?

§482.24(b)(2) -- The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

§482.24(b)(3) -- The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with federal or state laws, court orders, or subpoenas.

Interpretive Guidelines §482.24(b)(3)

The hospital has sufficient safeguards to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, and policy; or duly authorized as having a need to know. No unauthorized access or dissemination of clinical records is permitted. Clinical records are kept secure and are only viewed when necessary by those persons having a part in the patient's care.

The right to confidentiality means safeguarding the content of information, including patient paper records, video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian. Hospital staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to that individual.

Confidentiality applies to both central records and clinical record information that may be kept at dispersed locations.

The hospital's patient record system must ensure the security of patient records. The hospital must ensure that unauthorized individuals cannot gain access to patient records and that individuals cannot alter patient records. Patient records must be secure at all times and in all locations. This includes open patient records for patients who are currently inpatients in the hospital and outpatients in outpatient clinics.

Survey Procedures §482.24(b)(3)

- Verify that only authorized persons are permitted access to records maintained by the medical records department.
- Verify that the hospital has a policy to grant patients direct access to his/her medical record if the responsible official (e.g., MD/DO responsible for patient's care) determines that direct access is not likely to have an adverse effect on the patient.
- Verify that medical records and other confidential patient information are released only for patient care evaluation, utilization review, treatment, quality assurance programs, in-house educational purposes, or in accordance with federal or state law, court orders, or subpoenas.
- Verify that copies of medical records and other confidential patient information are released outside the hospital only upon written authorization of the patient, legal guardian, or person with an appropriate -- power of attorney to act on the patient's behalf, or only

if there is a properly executed subpoena or court order, or as mandated by federal and state law.

- Verify that precautions are taken to prevent unauthorized persons from gaining physical access or electronic access to information in patient records.
- Observe the hospital's security practices for patient records. Are patient records left unsecured or unattended? Are patient records unsecured or unattended in hallways, patient rooms, nurse's stations, or on counters where an unauthorized person could gain access to patient records?
- Verify that there is an established system in place that addresses protecting the confidentiality of medical information.
- If the hospital uses electronic patient records, are appropriate security safeguards in place? Is access to patient records controlled?
- Verify that adequate precautions are taken to prevent physical or electronic altering, damaging or deletion/destruction of patient records or information in patient records.

(a) *Standard: Content of record.* The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

Interpretive Guidelines §482.24(c)

The medical record must contain information such as notes, documentation, records, reports, recordings, test results, assessments etc. to:

- Justify admission;
- Justify continued hospitalization;
- Support the diagnosis;
- Describe the patient's progress;
- Describe the patient's response to medications; and
- Describe the patient's response to services such as interventions, care, treatments, etc.

The medical record must contain complete information/documentation regarding evaluations, interventions, care provided, services, care plans, discharge plans, and the patient's response to those activities.

Patient medical record information, such as, laboratory reports, test results, consults, assessments, radiology reports, dictated notes, etc. must be promptly filed in the patient's medical record in order to be available to the physician and other care providers to use in making assessments of the patient's condition, to justify continued hospitalization, to support the diagnosis, to describe the patient's progress, and to describe the patient's response to medications,

interventions, and services, in planning the patient's care, and in making decisions on the provision of care to the patient.

§482.24(c)(1) -- All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.

Interpretive Guidelines §482.24(c)(1)

All entries in the medical record must be **legible**. Orders, progress notes, nursing notes, or other entries in the medical record that are not legible may be misread or misinterpreted and may lead to medical errors or other adverse patient events.

All entries in the medical record must be **complete**. A medical record is considered complete if it contains sufficient information to identify the patient; support the diagnosis/condition; justify the care, treatment, and services; document the course and results of care, treatment, and services; and promote continuity of care among providers. With these criteria in mind, an individual entry into the medical record must contain sufficient information on the matter that is the subject of the entry to permit the medical record to satisfy the completeness standard.

All entries in the medical record must be **dated, timed, and authenticated**, in written or electronic form, by the person responsible for providing or evaluating the service provided.

- The time and date of each entry (orders, reports, notes, etc.) must be accurately documented. Timing establishes when an order was given, when an activity happened or when an activity is to take place. Timing and dating entries is necessary for patient safety and quality of care. Timing and dating of entries establishes a baseline for future actions or assessments and establishes a timeline of events. Many patient interventions or assessments are based on time intervals or timelines of various signs, symptoms, or events. (71 FR 68687)
- The hospital must have a method to establish the identity of the author of each entry. This would include verification of the author of faxed orders/entries or computer entries.
- The hospital must have a method to require that each author takes a specific action to verify that the entry being authenticated is his/her entry or that he/she is responsible for the entry, and that the entry is accurate.

The requirements for dating and timing do not apply to orders or prescriptions that are generated outside of the hospital until they are presented to the hospital at the time of service. Once the hospital begins

processing such an order or prescription, it is responsible for ensuring that the implementation of the order or prescription by the hospital is promptly dated, and timed in the patient's medical record.

In the case of a pre-established electronic order set, the same principles would apply, so that the practitioner would date, time and authenticate the final order that resulted from the electronic selection/annotation process, with the exception that pages with internal changes would not need to be initialed or signed if they are part of an integrated single electronic document.

Authentication of medical record entries may include written signatures, initials, computer key, or other code. For authentication, in written or electronic form, a method must be established to identify the author. When rubber stamps or electronic authorizations are used for authentication, the hospital must have policies and procedures to ensure that such stamps or authorizations are used only by the individuals whose signature they represent. There shall be no delegation of stamps or authentication codes to another individual. It should be noted that some insurers and other payers may have a policy prohibiting the use of rubber stamps as a means of authenticating the medical records that support a claim for payment. Medicare payment policy, for example, no longer permits such use of rubber stamps. Thus, while the use of a rubber stamp for signature authentication is not prohibited under the CoPs and analysis of the rubber stamp method per se is not an element of the survey process, hospitals may wish to eliminate their usage in order to avoid denial of claims for payment.

Where an electronic medical record is in use, the hospital must demonstrate how it prevents alterations of record entries after they have been authenticated. Information needed to review an electronic medical record, including pertinent codes and security features, must be readily available to surveyors to permit their review of sampled medical records while on-site in the hospital.

When state law and/or hospital policy requires that entries in the medical record made by residents or non-physicians be countersigned by supervisory or attending medical staff members, then the medical staff rules and regulations must address counter-signature requirements and processes.

A system of auto-authentication in which a physician or other practitioner authenticates an entry that he or she cannot review (e.g., because it has not yet been transcribed, or the electronic entry cannot be displayed) is not consistent with these requirements. There must be a method of determining that the practitioner did, in fact, authenticate the entry after it

was created. In addition, failure to disapprove an entry within a specific time period is not acceptable as authentication.

The practitioner must separately date and time his/her signature authenticating an entry, even though there may already be a date and time on the document, since the latter may not reflect when the entry was authenticated. For certain electronically-generated documents, where the date and time that the physician reviewed the electronic transcription is automatically printed on the document, the requirements of this section would be satisfied. However, if the electronically-generated document only prints the date and time that an event occurred (e.g., EKG printouts, lab results, etc.) and does not print the date and time that the practitioner actually reviewed the document, then the practitioner must either authenticate, date, and time this document itself or incorporate an acknowledgment that the document was reviewed into another document (such as the H&P, a progress note, etc.), which would then be authenticated, dated, and timed by the practitioner.

Survey Procedures §482.24(c)(1)

Review a sample of open and closed medical records.

- Determine whether all medical record entries are legible. Are they clearly written in such a way that they are not likely to be misread or misinterpreted?
- Determine whether orders, progress notes, nursing notes, or other entries in the medical record are complete. Does the medical record contain sufficient information to identify the patient; support the diagnosis/condition; justify the care, treatment, and services; document the course and results of care, treatment, and services; and promote continuity of care among providers?
- Determine whether medical record entries are dated, timed, and appropriately authenticated by the person who is responsible for ordering, providing, or evaluating the service provided.
- Determine whether all orders, including verbal orders, are written in the medical record and signed by the practitioner who is caring for the patient and who is authorized by hospital policy and in accordance with state law to write orders.
- Determine whether the hospital has a means for verifying signatures, both written and electronic, written initials, codes, and stamps when such are used for authorship identification. **For electronic medical records, ask the hospital to demonstrate the security features that maintain the integrity of entries and verification of electronic signatures and authorizations.** Examine the hospital's policies and procedures for using the system, and determine if documents are being authenticated after they are created.

§482.24(c)(2) -- All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient only if such a practitioner is acting in accordance with state law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

§482.24(c)(3) -- Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:

- (i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;
- (ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;
- (iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and
- (iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or by another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with state law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

§482.24(c)(4) -- All records must document the following, as appropriate:

- (i) Evidence of --
 - (A) A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

Interpretive Guidelines §482.24(c)(4)(i)(A)

The medical record must include documentation that a medical history and physical examination (H&P) was completed and documented for each patient no more than 30 days prior to hospital admission or registration, or 24 hours after hospital admission or registration, but in all cases prior to surgery or a procedure requiring anesthesia services.

The purpose of an H&P is to determine whether there is anything in the patient's overall condition that would affect the planned course of the patient's treatment, such as an allergy to a medication that must be avoided, or a co-morbidity that requires certain additional interventions to reduce risk to the patient.

The H&P documentation must be placed in the medical record within 24 hours of admission or registration, but in all cases prior to surgery or a procedure requiring anesthesia services, including all inpatient, outpatient, or same-day surgeries or procedures. (71 FR 68676) The H&P may be handwritten or transcribed. An H&P that is completed within 24 hours of the patient's admission or registration, but after surgery or a procedure requiring anesthesia would not be in compliance.

§482.24(c)(4) -- *[All records must document the following, as appropriate:*

- (i) Evidence of --]
 - (B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

Interpretive Guidelines §482.24(c)(4)(i)(B)

When an H&P is completed within the 30 days before admission or registration, the hospital must ensure that an updated medical record entry documenting an examination for any changes in the patient's condition is placed in the patient's medical record within 24 hours after admission or registration, but, in all cases involving surgery or a procedure requiring anesthesia services, prior to the surgery or procedure. The examination must be conducted by a practitioner who is credentialed and privileged by the hospital's medical staff to perform an H&P. The update note must document an examination for any changes in the patient's condition since the time that the patient's H&P was performed that might be significant for the planned course of treatment. The physician, oromaxillofacial surgeon, or qualified licensed individual uses his/her clinical judgment, based upon his/her assessment of the patient's condition and co-morbidities, if any, in relation to the patient's planned course of treatment to decide the extent of the update assessment needed as well as the information to be included in the update note in the patient's medical record. If, upon examination, the licensed practitioner finds no change in the patient's condition since the H&P was completed, he/she may indicate in the patient's medical record that the H&P was reviewed, the patient was examined, and that "no change" has occurred in the patient's condition since the H&P was completed. (71 FR 68676) Any changes in the patient's condition must be documented by the practitioner in the update note and placed in the patient's medical record within 24 hours of admission or registration, but prior to surgery or a procedure requirement anesthesia services.

Additionally, if the practitioner finds that the H&P done before admission is incomplete, inaccurate, or otherwise unacceptable, the practitioner reviewing the H&P, examining the patient, and completing the update may disregard the existing H&P, and conduct and document in the medical record a new H&P within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia.

§482.24(c)(4)(ii) -- Admitting diagnosis.

Interpretive Guidelines §482.24(c)(4)(ii)

All inpatient medical records must contain the admitting diagnosis.

§482.24(c)(4)(iii) -- Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.

Interpretive Guidelines §482.24(c)(4)(iii)

All patient records, both inpatient and outpatient, must contain the results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient. This information must be promptly filed in the patient's medical record in order to be available to the physician or other care providers to use in making assessments of the patient's condition, to justify treatment or continued hospitalization, to support or revise the patient's diagnosis, to support or revise the plan of care, to describe the patient's progress and to describe the patient's response to medications, treatments, and services.

[All records must document the following, as appropriate:]

§482.24(c)(4)(iv) -- Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

Interpretive Guidelines §482.24(c)(2)(iv)

All patient medical records, both inpatient and outpatient, must document: Complication; Hospital-acquired infections; Unfavorable reactions to drugs; and Unfavorable reactions to anesthesia.

[All records must document the following, as appropriate:]

§482.24(c)(4)(v) -- Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by federal or state law if applicable, to require written patient consent.

Interpretive Guidelines §482.24(c)(4)(v)

Informed consent is discussed in three locations in the CMS Hospital CoPs. See also the guidelines for 42 CFR 482.13(b)(2) pertaining to patients' rights, and the guidelines for 42 CFR 482.51(b)(2), pertaining to surgical services. The medical record must contain a document recording the patient's informed consent for those procedures and treatments that have been specified as requiring informed consent. Medical staff policies should address which procedures and treatments require written informed consent. There may also be applicable federal or state law requiring informed consent. The informed consent form contained in the medical record should provide evidence that it was properly executed. Signature of the patient or the patient's legal representative; and date and time the informed consent form is signed by the patient or the patient's legal representative.

§482.24(c)(4)(vi) -- All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.

Interpretive Guidelines §482.24(c)(4)(vi)

The requirement means that the stated information is necessary to monitor the patient's condition and that this and other necessary information must be in the patient's medical record. In order for necessary information to be used it must be promptly filed in the medical record so that health care staff involved in the patient's care can access/retrieve this information in order to monitor the patient's condition and provide appropriate care.

The medical record must contain: All practitioner's orders (properly authenticated); All nursing notes (including nursing care plans); All reports of treatment (including complications and hospital-acquired infections); All medication records (including unfavorable reactions to drugs); All radiology reports; All laboratory reports; All vital signs; and All other information necessary to monitor the patient's condition.

[All records must document the following, as appropriate:]

§482.24(c)(4)(vii) -- Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.

Interpretive Guidelines §482.24(c)(4)(vii)

All patient medical records must contain a discharge summary. A discharge summary discusses the outcome of the hospitalization, the disposition of the patient, and provisions for follow-up care. Follow-up

care provisions include any post hospital appointments, how post hospital patient care needs are to be met, and any plans for post-hospital care by providers such as home health, hospice, nursing homes, or assisted living.

[All records must document the following, as appropriate:]

§482.24(c)(4)(viii) -- Final diagnosis with completion of medical records within 30 days following discharge.

Interpretive Guidelines §482.24(c)(4)(viii)

All medical records must contain a final diagnosis. All medical records must be complete within 30 days of discharge or outpatient care.

Survey Procedures §482.24(c)(4)(viii)

Select a sample of patients who have been discharged for more than 30 days. Request their medical records. Are those records complete? Does each record have the patient's final diagnosis?

B. Federal Regulations -- Long-Term Care Facility Conditions of Participation [Excepts Pertaining to Medical Records]²

§483.20 Resident Assessment

The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity.

Intent §483.20

To provide the facility with ongoing assessment information necessary to develop a care plan, to provide the appropriate care and services for each resident, and to modify the care plan and care/services based on the resident's status. The facility is expected to use resident observation and communication as the primary source of information when completing the RAI. In addition to direct observation and communication with the resident, the facility should use a variety of other sources, including communication with licensed and non-licensed staff members on all shifts and may include discussions with the resident's physician, family members, or outside consultants and review of the resident's record.

² See http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf.

- (a) *Admission orders.* At the time each resident is admitted, the facility must have physician orders for the resident's immediate care.
- (b) *Comprehensive assessments --*
- (1) *Resident assessment instrument.* A facility must make a comprehensive assessment of a resident's needs, using the resident assessment instrument (RAI) specified by the state. The assessment must include at least the following:
- (i) Identification and demographic information.
 - (ii) Customary routine.
 - (iii) Cognitive patterns.
 - (iv) Communication.
 - (v) Vision.
 - (vi) Mood and behavior patterns.
 - (vii) Psychosocial well-being.
 - (viii) Physical functioning and structural problems.
 - (ix) Continence.
 - (x) Disease diagnoses and health conditions.
 - (xi) Dental and nutritional status.
 - (xii) Skin condition.
 - (xiii) Activity pursuit.
 - (xiv) Medications.
 - (xv) Special treatments and procedures.
 - (xvi) Discharge potential.
 - (xvii) Documentation of summary information regarding the additional assessment performed on the care areas triggered by the completion of the Minimum Data Set (MDS).
 - (xviii) Documentation of participation in assessment.

The assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members on all shifts.

Intent §483.20(b)

To ensure that the RAI is used in conducting comprehensive assessments as part of an ongoing process through which the facility identifies the resident's functional capacity and health status.

§483.20(b) Guidelines

The information required in §483.20(b)(i-xvi) is incorporated into the MDS, which forms the core of each state's approved RAI. Additional assessment information is also gathered using triggered CAAs [care area assessments].

Each facility must use its state-specified RAI (which includes the MDS, utilization guidelines *and* the CAAs) to assess newly admitted residents, conduct an annual reassessment and assess those residents who experience a significant change in status. The facility is responsible for addressing all needs and strengths of residents regardless of whether the issue is included in the MDS or CAAs. The scope of the RAI does not limit the facility's responsibility to assess and address all care needed by the resident.

Furthermore:

(xvii) Documentation of summary information regarding the additional assessment performed *on the care areas triggered by the completion of the MDS.*

“Documentation of summary information (xvii) regarding the additional assessment performed through the CAAs refers to documentation concerning which CAAs have been triggered, documentation of assessment information in support of clinical decision making relevant to the CAAs, documentation regarding where, in the clinical record, information related to the CAAs can be found, and for each triggered CAA, whether the identified problem was included in the care plan.

- (2) *When required.* Subject to the timeframes prescribed in §413.343(b) of this chapter, a facility must conduct a comprehensive assessment of a resident in accordance with the timeframes specified in paragraphs (b)(2)(i) through (iii) of this section. The timeframes prescribed in §413.343(b) of this chapter do not apply to CAHs.
- (i) Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition. (For purposes of this section, “readmission” means a return to the facility following a temporary absence for hospitalization or for therapeutic leave.)
 - (ii) Within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. (For purposes of this section, a “significant change” means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires interdisciplinary review or revision of the care plan, or both.)
 - (iii) Not less often than once every 12 months.

Interpretive Guidelines §483.20(b)(2)(iii)

The annual resident assessment must be completed within 366 days after *the ARD* of the most recent comprehensive resident assessment. (NOTE: For information on assessment scheduling for the MDS, see Chapter 2 of the Long-Term Care Facility Resident Assessment Instrument User's Manual, Version 3.0, effective 10/1/2010, which is located on the CMS MDS 3.0 website

http://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp#TopOfPage).

Probes §483.20(b)(2)

- Has each resident in the sample been comprehensively assessed using the state-specified RAI within the regulatory timeframes (i.e., within 14 days after admission, on significant change in status, and at least annually)?
- Has the facility identified, in a timely manner, those residents who have experienced a change?
- Has the facility reassessed residents using the state-specific RAI who had a significant change in status within 14 days after determining the change was significant?
- Has the facility gathered supplemental assessment information based on triggered CAAs prior to establishing the care plan?
- Does information in the RAI correspond with information obtained during observations of and interviews with the resident, facility staff and resident's family?

(c) *Quarterly review assessment.* A facility must assess a resident using the quarterly review instrument specified by the state and approved by CMS not less frequently than once every 3 months.

Interpretive Guidelines §483.20(c)

At least each quarter, the facility shall review each resident with respect to those MDS items specified under the state's quarterly review requirement. At a minimum, this would include all items contained in CMS' standard quarterly review form. A Quarterly review assessment must be completed within 92 days of the *ARD* of the most recent, clinical assessment. If the resident has experienced a significant change in status, the next quarterly review is due no later than 3 months after the *ARD* of the significant change reassessment.

Probes §483.20(c)

- Is the facility assessing and acting, no less than once every 3 months, on the results of resident's functional and cognitive status examinations?
- Is the quarterly review of the resident's condition consistent with information in the progress notes, the plan of care and your resident observations and interviews?

(d) *Use.* A facility must maintain all resident assessments completed within the previous 15 months in the resident's active record and use the results of the assessments to develop, review, and revise the resident's comprehensive plan of care.

Interpretive Guidelines §483.20(d)

The requirement to maintain 15 months of data in the resident's active clinical record applies regardless of form of storage to all MDS *records, including the CAA Summary, Quarterly Assessment records, Identification Information and Entry, Discharge and Reentry Tracking Records and MDS Correction Requests (including signed attestation).* MDS assessments must be kept in the resident's active clinical record for 15 months following the final completion date *for all assessments and correction requests. Other assessment types require maintaining them in the resident's active clinical record for 15 months following:*

- The entry date for tracking records including re-entry; and
- The date of discharge or death for discharge and death in facility records.

Facilities may maintain MDS data electronically regardless of whether the entire clinical record is maintained electronically and regardless of whether the facility has an electronic signature process in place.

Facilities that maintain their MDS data electronically and do not utilize an electronic signature process must ensure that hard copies of the MDS assessment signature pages are maintained for every MDS assessment conducted in the resident's active clinical record for 15 months. (This includes enough information to identify the resident and type and date of assessment linked with the particular assessment's signature pages),

The information, *regardless of form of storage (i.e., hard copy or electronic), must be kept in a centralized location and must be readily and easily accessible. This information must be available to all professional staff members (including consultants) who need to review the information in order to provide care to the resident. (This information must also be*

made readily and easily accessible for review by the State Survey agency and CMS.)

After the 15-month period, RAI information may be thinned from the clinical record and stored in the medical records department, provided that it is easily retrievable if requested by clinical staff, the state agency, or CMS.

- (e) *Coordination.* A facility must coordinate assessments with the preadmission screening and resident review program under Medicaid in part 483, subpart C to the maximum extent practicable to avoid duplicative testing and effort.
- (f) *Automated data processing requirement --*
 - (1) *Encoding data.* Within 7 days after a facility completes a resident's assessment, a facility must encode the following information for each resident in the facility:
 - (i) Admission assessment.
 - (ii) Annual assessment updates.
 - (iii) Significant change in status assessments.
 - (iv) Quarterly review assessments.
 - (v) A subset of items upon a resident's transfer, reentry, discharge, and death.
 - (vi) Background (face-sheet) information, if there is no admission assessment.

Intent §483.20(f)(1)

Facilities are required to encode MDS data for each resident in the facility.

Interpretive Guidelines §483.20(f)(1)

Background (face-sheet) information refers to the MDS Entry tracking record, while the discharge subset of items refers to the MDS Discharge assessment.

- (2) *Transmitting data.* Within 7 days after a facility completes a resident's assessment, a facility must be capable of transmitting to the CMS System information for each resident contained in the MDS in a format that conforms to standard record layouts and data dictionaries, and that passes standardized edits defined by CMS and the state.
- (3) *Transmittal requirements.* Within 14 days after a facility completes a resident's assessment, a facility must electronically transmit encoded, accurate, and complete MDS data to the CMS System, including the following:

- (i) Admission assessment.
- (ii) Annual assessment.
- (iii) Significant change in status assessment.
- (iv) Significant correction of prior full assessment.
- (v) Significant correction of prior quarterly assessment.
- (vi) Quarterly review.
- (vii) A subset of items upon a resident's transfer, reentry, discharge, and death.
- (viii) Background (face-sheet) information, for an initial transmission of MDS data on a resident that does not have an admission assessment.

Intent §483.20(f)(3)

Facilities are required to electronically transmit MDS data to the CMS System for each resident in the facility. The CMS System for MDS data is named the QIES ASAP System.

Interpretive Guidelines §483.20(f)(3)

Background (face-sheet) information refers to the MDS Entry tracking record, while the discharge subset of items refers to the MDS Discharge assessment.

- (4) *Data format.* The facility must transmit data in the format specified by CMS or, for a state which has an alternate RAI approved by CMS, in the format specified by the state and approved by CMS.

Intent §483.20(f)(1-4)

The intent is to enable a facility to better monitor a resident's decline and progress over time. Computer-aided data analysis facilitates a more efficient, comprehensive and sophisticated review of health data. The primary purpose of maintaining the assessment data is so a facility can monitor resident progress over time. The information should be readily available at all times.

Interpretive Guidelines §483.20(f)(1-4)

“Encoding” means entering MDS information into a computer.

“Transmitting data” refers to electronically sending encoded MDS information, from the facility to the *QIES ASAP System*, using a modem and communications software.

“Capable of transmitting” means that the facility has encoded and edited according to CMS specifications, the record accurately reflects the

resident's overall clinical status as of the assessment reference date, and the record is ready for transmission.

"Passing standard edits" means that the encoded responses to MDS items are consistent and within range, in accordance with CMS specified standards. In general, inconsistent responses are either not plausible or ignore a skip pattern on the MDS. An example of inconsistency would be if one or more MDS items on a list were checked as present, and the "None of the Above" response was also checked for the same list. Out of range responses are invalid responses, such as using a response code of 2 for an MDS item for which the valid responses are zero or 1.

"Transmitted" means electronically transmitting to the *QIES ASAP System*, an MDS record that passes CMS' standard edits *and is accepted into the system*, within 14 days of the final completion date, or event date in the case of Entry, Discharge and Death in Facility situations, of the record.

"Accurate" means that the encoded MDS data matches the MDS form in the clinical record. Also refer to guidance regarding accuracy at §483.20(g), and the information accurately reflects the resident's status as of the Assessment Reference Date (*ARD*).

"Complete" means that all items required according to the record type, and in accordance with CMS' record specifications and state required edits are in effect at the time the record is completed.

In accordance with the final rule, facilities will be responsible to edit the encoded MDS data to ensure that it meets the standard edit specifications.

We encourage facilities to use software that has a programmed capability to automatically edit MDS records according to CMS' edit specifications.

For §483.20(f)(1)(v), the subset of items required upon a resident's entry, transfer, discharge and death are contained in the *Entry and Death in Facility Tracking records and Discharge assessments*. Refer to *Chapter 2 of Appendix R (the MDS manual)* for further information about these records.

All nursing homes must computerize MDS information. The facility must edit MDS information using standard CMS-specified edits, revise the information to conform to the edits and to be accurate, and be capable of transmitting that data to the *QIES ASAP* system within 7 days of:

- Completing a comprehensive assessment (the *care plan completion date*);

- Completing an assessment that is not comprehensive (the *MDS completion date*);
- A discharge event (the date of death or discharge);
- An *entry* event (the date of entry (admission or reentry)); or
- Completing a correction request.

Submission must be according to state and federal time frames.

Therefore the facility must:

- Encode the MDS and *CAAs Summary* (where applicable) in machine readable format; *and*
- Edit the MDS and *CAA Summary* (where applicable) according to edits specified by CMS. Within the 7 day time period specified above for editing, the facility must revise any information on the encoded MDS and *CAA Summary* (if applicable) that does not pass CMS-specified edits, revise any otherwise inaccurate information, and make the information ready for submission. The MDS Vendor software used at the facility should have an automated editing process that alerts the user to entries in an MDS record that do not conform with the CMS-specified edits and that prompts the facility to complete revisions within the 7-day editing and revision period. After editing and revision, MDS information and *CAA summary* information (if applicable) must always accurately reflect the resident's overall clinical status as of the original ARD for an assessment or the original event date for a discharge or entry.

Electronically submit MDS information to the *QIES ASAP system* within 14 days of:

- Completing a comprehensive assessment (the care plan completion date);
- Completing an assessment that is not comprehensive (the MDS completion date);
- A discharge event (the date of death or discharge);
- An entry event (the date of entry (admission or reentry)); or
- Completing a correction request.

For a discussion of the process that a facility should follow in the event an error is discovered in an MDS record after editing and revision but before it is transmitted to the *QIES ASAP system*, refer to Appendix R of the State Operations Manual, *Chapter 5*.

Facilities are required to maintain 15 months of assessment data in the resident's active clinical record. Refer to the interpretive guidelines at §483.20(d) for information regarding this requirement.

A facility must complete and submit to the *QIES ASAP system* a subset of items when a resident *enters the facility (entry tracking record -- admission or reentry)*, is discharged from the facility (discharge

assessment -- return anticipated or return not anticipated) or dies in the facility (death in facility tracking record).

(5) *Resident-identifiable information.*

- (i) A facility may not release information that is resident-identifiable to the public.
- (ii) The facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so.

(g) *Accuracy of assessments.* The assessment must accurately reflect the resident's status.

Interpretive Guidelines §483.20(g)

“The accuracy of the assessment” means that the appropriate, qualified health professional correctly documents the resident’s medical, functional, and psychosocial problems and identifies resident strengths to maintain or improve medical status, functional abilities, and psychosocial status. The initial comprehensive assessment provides baseline data for ongoing assessment of resident progress.

(h) *Coordination.* A registered nurse must conduct or coordinate each assessment with the appropriate participation of health professionals.

Interpretive Guidelines §483.20(h)

According to the Utilization Guidelines for each state’s RAI, the physical, mental and psychosocial condition of the resident determines the appropriate level of involvement of physicians, nurses, rehabilitation therapists, activities professionals, medical social workers, dietitians, and other professionals, such as developmental disabilities specialists, in assessing the resident, and in correcting resident assessments. Involvement of other disciplines is dependent upon resident status and needs.

Probes §483.20(g)(h)

- Have appropriate health professionals assessed the resident? For example, has the resident’s nutritional status been assessed by someone who is knowledgeable in nutrition and capable of correctly assessing a resident?
- If the resident’s medical status, functional abilities, or psychosocial status declined and the decline was not clinically unavoidable, were

the appropriate health professionals involved in assessing the resident?

- Based on your total review of the resident, is each portion of the assessment accurate?
- Are the appropriate certifications in place, including the RN Coordinator's certification of completion of an assessment or Correction Request, and the certification of individual assessors of the accuracy and completion of the portion(s) of the assessment or tracking *record* completed or corrected. On an assessment or correction request, the RN Assessment Coordinator is responsible for certifying overall completion once all individual assessors have completed and signed their portion(s) of the MDS. When MDS *records* are completed directly on the facility's computer, (e.g., no paper form has been manually completed), the RN Coordinator signs and dates the computer generated hard copy, *or provides an electronic signature*, after reviewing it for completeness, including the signatures of all individual assessors. Backdating a completion date is not acceptable -- *note that recording the actual date of completion is not considered backdating. For example, if an MDS was completed electronically and a hard copy was printed two days later, writing the date the MDS was completed on the hard copy is not considered backdating.*

(i) *Certification.*

- (1) A registered nurse must sign and certify that the assessment is completed.
- (2) Each individual who completes a portion of the assessment must sign and certify the accuracy of that portion of the assessment.

Interpretive Guidelines §483.20(i)

Whether the MDS *assessments* are manually completed, or computer generated following data entry, each individual assessor is responsible for certifying the accuracy of responses relative to the resident's condition and discharge or entry status. Manually completed forms are signed and dated by each individual assessor the day they complete their portion(s) of the MDS record. When MDS forms are completed directly on the facility's computer (e.g., no paper form has been manually completed), then each individual assessor signs and dates a computer generated hard copy, *or provides an electronic signature*, after they review it for accuracy of the portion(s) they completed. Backdating completion dates is not acceptable -- *note that recording the actual date of completion is not considered backdating. For example, if an MDS was completed electronically and a hard copy was printed two days later, writing the date the MDS was completed on the hard copy is not considered backdating.*

(j) *Penalty for falsification.*

- (1) Under Medicare and Medicaid, an individual who willfully and knowingly --
 - (i) Certifies a material and false statement in a resident assessment is subject to a civil money penalty of not more than \$1,000 for each assessment; or
 - (ii) Causes another individual to certify a material and false statement in a resident assessment is subject to a civil money penalty of not more than \$5,000 for each assessment.
- (2) Clinical disagreement does not constitute a material and false statement.

Interpretive Guidelines §483.20(j)

MDS information serves as the clinical basis for care planning and delivery. With the introduction of additional uses of MDS information such as for payment rate setting and quality monitoring, MDS information as it is reported impacts a nursing home's payment rate and standing in terms of the quality monitoring process. A pattern within a nursing home of clinical documentation or of MDS assessment or reporting practices that result in higher RUG scores, untriggering CAA(s), or unflagging QI(s), where the information does not accurately reflect the resident's status, may be indicative of payment fraud or avoidance of the quality monitoring process. Such practices may include but are not limited to a pattern or high prevalence of the following:

- Submitting MDS Assessments (including any reason(s) for assessment, routine or non-routine) or tracking *records*, where the information does not accurately reflect the resident's status as of the ARD, or the Discharge or *Entry* date, as applicable;
- Submitting correction(s) to information in the *QIES ASAP system* where the corrected information does not accurately reflect the resident's status as of the original ARD, or the original Discharge or Entry date, as applicable, or where the record it claims to correct does not appear to have been in error;
- Submitting Significant Correction Assessments where the assessment it claims to correct does not appear to have been in error;
- Submitting Significant Change in Status Assessments where the criteria for significant change in the resident's status do not appear to be met;
- Delaying or withholding MDS Assessments (including any reason(s) for assessment, routine or non-routine), Discharge or Entry Tracking information, or correction(s) to information in the *QIES ASAP system*.

When such patterns or practices are noticed, they should be reported by the State Agency to the proper authority.

(k) *Comprehensive care plans.*

- (1) The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The care plan must describe the following --
- (i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under §483.25; and
 - (ii) Any services that would otherwise be required under §483.25 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(b)(4).

Interpretive Guidelines §483.20(k)

An interdisciplinary team, in conjunction with the resident, resident's family, surrogate, or representative, as appropriate, should develop quantifiable objectives for the highest level of functioning the resident may be expected to attain, based on the comprehensive assessment. The interdisciplinary team should show evidence in the *CAA* summary or clinical record of the following:

- The resident's status in triggered *CAA* areas;
- The facility's rationale for deciding whether to proceed with care planning; and
- Evidence that the facility considered the development of care planning interventions for all *CAAs* triggered by the *MDS*.

The care plan must reflect intermediate steps for each outcome objective if identification of those steps will enhance the resident's ability to meet his/her objectives. Facility staff will use these objectives to monitor resident progress. Facilities may, for some residents, need to prioritize their care plan interventions. This should be noted in the clinical record or on the plan or care.

The requirements reflect the facility's responsibilities to provide necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. However, in some cases, a resident may wish to refuse certain services or treatments that professional staff believe may be indicated to assist the resident in reaching his or her highest practicable level of well-being. Desires of the resident should be documented in the clinical record (see guidelines at §483.10(b)(4) for additional guidance concerning refusal of treatment).

- (2) A comprehensive care plan must be --
 - (i) Developed within 7 days after completion of the comprehensive assessment;
 - (ii) Prepared by an interdisciplinary team, that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and
 - (iii) Periodically reviewed and revised by a team of qualified persons after each assessment.

- (3) The services provided or arranged by the facility must --
 - (i) Meet professional standards of quality; and
 - (ii) Be provided by qualified persons in accordance with each resident's written plan of care.

- (l) *Discharge summary.* When the facility anticipates discharge a resident must have a discharge summary that includes --
 - (1) A recapitulation of the resident's stay;
 - (2) A final summary of the resident's status to include items in paragraph (b)(2) of this section, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative; and
 - (3) A post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.

Interpretive Guidelines §483.20(l)(3)

A post-discharge plan of care for an anticipated discharge applies to a resident whom the facility discharges to a private residence, to another NF or SNF, or to another type of residential facility such as a board and care home or an intermediate care facility for individuals with mental retardation. Resident protection concerning transfer and discharge are found at §483.12. A "post-discharge plan of care" means the discharge planning process which includes: assessing continuing care needs and developing a plan designed to ensure the individual's needs will be met after discharge from the facility into the community.

- (m) *Preadmission screening for mentally ill individuals and individuals with intellectual disability.*

- (1) A nursing facility must not admit, on or after January 1, 1989, any new resident with --
- (i) Mental illness as defined in paragraph (f)(2)(i) of this section, unless the state mental health authority has determined, based on an independent physical and mental evaluation performed by a person or entity other than the state mental health authority, prior to admission,
 - (A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and
 - (B) If the individual requires such level of services, whether the individual requires specialized services; or
 - (ii) Mental retardation, as defined in paragraph (f)(2)(ii) of this section, unless the state intellectual disability or developmental disability authority has determined prior to admission --
 - (A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and
 - (B) If the individual requires such level of services, whether the individual requires specialized services for intellectual disability.

§483.75(l) Clinical Records

- (1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are--
- (i) Complete;
 - (ii) Accurately documented;
 - (iii) Readily accessible; and
 - (iv) Systematically organized.

Intent §483.75(l)(1)

To assure that the facility maintains accurate, complete and organized clinical information about each resident that is readily accessible for resident care.

Interpretive Guidelines §483.75(l)(1)

A complete clinical record contains an accurate and functional representation of the actual experience of the individual in the facility. It must contain enough information to show that the facility knows the status of the individual, has adequate plans of care, and provides sufficient evidence of the effects of the care provided. Documentation should provide a picture of the resident's progress, including response to treatment, change in condition, and changes in treatment.

The facility determines how frequently documentation of an individual's progress takes place apart from the annual comprehensive assessment, periodic reassessments when a significant change in status occurs, and quarterly monitoring assessments. Good practice indicates that for functional and behavioral objectives, the clinical record should document change toward achieving care plan goals. Thus, while there is no "right" frequency or format for "reporting" progress, there is a unique reporting schedule to chart each resident's progress in maintaining or improving functional abilities and mental and psychosocial status. Be more concerned with whether the staff has sufficient progress information to work with the resident and less with how often that information is gathered.

In cases in which facilities have created the option for an individual's record to be maintained by computer, rather than hard copy, electronic signatures are acceptable. In cases when such attestation is done on computer records, safeguards to prevent unauthorized access, and reconstruction of information must be in place. The following guideline is an example of how such a system may be set up:

- There is a written policy, at the health care facility, describing the attestation policy(ies) in force at the facility.
- The computer has built-in safeguards to minimize the possibility of fraud.
- Each person responsible for an attestation has an individualized identifier.
- The date and time is recorded from the computer's internal clock at the time of entry
- An entry is not to be changed after it has been recorded.
- The computer program controls what sections/areas any individual can access or enter data, based on the individual's personal identifier (and, therefore his/her level of professional qualifications).

§483.75(l)(5) the clinical record must contain --

- (i) Sufficient information to identify the resident;
- (ii) A record of the resident's assessments;
- (iii) the plan of care and services provided;
- (iv) The results of any preadmission screening conducted by the state; and
- (v) progress notes.

§483.75(l)(2) Clinical records must be retained for --

- (i) The period of time required by state law; or
- (ii) Five years from the date of discharge when there is no requirement in state law; or,

- (iii) For a minor, 3 years after a resident reaches legal age under state law.

§483.20(f)(5) Resident-identifiable information.

- (i) A facility may not release information that is resident-identifiable to the public.
- (ii) The facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so.

Interpretive Guidelines §483.20(f)(5)

Automated RAI data are part of a resident's clinical record and as such are protected from improper disclosure by facilities under current law. Facilities are required by §§1819(c)(1)(A)(iv) and 1919(c)(1)(A)(iv) of the Act and 42 CFR Part 483.75(l)(3) and (l)(4), to keep confidential all information contained in the resident's record and to maintain safeguards against the unauthorized use of a resident's clinical record information, regardless of the storage method of the records.

§483.75(l)(3) The facility must safeguard clinical record information against loss, destruction, or unauthorized use;

Intent §483.75(l)(3)

To maintain the safety and confidentiality of the resident's record.

Procedures §483.75(l)(3)

Determine through observations and interviews with staff, the policy and implementation of that policy, for maintaining confidentiality of residents' records.

Probes §483.75(1)(3)

- How does the facility ensure confidentiality of resident records
- If there is a problem with confidentiality, is it systematic, that is, does the problem lie in the recordkeeping system, or with a staff person's use of records (e.g., leaving records in a place easily accessible to residents, visitors, or other unauthorized persons)?

C. Federal Regulations -- Home Health Conditions of Participation [Excepts Pertaining to Medical Records (including plans of care)]³

§484.10 Condition of Participation: Patient Rights.

(a) Standard: Notice of rights.

- (1) The HHA must provide the patient with a written notice of the patient's rights in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment.
- (2) The HHA must maintain documentation showing that it has complied with the requirements of this section.

Interpretive Guidelines §484.10(a)(1)

In the stratified sample of clinical records selected for review, look for notations that a statement of the patient's rights, including the statement concerning the collection and reporting of OASIS information, has been given to the patient by the HHA staff **prior to care being initiated**. This written statement must have been provided during admission, the patient's initial evaluation visit, or the patient's first professional visit.

The OASIS database is subject to the requirements of the Federal Privacy Act of 1974. The Privacy Act allows the disclosure of information from a system of records without an individual's consent if the information is to be used for a purpose that is compatible with the purposes for which the information was collected. However, under existing patient's rights regulations, the HHA must provide the patient with a written notice of this collection of information (i.e., OASIS in advance of furnishing care to the patient).

Before comprehensive assessments (that include collection of OASIS data items) are conducted, the HHA must tell patients about OASIS and explain their rights with respect to the collection and reporting of OASIS information. These rights include:

- The right to be informed that OASIS information will be collected and for what purpose;
- The right to have the information kept confidential and secure;
- The right to be informed that OASIS information will not be disclosed except for legitimate purposes allowed by the Privacy Act;

³ See <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2c0d6cefce8daa249571bfb22e865528&rgn=div5&view=text&node=42:5.0.1.1.3&idno=42#42:5.0.1.1.3.2.7.6>.

- The right to refuse to answer a specific question; and
- The right to see, review, and request changes on their assessment.

If the HHA chooses to continue to collect OASIS information from non-Medicare/non-Medicaid patients the patient should be provided with the Notice about Privacy (for non-Medicare/non-Medicaid patients). If a home visit is made, the verification could also include a conversation with the patient and any material on patient rights that the patient has received from the HHA. A notation in the clinical record might also include a statement regarding any limitations the patient had in being able to understand the information.

Probes §484.10(a)(1)

- How do HHA employees, and staff used by the HHA under an arrangement or contract, implement HHA procedures for informing patients of their rights?
- What are the HHA's admission policies concerning the OASIS Privacy Act Statement?
- How does the HHA assure that the patient understands the OASIS Privacy Act Statement? Is the patient given a copy of the OASIS Privacy Act Statement?
- What is the HHA's policy and procedure for requests to see, copy, review, or change assessment information?
- Does the patient receive a written copy of the HHA's response when a change request is not granted?

(d) *Standard: Confidentiality of medical records.* The patient has the right to confidentiality of the clinical records maintained by the HHA. The HHA must advise the patient of the agency's policies and procedures regarding disclosure of clinical records.

Probes §484.10(d)

- How does the HHA ensure the confidentiality of the patient's clinical record?
- If the HHA leaves a portion of the clinical record in the home (such as in some high technology situations when frequent clinical entries are important), how does the HHA instruct the patient or caretaker about protecting the confidentiality of the record?
- What documentation in the clinical record indicates that the HHA informed the patient of the HHA's policies and procedures concerning clinical record disclosure?

§484.11 Condition of Participation: Release of Patient Identifiable OASIS Information.

The HHA and agent acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient identifiable information contained in the clinical record, including OASIS data, and may not release patient identifiable OASIS information to the public.

Interpretive Guidelines §484.11

Protection of confidentiality of OASIS information is two-fold; the HHA has a responsibility to keep OASIS information confidential and CMS has a responsibility to keep it confidential, once it has been transmitted to the OASIS state system.

Under this condition of participation, the HHA is required to maintain the confidentiality of OASIS data while it is being used for patient care and may not release it without the consent of the patient for any reason other than for what it is intended, which is to appropriately deliver patient care. HHAs must have policies and procedures for limiting access to OASIS information to only those persons the HHA designates.

If the HHA contracts with a vendor for transmission of its OASIS data, a written agreement that addresses the confidentiality of that data must be in place. Violations of data confidentiality by an entity contracted by the HHA are still the responsibility of the HHA and would constitute condition-level non-compliance; therefore the HHA is ultimately responsible for compliance with the confidentiality requirements and is the responsible party if the contractor does not meet the requirements.

For privacy and security reasons, communication of OASIS information (from branch to branch, branch to parent, parent to vendor, etc.) must be done in accordance with CMS policies on the communication of patient-identifiable information. HHAs must have processes in place to assure that access to and transfer and delivery of OASIS information is limited to only authorized personnel.

HHAs that contract with accrediting organizations (AO), such as the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) and the Community Health Accreditation Program (CHAP), for determining compliance with the Medicare Conditions of Participation may share Outcome-based Quality Improvement /Monitoring (OBQI/M) reports with representatives of the appropriate AO on survey. The AO has a responsibility to review the OBQI/M reports and the HHA must provide the reports in the course of normal HHA business. State Agencies and

Regional Offices may not share OBQI/M reports with the AO because no data use agreement exists with the SA/RO and the AO.

The other step in assuring confidentiality of the OASIS data is at the federal level and involves the Federal Privacy Act of 1974. Coverage under the Federal Privacy Act begins when the data reaches the state agency. The Privacy Act requires that policies and procedures related to the collection of information be made available to the public describing the reasons for collecting OASIS data, what will be done with it, and who will have access to it in an identifiable format. The Privacy Act puts into place certain processes that protect patient identifiable data from unauthorized use and disclosure. Provisions of the Privacy Act as they relate to the collection of OASIS data are described in detail on the OASIS Statement of Patient Privacy Rights (See §484.10(a)).

Onsite Activity -- Verify that the HHA has established a mechanism to ensure confidentiality of OASIS data. Interview the administrator and staff regarding:

- Protecting confidentiality of OASIS data (written and/or electronic).
- Assignment and maintenance of secure passwords for data encoding and transmission.
- Determine how OASIS data, whether in hard copy or electronic format is kept confidential before and after transmission to the state agency.

Interview the HHA administrator or system administrator for:

- Knowledge and application of rights to add, edit, or otherwise modify encoded OASIS data;
- Assignment of passwords;
- Assurance that only specified staff have contact with assessment information; and
- Actions taken when an employee with access to the system leaves the HHA's employment.

If possible, observe security of the OASIS data-entry location. Observe if the computer screen is logged off or password protected when not attended.

If applicable, review vendor contracts for provisions protecting confidentiality of OASIS data and determine what systems are in place to assure confidentiality throughout the transmission process. Vendors must be aware of the requirements and security policies of the HHA.

If questions are raised through interview or record review, review HHA's policies regarding confidentiality of patient information.

§484.14 Condition of Participation: Organization, Services, and Administration.

- (g) *Standard: Coordination of patient services.* All personnel furnishing services maintain liaison to ensure that their efforts are coordinated effectively and support the objectives outlined in the plan of care. The clinical record or minutes of case conferences establish that effective interchange, reporting, and coordination of patient care does occur. A written summary report for each patient is sent to the attending physician at least every 60 days.

§484.18 Condition of Participation: Acceptance of Patients, Plan of Care, and Medical Supervision.

Patients are accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence. Care follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine.

Interpretive Guidelines §484.18

It is CMS' policy to require that the HHA must have a plan of care for each patient, regardless of the patient's Medicare status or that nurse practice acts do not specifically require a physician's order. The CoPs do not require a physician's order for services furnished by the HHA that are not related to the patient's illness, injury, or treatment of the patient's medical, nursing, or social needs.

Medical orders may authorize a specific range in the frequency of visits for each service (i.e., 2-4 visits per week) to ensure that the most appropriate level of service is provided to the patient. However, ranges include "0" as a frequency are not allowed, because "0" is not a frequency. The regulation requires the HHA to alert the physician to any changes that suggest a need to alter the plan of care. If the HHA provides fewer visits than the physician orders, it has altered the plan of care and the physician must be notified. The HHA must maintain documentation in the clinical record indicating that the physician was notified and is aware of the missed visit.

- (a) *Standard: Plan of care.* The plan of care developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan. Orders for therapy services include the

specific procedures and modalities to be used and the amount, frequency, and duration. The therapist and other agency personnel participate in developing the plan of care.

Interpretive Guidelines §484.18(a)

A statutory change renamed the “plan of treatment” to “the plan of care.” These terms are synonymous. Neither is to be confused with a nursing care plan.

The conditions do not require an HHA to either develop or maintain a nursing care plan as opposed to a medical plan of care. This does not preclude an HHA from using nursing care plans if it believes that such plans strengthen patient care management, the organization and delivery of services, and the ability to evaluate patient outcomes.

Review a case-mix, stratified sample of clinical records (see §2200B) to determine if the requirements of this standard are met.

Written HHA policies and procedures should specify that all clinical services are implemented only in accordance with a plan of care established by a physician’s written orders. Policies should also specify if the HHA:

- Accepts physician’s orders on referral communicated verbally by an institution’s discharge planner, nurse practitioner, physician’s assistant, or other authorized staff member followed by written, signed and dated physician’s orders, in order to begin HHA services as soon as possible.
- Accepts signed physician certification and recertification of plans of care, as well as signed orders changing the plan of care, by telecommunication systems (“fax”), which are filed in the clinical record.

The plan of care must be established and authorized in writing by the physician based on an evaluation of the patient’s immediate and long-term needs. The HHA staff, and if appropriate, other professional personnel, shall have a substantial role in assessing patient needs, consulting with the physician, and helping to develop the overall plan of care.

The patient has the right, and should be encouraged, to participate in the development of the plan of care before care is started and when changes in the established plan of care are implemented. (See §484.10(c)(2).)

- (b) *Standard: Periodic review of plan of care.* The total plan of care is reviewed by the attending physician and HHA personnel as often as the severity of the

patient's condition requires, but at least once every 60 days or more frequently when there is a beneficiary elected transfer; a significant change in condition resulting in a change in the case-mix assignment; or a discharge and return to the same HHA during the 60-day episode. Agency professional staff promptly alert the physician to any changes that suggest a need to alter the plan of care.

Interpretive Guidelines §484.18(b)

Changes in the patient's condition that require a change in the plan of care should be documented in the patient's clinical record.

- (c) *Standard: Conformance with physician orders.* Drugs and treatments are administered by agency staff only as ordered by the physician with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per agency policy developed in consultation with a physician, and after an assessment for contraindications. Verbal orders are put in writing and signed and dated with the date of receipt by the registered nurse or qualified therapist (as defined in §484.4 of this chapter) responsible for furnishing or supervising the ordered services. Verbal orders are only accepted by personnel authorized to do so by applicable state and federal laws and regulations as well as by the HHA's internal policies.

Interpretive Guidelines §484.18(c)

Review HHA policies and procedures in regard to obtaining physician orders, changes in orders, and verbal orders. All physician orders must be included in the patient's clinical record. Plans of care must be signed and dated by the physician.

Verbal orders must be countersigned by the physician as soon as possible. Ask HHA's, whose pattern of obtaining signed physicians' orders exceeds the HHA's policy or state law, to clarify or explain what circumstances created the time lapse, and how they are approaching a resolution to the problem.

Other designated HHA personnel who accept verbal orders must do so in accordance with state and federal law and regulations and HHA policy. Verbal orders must be signed and dated by the registered nurse or qualified therapist who is furnishing or supervising the ordered service. It is the RN's or therapist's responsibility to make any necessary revisions to the plan of care based on that order.

§484.20 Condition of Participation: Reporting OASIS Information.

HHAs must electronically report all OASIS data collected in accordance with §484.55.

Interpretive Guidelines §484.20

HHA's must, at least monthly, electronically report OASIS data on all applicable patients in a format that meets CMS electronic data and edit specifications. For purposes of this requirement, the term "reporting" means electronic reporting.

Effective December 8, 2003, the collection of OASIS data on the non-Medicare/non-Medicaid patients of an HHA was temporarily suspended. HHAs must continue to comply with the aspects of the regulation at 42 CFR 484.55 regarding the comprehensive assessment of patients.

HHAs may continue to collect OASIS data on their non-Medicare/non-Medicaid patients for their own use. HHAs must continue to collect, encode, and transmit OASIS data for their non-maternity Medicare and Medicaid patients that are age 18 and over and receiving skilled services.

Private pay patients are defined to include any patient for whom (M0150) the Current Payment Source for Home Care does not include any of the following responses:

- 1- Medicare (Traditional fee-for-service)
- 2- Medicare (HMO/ managed care)
- 3- Medicaid (Traditional fee-for-service)
- 4- Medicaid(HMO/managed care).

If a patient has a private pay insurance and M0150 response 1, 2, 3, or 4 as an insurance to which the agency is billing the services, the comprehensive assessment including OASIS must be collected and transmitted. Medicare (HMO/managed care) does include Medicare Advantage (MA), formerly known as Medicare+Choice (M+C) plans and Medicare PPO plans.

HHAs or contracted entities acting on behalf of the HHA can report OASIS data to the state agency using the HAVEN software CMS provides free of charge or by using HAVEN-like software that conforms to the same specifications used to develop HAVEN.

Reported OASIS data will be analyzed and findings made available to HHA's by way of reports that will help HHA's identify their performance level in the provision of care to the patient population they serve as compared with other HHA's on either a national, state or local level.

As part of the ongoing survey process, state agencies may establish policies in keeping with unannounced surveys that include the ongoing request, at specified intervals, for the submission of a current census

(number) of patients being serviced by the HHA. Census information should include only a count of non-Medicare/non-Medicaid patients. Since OASIS data on non-Medicare/non-Medicaid patients will be received by the OASIS state system in an unidentifiable format, names of non-Medicare/non-Medicaid patients on the census are not appropriate.

With this information, surveyors can conduct a gross comparison of patient counts to data from the OASIS state system and monitor, offsite, if required OASIS data are being transmitted to the state.

- (a) *Standard: Encoding and transmitting OASIS data.* An HHA must encode and electronically transmit each completed OASIS assessment to the state agency or the CMS OASIS contractor, regarding each beneficiary with respect to which such information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the beneficiary.

Interpretive Guidelines §484.20(a)

After OASIS data are collected and completed by the qualified clinician as part of the comprehensive assessment at the required time points (i.e., start of care, resumption of care, follow-up, transfer to inpatient facility with or without discharge, discharge to community, and death at home), HHAs may take up to seven calendar days after the date of completion of the comprehensive assessment to enter (encode) the OASIS data into their computers using HAVEN or HAVEN-like software. The day the clinician completes the assessment is day zero for purposes of calculating the 7-day window. Encoding of all OASIS data items must be complete (i.e., locked) in order to accurately compute the information (health insurance prospective payment system or HIPPS code) necessary for billing Medicare patients under the prospective payment system.

Pre-Survey Activity -- Check with the state OASIS Education or Automation Coordinator and/or review OASIS data management reports to determine if OASIS items are encoded, checked for errors and locked within 7 days of collection using Haven or Haven-like software (i.e., made transmission ready).

Onsite Activity -- Check to see if the HHA is transmitting its own data or has an arrangement with an outside entity acting on behalf of the HHA to electronically submit OASIS data to the state agency. If so, make sure a written contract exists that describes the arrangement the HHA has with the outside entity to enter and transmit OASIS data on behalf of the HHA.

Determine the process for encoding and locking OASIS data being readied for transmission to the state.

If questions are raised through interview or record review, review the HHA's policies regarding encoding time frames.

Initial Survey -- New HHA's seeking initial certification must apply for appropriate state and federal HHA identification and passwords and be able to demonstrate compliance with collecting, completing, encoding and reporting OASIS data for all applicable patients in an electronic format that meets CMS specifications prior to the initial survey.

- (b) *Standard: Accuracy of encoded OASIS data.* The encoded OASIS data must accurately reflect the patient's status at the time of assessment.

Interpretive Guidelines §484.20(b)

Check to see how the HHA monitors the accuracy of their data to ensure the data collected, encoded, and reported accurately reflects the patient's status at the time of the assessment. Some tips for establishing a program to monitor the quality and accuracy of OASIS data are found in Chapter 12 of the OASIS Implementation Manual -- Data Quality Audits.

Onsite Activity -- When reviewing the clinical records, determine that a visit was made to conduct the assessment, as applicable. Also, determine that other clinical information in the patient record does not contradict OASIS data collected during the assessment, encoded or reported.

New patient admission -- If possible, include a home visit for a newly admitted patient who is scheduled to have a comprehensive assessment done. Determine that the OASIS data collected accurately reflects the patient's status at the time of the assessment.

Patient currently on service -- If a home visit is made on a patient for whom an assessment has already been conducted and is not now scheduled to have one conducted, review the most current assessment and compare it with your observation of patient status, keeping in mind the patient's progress/decline and the normal progression of the clinical condition.

Determine that other clinical information in the patient record does not contradict OASIS data.

- (c) *Standard: Transmittal of OASIS data.* An HHA must --

- (1) For all completed assessments, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section.

Interpretive Guidelines §484.20(c)(1)

By the last day of the current month, HHA's must electronically transmit all OASIS data collected, encoded, and locked in the previous month for each patient (as applicable), to the state agency or CMS OASIS contractor. At a minimum, HHA's must transmit OASIS data at least monthly; HHA's may transmit OASIS data more frequently, if desired, and are free to develop schedules for transmitting data to best suit their needs.

Rejected data that requires correcting and re-transmitting must be received by the OASIS state system within the same required time frame. Submission of data with identified fatal errors does not justify extending the required time frame. While overdue assessments will be accepted, HHA's (or their contracted vendors) may not wait until the end of the month to transmit their OASIS data in case errors are identified that require retransmittal or system problems develop that prevent transmission.

Entities submitting OASIS data to the state agency or CMS OASIS contractor on behalf of the HHA (i.e., corporate offices or vendors under contract) must share the feedback reports with the HHA in order for them to monitor their encoding and transmission process.

Pre-Survey Activity -- Check with the state OASIS Education or Automation Coordinator and/or review OASIS data management reports to determine if OASIS data are being transmitted as required. Determine whether the HHA is: (1) submitting data less often than monthly; and/or (2) has greater than 20 percent of records rejected in accordance with pre-survey preparation guidelines (SOM Section 2200).

Onsite Activity -- If either probe noted above is triggered, investigate compliance with OASIS transmission requirements of this section, during the survey through the partial extended survey process. Ask the HHA to demonstrate how it creates, saves and transmits OASIS data to the state agency. Randomly select patient assessments and ask the HHA for the final validation report to demonstrate that they were received by the state.

- (2) Successfully transmit test data to the state agency or CMS OASIS contractor.

Interpretive Guidelines §484.20(c)(2)

Determine that all required OASIS assessments are being transmitted.

Certain missing information or inconsistencies will cause a record to be completely rejected requiring correction by the HHA and retransmission. These are called fatal errors. For example, a fatal error will occur when a record is submitted without the HHA's state-assigned identification number, without the patient's last name, when the record is a duplicate of one previously received or the record is missing or has an incorrect branch identification number in M0016. A complete listing of current record rejection criteria is available in the HHA Error Message Guide on the OASIS website (<http://www.cms.hhs.gov/oasis/usermanu.asp>).

HHA's have the ability to electronically correct nearly all errors found in their production OASIS submissions that have been transmitted to the SA or CMS OASIS contractor. There is no current time limit to correcting errors in previously submitted records. SA should not be accepting requests for manual key field changes. Instead, HHA's should use the inactivation procedures to correct assessments containing key field errors. HAVEN 5.0 or above will give HHA's the ability to electronically correct nearly any kind of assessment errors.

- (3) Transmit data using electronics communications software that provides a direct telephone connection from the HHA to the state agency or CMS OASIS contractor.

Interpretive Guidelines §484.20(c)(3)

The purpose of making a test transmission to the state agency or CMS OASIS contractor is to establish connectivity. Once the test has been successfully completed, HHA's must not routinely use the test function to prepare their submission of production (required) OASIS data.

Initial Survey -- New HHA's seeking initial certification must apply for state and federal HHA identification numbers and passwords in order to demonstrate compliance with the OASIS submission requirements prior to Medicare approval.

Prior to the initial survey, HHA's must demonstrate connectivity to the OASIS state system by --

- Making a test transmission of any start of care or resumption of care OASIS data that passes CMS edit checks; and
- Receiving validation reports back from the state confirming transmission of data.

- (4) Transmit data that includes the CMS-assigned branch identification number, as applicable.

Interpretive Guidelines §484.20(c)(4)

HHA's must have a computer system that supports dial-up communications for the transmission of OASIS data to the state agency or CMS OASIS contractor, transmits the export files, and receives validation information. Corporate offices or contracted vendors submitting OASIS data on behalf of the HHA must provide the HHA with either an electronic copy of the validation information received from the state agency or CMS OASIS contractor, or a summary of that information.

All HHA's must use of the Medicare Data Communication Network (MDCN) to connect to the state agency for submission of OASIS data. When incorporation is complete, OASIS data from branch locations may be submitted directly by the branch as long as the appropriate user identification and passwords have been obtained.

- (d) *Standard: Data Format.* The HHA must encode and transmit data using the software available from CMS or software that conforms to CMS standard electronic record layout, edit specifications, and data dictionary, and that includes the required OASIS data set.

Interpretive Guidelines §484.20(d)

Reasons for non-submission include lack of compliance with the requirement to electronically transmit OASIS data by the HHA, or transmission using an improper format. HHA's must encode and transmit data using the HAVEN software available from CMS or HAVEN-like software that conforms to **all** CMS data transmission specifications available on the OASIS website. The software must also include the most current version of the OASIS data items which are available on the OASIS website at all times.

Pre-Survey Activity -- Review any OASIS state system data management reports to determine if there are indications of problems with OASIS data transmission. Check with the State OASIS Education or Automation coordinator to see if he/she has identified a problem with OASIS data transmission.

Onsite Activity -- If problems with OASIS data transmission were determined during presurvey activity, on survey, interview the appropriate staff to assess the extent of the problem, and to identify steps the HHA is taking to correct any transmission problems.

§484.30 Condition of Participation: Skilled Nursing Services.

The HHA furnishes skilled nursing services by or under the supervision of a registered nurse and in accordance with the plan of care.

- (a) *Standard: Duties of the registered nurse.* The registered nurse makes the initial evaluation visit, regularly reevaluates the patient's nursing needs, initiates the plan of care and necessary revisions, furnishes those services requiring substantial and specialized nursing skill, initiates appropriate preventive and rehabilitative nursing procedures, prepares clinical and progress notes, coordinates services, informs the physician and other personnel of changes in the patient's condition and needs, counsels the patient and family in meeting nursing and related needs, participates in in-service programs, and supervises and teaches other nursing personnel.

Interpretive Guidelines 484.30(a)

An RN is required to make the initial evaluation visit except in those circumstances where the physician has ordered only therapy services. If the physician orders only therapy services, it would be acceptable for the appropriate therapist (physical therapist or speech-language pathologist) to perform the initial evaluation visit. This does not mean that an HHA is precluded from having the RN perform all initial evaluation visits if the HHA believes that this promotes coordinated patient care, and/or if this is part of the HHA's own policies, procedures, and particular approach to patient care services.

Review a case-mix, stratified sample of clinical records according to the HHA survey and certification process, and make home visits to determine if RNs perform their responsibilities within the state's nurse practice act and in compliance with the plan of care.

- (b) *Standard: Duties of the licensed practical nurse.* The licensed practical nurse furnishes services in accordance with agency policies, prepares clinical and progress notes, assists the physician and registered nurse in performing specialized procedures, prepares equipment and materials for treatments observing aseptic technique as required, and assists the patient in learning appropriate self-care techniques.

Interpretive Guidelines §484.30(b)

Determine if services are provided in accordance with the HHA's professional practice standards and with guidance and supervision from RNs. Make the same comparisons set forth in the §484.30(a) probe when reviewing duties of the LPN.

§484.32 Condition of Participation: Therapy Services.

Any therapy services offered by the HHA directly or under arrangement are given by a qualified therapist or by a qualified therapy assistant under the supervision of a qualified therapist and in accordance with the plan of care. The qualified therapist assists the physician in evaluating level of function, helps develop the plan of care (revising it as necessary), prepares clinical and progress notes, advises and consults with the family and other agency personnel, and participates in in-service programs.

Probes §484.32

- How does the HHA ensure that therapy services furnished by staff under arrangement or contract meet the requirements of this condition?
- Does the clinical record documentation describe the patient responses to therapy?
- How does the HHA coordinate therapy services with other skilled services to complete the plan of care and promote positive therapeutic outcomes?

(a) *Standard: Supervision of physical therapy assistant and occupational therapy assistant.* Services furnished by a qualified physical therapy assistant or qualified occupational therapy assistant may be furnished under the supervision of a qualified physical or occupational therapist. A physical therapy assistant or occupational therapy assistant performs services planned, delegated, and supervised by the therapist, assists in preparing clinical notes and progress reports, and participates in educating the patient and family, and in in-service programs.

Interpretive Guidelines §484.32(a)

Specific instructions for assistants must be based on treatments prescribed in the plan of care, patient evaluations by the therapist, and accepted standards of professional practice. The therapist evaluates the effectiveness of the services furnished by the assistant.

Documentation in the clinical record should show that communication and supervision exist between the assistant and therapist about the patient's condition, the patient's response to services furnished by the assistant, and the need to change the plan of care.

§484.34 Condition of Participation: Medical Social Services.

If the agency furnishes medical social services, those services are given by a qualified social worker or by a qualified social work assistant under the supervision of a qualified social worker, and in accordance with the plan of care. The social worker

assists the physician and other team members in understanding the significant social and emotional factors related to the health problems, participates in the development of the plan of care, prepares clinical and progress notes, works with the family, uses appropriate community resources, participates in discharge planning and in-service programs, and acts as a consultant to other agency personnel.

§484.48 Condition of Participation: Clinical Records.

A clinical record containing pertinent past and current findings in accordance with accepted professional standards is maintained for every patient receiving home health services. In addition to the plan of care, the record contains appropriate identifying information; name of physician; drug, dietary, treatment, and activity orders; signed and dated clinical and progress notes; copies of summary reports sent to the attending physician; and a discharge summary. The HHA must inform the attending physician of the availability of a discharge summary. The discharge summary must be sent to the attending physician upon request and must include the patient's medical and health status at discharge.

Interpretive Guidelines §484.48

The clinical record must provide a current, organized, and clearly written synopsis of the patient's course of treatment, including services provided for the HHA by arrangement or contract. The clinical record should facilitate effective, efficient, and coordinated care.

Questionable patterns, rather than isolated instances, in clinical records are an indicator that the quality of care provided by the HHA needs to be carefully assessed for compliance with the plan of care, coordination of service, concurrence with the HHA's stated policies and procedures, and evaluations of patient outcomes. However, isolated instances, depending on their nature and severity, can serve as the basis of a deficiency and enforcement action (e.g., immediate and serious threat as outlined in Appendix Q).

Electronic Signatures

While the regulations specify that documents must be signed, they do not prohibit the use of electronic signatures. HHA's that have created the option for an individual's record to be maintained by computer, rather than hard copy, may use electronic signatures as long as there is a process for reconstruction of the information, and there are safeguards to prevent unauthorized access to the records. If necessary, review written policies maintained by the HHA describing the clinical record and authentication policy(ies) in force. Clinical, progress notes, and summary reports as defined at §484.2 must be maintained on all patients.

Physician's Rubber Stamp Signatures

Home health agencies may accept a physician's rubber stamp signature for their clinical record documentation if this is permitted by federal, state and local law and authorized by the HHA's policy. The individual whose signature the stamp represents must place in the Administrative office of the agency a signed statement attesting that he/she is the only one who has the stamp and uses it. All state licensure and state practice regulations continue to apply to Medicare approved HHA's. Where state law is more restrictive than Medicare, the provider needs to apply the state law standard. Note that this does not supersede any current policy related to Medicare coverage and eligibility rules or instructions from the Regional Home Health Intermediaries.

Correction of Clinical Records

The HHA is encouraged to create policies and procedures that govern correction of clinical records. It is prudent for the HHA to include latitude for correction of records in the event of staff turnover or staff schedules. For example, a clinical supervisor may be permitted by agency policy to make corrections when the original clinician is no longer available due to staff turnover.

When a comprehensive assessment is corrected, the HHA must maintain the original assessment record as well as all subsequent corrected assessments in the patient's clinical record for 5 years, or longer, in accordance with the clinical record requirements at 42 CFR 484.48. If maintained electronically, the HHA must be capable of retrieving and reproducing a hard copy of these assessments upon request. It is acceptable to have multiple corrected assessments for an OASIS assessment, as long as the OASIS and the clinical record are documented in accordance with the requirements at 42 CFR 484.48, Clinical records.

Clinical Implications of Corrected Assessment Records

When corrections are made to an assessment already submitted to the state system, the HHA must determine if there is an impact on the patient's current care plan. If there is an impact, in addition to the correction made to the assessment, the HHA must make corresponding changes to the current plan of care. If there are any other records where the correction has an impact, for example, the Home Health Resource Group, the Plan of Treatment, or the Request for Anticipated Payment, the agency should make corresponding changes to that record, as applicable. The agency should establish a procedure to review the impact of any corrections made to assessment records and make corresponding changes to other records that are affected.”

Some agencies use a manual corrections form for one or more OASIS items that can be acceptable after confirming the correction with the original clinician or as described in the agency's policies and procedures. As long as the correction form clearly identifies the item or items of the specific assessment and remain with the original assessment as part of the permanent record in order to have a complete picture of the entire assessment; these suggestions are consistent with CMS's overall guidelines for maintaining clinical records in accordance with accepted professional standards.

The regulations do not dictate the form to be used as a progress note and/or a summary report. Notations should be appropriately labeled and should provide an overall, comprehensive view of the patient's total progress and/or current summary report including social, emotional, or behavioral adjustments relative to the diagnosis, treatment, rehabilitation potential, and anticipated outcomes toward recovery or further debilitation.

The regulation does not dictate the frequency with which progress notes must be written. If necessary, review the HHA's policies and procedures concerning the frequency of preparing progress notes.

The discharge summary need not be a separate piece of paper and may be incorporated into the routine summary reports already furnished to the physician.

Probes §484.48

- Are there patterns in the clinical records that are of concern?
- Do clinical records document patient progress and outcomes of care based on changes in the patient's condition?
- How does the HHA inform the attending physician of the availability of a discharge summary?
- How does the HHA ensure that the discharge summary is sent to the attending physician upon his/her request?
- If you have concerns about any part of the clinical record or correction policy ask the HHA to explain its process.

(a) *Standards: Retention of records.* Clinical records are retained for 5 years after the month the cost report to which the records apply is filed with the intermediary, unless state law stipulates a longer period of time. Policies provide for retention even if the HHA discontinues operations. If a patient is transferred to another health facility, a copy of the record or abstract is sent with the patient.

Interpretive Guidelines §484.48(a)

An HHA may store clinical and health insurance records electronically (i.e., on disk, on microfilm, or on optical disk imaging systems). This includes the storage of OASIS information. All material must be available for review by CMS, the intermediary, Department of Health and Human Services, or other specially designated components for bill review, audit, or other examination during the retention period.

With respect to a state agency or federal survey to ensure compliance with the Conditions of Participation, clinical records requested by the surveyor, along with the equipment necessary to read them, must be made available during the course of the unannounced survey.

The final validation reports from submission of OASIS records and OBQI/M reports are not part of the clinical record and as such need not be retained for 5 years. It is recommended that final validation reports be retained for a period of 12 months until the new expected annual OBQI/M reports are received.

- (b) *Standards: Protection of records.* Clinical record information is safe-guarded against loss or unauthorized use. Written procedures govern use and removal of records and the conditions for release of information. Patient's written consent is required for release of information not authorized by law.

Probes §484.48(b)

- How are clinical records stored to protect them from physical destruction and unauthorized use?
- What written policies and procedures govern the use, removal, and release of clinical records?
- How does the HHA make the records available for all personnel furnishing services on behalf of the HHA?

§484.52 Condition of Participation: Evaluation of the Agency's Program.

The HHA has written policies requiring an overall evaluation of the agency's total program at least once a year by the group of professional personnel (or a committee of this group), HHA staff, and consumers, or by professional people outside the agency working in conjunction with consumers. The evaluation consists of an overall policy and administrative review and a clinical record review. The evaluation assesses the extent to which the agency's program is appropriate, adequate, effective, and efficient. Results of the evaluation are reported to and acted upon by those responsible for the operation of the agency and are maintained separately as administrative records.

- (b) *Standard: Clinical record review.* At least quarterly, appropriate health professionals, representing at least the scope of the program, review a sample of both active and closed clinical records to determine whether established policies are followed in furnishing services directly or under arrangement. There is a continuing review of clinical records for each 60-day period that a patient receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care.

Interpretive Guidelines §484.52(b)

Quarterly reviews need not be performed at a joint, sit-down meeting of the professionals performing the review. Each professional may review the records separately, at different times.

The HHA should evaluate all services provided for consistency with professional practice standards for HHA's and the HHA's policies and procedures, compliance with the plan of care, the appropriateness, adequacy, and effectiveness of the services offered, and evaluations of anticipated patient outcomes. Evaluations should be based on specific record review criteria that are consistent with the HHAs admission policies and other

HHA specific patient care policies and procedures. The review by appropriate health professionals should include those professionals representing the scope of services provided in that quarter. Therefore, for example, if no speech therapy services were performed, the speech therapist need not be a part of that quarterly review.

If the survey reveals that one (or more) approved services are never, or rarely, provided either for Medicare/Medicaid patients or non-Medicare/Medicaid patients, undertake the following actions to determine whether the HHA is complying with the patients' plans of care (§484.18):

- Review the HHA's policies relevant to the evaluation of patient care needs.
- Review HHA contracts for unserved or underserved services, if they are provided under contract or arrangement.
- Review plans of care to determine if the services were ordered by a physician but not delivered.
- Ask the HHA under what circumstances it would contact the patient's physician to request modification of a patient's plan of care.

Probes §484.52(b)

1. What patterns or problems does the summary report of the clinical record reviews identify?

2. What is the HHA's plan of correction? Are time frames for implementation and another evaluation review planned?
3. How does the HHA select the clinical records to be reviewed?
4. How do the procedures for review ensure that the review will ascertain whether:
5. HHA policies and procedures are followed?
 - Patients are being helped to attain and maintain their highest practicable functional capacity?
 - Goals or anticipated patient outcomes are appropriate to the diagnosis(es), plan of care, services provided, and patient potential?

§484.55 Condition of Participation: Comprehensive Assessment of Patients.

Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes. The comprehensive assessment must identify the patient's continuing need for home care and meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment. The comprehensive assessment must also incorporate the use of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Secretary.

Interpretive Guidelines §484.55

The comprehensive assessment includes the collection of OASIS data items for most patients, as described below, by a qualified clinician (i.e., an RN, physical therapist, occupational therapist, or speech language pathologist). For Medicare patients, there are some additional requirements. HHAs are expected to conduct a comprehensive assessment of each patient that accurately reflects the patient's current health status and includes information to establish and monitor a plan of care. The plan of care must be reviewed and updated at least every 60 days or as often as the severity of the patient's condition requires, per the requirements at 42 CFR 484.18 (a) and (b).

The requirement to conduct a drug regimen review at §484.55(c) as part of the comprehensive assessment applies to **all** patients serviced by the HHA.

...in addition to an initial assessment visit, the HHA must also conduct a start of care comprehensive assessment with OASIS data items

integrated on patients to whom the requirements are applicable. Subsequent comprehensive assessments (updates and recertification) must be conducted at certain time points during the admission. These updates must include certain data items (i.e., those in the current OASIS data set). The recertification, transfer to an inpatient facility, resumption of care, significant change in condition (SCIC), and discharge comprehensive assessment apply to all patients, but it does not have to include OASIS for private pay patients. The recertification comprehensive assessment can be completed before the 5 day window as long as it continues to be done “not less frequently than the last five days of every 60 day episode beginning with the start-of-care date.”

OASIS data items are not meant to be the only items included in an HHA’s assessment process. They are standardized health assessment items that must be incorporated into an HHA’s own existing assessment policies and process. An example of a comprehensive assessment showing an integration of the OASIS data items with other agency assessment items can be found in “Appendix C: Sample Clinical Records Incorporating OASIS B-1 Data Set,” in the OASIS User’s Manual. For therapy-only cases, the comprehensive assessment should incorporate OASIS data items as well as other assessment data items the HHA currently collects for therapy patients, as opposed to simply adding them at the beginning or end.

Medicare patients: For Medicare patients, the HHA must include a determination of the patient’s eligibility for the home health benefit, including homebound status.

Incorporating OASIS items: HHA’s must incorporate the OASIS data items into their own assessment instrument using the exact language of the items, replacing similar items/questions on their current assessment tool as opposed to simply adding the OASIS items at the beginning or end of the existing assessment tool.

(a) *Standard: Initial assessment visit.*

- (1) A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient; and, for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status. The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start of care date.

Interpretive Guidelines §484.55(a)(1)

The initial assessment visit is conducted to determine the immediate care and support needs of the patient.

For Medicare patients, the initial assessment visit must include a determination of the patient's eligibility for the home health benefit, including homebound status. Verification of a patient's eligibility for the Medicare home health benefit including homebound status does not apply to Medicaid patients, beneficiaries receiving Medicare outpatient services, or private pay patients.

Review a case-mix, stratified sample of clinical records and make home visits according to the survey process (see §§2200 and 2202) to determine compliance with this requirement.

For Medicare patients, if the initial assessment indicates that the patient is not eligible for the Medicare home health care benefit (i.e., the patient is not homebound, has no skilled need, etc.), and the HHA does not admit the patient, then there is no indication for the HHA to conduct a comprehensive assessment or to collect, encode, or transmit OASIS data to the state.

- (2) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.

Interpretive Guidelines §484.55(a)(2)

For non-Medicare patients, if the need for a single therapy service establishes initial home health eligibility, the corresponding practitioner, (including a physical therapist, speech-language pathologist, or occupational therapist) can conduct the initial assessment visit.

For the Medicare home health benefit, occupational therapy services provided at the start of care alone do not establish eligibility; therefore, occupational therapists may not conduct the initial assessment visit under Medicare. Patients needing only occupational therapy services on admission to the agency may qualify for eligibility under programs other than Medicare.

When physical therapy (PT), speech language pathology (SLP), or occupational therapy (OT) is the only service ordered by the physician, a

PT, SLP, or OT may complete the initial assessment visit if the need for that service establishes program eligibility.

Review a case-mix, stratified sample of clinical records and make home visits according to the survey process (see §§2200 and 2202) to determine compliance with this requirement. For a sample of patients, determine who conducted the initial assessments, if the homebound status for Medicare was identified, and the dates of the referral and initial assessments.

Probes §484.55(a)(2)

Review patient records in which therapy (occupational therapy, physical therapy, or speech language pathology) was the only skilled service provided. Determine if the appropriate discipline completed the initial assessment. According to state law, some HHA's may use RNs for initial assessments in therapy-only cases.

(b) *Standard: Completion of the comprehensive assessment.*

- (1) The comprehensive assessment must be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care.
- (2) Except as provided in paragraph (b)(3) of this section, a registered nurse must complete the comprehensive assessment and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status.
- (3) When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. The occupational therapist may complete the comprehensive assessment if the need for occupational therapy establishes program eligibility.

(c) *Standard: Drug regimen review.* The comprehensive assessment must include a review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.

(d) *Standard: Update of the comprehensive assessment.* The comprehensive assessment must be updated and revised (including the administration of the

OASIS) as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but not less frequently than --

- (1) The last 5 days of every 60 days beginning with the start-of-care date, unless there is a --
 - (i) Beneficiary elected transfer;
 - (ii) Significant change in condition; or
 - (iii) Discharge and return to the same HHA during the 60-day episode.
- (2) Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests;
- (3) At discharge.

(e) *Standard: Incorporation of OASIS data items.* The OASIS data items determined by the Secretary must be incorporated into the HHA's own assessment and must include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only.

D. Federal Regulations -- Conditions for Participation, Hospice [Excepts Pertaining to Medical Records]⁴

§418.22 Certification of Terminal Illness.

- (b) *Content of certification.* Certification will be based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness. The certification must conform to the following requirements:
 - (1) The certification must specify that the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course.
 - (2) Clinical information and other documentation that support the medical prognosis must accompany the certification and must be filed in the medical record with the written certification as set forth in paragraph (d)(2) of this section. Initially, the clinical information may be provided verbally, and must be documented in the medical record and included as part of the hospice's eligibility assessment.

⁴ See http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=aec381340057f7b4eb73bab508d2a3e8&tpl=/ecfrbrowse/Title42/42cfr418_main_02.tpl.

- (3) The physician must include a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less as part of the certification and recertification forms, or as an addendum to the certification and recertification forms.
- (i) If the narrative is part of the certification or recertification form, then the narrative must be located immediately prior to the physician's signature.
 - (ii) If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must also sign immediately following the narrative in the addendum.
 - (iii) The narrative shall include a statement directly above the physician signature attesting that by signing, the physician confirms that he/she composed the narrative based on his/her review of the patient's medical record or, if applicable, his/her examination of the patient.
 - (iv) The narrative must reflect the patient's individual clinical circumstances and cannot contain check boxes or standard language used for all patients.
 - (v) The narrative associated with the third benefit period recertification and every subsequent recertification must include an explanation of why the clinical findings of the face-to-face encounter support a life expectancy of 6 months or less.
- (4) The physician or nurse practitioner who performs the face-to-face encounter with the patient described in paragraph (a)(4) of this section must attest in writing that he or she had a face-to-face encounter with the patient, including the date of that visit. The attestation of the nurse practitioner or a non-certifying hospice physician shall state that the clinical findings of that visit were provided to the certifying physician for use in determining continued eligibility for hospice care.
- (5) All certifications and recertifications must be signed and dated by the physician(s), and must include the benefit period dates to which the certification or recertification applies.

(c) *Sources of certification.*

- (1) For the initial 90-day period, the hospice must obtain written certification statements (and oral certification statements if required under paragraph (a)(3) of this section) from --
- (i) The medical director of the hospice or the physician member of the hospice interdisciplinary group; and
 - (ii) The individual's attending physician, if the individual has an attending physician. The attending physician must meet the definition of physician specified in §410.20 of this subchapter.

(2) For subsequent periods, the only requirement is certification by one of the physicians listed in paragraph (c)(1)(i) of this section.

(d) *Maintenance of records.* Hospice staff must --

(1) Make an appropriate entry in the patient's medical record as soon as they receive an oral certification; and

(2) File written certifications in the medical record.

§418.26 Discharge from Hospice Care.

(a) *Reasons for discharge.* A hospice may discharge a patient if --

(3) The hospice determines, under a policy set by the hospice for the purpose of addressing discharge for cause that meets the requirements of paragraphs (a)(3)(i) through (a)(3)(iv) of this section, that the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the hospice to operate effectively is seriously impaired. The hospice must do the following before it seeks to discharge a patient for cause:

(iv) Document the problem(s) and efforts made to resolve the problem(s) and enter this documentation into its medical records.

(b) *Discharge order.* Prior to discharging a patient for any reason listed in paragraph (a) of this section, the hospice must obtain a written physician's discharge order from the hospice medical director. If a patient has an attending physician involved in his or her care, this physician should be consulted before discharge and his or her review and decision included in the discharge note.

§418.52 Condition of Participation: Patient's Rights.

(c) *Standard: Rights of the patient.* The patient has a right to the following:

(5) Have a confidential clinical record. Access to or release of patient information and clinical records is permitted in accordance with 45 CFR parts 160 and 164.

(e) *Standard: Patient outcome measures.*

(1) The comprehensive assessment must include data elements that allow for measurement of outcomes. The hospice must measure and document data in the same way for all patients. The data elements must take into consideration aspects of care related to hospice and palliation.

- (2) The data elements must be an integral part of the comprehensive assessment and must be documented in a systematic and retrievable way for each patient. The data elements for each patient must be used in individual patient care planning and in the coordination of services, and must be used in the aggregate for the hospice's quality assessment and performance improvement program.

§418.56 Condition of Participation: Interdisciplinary Group, Care Planning, and Coordination of Services.

The hospice must designate an interdisciplinary group or groups as specified in paragraph (a) of this section which, in consultation with the patient's attending physician, must prepare a written plan of care for each patient. The plan of care must specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment as such needs relate to the terminal illness and related conditions.

- (d) *Standard: Content of the plan of care.* The hospice must develop an individualized written plan of care for each patient.
- (e) *Standard: Coordination of services.* The hospice must develop and maintain a system of communication and integration, in accordance with the hospice's own policies and procedures, to --
 - (4) Provide for and ensure the ongoing sharing of information between all disciplines providing care and services in all settings, whether the care and services are provided directly or under arrangement.
 - (5) Provide for an ongoing sharing of information with other non-hospice healthcare providers furnishing services unrelated to the terminal illness and related conditions.

§418.58 Condition of Participation: Quality Assessment and Performance Improvement.

The hospice must maintain documentary evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS.

§418.104 Condition of Participation: Clinical Records.

A clinical record containing past and current findings is maintained for each hospice patient. The clinical record must contain correct clinical information that is available to the patient's attending physician and hospice staff. The clinical record may be maintained electronically.

- (a) *Standard: Content.* Each patient's record must include the following:

- (1) The initial plan of care, updated plans of care, initial assessment, comprehensive assessment, updated comprehensive assessments, and clinical notes.
 - (2) Signed copies of the notice of patient rights in accordance with §418.52 and election statement in accordance with §418.24.
 - (3) Responses to medications, symptom management, treatments, and services.
 - (4) Outcome measure data elements, as described in §418.54(e) of this subpart.
 - (5) Physician certification and recertification of terminal illness as required in §§418.22 and 418.25 and described in §§418.102(b) and 418.102(c) respectively, if appropriate.
 - (6) Any advance directives as described in §418.52(a)(2).
 - (7) Physician orders.
- (b) *Standard: Authentication.* All entries must be legible, clear, complete, and appropriately authenticated and dated in accordance with hospice policy and currently accepted standards of practice.
- (c) *Standard: Protection of information.* The clinical record, its contents and the information contained therein must be safeguarded against loss or unauthorized use. The hospice must be in compliance with the Department's rules regarding personal health information as set out at 45 CFR parts 160 and 164.
- (d) *Standard: Retention of records.* Patient clinical records must be retained for 6 years after the death or discharge of the patient, unless state law stipulates a longer period of time. If the hospice discontinues operation, hospice policies must provide for retention and storage of clinical records. The hospice must inform its state agency and its CMS Regional office where such clinical records will be stored and how they may be accessed.
- (e) *Standard: Discharge or transfer of care.*
- (1) If the care of a patient is transferred to another Medicare/Medicaid-certified facility, the hospice must forward to the receiving facility, a copy of --
 - (i) The hospice discharge summary; and
 - (ii) The patient's clinical record, if requested.

- (2) If a patient revokes the election of hospice care, or is discharged from hospice in accordance with §418.26, the hospice must forward to the patient's attending physician, a copy of --
 - (i) The hospice discharge summary; and
 - (ii) The patient's clinical record, if requested.

- (3) The hospice discharge summary as required in paragraph (e)(1) and (e)(2) of this section must include --
 - (i) A summary of the patient's stay including treatments, symptoms and pain management.
 - (ii) The patient's current plan of care.
 - (iii) The patient's latest physician orders. and
 - (iv) Any other documentation that will assist in post-discharge continuity of care or that is requested by the attending physician or receiving facility.

- (f) *Standard: Retrieval of clinical records.* The clinical record, whether hard copy or in electronic form, must be made readily available on request by an appropriate authority.

§418.106 Condition of Participation: Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment.

(b) *Standard: Ordering of drugs.*

- (1) Only a physician as defined by section 1861(r)(1) of the Act, or a nurse practitioner in accordance with the plan of care and state law, may order drugs for the patient.

- (2) If the drug order is verbal or given by or through electronic transmission --
 - (i) It must be given only to a licensed nurse, nurse practitioner (where appropriate), pharmacist, or physician; and
 - (ii) The individual receiving the order must record and sign it immediately and have the prescribing person sign it in accordance with state and federal regulations.

(e) *Standard: Labeling, disposing, and storing of drugs and biologicals*

(2) *Disposing.*

- (C) Document in the patient's clinical record that the written policies and procedures for managing controlled drugs was provided and discussed.

§418.108 Condition of Participation: Short-Term Inpatient Care.

- (c) *Standard: Inpatient care provided under arrangements.* If the hospice has an arrangement with a facility to provide for short-term inpatient care, the

arrangement is described in a written agreement, coordinated by the hospice, and at a minimum specifies --

- (3) That the hospice patient's inpatient clinical record includes a record of all inpatient services furnished and events regarding care that occurred at the facility; that a copy of the discharge summary be provided to the hospice at the time of discharge; and that a copy of the inpatient clinical record is available to the hospice at the time of discharge;

§418.112 Condition of Participation: Hospices that Provide Hospice Care to Residents of a SNF/NF or ICF/IID.

(d) *Standard: Hospice plan of care.* In accordance with §418.56, a written hospice plan of care must be established and maintained in consultation with SNF/NF or ICF/IID representatives. All hospice care provided must be in accordance with this hospice plan of care.

- (1) The hospice plan of care must identify the care and services that are needed and specifically identify which provider is responsible for performing the respective functions that have been agreed upon and included in the hospice plan of care.
- (2) The hospice plan of care reflects the participation of the hospice, the SNF/NF or ICF/IID, and the patient and family to the extent possible.
- (3) Any changes in the hospice plan of care must be discussed with the patient or representative, and SNF/NF or ICF/IID representatives, and must be approved by the hospice before implementation.

(e) *Standard: Coordination of services.* The hospice must:

- (1) Designate a member of each interdisciplinary group that is responsible for a patient who is a resident of a SNF/NF or ICF/IID. The designated interdisciplinary group member is responsible for:
 - (i) Providing overall coordination of the hospice care of the SNF/NF or ICF/IID resident with SNF/NF or ICF/IID representatives; and
 - (ii) Communicating with SNF/NF or ICF/IID representatives and other health care providers participating in the provision of care for the terminal illness and related conditions and other conditions to ensure quality of care for the patient and family.
- (2) Ensure that the hospice IDG communicates with the SNF/NF or ICF/IID medical director, the patient's attending physician, and other physicians participating in the provision of care to the patient as needed to coordinate the hospice care of the hospice patient with the medical care provided by other physicians.

- (3) Provide the SNF/NF or ICF/IID with the following information:
 - (i) The most recent hospice plan of care specific to each patient;
 - (ii) Hospice election form and any advance directives specific to each patient;
 - (iii) Physician certification and recertification of the terminal illness specific to each patient;
 - (iv) Names and contact information for hospice personnel involved in hospice care of each patient;
 - (v) Instructions on how to access the hospice's 24-hour on-call system;
 - (vi) Hospice medication information specific to each patient; and
 - (vii) Hospice physician and attending physician (if any) orders specific to each patient.

§418.205 Special Requirements for Hospice Pre-Election Evaluation and Counseling Services.

(b) *General.*

(4) *Documentation.*

- (i) If the individual's physician initiates the request for services of the hospice medical director or physician, appropriate documentation is required.
- (ii) The request or referral must be in writing, and the hospice medical director or physician employee is expected to provide a written note on the patient's medical record.
- (iii) The hospice agency employing the physician providing these services is required to maintain a written record of the services furnished.
- (iv) If the services are initiated by the beneficiary, the hospice agency is required to maintain a record of the services and documentation that communication between the hospice medical director or physician and the beneficiary's physician occurs, with the beneficiary's permission, to the extent necessary to ensure continuity of care.

E. Federal Regulations -- Comprehensive Outpatient Rehabilitation Facilities Conditions of Participation [Excepts Pertaining to Medical Records]

§485.56 Condition of Participation: Governing Body and Administration.

- (4) Criteria for patient admission, continuing care, and discharge.
- (5) Procedures for preparing and maintaining clinical records on all patients.

- (6) A procedure for explaining to the patient and the patient's family the extent and purpose of the services to be provided.
- (7) A procedure to assist the referring physician in locating another level of care for -- patients whose treatment has terminated and who are discharged.
- (8) A requirement that patients accepted by the facility must be under the care of a physician.
- (9) A requirement that there be a plan of treatment established by a physician for each patient.
- (10) A procedure to ensure that the group of professional personnel reviews and takes appropriate action on recommendations from the utilization review committee regarding patient care policies.

F. Federal Regulations -- Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services [Excepts Pertaining to Medical Records]⁵

§485.711 Condition of Participation: Plan of Care and Physician Involvement.

For each patient in need of outpatient physical therapy or speech pathology services, there is a written plan of care established and periodically reviewed by a physician, or by a physical therapist or speech pathologist respectively.

- (a) *Standard: Medical history and prior treatment.* The following are obtained by the organization before or at the time of initiation of treatment:
 - (1) The patient's significant past history.
 - (2) Current medical findings, if any.
 - (3) Diagnosis(es), if established.
 - (4) Physician's orders, if any.
 - (5) Rehabilitation goals, if determined.

⁵ See <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=41203e44b7b2b8457802dc82530232af;rgn=div5;view=text;node=42%3A5.0.1.1.4;idno=42;cc=ecfr#42:5.0.1.1.4.6.7.1>.

- (6) Contraindications, if any.
- (7) The extent to which the patient is aware of the diagnosis(es) and prognosis.
- (8) If appropriate, the summary of treatment furnished and results achieved during previous periods of rehabilitation services or institutionalization.

(b) *Standard: Plan of care.*

- (1) For each patient there is a written plan of care established by the physician or by the physical therapist or speech-language pathologist who furnishes the services.
- (2) The plan of care for physical therapy or speech pathology services indicates anticipated goals and specifies for those services the --
 - (i) Type;
 - (ii) Amount;
 - (iii) Frequency; and
 - (iv) Duration.
- (3) The plan of care and results of treatment are reviewed by the physician or by the individual who established the plan at least as often as the patient's condition requires, and the indicated action is taken.
- (4) Changes in the plan of care are noted in the clinical record. If the patient has an attending physician, the therapist or speech-language pathologist who furnishes the services promptly notifies him or her of any change in the patient's condition or in the plan of care.

§485.721 Condition of Participation: Clinical Records.

The organization maintains clinical records on all patients in accordance with accepted professional standards, and practices. The clinical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.

- (a) *Standard: Protection of clinical record information.* The organization recognizes the confidentiality of clinical record information and provides safeguards against loss, destruction, or unauthorized use. Written procedures govern the use and removal of records and the conditions for release of information. The patient's written consent is required for release of information not authorized by law.
- (b) *Standard: Content.* The clinical record contains sufficient information to identify the patient clearly, to justify the diagnosis(es) and treatment, and to document the results accurately. All clinical records contain the following general categories of data:

- (1) Documented evidence of the assessment of the needs of the patient, of an appropriate plan of care, and of the care and services furnished.
 - (2) Identification data and consent forms.
 - (3) Medical history.
 - (4) Report of physical examinations, if any.
 - (5) Observations and progress notes.
 - (6) Reports of treatments and clinical findings.
 - (7) Discharge summary including final diagnosis(es) and prognosis.
- (c) *Standard: Completion of records and centralization of reports.* Current clinical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's clinical record. Each physician signs the entries that he or she makes in the clinical record.
- (d) *Standard: Retention and preservation.* Clinical records are retained for at least:
- (1) The period determined by the respective state statute, or the statute of limitations in the state; or
 - (2) In the absence of a state statute --
 - (i) Five years after the date of discharge; or
 - (ii) In the case of a minor, 3 years after the patient becomes of age under state law or 5 years after the date of discharge, whichever is longer.
- (e) *Standard: Indexes.* Clinical records are indexed at least according to name of patient to facilitate acquisition of statistical medical information and retrieval of records for research or administrative action.
- (f) *Standard: Location and facilities.* The organization maintains adequate facilities and equipment, conveniently located, to provide efficient processing of clinical records (reviewing, indexing, filing, and prompt retrieval).

G. Federal Regulations -- Conditions for Coverage, Ambulatory Surgical Center [Excepts Pertaining to Medical Records]⁶

§416.47 Condition for Coverage -- Medical Records.

The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.

- (a) *Standard: Organization.* The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.
- (b) *Standard: Form and content of record.* The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:
 - (1) Patient identification.
 - (2) Significant medical history and results of physical examination.
 - (3) Pre-operative diagnostic studies (entered before surgery), if performed.
 - (4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body.
 - (5) Any allergies and abnormal drug reactions.
 - (6) Entries related to anesthesia administration.
 - (7) Documentation of properly executed informed patient consent.
 - (8) Discharge diagnosis.

H. Federal Regulations -- Conditions for Coverage, End Stage Renal Disease Facility [Excepts Pertaining to Medical Records]⁷

§494.170 Condition: Medical Records.

The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and

⁶ See <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=aec381340057f7b4eb73bab508d2a3e8&rgn=div8&view=text&node=42:3.0.1.1.3.3.1.8&idno=42>.

⁷ See http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=aec381340057f7b4eb73bab508d2a3e8&tpl=/ecfrbrowse/Title42/42cfr494_main_02.tpl.

equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.

(a) *Standard: Protection of the patient's record.* The dialysis facility must --

- (1) Safeguard patient records against loss, destruction, or unauthorized use; and
- (2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following:
 - (i) The transfer of the patient to another facility.
 - (ii) Certain exceptions provided for in the law.
 - (iii) Provisions allowed under third party payment contracts.
 - (iv) Approval by the patient.
 - (v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program.
- (3) Obtaining written authorization from the patient or legal representative before releasing information that is not authorized by law.

(b) *Standard: Completion of patient records and centralization of clinical information.*

- (1) Current medical records and those of discharged patients must be completed promptly.
- (2) All clinical information pertaining to a patient must be centralized in the patient's record, including whether the patient has executed an advance directive. These records must be maintained in a manner such that each member of the interdisciplinary team has access to current information regarding the patient's condition and prescribed treatment.
- (3) The dialysis facility must complete, maintain, and monitor home care patients' records, including the records of patients who receive supplies and equipment from a durable medical equipment supplier.

(c) *Standard: Record retention and preservation.* In accordance with 45 CFR §164.530(j)(2), all patient records must be retained for 6 years from the date of the patient's discharge, transfer, or death.

(d) *Standard: Transfer of patient record information.* When a dialysis patient is transferred, the dialysis facility releasing the patient must send all requested medical record information to the receiving facility within 1 working day of the transfer.

I. Federal Regulations -- Facility Conditions of Participation, Psychiatric Hospitals [Excepts Pertaining to Medical Records]⁸

§482.1 Basis and Scope (Conditions of Participation for Hospitals; Subpart A, General Provisions)

(a) *Statutory basis.*

(2) Section 1861(f) of the Act provides that an institution participating in Medicare as a psychiatric hospital must meet certain specified requirements imposed on hospitals under section 1861(e), must be primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons, must maintain clinical records and other records that the Secretary finds necessary, and must meet staffing requirements that the Secretary finds necessary to carry out an active program of treatment for individuals who are furnished services in the hospital. A distinct part of an institution can participate as a psychiatric hospital if the institution meets the specified 1861(e) requirements and is primarily engaged in providing psychiatric services, and if the distinct part meets the records and staffing requirements that the Secretary finds necessary.

§482.60 Special Provisions Applying to Psychiatric Hospitals.

Psychiatric hospital must --

(c) Maintain clinical records on all patients, including records sufficient to permit CMS to determine the degree and intensity of treatment furnished to Medicare beneficiaries, as specified in §482.61.

§482.61 Condition of Participation: Special Medical Record Requirements for Psychiatric Hospitals.

The medical records maintained by a psychiatric hospital must permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.

(a) *Standard: Development of assessment/diagnostic data.* Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.

⁸ See <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=41203e44b7b2b8457802dc82530232af;rgn=div5;view=text;node=42%3A5.0.1.1.1;idno=42;cc=ecfr#42:5.0.1.1.1.5.4.1>.

- (1) The identification data must include the patient's legal status.
 - (2) A provisional or admitting diagnosis must be made on every patient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.
 - (3) The reasons for admission must be clearly documented as stated by the patient and/or others significantly involved.
 - (4) The social service records, including reports of interviews with patients, family members, and others, must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.
 - (5) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.
- (b) *Standard: Psychiatric evaluation.* Each patient must receive a psychiatric evaluation that must --
- (1) Be completed within 60 hours of admission;
 - (2) Include a medical history;
 - (3) Contain a record of mental status;
 - (4) Note the onset of illness and the circumstances leading to admission;
 - (5) Describe attitudes and behavior;
 - (6) Estimate intellectual functioning, memory functioning, and orientation; and
 - (7) Include an inventory of the patient's assets in descriptive, not interpretative, fashion.
- (c) *Standard: Treatment plan.*
- (1) Each patient must have an individual comprehensive treatment plan that must be based on an inventory of the patient's strengths and disabilities. The written plan must include --
 - (i) A substantiated diagnosis;
 - (ii) Short-term and long-range goals;
 - (iii) The specific treatment modalities utilized;
 - (iv) The responsibilities of each member of the treatment team; and
 - (v) Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

(2) The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.

(d) *Standard: Recording progress.* Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the patient as specified in §482.12(c), nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

(e) *Standard: Discharge planning and discharge summary.* The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

§412.27 Excluded Psychiatric Units: Additional Requirements.

In order to be excluded from the prospective payment system..., a psychiatric unit must meet the following requirements:

(c) Maintain medical records that permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the unit, and that meet the following requirements:

(1) *Development of assessment/diagnostic data.* Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.

(i) The identification data must include the inpatient's legal status.

(ii) A provisional or admitting diagnosis must be made on every inpatient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(iii) The reasons for admission must be clearly documented as stated by the inpatient or others significantly involved, or both.

(iv) The social service records, including reports of interviews with inpatients, family members, and others must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

(v) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

- (2) *Psychiatric evaluation.* Each inpatient must receive a psychiatric evaluation that must --
- (i) Be completed within 60 hours of admission;
 - (ii) Include a medical history;
 - (iii) Contain a record of mental status;
 - (iv) Note the onset of illness and the circumstances leading to admission;
 - (v) Describe attitudes and behavior;
 - (vi) Estimate intellectual functioning, memory functioning, and orientation; and
 - (vii) Include an inventory of the inpatient's assets in descriptive, not interpretative fashion.
- (3) *Treatment plan.*
- (i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include a substantiated diagnosis; short-term and long-term goals; the specific treatment modalities utilized; the responsibilities of each member of the treatment team; and adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out; and
 - (ii) The treatment received by the inpatient must be documented in such a way as to assure that all active therapeutic efforts are included.
- (4) *Recording progress.* Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the inpatient, a nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the inpatient but must be recorded at least weekly for the first 2 months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the inpatient's progress in accordance with the original or revised treatment plan.
- (5) *Discharge planning and discharge summary.* The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the inpatient's hospitalization in the unit and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

J. Federal Regulations -- Conditions for Certification, Rural Health Clinics, and Conditions for Coverage, FQHCs [Excepts Pertaining to Medical Records]

§491 Certification of Certain Health Facilities

Subpart A -- Rural Health Clinics: Conditions for Certification; and FQHCs
Conditions for Coverage

§491.10 Patient Health Records.

(a) *Records system.*

- (1) The clinic or center maintains a clinical record system in accordance with written policies and procedures.
- (2) A designated member of the professional staff is responsible for maintaining the records and for insuring that they are completely and accurately documented, readily accessible, and systematically organized.
- (3) For each patient receiving health care services, the clinic or center maintains a record that includes, as applicable:
 - (i) Identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;
 - (ii) Reports of physical examinations, diagnostic and laboratory test results, and consultative findings;
 - (iii) All physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress;
 - (iv) Signatures of the physician or other health care professional.

(b) *Protection of record information.*

- (1) The clinic or center maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.
- (2) Written policies and procedures govern the use and removal of records from the clinic or center and the conditions for release of information.
- (3) The patient's written consent is required for release of information not authorized to be released without such consent.

(c) *Retention of records.* The records are retained for at least 6 years from date of last entry, and longer if required by state statute.

K. Federal Regulations -- Conditions of Participation, Intermediate Care Facilities for the Mentally Retarded [Developmentally Disabled] [Excepts Pertaining to Medical Records]⁹

Subpart I -- Conditions of Participation for Intermediate Care Facilities for Individuals with Intellectual Disabilities

§483.410 Condition of Participation: Governing Body and Management.

(c) *Standard: Client records.*

- (1) The facility must develop and maintain a recordkeeping system that includes a separate record for each client and that documents the client's health care, active treatment, social information, and protection of the client's rights.
- (2) The facility must keep confidential all information contained in the clients' records, regardless of the form or storage method of the records.
- (3) The facility must develop and implement policies and procedures governing the release of any client information, including consents necessary from the client, or parents (if the client is a minor) or legal guardian.
- (4) Any individual who makes an entry in a client's record must make it legibly, date it, and sign it.
- (5) The facility must provide a legend to explain any symbol or abbreviation used in a client's record.
- (6) The facility must provide each identified residential living unit with appropriate aspects of each client's record.

§483.440 Condition of Participation: Active Treatment Services.

(b) *Standard: Admissions, transfers, and discharge.*

- (4) If a client is to be either transferred or discharged, the facility must --
 - (i) Have documentation in the client's record that the client was transferred or discharged for good cause

⁹ See <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=82d96ee680e3f752e0d847653203c6df;rgn=div5;view=text;node=42%3A5.0.1.1.2;idno=42;cc=ecfr#42:5.0.1.1.2.9>.

- (5) At the time of the discharge, the facility must --
 - (i) Develop a final summary of the client's developmental, behavioral, social, health and nutritional status and, with the consent of the client, parents (if the client is a minor) or legal guardian, provide a copy to authorized persons and agencies; and
 - (ii) Provide a post-discharge plan of care that will assist the client to adjust to the new living environment.

§483.460 Condition of Participation: Health Care Services.

(h) *Standard: Documentation of dental services.*

- (1) If the facility maintains an in-house dental service, the facility must keep a permanent dental record for each client, with a dental summary maintained in the client's living unit.
- (2) If the facility does not maintain an in-house dental service, the facility must obtain a dental summary of the results of dental visits and maintain the summary in the client's living unit.

(j) *Standard: Drug regimen review.*

- (1) The pharmacist must prepare a record of each client's drug regimen reviews and the facility must maintain that record.
- (2) An individual medication administration record must be maintained for each client.

EHR PAYMENT INCENTIVES FOR PROVIDERS INELIGIBLE FOR PAYMENT INCENTIVES AND OTHER FUNDING STUDY

Files Available for This Report

- Main Report <http://aspe.hhs.gov/daltcp/reports/2013/EHRPI.shtml>
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI.pdf>
- APPENDIX A. Medicare and Medicaid EHR Incentive Programs
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendA>
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendA.pdf>
- APPENDIX B. Definitions and Certification of EHR Technology
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendB>
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendB.pdf>
- APPENDIX C. Public Health Service Act Section 3000(3) as Added by HITECH
Section 13101 -- Provider Analysis
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendC>
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendC.pdf>
- APPENDIX D. Ineligible Provider Characteristics
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendD>
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendD.pdf>
- APPENDIX E. Long-Term and Post-Acute Care Provider Profiles
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendE>
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendE.pdf>
- APPENDIX F. Behavioral Health Provider Profiles
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- APPENDIX G. Safety Net Provider Profiles
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- APPENDIX H. Other Health Care Provider Profiles
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- APPENDIX I. Table Summary of Patient Protection and Affordable Care Act Provisions with Relationship to Ineligible Providers and Health IT Use
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendI>
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendI.pdf>
- APPENDIX J. Behavioral Health Provider Analysis
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendJ>
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendJ.pdf>
- APPENDIX K. Grant, Demonstrations and Cooperative Agreement Programs
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendK>
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendK.pdf>
- APPENDIX L. Loan Programs
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendL>
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- APPENDIX M. Technical Assistance Programs
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendM>
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendM.pdf>
- APPENDIX N. Administrative Infrastructure Building Programs
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendN>
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendN.pdf>
- APPENDIX O. Anti-Kickback Statute EHR Safe Harbor Regulations
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendO>
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendO.pdf>
- APPENDIX P. Private Sector Programs to Advance Certified EHR Technology
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendP>
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendP.pdf>
- APPENDIX Q. Regulations for Medical Records
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendQ>
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendQ.pdf>
- APPENDIX R. Technical Advisory Group Summary
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendR>
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendR.pdf>
- APPENDIX S. Evaluating Benefits and Costs of New Incentives for EHR Adoption by Ineligible Providers
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendS>
<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendS.pdf>

APPENDIX T. CIO Consortium EMR Cost Study Data

<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendT>

<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendT.pdf>

APPENDIX U. Abbreviations and Acronyms

<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendU>

<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendU.pdf>

APPENDIX V. References

<http://aspe.hhs.gov/daltcp/reports/2013/EHRPlap.shtml#appendV>

<http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendV.pdf>