Medicare
State Operations Manual
Provider Certification

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

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HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
List of Appendices	(2 pp.)	(2 pp.)
Appendix A		
Table of Contents	A-1 – A-2 (2 pp.)	A-1 – A-2 (2 pp.)
Appendix B		
Title Page	(1 p.)	(1 p.)
Table of Contents	B-1 (1 p.)	B-1 (1 p.)
	B-15 – B-16.1 (3 pp.)	B-15 – B-16 (2 p.)
	B-17 – B-20.3 (7 pp.)	B-17 – B-20 (4 pp.)
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	B-39 – B-41 (11 pp.)	B-39 – B-42 (4 pp.)
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	B-65 – B-79 (15 pp.)	B-65 (1 p.)

NEW/REVISED MATERIAL--*EFFECTIVE DATE:* October 1, 2000

List of Appendices, this list is revised to include the addition of new Appendices' titles formerly added in previous revisions.

Appendix A, Interpretive Guidelines and Survey Procedures—Hospital--Table of Contents, is revised to correct the exclusion of §482.45, Organ Tissue and Eye Procurement inadvertently left out in a previous revision.

Appendix B, Interpretive Guidelines for Home Health Agencies, updates current guidance for home health surveys to include instruction for surveying the new Outcome and Assessment Information Set (OASIS) regulations based on recommendations by State survey agencies, HCFA regional offices, and other interested parties. As part of this update, G-tag 167 has been discontinued. A new tag concerning drug review, G-337, is applicable to all patients serviced by the home health agency. This update also includes regulatory language and guidance that recently amended existing conditions of participation for home health agencies as a result of the July 3, 2000 publication of the final rule for implementation of the prospective payment system for home health agencies. This rule was effective October 1, 2000.

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

APPENDICES

APPENDICES

APPENDIX A

Interpretive Guidelines and Survey Procedures - Hospitals

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
§482.2 Condition of Participation: Provision of emergency services by nonparticipating hospitals. (a) The services of an institution that does not have an agreement to participate in the Medicare program may, nevertheless, be reimbursed under the program if-- (1) The services are emergency services; and (2) The institution meets the requirements of section 1861(e)(1) through (5) and (7) of the Act. See 42 CFR 405.152, 405.157, and 405.158 for provisions regarding emergency services. (b) Section 440.170(e) of this chapter defines emergency hospital services for purposes of Medicaid reimbursement.	§482.2 Condition of Participation: Provision of emergency services nonparticipating hospitals. (2) The statutory requirements that a hospital must meet are: o The hospital is primarily engaged in providing, by or under the supervision of physicians, to inpatients, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled or sick persons, or rehabilitation services for the injured, disabled, or sick persons. o The hospital maintains clinical records on all patients. o The hospital has medical staff bylaws. o The hospital has a requirement that every Medicare patient must be under the care of a physician.	§482.2 Condition of Participation: Provision of emergency services nonparticipating hospitals. (2) Document that the statutory requirements are met.

APPENDIX B

SURVEY PROCEDURES FOR THE APPLICATION OF CONDITIONS OF PARTICIPATION FOR HOME HEALTH AGENCIES INTERPRETIVE GUIDELINES

INTERPRETIVE GUIDELINES - HOME HEALTH AGENCIES

APPENDIX B

Conditions of Participation: Home Health Agencies

PATIENT RIGHTS (42 CFR 484.10)

RELEASE OF PATIENT IDENTIFIABLE OASIS INFORMATION (42 CFR 484.11)

COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAWS, DISCLOSURE AND OWNERSHIP INFORMATION, AND ACCEPTED PROFESSIONAL STANDARDS AND PRINCIPLES (42 CFR 484.12)

ORGANIZATION, SERVICES, AND ADMINISTRATION (42 CFR 484.14)

GROUP OF PROFESSIONAL PERSONNEL (42 CFR 484.16)

ACCEPTANCE OF PATIENTS, PLAN OF CARE, AND MEDICAL SUPERVISION (42 CFR 484.18)

REPORTING OF OASIS INFORMATION (42 CFR 484.20)

SKILLED NURSING SERVICES (42 CFR 484.30)

THERAPY SERVICES (42 CFR 484.32)

MEDICAL SOCIAL SERVICES (42 CFR 484.34)

HOME HEALTH AIDE SERVICES (42 CFR 484.36)

QUALIFYING TO FURNISH OUTPATIENT PHYSICAL THERAPY OR SPEECH PATHOLOGY SERVICES (42 CFR 484.38)

CLINICAL RECORDS (42 CFR 484.48)

EVALUATION OF THE AGENCY'S PROGRAM (42 CFR 484.52)

COMPREHENSIVE ASSESSMENT OF PATIENTS (42 CFR 484.55)

The Interpretive Guidelines serve to interpret and clarify the Conditions of Participation for home health agencies (HHAs). The Interpretive Guidelines merely define or explain the relevant statute and regulations and do not impose any requirements that are not otherwise set forth in statute or regulation.

Conduct the HHA survey in accordance with the appropriate protocols and look to the substantive requirements in the statute and regulations to determine whether a citation of non-compliance is appropriate. Base any deficiency on a violation of the statute or regulations, which, in turn, is to be based on observations of the HHA's performance or practices. (See §2712.)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§484.10(a) Standard: Notice of rights	
G102	(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.	§484.10(a)(1) GUIDELINES: 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: 1) the right to be informed that OASIS information will be collected and for what purpose; 2) the right to have the information kept confidential and secure; 3) the right to be informed that OASIS information will not be disclosed except for legitimate purposes allowed by the Privacy Act; 4) the right to refuse to answer a specific question; and 5) the right to see, review, and request changes on their assessment. A standard notice to patients that explains these rights in plain language was published in the Federal Register on June 18, 1999, (64 FR 32984) and is available in English and Spanish on the OASIS website (www.hcfa.gov/medicaid/oasis/oasishmp.htm). HHAs must present and explain this required notice to beneficiaries before their initial OASIS assessment. The documentation maintained by an HHA to show that the patient was informed of the patient's rights might include a patient rights statement, signed and dated by the patient or some other documentation consistent with the HHA's policies and procedures. Review HHA admission information to determine if the OASIS Statement of Patient Privacy Rights (for Medicare/Medicaid patients) or the Notice about Privacy (for non-Medicare/non-Medicaid patients) is included concerning OASIS data collection and transmission. 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.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		§484.10(a)(1) PROBE: 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?
G103	(2) The HHA must maintain documentation showing that it has complied with the requirements of this section.	
	§484.10(b) Standard: Exercise of rights and respect for property and person.	
G104	(1) The patient has the right to exercise his or her rights as a patient of the HHA.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§484.10(c) Standard: Right to be informed and to participate in planning care and treatment.	§484.10(c) Guidelines: During home visits, discuss the services that the patient is receiving specific to the medical plan of care. Determine if the patient response shows that the HHA has offered specific instructions in areas mentioned in the standard. For example, if the patient is recovering from a fractured hip and has been receiving physical therapy services for several weeks, ask the patient to show or explain to you what exercises he or she has been doing, how often they are to be done, and what results are anticipated. Also, ask how often the physical therapist comes, when the therapist is expected next, and how plans for therapy have changed as the condition has changed. If the patient responds that he/she has written instructions telling him or her what to do, request to see them. Ask the patient how he or she participated in developing the plan of care to be furnished by the HHA and when he/she was told about changes in the plan of care. The HHA may discuss changes with the patient by telephone prior to the HHA visit or at the time of the visit, but the patient should feel that he or she has time to consider the implications of the change(s) and concur or object to them prior to implementation. Advance directives generally refer to written statements, completed in advance of a serious illness, about how an individual wants medical decisions made. The two most common forms of advance directives are a living will and a durable medical power of attorney for health care. Section 1866(a)(1)(Q), as implemented by 42 CFR 484.10(c)(2)(ii), requires HHAs to maintain written policies and procedures regarding advance directives. The specific requirements HHAs must meet with respect to advance directives are set forth at 42 CFR 489, Subpart I. Under these provisions, the HHA must: 1) provide all adult individuals with written information about their rights under State law to: (a) make decisions about their medical care; (b) accept or refuse medical or surgical treatment; and (c) formulate, at the individual's option, an advance directive; 2) inform patients about the HHA's written policies on implementing advance directives; 3) document in the patient's medical record whether he or she has executed an advance directive; 4) not condition the provision of care or otherwise discriminate against an individual based on whether he or she has executed an advance directive; 5) ensure compliance with the related State requirements on advance directives; and 6) provide staff and community education on issues concerning advance directives. This information must be furnished in advance of the individual coming under the care of the HHA and may be provided during admission, the patient's initial evaluation, or the patient's first professional visit.
G108	(1) The patient has the right to be informed, in advance, about the care to be furnished, and of any changes in the care to be furnished. (i) The HHA must advise the patient in advance of the disciplines that will furnish care, and the frequency of visits proposed to be furnished. (ii) The HHA must advise the patient in advance of any change in the plan of care before the change is made.	
G 109	(2) The patient has the right to participate in the planning of the care. (i) The HHA must advise the patient in advance of the right to participate in planning the care or treatment and in planning changes in the care or treatment.	
G 110	(ii) The HHA complies with the requirements of Subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. The HHA	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	must inform and distribute written information to the patient, in advance, concerning its policies on advance directives, including a description of applicable State law. The HHA may furnish advanced directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.	§484.10(c) Probes: (1) What documentation in the clinical records indicates that the HHA advised the patient, in advance, of his or her right to participate in planning the care or treatment to be provided? What documentation indicates that the HHA informed the patient about the types of services to be provided, the disciplines involved, the frequency of the services, and the anticipated outcomes? (2) How does the HHA inform the patient about changes in the plan of care and solicit the patient's participation in that care prior to the change being implemented? (3) How does the agency advise patients of the need for the physician to agree with the plan of treatment and with any changes to that plan? (4) During home visits, ask the patients how they would seek advice or care from their physician, the HHA or its representatives if problems, concerns, or emergencies which are part of the medical problems for which they are being treated by the HHA occur. (5) How do HHA employees implement advance directives requirements?
	§484.10(d) Standard: Confidentiality of medical records.	§484.10(d) Guidelines: For specific requirements concerning the confidentiality of OASIS data, see the guidelines at §484.11. §484.10(d) Probes: (1) How does the HHA ensure the confidentiality of the patient's clinical record? (2) 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? (3) What documentation in the clinical record indicates that the HHA informed the patient of the HHA's policies and procedures concerning clinical record disclosure?
G111	The patient has the right to confidentiality of the clinical records maintained by the HHA.	
G112	The HHA must advise the patient of the agency's policies and procedures regarding disclosure of clinical records.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§484.10(e) Standard: Patient liability for payment.	§484.10(e) Guidelines: During home visits, ask the patient whether the HHA has notified him or her of covered and noncovered services. Also, discuss whether the HHA has described any services for which the patient might have to pay and how payment sources might change (or have changed) during the course of care. Again, consider the patient's ability to understand and retain payment information. The subject of payment for home care services is often complex and confusing, particularly early in the course of treatment when the patient's illness or limitations appears to be the more pressing problem. Look for a written statement in the home that might serve as a resource or reminder to the patient about the information the HHA has presented. Also, note whether there are subsequent written statements about payments for items or services of which the HHA has become aware. In your evaluation of compliance with this standard, consider whether the HHA is making a reasonable attempt to help the patient understand how the charges for HHA services will be covered or not covered over the course of treatment. Based on the information provided by the HHA, do you believe that the patient has a reasonable understanding of how payment for home care services will likely occur and can make reasonable, informed decisions about financial matters related to the HHA's care and treatment of him or her. Do NOT try to advise the patient about financial, coverage, or payment issues. §484.10(e) Probes: 1. What process is followed by the HHA to inform the patient of home care charges and probable payment sources, patient's payment liability (if any), and of changes in payment sources and patient liabilities? 2. What documentation in the clinical record indicates that the HHA informed the patient of Federally-funded or aided covered and noncovered services?
G113	(1) The patient has the right to be advised, before care is initiated, of the extent to which payment for the HHA services may be expected from Medicare or other sources, and the extent to which payment may be required from the patient.	
G114	Before the care is initiated, the HHA must inform the patient, orally and in writing, of-- (i) The extent to which payment may be expected from Medicare, Medicaid, or any other Federally funded or aided program known to the HHA; (ii) The charges for services that will not be covered by Medicare; and (iii) The charges that the individual may have to pay.	
G115	(2) The patient has the right to be advised orally and in writing of any changes in the information provided in accordance with paragraph (e)(1) of this section when they occur. The HHA must advise the patient of these changes orally and in	

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	writing as soon as possible, but no later than 30 calendar days from the date that the HHA becomes aware of a change.	
G116	§484.10(f) Standard: Home health hotline. The patient has the right to be advised of the availability of the toll-free HHA hotline in the State. When the agency accepts the patient for treatment or care, the HHA must advise the patient in writing of the telephone number of the home health hotline established by the State, the hours of its operation, and that the purpose of the hotline is to receive complaints or questions about local HHAs. The patient also has the right to use this hotline to lodge complaints concerning the implementation of the advanced directives requirements.	§484.10(f) Guidelines: During home visits, ask the patient for the number of the HHA State hotline, when he/she would use it, and what he/she would expect as a result of its use. If the patient has difficulty answering questions about the hotline, ask the patient for a copy of the written information that the HHA has provided. Federal facilities are not required to participate in the HHA State hotline.

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G310	§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 information to the public.	§484.11 Guidelines: Protection of confidentiality of OASIS information is two-fold; the HHA has a responsibility to keep OASIS information confidential and HCFA 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 requirements are not met by the contractor. 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 HCFA 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.

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		§484.11 Guidelines (continued): 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: o Protecting confidentiality of OASIS data (written and/or electronic). o 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: o Knowledge and application of rights to add, edit, or otherwise modify encoded OASIS data; o Assignment of passwords; o Assurance that only specified staff have contact with assessment information; and o 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.

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		§484.11 Probes: How does the HHA assure that only specified personnel have access to OASIS assessment information? How is the security of passwords maintained? What policies and procedures address password assignment and use? How does the HHA assure that the computer is "logged off" or password protected when the data entry operator is away from the computer, i.e., at lunch or break times? Who in the HHA has the password information needed to electronically report OASIS data to the State agency? At least two staff persons should have the password. If the HHA has branches, how is OASIS data protected and kept secure during transfer from the branch to the parent agency? If the HHA contracts out OASIS encoding and reporting, what systems are in place to assure that the contracted vendor maintains confidentiality of OASIS data?
G117	§484.12 Condition of Participation: Compliance with Federal, State and local laws, disclosure and ownership information, and accepted professional standards and principles.	

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G141	§484.14(e) Standard: Personnel policies. Personnel practices and patient care are supported by appropriate, written personnel policies. Personnel records include qualifications and licensure that are kept current.	§484.14(e) GUIDELINES: The numbers and qualifications of personnel available to provide services must be sufficient to implement the plans of care and the medical, nursing, and rehabilitative needs of the patients admitted by the HHA. §484.14(e) PROBES: 1- What does the HHA include in the personnel records about the qualifications and licensure of its employees? 2- If the HHA does not keep duplicate personnel records of staff hired under arrangement, how does it ensure that records are kept current?
G142	§484.14(f) Standard: Personnel under hourly or per visit contracts. If personnel under hourly or per visit contracts are used by the HHA, there is a written contract between those personnel and the agency that specifies the following: (1) Patients are accepted for care only by the primary HHA. (2) The services to be furnished. (3) The necessity to conform to all applicable agency policies, including personnel qualifications. (4) The responsibility for participating in developing plans of care.	§484.14(f) GUIDELINES: If an HHA, which has been established as hospital-based for Medicare payment purposes, has arranged with the hospital to provide the second qualifying service or other HHA services (see 42 CFR 484.14(a)) through hospital employees, the HHA would not be required to have an hourly or per visit contract with these hospital employees. The HHA should identify in its records the names of these employees and the amount of time they spend at the HHA. However, if these hospital employees provide services to the HHA outside of their own usual working hours or shifts (i.e., "moonlight" as HHA employees, as opposed to working overtime for the hospital), a contract as specified in standard (f) applies. §484.14(f) PROBES: 1- How does the HHA orient contractual personnel to HHA objectives, policies, procedures, and programs? 2- How does the HHA evaluate whether contractual personnel inform the patient of his/her rights prior to the beginning of care or when there are changes in care? 3- How are contractual personnel monitored by the HHA to confirm that the care provided is consistent with the plans of care and that their services meet the terms of the contract?

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	(5) The manner in which services will be controlled, coordinated, and evaluated by the primary HHA. (6) The procedures for submitting clinical and progress notes, scheduling of visits, periodic patient evaluation. (7) The procedures for payment for services furnished under the contract.	4- Who reviews the recertification requests to determine if continuing patient care is indicated as a probable medical necessity?
	§484.14(g) Standard: Coordination of patient services.	§484.14(g) PROBES: 1- What is the HHA's policy related to facilitating exchange of information among staff? 2- How does coordination of care among staff and/or contract personnel providing services to individual patients occur? 3- How does the HHA ensure that patients' written summary reports sent to attending physicians every 60 days meet the regulatory requirements of §484.2? Refer to §484.48 regarding guidelines for the attending physician's written summary report.
G143	All personnel furnishing services maintain liaison to ensure that their efforts are coordinated effectively and support the objectives outlined in the plan of care.	
G144	The clinical record or minutes of case conferences establish that effective interchange, reporting, and coordination of patient care does occur.	
G145	A written summary report for each patient is sent to the attending physician at least every 60 days.	

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	timing. Other costs related to capital expenditures include title fees, permit and license fees, broker commissions, architect, legal, accounting, and appraisal fees; interest, finance, or carrying charges on bonds, notes and other costs incurred for borrowing funds. (ii) If the anticipated source of financing is, in any part, the anticipated payment from title V (Maternal and Child Health and Crippled Children's Services) or title XVIII (Medicare) or title XIX (Medicaid) of the Social Security Act, the plan specifies the following: (A) Whether the proposed capital expenditure is required to conform, or is likely to be required to conform, to current standards, criteria, or plans developed in accordance with the Public Health Service Act or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963. (B) Whether a capital expenditure proposal has been submitted to the designated planning agency for approval in accordance with section 1122 of the Act (42 U.S.C. 1320a-1) and implementing regulations. (C) Whether the designated planning agency has approved or disapproved the proposed capital expenditure if it was presented to that agency.	

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G148	(3) Preparation of plan and budget. The overall plan and budget is prepared under the direction of the governing body of the HHA by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the HHA.	
G149	(4) Annual review of plan and budget. The overall plan and budget is reviewed and updated at least annually by the committee referred to in paragraph (i)(3) of this section under the direction of the governing body of the HHA.	
	§484.14(j) Standard: Laboratory Services.	§484.14(j)(1) Guidelines: Determine if the HHA is providing laboratory testing as set forth at 42 CFR 493. If the HHA is performing testing, request to see the CLIA certificate for the level of testing being performed, i.e., a certificate of waiver, certificate for provider-performed microscopy procedures, certificate of accreditation, certificate of registration, or certificate of compliance (issued upon the determination of compliance after an on-site survey.) HHAs holding a certificate of waiver are limited to performing only those tests determined to be in the waived category. Some tests that an HHA may perform that fall into the waived category include: o Dipstick/tablet reagent urinalysis; o Blood glucose by glucose monitoring devices cleared by the Food and Drug Administration (FDA) specifically for home use; o Some prothrombin time tests; and o Some glycosolated hemoglobin tests. For a complete listing of waived tests, refer to HCFA's website at www.HCFA.gov.
G150	(1) If the HHA engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the FDA, such testing must be in compliance with all applicable requirements of part 493 of this chapter.	

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		§484.14(j)(1) Guidelines (continued): HHAs holding a certificate for provider-performed microscopy procedures are limited to performing only those tests determined to be in the provider-performed microscopy procedure category or in combination with waived tests: The tests in the provider-performed microscopy procedures category (e.g., wet mounts, urine sediment examinations, and nasal smears for granulocytes) are not typical of those performed in an HHA; however, if they are conducted by HHA staff under a certificate for provider-performed microscopy procedures, they must be performed by a practitioner as specified at §493.19 (i.e., a physician, nurse midwife, nurse practitioner, physician assistant, or dentist). If not performed by these personnel, the HHA would require a registration certificate (which allows the performance of such testing until a determination of compliance is made), certificate of accreditation, or certificate of compliance. For a complete listing of provider-performed microscopy procedures, refer to HCFA's website at www.HCFA.gov. If the HHA performs any other testing procedures, (i.e., moderate or high complexity testing), it would require a registration certificate, a certificate of accreditation, or a certificate of compliance. While some prothrombin testing is in the waived category, as mentioned above, other prothrombin testing is considered moderate complexity testing depending on the skill level required to operate the instrument. For a complete listing of moderate and high complexity tests, refer to HCFA's website at www.HCFA.gov. Assisting individuals in administering their own tests, such as fingerstick blood glucose or prothrombin testing, is not considered testing subject to the CLIA regulations. However, if the HHA staff is actually responsible for measuring the blood glucose level or prothrombin times of patients with an FDA approved blood glucose or prothrombin time monitor, and no other tests are being performed, request to see the facility's certificate of waiver, since glucose testing with a blood glucose meter (approved by the FDA specifically for home use) and some prothrombin time tests are waived tests under the provisions at 42 CFR 493.15. If the facility does not possess the appropriate CLIA certificate, inform the facility that it is in violation of CLIA law and that it must apply immediately to the State agency for the appropriate certificate. The facility is out of compliance with 42 CFR 484.14(j). Also, refer this facility's non-compliance to the department within the State agency responsible for CLIA surveys.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(2) If the HHA chooses to refer specimens for laboratory testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.	§484.14(j)(2) Guidelines: If the HHA refers specimens for laboratory testing to an outside laboratory, the referral laboratory must be CLIA-certified. The HHA should have a copy of the referral laboratory's CLIA certificate in its administrative records.

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G151	§484.16 Condition of Participation: Group of professional personnel.	§484.16 GUIDELINES: If an HHA has a branch(es), the annual review includes services delivered through the branch(es). The parent agency's group of professional personnel or a subcommittee of the group may also serve as the subunit's group of professional personnel or the subunit may establish its own group. If the HHA is part of a larger organization (e.g., a State, county, hospital) and the parent organization's policies are mostly applicable to the HHA, the HHA does not have to develop new policies. Rather, the HHA should review and revise patient policies to accommodate the conditions of participation, the patient care needs of the HHA and the quality of services to be provided.
G152	A group of professional personnel, which includes at least one physician and one registered nurse (preferably a public health nurse), and with appropriate representation from other professional disciplines,	
G153	establishes and annually reviews the agency's policies governing scope of services offered, admission and discharge policies, medical supervision and plans of care, emergency care, clinical records, personnel qualifications, and program evaluation. At least one member of the group is neither an owner nor an employee of the agency.	
	§484.16(a) Standard: Advisory and evaluation function.	§484.16(a) PROBE: What documentation is there of advice concerning professional issues, evaluation of the professional service program, or assistance in maintaining liaison with other community groups by the professional group?
G154	The group of professional personnel meets frequently to advise the agency on professional issues, to participate in the evaluation of the agency's	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		§484.18(a) Probes: 1. How does an HHA evaluate whether the plan of care, and the coordination of services, help the patient attain and maintain his or her highest practicable functional capacity based on medical, nursing, and rehabilitative needs? 2. How does the HHA monitor the delivery of services, including those provided under arrangement or contract, to ensure compliance with the specificity and frequency of services ordered in the plan of care? 3. If a range of visits is ordered, how does the HHA ensure that the frequency of visits meets the clinical needs of the patient?
	§484.18(b) Standard: Periodic review of plan of care .	§484.18(b) Guidelines: Changes in the patient's condition that require a change in the plan of care should be documented in the patient's clinical record. When a Medicare beneficiary elects to transfer to a different HHA or is discharged and returns to the same HHA, it warrants a new clock for purposes of payment, OASIS assessment, and physician certification of the new plan of care. When a new 60-day episode begins, the original 60-day episode payment is proportionally adjusted to reflect the length of time the beneficiary remained under the HHA's care before the intervening event. The proportional payment is the Partial Episode Payment (PEP) adjustment. A Significant Change In Condition (SCIC) adjustment occurs when a Medicare beneficiary experiences a significant change in condition during a 60-day episode that was not envisioned in the original plan of care. In order to receive a new case-mix assignment for purposes of SCIC payment during the 60-day episode, the HHA must complete an OASIS assessment and obtain the necessary physician change orders reflecting the significant change in treatment approach in the patient's plan of care. Refer to current policy for the use of the OASIS assessment for SCIC adjustments.
G163	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.	
G164	Agency professional staff promptly alert the physician to any changes that suggest a need to alter the plan of care.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§484.18(c) Standard: Conformance with physician orders.	§484.18(c) Guidelines: 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. Orders must be obtained prior to any reduction or termination of services. Verbal orders must be countersigned by the physician as soon as possible. Ask HHAs, 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. §484.18(c) Probes: How does the HHA secure the physician's signature on verbal, change, or renewal orders? How does the HHA ensure that verbal orders are accepted, co-signed by the nurse or therapist, and countersigned by the physician appropriately?
G165	Drugs and treatments are administered by agency staff only as ordered by the physician.	
G166	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.	
	See §484.55(c) Tag 167 expired on 6/1/99. A new tag concerning drug review is found at G337 and is applicable to all patients serviced by the HHA.	
G300	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.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
G320	§484.20 Condition of participation: Reporting OASIS information. HHAs must electronically report all OASIS data collected in accordance with §484.55.	§484.20 Guidelines: HHAs must, at least monthly, electronically report OASIS data on all applicable patients in a format that meets HCFA electronic data and edit specifications. For purposes of this requirement, the term "reporting" means electronic reporting. OASIS data on non-Medicare/non-Medicaid patients receiving skilled services are reported when the requirement to mask non-Medicare/non-Medicaid OASIS data is effective so that their personally identifiable information remains unidentifiable except to the reporting HHA. At that time, HHAs using software developed by private vendors must use software that is appropriately masking non-Medicare/non-Medicaid records for all assessments in a similar manner to the functionality provided by the Home Assessment Validation Entry (HAVEN) software and be able to cross-reference a masked code to the name of the patient, as HAVEN does. HHAs or contracted entities acting on behalf of the HHA can report OASIS data to the State agency using the HAVEN software HCFA 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 HHAs by way of reports that will help HHAs identify their performance level in the provision of care to the patient population they serve as compared with other HHAs 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.
G321	§484.20(a) Standard: Encoding OASIS data. The HHA must encode and be capable of transmitting OASIS data for each agency patient within 7 days of completing an OASIS data set.	§484.20(a) Guidelines: 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.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		§484.20(a) Guidelines (continued): Pre-Survey Activity - Check with the State OASIS Education or Automation Coordinator and/or review OASIS data management reports to determine if encoding is completed within 7 days after completing the OASIS data set. 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 HHAs 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 HCFA specifications prior to the initial survey. Check with the OASIS Automation Coordinator for information on assignment of test identification numbers and passwords.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
G322	§484.20(b) Standard: Accuracy of encoded OASIS data. The encoded OASIS data must accurately reflect the patient's status at the time of assessment.	§484.20(b) Guidelines: 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. §484.20(b) Probes: How does the HHA conduct clinical and data entry audits to verify that collected OASIS data is consistent with reported OASIS data? How does the HHA assure consistency? How does the HHA review the final validation reports for accuracy purposes? Has the HHA identified any discrepancies in data collected and reported? If so, how were discrepancies addressed? How does the HHA handle the correction of errors?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
G323	§484.20(c) Standard: Transmittal of OASIS data. The HHA must- (1) Electronically transmit accurate, completed, encoded and locked OASIS data for each patient to the State agency or HCFA OASIS contractor at least monthly;	§484.20(c)(1) Guidelines: By the last day of the current month, HHAs must electronically transmit all OASIS data collected, encoded, and locked in the previous month for each patient (as applicable), to the State agency or HCFA OASIS contractor. At a minimum, HHAs must transmit OASIS data at least monthly; HHAs 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, HHAs (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 re-transmittal or system problems develop that prevent transmission. Entities submitting OASIS data to the State agency or HCFA 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. Onsite Activity - 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. §484.20(c)(1) Probes: Is the HHA successfully transmitting OASIS data at least once a month? Review the HHA's OASIS validation reports. If the HHA's corporate office or contracted vendor submits OASIS data on its behalf, are feedback reports being shared with the HHA? What is the HHA's back-up plan if it is unable to submit OASIS data to the State agency? If questions arise, review HHA policies and procedures regarding OASIS data transmission.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
G324	(2) For all assessments completed in the previous month, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section:	§484.20(c)(2) Guidelines: 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. An example of a fatal error is when a record is submitted without the HHA's State-assigned identification number, without the patient's last name, or the record is a duplicate of one previously received. A complete listing of current record rejection criteria is available on the OASIS website (www.hcfa.gov/medicaid/oasis/oasishmp.htm). HHAs may correct mistakes to records that have been transmitted to the State agency or HCFA OASIS contractor. Until the system to completely automate correction of errors is available to HHAs, non-key fields may be updated and re-transmitted to the OASIS State system. Corrections to key fields must be communicated to the State agency and manually made there. A description of key fields vs. non-key fields is available on the OASIS website (www.hcfa.gov/medicaid/oasis/oasishmp.htm). §484.20(c)(2) Probes What kind of errors is the HHA finding and correcting? How is the HHA responding to identified fatal errors? How does the HHA verify that assessment data is consistent with the required format? What are the established times of OASIS data transmission to the State? (They must be at least monthly.) Are all required OASIS assessments that are locked in the previous month, transmitted during the next month? Who is assigned to transmit OASIS data? If questions arise during interview and record review, review the HHA policies on OASIS data transmission.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
G325	(3) Successfully transmit test data to the State agency or HCFA OASIS contractor beginning 3/26/99 and no later than 4/26/99.	§484.20(c)(3) Guidelines: The purpose of making a test transmission to the State agency or HCFA OASIS contractor is to establish connectivity. Once the test has been successfully completed, HHAs must not routinely use the test function to prepare their submission of production (required) OASIS data. Initial Survey - New HHAs 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. HHAs must demonstrate connectivity to the OASIS State system by-- 1) making a test transmission of any start of care or resumption of care OASIS data that passes HCFA edit checks; and 2) receiving validation reports back from the State confirming transmission of data. **NOTE**: The OASIS system is not authorized to maintain unmasked OASIS information on non-Medicare/non-Medicaid patients receiving skilled services. If the HHA has indicated at M0150 that the patient is a non-Medicare/non-Medicaid patient, the data should be masked when the requirement to mask non-Medicare/non-Medicaid data is effective. Unmasked data on non-Medicare/non-Medicaid patients receiving skilled services are rejected by the State system.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
G326	(4) Transmit data using electronic communications software that provides a direct telephone connection from the HHA to the State agency or HCFA OASIS contractor.	§484.20(c)(4) Guidelines HHAs must have a computer system that supports dial-up communications for the transmission of OASIS data to the State agency or HCFA 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 HCFA OASIS contractor, or a summary of that information. All HHAs 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.
G327	§484.20(d) Standard: Data format. The HHA must encode and transmit data using the software available from HCFA or software that conforms to HCFA standard electronic record layout, edit specification, and data dictionary, and that includes the required OASIS data set.	§484.20(d) Guidelines: 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. HHAs must encode and transmit data using the HAVEN software available from HCFA or HAVEN-like software that conforms to all HCFA 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 pre-survey 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. §484.20(d) Probes: What steps did the HHA take to correct transmission problems, i.e., change in software vendor, notifying the State, or using HAVEN as a backup software program?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	Subpart C--Furnishing of Services	
G168	§484.30 Condition of Participation: Skilled nursing services.	
G169	The HHA furnishes skilled nursing services by or under the supervision of a registered nurse; and	
G170	in accordance with the plan of care.	
	§484.30(a) Standard: Duties of the registered nurse.	§484.30(a) Guidelines: 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. (See §484.12(c).) See §§2200 and 2202 of the SOM.
G171	The registered nurse makes the initial evaluation visit,	
G172	regularly re-evaluates the patient's nursing needs,	
G173	initiates the plan of care and necessary revisions,	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
G174	furnishes those services requiring substantial and specialized nursing skill,	§484.30(a) Probes: How does the HHA confirm that services requiring specialized nursing skills are furnished by individuals with the appropriate qualifications?
G175	initiates appropriate preventive and rehabilitative nursing procedures,	
G176	prepares clinical and progress notes, coordinates services, informs the physician and other personnel of changes in the patient's condition and needs,	
G177	counsels the patient and family in meeting nursing and related needs,	
G178	participates in in-service programs, and supervises and teaches other nursing personnel.	
	§484.30(b) Standard: Duties of the licensed practical nurse.	§484.30(b) Guidelines: 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.
G179	The licensed practical nurse furnishes services in accordance with agency policies,	
G180	prepares clinical and progress notes,	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
G303	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.	Forms HCFA-486 (and HCFA-487, if necessary) may 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. §484.48 Probes: 1. Are there patterns in the clinical records that are of concern? 2. Do clinical records document patient progress and outcomes of care based on changes in the patient's condition? 3. How does the HHA inform the attending physician of the availability of a discharge summary? 4. How does the HHA ensure that the discharge summary is sent to the attending physician upon his/her request?
	§484.48(a) Standard: Retention of records.	§484.48(a) Guidelines: 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 HCFA, 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.
G237	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.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
G238	If a patient is transferred to another health facility, a copy of the record or abstract is sent with the patient.	
	§484.48(b) Standard: Protection of records.	§484.48(b) Probes: 1. How are clinical records stored to protect them from physical destruction and unauthorized use? 2. What written policies and procedures govern the use, removal, and release of clinical records? 3. How does the HHA make the records available for all personnel furnishing services on behalf of the HHA?
G239	Clinical record information is safeguarded against loss or unauthorized use.	
G240	Written procedures govern use and removal of records and the conditions for release of information.	
G241	Patient's written consent is required for release of information not authorized by law.	
G242	§484.52 Condition of Participation: Evaluation of the agency's program.	§484.52 Guidelines: All aspects of the HHA's evaluation are not required to have been done at the same time or by the same evaluators. For example, fiscal, patient care, and administrative policies may be evaluated by different members or committees of the group responsible for performing the evaluation at different times of the year. Patient care services should have been evaluated by providers and consumers.
G243	The HHA has written policies requiring an overall evaluation of the agency's total program	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
G251	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.	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): o Review the HHA's policies relevant to the evaluation of patient care needs. o Review HHA contracts for unserved or underserved services, if they are provided under contract or arrangement. o Review plans of care to determine if the services were ordered by a physician but not delivered. o Ask the HHA under what circumstances it would contact the patient's physician to request modification of a patient's plan of care. §484.52(b) Probes: 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: o HHA policies and procedures are followed? o Patients are being helped to attain and maintain their highest practicable functional capacity? o Goals or anticipated patient outcomes are appropriate to the diagnosis(es), plan of care, services provided, and patient potential?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
G330	§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.	§484.55 Guidelines: 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. For patients to whom the collection of OASIS data items does not apply, refer to the requirements at §484.18 to determine compliance with patient comprehensive assessments. HHAs are expected to conduct an assessment 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. Patients for which OASIS applies: The regulations require a comprehensive assessment, with OASIS data items integrated, for all patients who receive skilled services from an HHA meeting Medicare's home health conditions of participation, except for those patients who are-- • Under age 18; • Receiving maternity services; • Receiving housekeeping or chore services only; or • Receiving only personal care services until further notice. This includes Medicare, Medicaid, managed care, and private pay patients accepted by the HHA. It also includes Medicaid patients receiving services under a waiver program or demonstration to the extent they do not fall into one of the exception categories listed above, who are receiving services subject to the Medicare conditions of participation. Under this condition, in addition to an initial assessment visit, the HHA must also conduct a start of care assessment with OASIS data items integrated on patients to whom the requirements are applicable. Subsequent comprehensive assessments (updates) 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. 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 comprehensive assessment tool. For therapy-only cases, the comprehensive assessment should incorporate OASIS data items with other assessment data 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.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		§484.55 Guidelines (continued): Eligibility for the Medicare home health benefit is defined in the Medicare Home Health Agency Manual, HCFA-Pub.11 at §204 (see www.hcfa.gov/pubforms/progman.htm) and includes conditions patients must meet to qualify for coverage, such as: ● Patient is confined to the home; ● Services are provided under a plan of care established and approved by a physician; ● Patient is under the care of a physician; and ● Patient needs skilled nursing care on an intermittent basis or physical therapy or speech therapy services or has continued need for occupational therapy. Incorporating OASIS items: HHAs must incorporate the OASIS data items into their own assessment instrument using the exact language of the items, replacing similar items/questions on their existing assessment tool as opposed to simply adding the OASIS items at the beginning or end.
G331	§484.55(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.	§484.55(a)(1) Guidelines: The initial assessment visit is conducted to determine the immediate care and support needs of the patient, and in the case of Medicare patients, to also determine eligibility for the home health benefit, including homebound status. 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. The required initial assessment visit at §484.55 (a)(1) and the "initial evaluation visit" at §484.30(a) may be completed during the same visit. See the guidelines at §484.55 above for Medicare eligibility requirements. For patients receiving only nursing services or both nursing and therapy services, a registered nurse must conduct the initial assessment visit.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		§484.55(a)(1) Guidelines (continued): Review a case-mix, stratified sample of clinical records and make home visits according to the survey process (see §§2200 and 2202 of the State Operations Manual) to determine compliance with this requirement. §484.55(a)(1) Probes: What are the HHA's policies for conducting the initial assessment? How is Medicare eligibility and homebound status determined?
G332	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.	§484.55(a)(1) Guidelines: In the absence of a physician-specified start of care date, the initial assessment visit is conducted within 48 hours of the referral. If the physician specified a start of care date, this supersedes the 48-hour time frame. Check the intake or clinical record for documentation of a specified start of care date. 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. §484.55(a)(1) Probes: How does the HHA assure that initial visits are conducted within the required time frames? Compare the date of the physician referral and the date of the initial assessment visit. If the initial visit is later than 48 hours or later than the physician-ordered start of care date, check the individual patient's clinical record. Sometimes a patient requests that a visit not be made until a more convenient time. That request must be documented in the clinical record as well as a notation that the physician was notified of and approves the patient's request for a delayed start of care. If the physician orders start of care to begin after the 48-hour time frame specified in the regulations, is there an order in the patient's chart specifying this start of care date?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
G333	(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.	§484.55(a)(2) Guidelines: 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. These instructions are consistent with the guidance at §484.30(a) which states, "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." Review a case-mix, stratified sample of clinical records and make home visits according to the survey process (see §§2200 and 2202 of the State Operations Manual) 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. **NOTE**: A patient who requires short term nursing determined at the start of care in addition to ongoing therapy is not considered a therapy-only case, i.e., a one-time visit by a nurse scheduled to remove sutures. Therefore, the initial assessment must be done by the RN.

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		§484.55(a)(2) Probes: How does the HHA assure that initial visits are conducted within the required time frames? Compare the date of the physician referral and the date of the initial assessment visit. If the difference is greater than 48 hours or later than the physician ordered start of care date, check the individual patient's clinical record. If a patient requests that a visit not be made until a more convenient time, the request should be documented in the clinical record. 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 HHAs may use RNs for initial assessments in therapy-only cases. Interview staff to determine how therapy-only initial assessment visits are conducted. How does the HHA ensure that the skilled disciplines completing the initial assessment are performing this task accurately? If questions are raised through interview and record review, review the HHA's policies regarding conducting and completing an initial assessment visit.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
G334	§484.55(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.	§484.55(b)(1) Guidelines: For patients to whom OASIS applies, when a patient is admitted to the HHA, a start of care comprehensive assessment that includes certain required OASIS data items, must be completed no later than 5 calendar days after the start of care date. Pre-Survey Activity - Review OASIS data management reports, as available, to determine if start of care comprehensive assessments are completed within the required time frame. Onsite Activity - Identify the start of care date. For all practical purposes, the start of care date is the first billable home visit. For payers other than Medicare, the first billable visit might be a visit made by a home health aide. Review any reasons presented for not completing the start of care comprehensive assessments within the required time frame (i.e., the HHA planned to complete the assessment within the required time frame but the patient refused the visit.). Document explanations for start of care comprehensive assessments completed outside of the required time frame. M0090 on the OASIS data set reflects the final date the qualified clinician completed the actual patient assessment. This is usually the date of the last home visit made to complete the comprehensive assessment but may reflect a date subsequent to the onsite visit when the qualified clinician needs to follow up, offsite, with the patient's family or physician in order to complete an OASIS clinical data item. Compare the start of care date at M0030 with the date the assessment was completed (M0090). M0090 should be no more than 5 days later than M0030. The HHA has 7 additional days from the date the patient assessment is completed (M0090) to encode (data-enter), edit, and ensure the accuracy of the OASIS data and to consult with the qualified clinician who conducted and completed the comprehensive assessment for purposes of clarification or to complete missing OASIS data items such as diagnosis codes, etc., and to lock (export) the data for future submission to the State agency. (See §484.20(a)). §484.55(b)(1) Probes: Was the start of care comprehensive assessment completed within 5 calendar days after the start of care date? Did the HHA provide acceptable explanations for start of care comprehensive assessments completed outside of the required time frame?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
G335	(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.	§484.55(b)(2) Guidelines: For patients receiving skilled nursing services, an RN must conduct and complete the comprehensive assessment, and for Medicare patients confirm eligibility, including homebound verification, for the Medicare home health benefit. See the guidelines at §484.55 for Medicare eligibility requirements. When nursing and therapy are both ordered at the start of care, the registered nurse performs the start of care comprehensive assessment. Either discipline may perform subsequent assessments if the discipline is still actively providing skilled services to the patient. §484.55(b)(2) Probes: Is the appropriate clinician conducting the comprehensive assessments, i.e., RN, physical therapist, occupational therapist, or speech-language pathologist? Check the signature of the clinician who completed the start of care assessment, and verify that it is a qualified clinician.
G336	(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.	§484.55(b)(3) Guidelines: For a therapy-only case, it is acceptable for a physical therapist or speech language pathologist to conduct and complete the comprehensive assessment at admission to the HHA. Occupational therapists may conduct and complete the assessment when the need for occupational therapy establishes program eligibility. **NOTE**: Occupational therapy alone does not establish eligibility for the Medicare home health benefit at the start of care; however, occupational therapy services only may qualify for eligibility under other programs, such as Medicaid. Therefore, occupational therapists may not conduct the start of care comprehensive assessment under Medicare. In contrast, the Medicare home health patient receiving services of multiple disciplines, i.e., skilled nursing, physical therapy, and occupational therapy, during the episode of care, can retain eligibility if, over time, occupational therapy is the only remaining skilled discipline providing care. At that time, an occupational therapist can conduct OASIS assessments, i.e., resumption of care, follow-up, transfer, and discharge assessments. For Medicare patients, at start of care, after the eligibility of the patient has been confirmed and the need for the qualifying service is established then the sequence of therapy services provided is irrelevant. Therefore, if physical, occupational and/or speech therapies are ordered, the order in which services are delivered is at the HHA's discretion based on the patient's plan of care. Since the need for occupational therapy alone does not constitute eligibility under Medicare, the HHA must provide the qualifying service, i.e., physical or speech therapy, prior to transfer or discharge.

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		§484.55(b)(3) Guidelines (continued) A qualified therapist may conduct and complete the comprehensive assessment, and for Medicare patients confirm eligibility, including homebound verification, for the Medicare home health benefit. See the guidelines at §484.55 for Medicare eligibility requirements. For patients receiving services from multiple skilled disciplines, the comprehensive assessment, including OASIS items, may be completed by different disciplines such as a registered nurse, physical therapist or speech language pathologist at subsequent time points. The same discipline is not required to complete the comprehensive assessment at every required time point. If an RN's entry into the case is known at start of care (i.e., nursing is scheduled, even if only for one skilled nurse visit), then the case is NOT considered to be therapy-only, and the RN must conduct the start of care comprehensive assessment. If the order for nursing is not known at start of care and originates from a verbal order after start of care, then the case is considered therapy-only at start of care, and the therapist can perform the start of care comprehensive assessment. Either discipline may perform subsequent comprehensive assessments. If it is the HHA's policy for the RN to perform a comprehensive assessment before the therapist's start of care visit, the nurse could perform a comprehensive assessment on or after the therapist's start of care date or the therapist could perform the start of care comprehensive assessment if this is a therapy only case. A comprehensive assessment performed BEFORE the start of care date (identified generally as being the first billable visit) cannot be entered into HAVEN (or HAVEN-like software). §484.55(b)(3) Probes: Are the appropriate clinicians conducting the comprehensive assessments, i.e., RN, physical therapist, occupational therapist, speech-language pathologist? Check the signature of the clinician who completed the start of care assessment (only one clinician takes responsibility for an assessment, although more than one may collaborate.) What is the HHA's policy regarding start of care visits in therapy cases? If the therapist does the start of care assessment, review the therapy start of care assessment record. Does the therapy assessment incorporate the required start of care OASIS data items?

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G337	§484.55(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.	§484.55(c) Guidelines: This requirement applies to all patients being serviced by the HHA, regardless of whether the specific requirements of OASIS apply. For patients to whom OASIS does not apply, the drug regimen review must be conducted in conjunction with the requirements at 42 CFR 484.18, Condition of Participation: Acceptance of patients, plan of care, and medical supervision. The drug regimen review must include documentation of medications the patient is taking. Review medications on the recertification plan of care (Form HCFA-485) and in clinical record notes to determine the accuracy of the medication regimen. This may be included as part of the case-mix, stratified sample of clinical records. Determine if clinical record documentation includes medication review, etc. In therapy-only cases, determine the HHA's policy for medication review. Drugs and treatments ordered by the patient's physician and not documented on the care plan should be recorded in the clinical record. This includes over-the-counter drugs. If the qualified clinician (RN or therapist) determines that the patient is experiencing problems with his/her medications or identifies any potential adverse effects and/or reactions, the physician must be alerted. The label on the bottle of a prescription medication constitutes the pharmacist's transcription or documentation of the order. Such medications are noted in the patient's clinical record and listed on Form HCFA-485. This is consistent with acceptable standards of practice. Federal regulations do not have additional requirements. If questions are raised through interview or record review, examine the HHA's policies on drug review and actions. Onsite Activity - Interview clinical staff, asking them to describe their process of drug review including: ● How are potential adverse effects and drug reactions identified? ● What steps does the HHA require its personnel to take? ● What process is followed when a patient is found to be noncompliant? ● How is the drug review completed if the patient is receiving only therapy services? ● How are drugs reviewed when medication orders are modified or changed after the start of care comprehensive assessment in multi-discipline cases and in therapy-only cases?

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		§484.55(c) Probes: What is the HHA's policy for medication review? How does the HHA respond to medication discrepancies and prescriptions from physicians other than the physician responsible for the patient's home health care? If HHA personnel identify patient sensitivity or other medication problems, what actions does the HHA require its personnel to take?
G338	§484.55(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,	§484.55(d) Guidelines: The term "major decline or improvement in the patient's health status" is the impetus for collecting and reporting OASIS data in the following situations: • as defined by the HHA (reason for assessment 5, other follow-up); • to assess a patient on return from an inpatient facility, other than a hospital, if the patient was not discharged upon transfer (resumption of care); and • as determined by HCFA. In the event an HHA determines that a patient's condition has improved or deteriorated beyond the HHA's expectations, the HHA may choose to collect and report additional assessment information. HHAs must code this as "Other follow-up". The start of care date does not change when an HHA conducts this optional assessment. The comprehensive assessment updates must include the appropriate OASIS data items as indicated on the current OASIS data set. The current OASIS data set is available on the HCFA OASIS website at: http://www.hcfa.gov/medicaid/oasis/oasishmp.htm §484.55(d) Probes: When the HHA uses the "Other Follow-up" comprehensive assessment, how does it define a major decline or improvement that would require a new comprehensive assessment? Within the sample records reviewed, look for patients who have had a major decline or improvement in health status, as defined by the HHA. Determine if an OASIS assessment (reason for assessment 5, other follow-up) was completed.

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G339	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:	§484.55(d)(1) Guidelines: The follow-up comprehensive assessment is conducted by the qualified clinician to identify the patient's current health status and continued need(s) for home health services. The follow-up comprehensive assessment must be performed within the last 5 days of the current 60-day certification period, i.e., between and including days 56-60. In HHAs that do not transmit any OASIS data for a month, verify that the HHA understands the transmission process and required comprehensive assessment time points. Review any validation reports the HHA has received from previous OASIS submissions to their respective State agency, i.e., OASIS initial feedback and final validation reports. As part of the case-mix, stratified sample of clinical records, review patient records to determine that follow-up comprehensive assessments with OASIS data are conducted, collected, and completed within the required time frames.
	(i) Beneficiary elected transfer; (ii) Significant change in condition resulting in a new case-mix assignment; or (iii) Discharge and return to the same HHA during the 60-day episode.	When a Medicare beneficiary elects to transfer to a different HHA or is discharged and returns to the same HHA, it warrants a new clock for purposes of payment, OASIS assessment, and physician certification of the new plan of care. A Significant Change In Condition (SCIC) adjustment occurs when a Medicare beneficiary experiences a significant change in condition during a 60-day episode that was not envisioned in the original plan of care. In order to receive a new case-mix assignment for purposes of SCIC payment during the 60-day episode, the HHA must complete an OASIS assessment and obtain the physician change orders reflecting the significant change in treatment approach in the patient's plan of care. Refer to current policy for use of the OASIS assessment for SCIC adjustments. §484.55(d)(1) Probes: How does the HHA determine when the follow-up comprehensive assessment is due? Ask clinical staff to describe their process. Does the M0090 item (date assessment completed) fall within the time frame required for the follow-up comprehensive assessment? How are follow-up comprehensive assessments completed if a skilled service is not projected at the time when the follow-up assessment is due? Are they incorporated into an aide supervisory visit, for example?

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G340	(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; or	§484.55(d)(2) Guidelines: As part of the case-mix, stratified sample of clinical records, review patient records to determine if comprehensive assessments with OASIS data items integrated are collected at required time points. Evaluate the validity of any reasons why an assessment was not completed within the required time frame. Updated comprehensive assessments are required: • Within 48 hours of (or knowledge of) the patient's return home from a hospital stay of 24 hours or more for any reason except diagnostic tests (resumption of care OASIS data set); and • Within 48 hours of (or knowledge of) the patient's return home from an inpatient stay (resumption of care OASIS data set). §484.55(d)(2) Probes: Does the M0090 item (date assessment completed) fall within the time frame required for the resumption of care comprehensive assessment?
G341	(3) At discharge.	§484.55(d)(3) Guidelines: Updated comprehensive assessments are required: • Within 48 hours of (or knowledge of) transfer to any inpatient facility (transfer to an inpatient facility comprehensive assessment with OASIS data items integrated, with or without agency discharge); and • Within 48 hours of (or knowledge of) discharge to the community or death at home (discharge OASIS assessment with OASIS data items integrated). Review patient clinical records to determine if OASIS data are collected at the required time points for discharge. Discharge assessments are required.

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		§484.55(d)(3) Probes: How does the HHA readmit patients after transfer ("on hold" or "discharge") and determine next assessment dates? Interview HHA staff and review the HHA's policy for inpatient facility admission. Does the HHA place the patient on hold or does the HHA discharge the patient for any inpatient facility admission? Does the M0090 item (date assessment completed) fall within the time frame required for the transfer (with or without agency discharge, discharge to the community or death at home comprehensive assessment?) What does the HHA do for unanticipated patient discharges?
G342	§484.55(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.	§484.55(e) Guidelines: HHAs must incorporate the OASIS data items into their own assessment instrument using the exact language of the items, replacing similar items/questions on their existing assessment tool as opposed to simply adding the OASIS items at the beginning or end. Review the HHA's comprehensive assessments to determine that required OASIS data items have been integrated into its comprehensive assessment tool. The comprehensive assessment forms (nursing or therapy) must include all required OASIS data items for each time point indicated. All comprehensive assessment forms, including those provided by vendors must be reviewed to ensure compliance with this standard. Appendix D of the OASIS Implementation Manual contains a checklist to assist HHAs in incorporating the appropriate OASIS items for each required assessment time point. Appending the OASIS data set to an HHA's existing assessment form is not appropriate.

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		§484.55(e) Guidelines (continued): Initial Surveys and Recertification Surveys after an OASIS Modification - For new HHAs seeking initial certification, or the first HHA survey after the July 19, 1999, effective date, or the first HHA survey after a required change to the OASIS data set, randomly select approximately 8 OASIS items and compare them to the HHA's comprehensive assessment. Include items that have skip patterns and multiple responses. During recertification surveys after an OASIS modification, review data items that have been modified. §484.55(e) Probes: Does the HHA have the required OASIS data items integrated into its comprehensive assessments, i.e., start of care, resumption of care, follow-up, transfer, discharge and death at home? Is the OASIS data set appended at the beginning or end of the HHA's assessment form, rather than integrated into the HHA's own comprehensive assessment tool?