

**§ 484.40**

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the conditions of participation for HHAs. A subdivision that has branch offices is considered a parent agency.

*Summary report* means the compilation of the pertinent factors of a patient's clinical notes that is submitted to the patient's physician, physician assistant, nurse practitioner, or clinical nurse specialist.

*Supervised practical training* means training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing covered services to an individual under the direct supervision of either a registered nurse or a licensed practical nurse who is under the supervision of a registered nurse.

*Verbal order* means a physician, physician assistant, nurse practitioner, or clinical nurse specialist order that is spoken to appropriate personnel and later put in writing for the purposes of documenting as well as establishing or revising the patient's plan of care.

[82 FR 4578, Jan. 13, 2017, as amended at 84 FR 51825, Sept. 30, 2019; 85 FR 27627, May 8, 2020]

**Subpart B—Patient Care**

SOURCE: 82 FR 4578, Jan. 13, 2017, unless otherwise noted.

**§ 484.40 Condition of participation: Release of patient identifiable OASIS information.**

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

**§ 484.45 Condition of participation: Reporting OASIS information.**

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

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

days of completing the assessment of the beneficiary.

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

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

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

(2) Successfully transmit test data to the QIES ASAP System or CMS OASIS contractor.

(3) Transmit data using electronic communications software that complies with the Federal Information Processing Standard (FIPS 140–2, issued May 25, 2001) from the HHA or the HHA contractor to the CMS collection site.

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

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

**§ 484.50 Condition of participation: Patient rights.**

The patient and representative (if any), have the right to be informed of the patient's rights in a language and manner the individual understands. The HHA must protect and promote the exercise of these rights.

(a) *Standard: Notice of rights.* The HHA must—

(1) Provide the patient and the patient's legal representative (if any), the following information during the initial evaluation visit, in advance of furnishing care to the patient:

(i) Written notice of the patient's rights and responsibilities under this rule, and the HHA's transfer and discharge policies as set forth in paragraph (d) of this section. Written notice must be understandable to persons who have limited English proficiency and accessible to individuals with disabilities;

(ii) Contact information for the HHA administrator, including the administrator's name, business address, and business phone number in order to receive complaints.

(iii) An OASIS privacy notice to all patients for whom the OASIS data is collected.

(2) Obtain the patient's or legal representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.

(3) [Reserved]

(4) Provide written notice of the patient's rights and responsibilities under this rule and the HHA's transfer and discharge policies as set forth in paragraph (d) of this section to a patient-selected representative within 4 business days of the initial evaluation visit.

(b) *Standard: Exercise of rights.* (1) If a patient has been adjudged to lack legal capacity to make health care decisions as established by state law by a court of proper jurisdiction, the rights of the patient may be exercised by the person appointed by the state court to act on the patient's behalf.

(2) If a state court has not adjudged a patient to lack legal capacity to make health care decisions as defined by state law, the patient's representative may exercise the patient's rights.

(3) If a patient has been adjudged to lack legal capacity to make health care decisions under state law by a court of proper jurisdiction, the patient may exercise his or her rights to the extent allowed by court order.

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

(1) Have his or her property and person treated with respect;

(2) Be free from verbal, mental, sexual, and physical abuse, including injuries of unknown source, neglect and misappropriation of property;

(3) Make complaints to the HHA regarding treatment or care that is (or fails to be) furnished, and the lack of respect for property and/or person by anyone who is furnishing services on behalf of the HHA;

(4) Participate in, be informed about, and consent or refuse care in advance of and during treatment, where appropriate, with respect to—

(i) Completion of all assessments;

(ii) The care to be furnished, based on the comprehensive assessment;

(iii) Establishing and revising the plan of care;

(iv) The disciplines that will furnish the care;

(v) The frequency of visits;

(vi) Expected outcomes of care, including patient-identified goals, and anticipated risks and benefits;

(vii) Any factors that could impact treatment effectiveness; and

(viii) Any changes in the care to be furnished.

(5) Receive all services outlined in the plan of care.

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

(7) Be advised, orally and in writing, of—

(i) The extent to which payment for HHA services may be expected from Medicare, Medicaid, or any other federally-funded or federal aid program known to the HHA,

(ii) The charges for services that may not be covered by Medicare, Medicaid, or any other federally-funded or federal aid program known to the HHA,

(iii) The charges the individual may have to pay before care is initiated; and

(iv) Any changes in the information provided in accordance with paragraph (c)(7) of this section when they occur. The HHA must advise the patient and representative (if any), of these changes as soon as possible, in advance of the next home health visit. The HHA must comply with the patient notice requirements at 42 CFR 411.408(d)(2) and 42 CFR 411.408(f).

(8) Receive proper written notice, in advance of a specific service being furnished, if the HHA believes that the service may be non-covered care; or in advance of the HHA reducing or terminating on-going care. The HHA must also comply with the requirements of 42 CFR 405.1200 through 405.1204.

(9) Be advised of the state toll free home health telephone hot line, its contact information, its hours of operation, and that its purpose is to receive complaints or questions about local HHAs.

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(10) Be advised of the names, addresses, and telephone numbers of the following Federally-funded and state-funded entities that serve the area where the patient resides:

- (i) Agency on Aging,
- (ii) Center for Independent Living,
- (iii) Protection and Advocacy Agency,
- (iv) Aging and Disability Resource Center; and
- (v) Quality Improvement Organization.

(11) Be free from any discrimination or reprisal for exercising his or her rights or for voicing grievances to the HHA or an outside entity.

(12) Be informed of the right to access auxiliary aids and language services as described in paragraph (f) of this section, and how to access these services.

(d) *Standard: Transfer and discharge.* The patient and representative (if any), have a right to be informed of the HHA's policies for transfer and discharge. The HHA may only transfer or discharge the patient from the HHA if:

(1) The transfer or discharge is necessary for the patient's welfare because the HHA and the physician or allowed practitioner who is responsible for the home health plan of care agree that the HHA can no longer meet the patient's needs, based on the patient's acuity. The HHA must arrange a safe and appropriate transfer to other care entities when the needs of the patient exceed the HHA's capabilities;

(2) The patient or payer will no longer pay for the services provided by the HHA;

(3) The transfer or discharge is appropriate because the physician or allowed practitioner who is responsible for the home health plan of care and the HHA agree that the measurable outcomes and goals set forth in the plan of care in accordance with § 484.60(a)(2)(xiv) have been achieved, and the HHA and the physician or allowed practitioner who is responsible for the home health plan of care agree that the patient no longer needs the HHA's services;

(4) The patient refuses services, or elects to be transferred or discharged;

(5) The HHA determines, under a policy set by the HHA for the purpose of addressing discharge for cause that

meets the requirements of paragraphs (d)(5)(i) through (d)(5)(iii) of this section, that the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the HHA to operate effectively is seriously impaired. The HHA must do the following before it discharges a patient for cause:

(i) Advise the patient, representative (if any), the physician(s) issuing orders for the home health plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) that a discharge for cause is being considered;

(ii) Make efforts to resolve the problem(s) presented by the patient's behavior, the behavior of other persons in the patient's home, or situation;

(iii) Provide the patient and representative (if any), with contact information for other agencies or providers who may be able to provide care; and

(iv) Document the problem(s) and efforts made to resolve the problem(s), and enter this documentation into its clinical records;

(6) The patient dies; or

(7) The HHA ceases to operate.

(e) *Standard: Investigation of complaints.* (1) The HHA must—

(i) Investigate complaints made by a patient, the patient's representative (if any), and the patient's caregivers and family, including, but not limited to, the following topics:

(A) Treatment or care that is (or fails to be) furnished, is furnished inconsistently, or is furnished inappropriately; and

(B) Mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and/or misappropriation of patient property by anyone furnishing services on behalf of the HHA.

(ii) Document both the existence of the complaint and the resolution of the complaint; and

(iii) Take action to prevent further potential violations, including retaliation, while the complaint is being investigated.

(2) Any HHA staff (whether employed directly or under arrangements) in the

normal course of providing services to patients, who identifies, notices, or recognizes incidences or circumstances of mistreatment, neglect, verbal, mental, sexual, and/or physical abuse, including injuries of unknown source, or misappropriation of patient property, must report these findings immediately to the HHA and other appropriate authorities in accordance with state law.

(f) *Standard: Accessibility.* Information must be provided to patients in plain language and in a manner that is accessible and timely to—

(1) Persons with disabilities, including accessible Web sites and the provision of auxiliary aids and services at no cost to the individual in accordance with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act.

(2) Persons with limited English proficiency through the provision of language services at no cost to the individual, including oral interpretation and written translations.

[82 FR 4578, Jan. 13, 2017, as amended at 84 FR 51825, Sept. 30, 2019; 85 FR 27628, May 8, 2020]

**§ 484.55 Condition of participation: Comprehensive assessment of patients.**

Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment. 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.

(a) *Standard: Initial assessment visit.*

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

(2) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy)

is the only service ordered by the physician who is responsible for the home health plan of care, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.

(b) *Standard: Completion of the comprehensive assessment.* (1) The comprehensive assessment must be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care.

(2) Except as provided in paragraph (b)(3) of this section, a registered nurse must complete the comprehensive assessment and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status.

(3) When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician or allowed practitioner, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. The occupational therapist may complete the comprehensive assessment if the need for occupational therapy establishes program eligibility.

(c) *Standard: Content of the comprehensive assessment.* The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:

(1) The patient's current health, psychosocial, functional, and cognitive status;

(2) The patient's strengths, goals, and care preferences, including information that may be used to demonstrate the patient's progress toward achievement of the goals identified by the patient and the measurable outcomes identified by the HHA;

(3) The patient's continuing need for home care;

(4) The patient's medical, nursing, rehabilitative, social, and discharge planning needs;

(5) A review of all medications the patient is currently using in order to