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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.

(6) The patient's primary caregiver(s), if any, and other available supports, including their:

(i) Willingness and ability to provide care, and

(ii) Availability and schedules;

(7) The patient's representative (if any);

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

(d) *Standard: Update of the comprehensive assessment.* The comprehensive assessment must be updated and revised (including the administration of the OASIS) as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but not less frequently than—

(1) The last 5 days of every 60 days beginning with the start-of-care date, unless there is a—

(i) Beneficiary elected transfer;

(ii) Significant change in condition; or

(iii) Discharge and return to the same HHA during the 60-day episode.

(2) Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests, or on physician or allowed practitioner-ordered resumption date;

(3) At discharge.

[84 FR 4578, Jan. 13, 2017, as amended at 85 FR 27628, May 8, 2020]

42 CFR Ch. IV (10–1–20 Edition)

§ 484.58 Condition of participation: Discharge planning.

(a) *Standard: Discharge planning.* An HHA must develop and implement an effective discharge planning process. For patients who are transferred to another HHA or who are discharged to a SNF, IRF or LTCH, the HHA must assist patients and their caregivers in selecting a post-acute care provider by using and sharing data that includes, but is not limited to HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The HHA must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

(b) *Standard: Discharge or transfer summary content.* (1) The HHA must send all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, to the receiving facility or health care practitioner to ensure the safe and effective transition of care.

(2) The HHA must comply with requests for additional clinical information as may be necessary for treatment of the patient made by the receiving facility or health care practitioner.

[84 FR 51883, Sept. 30, 2019]

§ 484.60 Condition of participation: Care planning, coordination of services, and quality of care.

Patients are accepted for treatment on the reasonable expectation that an HHA can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence. Each patient must receive an individualized written plan of care, including any revisions or additions. The individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. The individualized plan of care must also specify the patient and caregiver education

and training. Services must be furnished in accordance with accepted standards of practice.

(a) *Standard: Plan of care.* (1) Each patient must receive the home health services that are written in an individualized plan of care that identifies patient-specific measurable outcomes and goals, and which is established, periodically reviewed, and signed by a doctor of medicine, osteopathy, or podiatry or allowed practitioner acting within the scope of his or her state license, certification, or registration. If a physician or allowed practitioner refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician or allowed practitioner is consulted to approve additions or modifications to the original plan.

(2) The individualized plan of care must include the following:

- (i) All pertinent diagnoses;
- (ii) The patient's mental, psychosocial, and cognitive status;
- (iii) The types of services, supplies, and equipment required;
- (iv) The frequency and duration of visits to be made;
- (v) Prognosis;
- (vi) Rehabilitation potential;
- (vii) Functional limitations;
- (viii) Activities permitted;
- (ix) Nutritional requirements;
- (x) All medications and treatments;
- (xi) Safety measures to protect against injury;
- (xii) A description of the patient's risk for emergency department visits and hospital re-admission, and all necessary interventions to address the underlying risk factors.
- (xiii) Patient and caregiver education and training to facilitate timely discharge;
- (xiv) Patient-specific interventions and education; measurable outcomes and goals identified by the HHA and the patient;
- (xv) Information related to any advanced directives; and
- (xvi) Any additional items the HHA or physician or allowed practitioner may choose to include.

(3) All patient care orders, including verbal orders, must be recorded in the plan of care.

(b) *Standard: Conformance with physician or allowed practitioner orders.* (1) Drugs, services, and treatments are administered only as ordered by a physician or allowed practitioner.

(2) Influenza and pneumococcal vaccines may be administered per agency policy developed in consultation with a physician, physician assistant, nurse practitioner, or clinical nurse specialist, and after an assessment of the patient to determine for contraindications.

(3) Verbal orders must be accepted only by personnel authorized to do so by applicable state laws and regulations and by the HHA's internal policies.

(4) When services are provided on the basis of a physician or allowed practitioner's verbal orders, a nurse acting in accordance with state licensure requirements, or other qualified practitioner responsible for furnishing or supervising the ordered services, in accordance with state law and the HHA's policies, must document the orders in the patient's clinical record, and sign, date, and time the orders. Verbal orders must be authenticated and dated by the physician or allowed practitioner in accordance with applicable state laws and regulations, as well as the HHA's internal policies.

(c) *Standard: Review and revision of the plan of care.* (1) The individualized plan of care must be reviewed and revised by the physician or allowed practitioner who is responsible for the home health plan of care and the HHA as frequently as the patient's condition or needs require, but no less frequently than once every 60 days, beginning with the start of care date. The HHA must promptly alert the relevant physician(s) or allowed practitioner(s) to any changes in the patient's condition or needs that suggest that outcomes are not being achieved and/or that the plan of care should be altered.

(2) A revised plan of care must reflect current information from the patient's updated comprehensive assessment, and contain information concerning the patient's progress toward the measurable outcomes and goals identified by the HHA and patient in the plan of care.

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(3) Revisions to the plan of care must be communicated as follows:

(i) Any revision to the plan of care due to a change in patient health status must be communicated to the patient, representative (if any), caregiver, and all physicians or allowed practitioners issuing orders for the HHA plan of care.

(ii) Any revisions related to plans for the patient's discharge must be communicated to the patient, representative, caregiver, all physicians or allowed practitioners issuing orders for the HHA 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).

(d) *Standard: Coordination of care.* The HHA must:

(1) Assure communication with all physicians or allowed practitioners involved in the plan of care.

(2) Integrate orders from all physicians or allowed practitioners involved in the plan of care to assure the coordination of all services and interventions provided to the patient.

(3) Integrate services, whether services are provided directly or under arrangement, to assure the identification of patient needs and factors that could affect patient safety and treatment effectiveness and the coordination of care provided by all disciplines.

(4) Coordinate care delivery to meet the patient's needs, and involve the patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care activities.

(5) Ensure that each patient, and his or her caregiver(s) where applicable, receive ongoing education and training provided by the HHA, as appropriate, regarding the care and services identified in the plan of care. The HHA must provide training, as necessary, to ensure a timely discharge.

(e) *Standard: Written information to the patient.* The HHA must provide the patient and caregiver with a copy of written instructions outlining:

(1) Visit schedule, including frequency of visits by HHA personnel and personnel acting on behalf of the HHA.

(2) Patient medication schedule/instructions, including: medication

name, dosage and frequency and which medications will be administered by HHA personnel and personnel acting on behalf of the HHA.

(3) Any treatments to be administered by HHA personnel and personnel acting on behalf of the HHA, including therapy services.

(4) Any other pertinent instruction related to the patient's care and treatments that the HHA will provide, specific to the patient's care needs.

(5) Name and contact information of the HHA clinical manager.

[82 FR 4578, Jan. 13, 2017, as amended at 85 FR 27628, May 8, 2020]

§ 484.65 Condition of participation: Quality assessment and performance improvement (QAPI).

The HHA must develop, implement, evaluate, and maintain an effective, ongoing, HHA-wide, data-driven QAPI program. The HHA's governing body must ensure that the program reflects the complexity of its organization and services; involves all HHA services (including those services provided under contract or arrangement); focuses on indicators related to improved outcomes, including the use of emergent care services, hospital admissions and re-admissions; and takes actions that address the HHA's performance across the spectrum of care, including the prevention and reduction of medical errors. The HHA must maintain documentary evidence of its QAPI program and be able to demonstrate its operation to CMS.

(a) *Standard: Program scope.* (1) The program must at least be capable of showing measurable improvement in indicators for which there is evidence that improvement in those indicators will improve health outcomes, patient safety, and quality of care.

(2) The HHA must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that enable the HHA to assess processes of care, HHA services, and operations.

(b) *Standard: Program data.* (1) The program must utilize quality indicator data, including measures derived from OASIS, where applicable, and other relevant data, in the design of its program.