

Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies

A Rule by the [Centers for Medicare & Medicaid Services](#) on 01/13/2017

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AGENCY:

Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION:

Final rule.

SUMMARY:

This final rule revises the conditions of participation (CoPs) that home health agencies (HHAs) must meet in order to participate in the Medicare and Medicaid programs. The requirements focus on the care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality care standards, and eliminate unnecessary procedural requirements. These changes are an integral part of our overall effort to achieve broad-based, measurable improvements in the quality of care furnished through the Medicare and Medicaid programs, while at the same time eliminating unnecessary procedural burdens on providers.

DATES:

These regulations are effective on July 13, 2017.

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SUPPLEMENTARY INFORMATION:**I. Background Information****A. The Home Health Benefit**

Home health services are covered for the elderly and disabled under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program, and are described in section 1861(m) of the Social Security Act (the Act). These services, provided under a plan of care that is established and periodically reviewed by a physician, must be furnished by, or under arrangement with, a home health agency (HHA) that participates in the Medicare or Medicaid programs. Services are provided on a visiting basis in the beneficiary's home, and may include the following:

- Part-time or intermittent skilled nursing care furnished by or under the supervision of a registered professional nurse.
- Physical therapy, speech-language pathology, and occupational therapy.

- Medical social services under the direction of a physician.
- Part-time or intermittent home health aide services.
- Medical supplies (other than drugs and biologicals) and durable medical equipment.
- Services of interns and residents if the HHA is owned by or affiliated with a hospital that has an approved medical residency training program.
- Services at hospitals, skilled nursing facilities, or rehabilitation centers when the services involve equipment too cumbersome to bring to the home.

Under the authority of sections 1861(o) and 1891 of the Act, the Secretary has established in regulations the requirements that an HHA must meet to participate in the Medicare program. These requirements are set forth in regulations at 42 CFR part 484 (/select-citation/2017/01/13/42-CFR-484), Home Health Services. Current regulations at 42 CFR 440.70 (/select-citation/2017/01/13/42-CFR-440.70)(d) specify that HHAs participating in the Medicaid program must also meet the Medicare Conditions of Participation (CoPs). Section 1861(o)(6) of the Act requires that an HHA must meet the CoPs specified in section 1891(a) of the Act, and other CoPs as the Secretary finds necessary in the interest of the health and safety of patients. Section 1891(a) of the Act establishes specific requirements for HHAs in several areas, including patient rights, home health aide training and competency, and compliance with applicable federal, state, and local laws. The CoPs for HHAs protect all individuals under the HHA's care, unless a requirement is specifically limited to Medicare beneficiaries. Section 1861(o) of the Act describes an HHA for purposes of participation in the Medicare program. All the requirements are stated generally, and are applicable to the HHA's overall activity, not specifically to Medicare patients. This provision, which was reaffirmed by the Congress in the Omnibus Budget Reconciliation Act (OBRA), 1987 amendments to section 1891(a) of the Act, has been in the law since the inception of the Medicare program, and CMS' interpretation of it has remained the same. Under section 1891(b) of the Act, the Secretary is responsible for assuring that the CoPs, and their enforcement, are adequate to protect the health and safety of individuals under the care of an HHA, and to promote the effective and efficient use of Medicare funds. To implement this requirement, State Survey Agencies and CMS-approved accrediting organizations conduct surveys of HHAs to determine whether they are complying with the CoPs.

B. Previous HHA Conditions of Participation Rules

On March 10, 1997 (62 FR 11004 (/citation/62-FR-11004)), we published a proposed rule, entitled, "Revision of the Conditions of Participation for Home Health Agencies and Use of the Outcome and Assessment Information Set (OASIS) as Part of the Revised Conditions of Participation for Home Health Agencies," that would have revised the entire set of HHA CoPs. Due to the significant volume of public comments and the rapidly changing nature of the HHA industry at that time, this rule, in its entirety, was never finalized.

Rather than finalizing all portions of the March 1997 rule, we published a final regulation (64 FR 3764 (/citation/64-FR-3764), January 25, 1999) that only finalized the OASIS regulations. The January 1999 final rule required that each patient receive from the HHA a patient-specific, comprehensive assessment that identifies the patient's medical, nursing, rehabilitation, social, and discharge planning needs.

We also issued an interim final rule with comment period on the same day (64 FR 3748 (/citation/64-FR-3748)) that required HHAs to use the OASIS data collection instrument that standardizes parts of the assessment and to transmit the data to CMS. That rule implemented sections 1891(c)(2)(C) and 1891(d)(1) of the Act, which require the Secretary to establish a standardized assessment instrument for measuring the quality of care and services furnished by HHAs. The OASIS data collection instrument and data transmission rule was finalized on December 23, 2005 (70 FR 76199 (/citation/70-FR-76199)).

Although the OASIS requirements were finalized in separate rules, we intended to proceed with another rule to finalize the remainder of the requirements of the March 1997 proposed rule. However, section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added section 1871(a)(3) to the Act. This section provided that, effective December 8, 2003, the Secretary, in consultation with the Director of the Office of Management and Budget (OMB), would have to establish and publish regular timelines for the publication of Medicare proposed regulations based on the previous publication of Medicare proposed or interim final regulations. Section 902 of the MMA further provided that the timeline could vary among different regulations, but could not be longer than 3 years, except under exceptional circumstances. Pursuant to the MMA, we issued a notice implementing this provision in the **Federal Register** on December 30, 2004 (69 FR 78442 (/citation/69-FR-78442)). In that notice, we interpreted section 902 as rendering ineffective any proposed Medicare regulations that had been outstanding for 3 years or more as of December 8, 2003; this included the proposed HHA CoPs. Therefore, out of an abundance of caution, we decided not to finalize the remaining provisions of the March 10, 1997 proposed rule, but begin rulemaking again.

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On October 9, 2014, we set forth proposed rules for HHAs that choose to participate in Medicare and Medicaid (79 FR 61164 (/citation/79-FR-61164)). We proposed to revise all of the existing CoPs, and to add several new CoPs to address aspects of home health care that we believe need attention.

C. Transforming the HHA Conditions of Participation

As the single largest payer for health care services in the United States, the Federal government assumes a critical responsibility for the delivery and quality of care furnished under its programs. Historically, we have adopted a quality assurance approach that has been directed toward identifying health care providers that furnish poor quality care or fail to meet minimum Federal standards. Facilities not meeting requirements would either correct the inappropriate practice(s) or would be terminated from participation in the Medicare or Medicaid programs. We have found that this problem-focused approach has inherent limits. Ensuring quality through the enforcement of prescriptive health and safety standards, rather than improving the quality of care for all patients, has resulted in expending much of our resources on dealing with marginal providers, rather than on stimulating broad-based improvements in the quality of care delivered to all patients.

Obtaining quality health care for Federal beneficiaries from CMS-certified providers and suppliers requires taking advantage of continuing advances in the health care delivery field. As a result, we are revising the home health agency requirements to focus on a patient-centered, data-driven, outcome-oriented process that promotes high quality patient care at all times for all patients. Before we began development of new proposed CoPs for Medicare and Medicaid participating HHAs, we received recommendations from home health providers, professional associations and practitioner communities, consumer advocates and state and other governmental agencies with an interest or responsibility in HHA regulation and oversight. We also took into account the comments that were submitted by the public on the March 1997 proposed rule and suggestions submitted by the HHA industry in the summer of 2011, as well as developments since that time within the industry. In light of this information, we have used the following principles to assist in the development of the new HHA CoPs:

Develop a more continuous, integrated care process across all aspects of home health services, based on a patient-centered assessment, care planning, service delivery, and quality assessment and performance improvement.

Use a patient-centered, interdisciplinary approach that recognizes the contributions of various skilled professionals and their interactions with each other to meet the patient's needs. Stress quality improvements by incorporating an outcome-oriented, data-driven, quality assessment and performance improvement program specific to each HHA.

Eliminate the focus on administrative process requirements that lack adequate consensus or evidence that they are predictive of either achieving clinically relevant outcomes for patients or preventing harmful outcomes for patients.

Safeguard patient rights.

We believe that the overall approach of the CoPs provides HHAs with greatly enhanced flexibility. At the same time, we believe the new requirements improve performance results for HHAs, in terms of achieving needed and desired outcomes for patients, and increasing patient satisfaction with services provided.

D. Organization of This Rule

This final rule is organized in the following manner:

- *Background Information.* This section summarizes the Home Health benefit, previous HHA CoP rules, and transforming the HHA CoP.
- *Provisions of the Proposed Regulations.* This section briefly summarizes all of the proposed requirements in numerical order by CoP number.
- *Home Health Crosswalk.* This section cross references former requirements to their new location.
- *Analysis of and Responses to Public Comments.* This section summarizes and responds to all public comments that were received in numerical order by CoP number.
- *Provisions of the Final Rule.* This section lists all changes that were made from the proposed version of the rule to the final version of the rule.
- *Good Cause to Waive Notice and Comment Rulemaking.* This section explains why notice-and-comment is impracticable, unnecessary, or contrary to the public interest.
- *Collection of Information and Regulatory Impact Analysis.* These sections describe the anticipated estimated burdens and savings that will result from the implementation of this final rule in a statistically typical HHA.
- *Regulatory Text.* This section sets forth the regulations that are being finalized in this rule.

II. Provisions of the Proposed Regulations

A. Overview

We proposed to make extensive changes in the organizational scheme to group together all CoPs directly related to patient care and place them near the beginning of part 484. Regulations concerning the organization and administration of an HHA would follow in a separate subpart entitled “Organizational Environment.”

B. Proposed Subpart A, General Provisions

We proposed to reorganize this section to clarify the basis and scope of this part. Part 484 is based on sections 1861(o) and 1891 of the Act, which establish the conditions that an HHA must meet in order to participate in the Medicare program. Part 484 is also based on section 1861(z) of the Act, which specifies the institutional planning standards that HHAs must meet. These provisions serve as the basis for survey activities for the purposes of determining whether an agency meets the requirements for participation in Medicare.

At § 484.2, we proposed to clarify some of the definitions for terms used in the HHA CoPs. We proposed to modify the definition for “branch office” by adding the requirement that the parent agency offer more than the sharing of services; specifically, that it provide supervision and administrative control of branches on a daily basis to the extent that the branch depends upon the parent agency’s supervision and administrative functions in order to meet the CoPs, and could not do so as an independent entity. Though the definition would no longer require the branch office to be “sufficiently close,” the parent agency would have to be available to meet the needs of any situation and respond to issues that could arise with respect to patient care or administration of the agency. A violation of a CoP in one branch office would apply to the entire HHA.

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We also proposed minor changes in the language of the current definitions for “clinical note,” “parent home health agency,” “proprietary agency,” and “subdivision.” We also proposed to eliminate current definitions of the terms “bylaws” and “supervision,” “home health agency,” “progress notes,” and “subunit.” On the effective date of this rule, any existing subunits, which already operate under their own provider number, will be considered distinct HHAs and will be required to independently meet all CoPs, including having an independent governing body and administrator. Subject to state-specific laws and regulations, this federal regulatory change will permit a subunit to apply to become a branch of its existing parent HHA if the parent provides “. . . direct support and administrative control” of the branch. The State Survey Agency and CMS Regional Office will continue to be responsible for approving an HHA’s application for a branch office, in accordance with current CMS guidance as set out in various survey and certification letters and section 2182.4B of the State Operations Manual. No new subunits will be approved upon implementation of this regulation, only “branch offices.”

Finally, we proposed to add definitions for the terms “in advance,” “quality indicator,” “representative,” “supervised practical training,” and “verbal order.” We proposed to define the term “representative” in a patient-centered manner that enables patients to choose their representatives, if they wish to do so. We proposed to define the term “verbal orders” to mean those physician orders that are delivered verbally (meaning spoken), by the physician, to a nurse or other qualified medical personnel, and recorded in the plan of care.

As discussed in detail in section III.D.4 of this preamble, we proposed modifications to the current personnel qualifications requirements, and proposed to relocate those requirements to § 484.80, “Home health aide services,” and § 484.115, “Personnel qualifications.”

We also proposed to retain the current definitions of “primary home health agency,” “public agency,” and “summary report” without change.

C. Proposed Subpart B, Patient Care

1. RELEASE OF PATIENT IDENTIFIABLE OASIS INFORMATION (PROPOSED § 484.40)

At § 484.40, we proposed to recodify the current requirements of § 484.11, which require an HHA and its agents to ensure the confidentiality of all patient-identifiable information in the clinical record, including the OASIS data.

2. REPORTING OASIS INFORMATION (PROPOSED § 484.45)

In this CoP, we proposed to include most of the current requirements of § 484.20, which relate to the electronic reporting of the OASIS data. We proposed to remove the requirement that an HHA transmit data using electronic communications software that provides a direct telephone connection from the HHA to the state agency or CMS OASIS contractor. In its place, we proposed to add a requirement that the OASIS data

be transmitted in accordance with current CMS transmission policy, which currently requires HHAs to transmit data using electronic communications software that complies with the Federal Information Processing Standard (FIPS 140-2, issued May 25, 2001).

3. PATIENT RIGHTS (PROPOSED § 484.50)

At § 484.50, we proposed revised patient rights provisions under six standards: (1) Notice of rights; (2) Exercise of rights; (3) Rights of the patient; (4) Transfer and discharge; (5) Investigation of complaints; and (6) Accessibility. In proposed § 484.50(a), we stated that each patient and patient representative (if the patient has one), would have the right to be informed of his or her rights in a language and manner the individual understands.

More specifically, under § 484.50(a)(1), we proposed that the HHA provide the patient and patient's representative with verbal notice of the patient's rights in the primary or preferred language of the patient or representative, and in a manner that the individual can understand, during the initial evaluation visit, and in advance of care being furnished by the HHA. We also proposed to require that the patient be provided a written copy of the patient rights information. The written information would be required to be provided in alternate formats free of charge for persons with disabilities, when necessary, to ensure effective communication. In addition, written notice would be required to be understandable to persons who had limited English proficiency. Furthermore, HHAs would be required to inform patients of the availability of the services and instruct patients how to access those services.

Proposed § 484.50(a) (2) would require the HHA to provide each patient with specific business contact information for the HHA's administrator so that patients and caregivers could report complaints and specific patient rights violations to the HHA administrator, and could ask questions about the care being provided. We also proposed at § 484.50(a)(3) that the HHA provide a copy of the OASIS privacy notice to all patients from whom the OASIS data are collected at the same time that the general notice of rights is provided to the patient. Finally, at § 484.50(a)(4), we proposed to require that the HHA obtain the patient's or representative's signature confirming that he or she received a copy of the notice of rights and responsibilities.

At § 484.50(b), "Exercise of rights," we proposed that, in the event that a patient was declared incompetent under state law by a court of proper jurisdiction, the rights of that patient could be exercised by the person appointed by the state court. If a state court had not made a declaration, any representative, as chosen by the patient, could exercise the rights of the patient in accordance with the patient's preferences. In situations where a patient has been adjudged to lack legal capacity under state law by a court of proper jurisdiction, the patient would be allowed to exercise his or her rights to the extent allowed by the court order.

Proposed § 484.50(c) set forth the explicit rights of each home health patient. At § 484.50(c) (1), we proposed that the patient would have a right to have his or her property and person treated with respect. At § 484.50(c) (2), we proposed that the patient would have a right to be free from verbal, mental, sexual and physical abuse, including injuries of unknown source, neglect, and misappropriation of property. Under proposed § 484.50(c)(3), the patient would have a right to make complaints to the HHA regarding treatment or care that was (or failed to be) furnished which the patient and/or their family believe was inappropriate. Under proposed § 484.50(c)(4), patients and their representatives would also have the right to participate in, be informed about, and consent to or refuse care. Moreover, each patient would have the right to participate in and be informed about the patient-specific comprehensive assessment, including an assessment of the patient's goals and care preferences. Additionally, each patient would have the right to participate in and be informed about the care that the HHA plans to furnish □ based on the needs identified during the

comprehensive assessment, establishing and revising that plan, the disciplines that will furnish care, the frequency of visits, identifying expected outcomes of care, and any factors that could impact treatment effectiveness. In accordance with proposed § 484.50(c)(4)(iii), each patient would also have the right to receive a copy of his or her individualized HHA plan of care, including all updated plans of care, as described in proposed § 484.60. HHAs would be required at § 484.50(c)(4)(viii) to inform the patient about any changes in the care to be furnished in advance of those changes being made in the patient's plan of care. In addition to being involved in the care planning process, we proposed to add a requirement at § 484.50(c)(5) that patients have the right to receive all of the services outlined in the plan of care. Additionally, we proposed to retain the current requirements from current § 484.10(d), which concern the patient's right to the confidentiality of his or her clinical records, under proposed § 484.50(c)(6). Proposed § 484.50(c)(7) would retain the requirements of the current standard at § 484.10(e), Patient liability for payment. This patient liability requirement would be related to the home health advance beneficiary notice (ABN) and home health change of care notices; therefore, we proposed to reference the current requirements at § 411.408(d)(2) and § 411.408(f). HHAs would be required to comply with all ABN requirements, including restrictions related to who may receive the ABN on the patient's behalf.

At § 484.50(c)(8), we proposed that a patient would have the right to 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. We proposed to incorporate a cross-reference to the regulations regarding expedited reviews, found at 42 CFR part 405 (/select-citation/2017/01/13/42-CFR-405), subpart J.

We proposed to retain the current regulations regarding the home health hotline at proposed § 484.50(c)(9). Patients would be advised that the purpose of the hotline was to receive complaints or questions about local HHAs. Additionally, under § 484.50(c)(10), patients would be advised of the names, addresses, and telephone numbers for relevant federally and state-funded consumer information, consumer protection, and advocacy agencies.

We also proposed at § 484.50(c)(11), that patients have the right to be free from discrimination or reprisal for exercising their rights, whether by voicing grievances to the HHA or to an outside entity. Finally, we proposed at § 484.50(c)(12) that patients have the right to be informed of their right to access auxiliary aids and language services, and to be provided instruction on how to access these services.

We proposed to add a new standard at § 484.50(d), which would mandate that all patients and representatives (if any), have the right to be informed of the HHA's policies governing admission, transfer, and discharge in advance of the HHA providing care. This proposed standard set forth the criteria by which an HHA could discharge or transfer a patient. Under this proposed standard, an HHA could only transfer, discharge, or terminate care for the following reasons: (1) If the physician responsible for the HHA plan of care and HHA agreed that the HHA could no longer meet the patient's needs, based on the patient's acuity; (2) when the patient or payer could no longer pay for the services provided by the HHA; (3) if the physician responsible for the HHA plan of care and HHA agreed that the patient no longer needed HHA services because the patient's health and safety had improved or stabilized sufficiently; (4) when the patient refused HHA services or otherwise elected to be transferred or discharged (including if the patient elected the Medicare hospice benefit); (5) when there was cause; (6) when a patient died; or (7) when the HHA ceased to operate.

In accordance with the requirements of proposed § 484.50(d)(1), if the care needs of a patient exceeded the HHA's ability to provide services, the HHA would be required to ensure that the patient received a safe and appropriate transfer to another care entity better suited to meeting the patient's needs.

We proposed to specify at § 484.50(d)(5) that we would permit discharge for cause if the patient's (or other persons in the patient's home) behavior was so disruptive, abusive, or uncooperative that the delivery of care to the patient or the ability of the HHA to operate effectively and safely was seriously impaired. Before discharging a patient for cause, the HHA would be required to advise the patient, the representative (if any), the physician who was responsible for the home health plan of care, and the patient's primary care practitioner or other health care professional who would be responsible for providing care and services to the patient after discharge from the HHA (if any) that a discharge for cause was being considered, make efforts to resolve the problem(s) presented by the patient's behavior or by other person(s) in the home (as applicable), or situation (such as a dangerous animal being loose in the home), document the problem(s) and efforts made to resolve the problem(s), and enter this documentation into its clinical records. Additionally, we proposed that the HHA would be required to provide the patient and representative (if any), with contact information for other agencies or providers who were potentially able to provide care following the discharge.

Given the vulnerability of home health patients and in the interest of patient safety, we proposed a standard at § 484.50(e), "Investigation of complaints," that would require the HHA to investigate complaints made by patients, representatives, caregivers, and families regarding treatment or care that was (or failed to be) furnished, or was furnished inconsistently or inappropriately. In addition, HHAs would be required to investigate allegations of mistreatment, neglect, or verbal, mental, psychosocial, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone furnishing services on behalf of the HHA. Proposed § 484.50(e)(1)(ii) would require the HHA to document both the existence and the resolution of the complaint, while § 484.50(e)(1)(iii) would require the HHA to take immediate action to prevent further potential abuse while the complaint was being investigated.

Proposed § 484.50(e)(2) would require any HHA staff, regardless of whether they are employed directly or obtained under arrangements with another entity, to immediately report to the HHA or other appropriate authorities any incidences of mistreatment, neglect, or abuse, and/or any misappropriation of patient property, which they have noticed during the normal course of providing services to patients.

To address effective communication with patients who are limited English proficiency (LEP) or have disabilities, we proposed a new standard at § 484.50(f), "Accessibility." We proposed that information that is provided to patients would have to be provided to the individual in plain language, and in a manner that is both accessible and timely.

In accordance with the requirements of the Medicare provider agreement, HHAs must not discriminate against Medicare beneficiaries, and if a participating HHA accepts non-Medicare patients at any given level of acuity, it must also accept Medicare beneficiaries at a similar level of acuity as a condition of participating in the Medicare program. HHAs that provide services to non-Medicare patients while refusing services to Medicare patients in similar situations risk having their provider agreements terminated, in accordance with § 489.53(a)(2).

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4. COMPREHENSIVE ASSESSMENT OF PATIENTS (PROPOSED § 484.55)

We proposed to retain the majority of the substantive requirements of current § 484.55, with significant reorganization. We proposed to retain the requirement that each patient be required to receive a patient-specific comprehensive assessment. We also proposed to retain the requirement that, for Medicare beneficiaries, the HHA would be required to verify the patient's eligibility for the Medicare home health benefit, including the patient's homebound status, at the specified timeframes. Furthermore, we proposed to retain all requirements related to the initial assessment visit at standard (a), as well as the completion of the comprehensive assessment requirements at standard (b).

We proposed to establish a new standard (c), "Content of the comprehensive assessment," that would incorporate much of the content currently set forth in the introductory paragraph of the CoP, the drug regimen review currently set forth in standard (c), and the incorporation of the OASIS data items requirement currently set forth at standard (e). We also proposed new content requirements, such as an assessment of psychosocial and cognitive status, which we believe would provide for a more holistic patient assessment. We believe that these assessment areas are essential in the establishment of a more complete understanding of the patient's condition (both medically and non-medically), strengths and limitations, preferences, and risk factors. Developing a more complete understanding of the patient will enable HHAs and physicians to develop a plan of care that is more comprehensive and more likely to achieve desired outcomes. We proposed to require that the comprehensive assessment must accurately reflect the patient's status, and would assess or identify (as applicable) the following:

- The patient's current health, psychosocial (new), functional (new), and cognitive (new) status;
- The patient's strengths, goals, and care preferences, including the patient's progress toward achievement of the goals identified by the patient and the measurable outcomes identified by the HHA (new);
- The patient's continuing need for home care;
- The patient's medical, nursing, rehabilitative, social, and discharge planning needs;
- A review of all medications the patient is currently using;
- The patient's primary caregiver(s), if any, and other available supports (new); and
- The patient's representative (if any) (new).

The assessment would also be required to incorporate items from the information collection set out in the OASIS data set, using the language and groupings of the OASIS items, as specified by the Secretary.

We proposed to retain the majority of the content of the requirements of current § 484.55(d), with one change. We proposed to revise § 484.55(d)(2) to allow for a physician-ordered resumption of care date. Adding the physician ordered resumption of care date as an alternative to the fixed 48 hour time frame for a post-hospital reassessment allows physicians to specify a resumption of care date that is tailored to the particular needs and preferences of each patient.

5. CARE PLANNING, COORDINATION OF SERVICES, AND QUALITY OF CARE (PROPOSED § 484.60)

We proposed to create a new condition of participation, "Care planning, coordination of services, and quality of care" at § 484.60. This section would specify that the HHA would have to provide the patient a plan of care that would set out the care and services necessary to meet the patient-specific needs identified in the comprehensive assessment, and the outcomes that the HHA anticipates would occur as a result of developing the individualized plan of care and subsequently implementing its elements.

In the CoP, we proposed that patients be accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, rehabilitative, and social needs could be met adequately by the agency in the patient's place of residence. Each patient would receive an individualized written plan of care which would specify the care and services necessary to meet the patient's needs, including the patient and caregiver education and training that the HHA will provide, specific to the patient's care needs. The individualized plan of care would be revised or added to at intervals as necessary to continue to meet patient care needs. We also proposed that the plan of care include the patient-specific measurable outcomes which the HHA anticipates would result from its implementation.

Under proposed § 484.60(a)(1), Plan of care, we proposed that all home health services furnished to patients would follow an individualized written plan of care, setting out, among other things, the frequency and duration of therapeutic interventions. The plan would be established, periodically reviewed, and signed by a doctor of medicine, osteopathy, or podiatric medicine acting within the boundaries of all applicable state laws and regulations. Under paragraph (a)(2), the individualized plan of care would be required to include all pertinent diagnoses; the patient's mental, psychosocial, and cognitive status; the types of services, supplies, and equipment required; the frequency and duration of visits to be made; prognosis; rehabilitation potential; functional limitations; activities permitted; nutritional requirements; all medications and treatments; safety measures to protect against injury; patient and caregiver education and training to facilitate timely discharge or referral; patient-specific measurable outcomes/goals; and any additional interventions/orders the HHA or physician chose to include.

Under paragraph (a)(3), if HHA services are initiated following a patient's hospital discharge, we proposed to require that the HHA include an assessment of the patient's level of risk for hospital emergency department visits and hospital re-admission. We proposed that HHAs would be required to include in the patient's individualized plan of care all appropriate interventions that are necessary to address and mitigate identified risk factors that contribute to the HHA's establishment of a particular risk level for a patient.

Proposed § 484.60(b), "Conformance with physician orders," would provide that drugs, services, and treatments be administered only as ordered by the physician who is responsible for the home health plan of care. We proposed to retain the current influenza and pneumococcal vaccination requirement at § 484.60(b)(2). Proposed § 484.60(b)(3) would maintain the requirement that only personnel authorized by applicable state laws and regulations and the HHA's internal policies, may accept verbal orders from physicians. We proposed at § 484.60(b)(4) that a registered nurse (RN) or other qualified practitioner licensed to practice by the state must document a verbal order in writing in the patient's clinical record, with a signature, time, and date. Verbal orders would also have to be recorded in the patient's plan of care. If a ☐ physician faxed orders or otherwise transmitted them through other electronic methods from his or her office, those orders would also be required to be included in the patient's clinical record and plan of care. We would also require that verbal orders be authenticated, dated, and timed by the physician according to the HHA's internal policies and applicable state laws and regulations.

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Under § 484.60(c), "Review and revision of the plan of care," we proposed that the individualized plan of care be reviewed and revised by the physician who was responsible for the HHA plan of care and the HHA as frequently as the patient's condition or needs requires, but no less frequently than once every 60 days, beginning with the start of care date. We proposed that the HHA promptly alert the physician who is responsible for the HHA plan of care to any changes in the patient's condition or needs that would suggest that measurable outcomes are not being achieved and/or that the HHA should alter the plan. At § 484.60(c)(2), we proposed to require that the HHA revise the plan of care, as necessary, to reflect current information

from the patient's updated comprehensive assessment, and to record the patient's progress towards meeting the patient-specific measurable outcomes and goals selected by the HHA and patient, as specified in the plan of care.

Furthermore, we proposed at paragraph (c)(3) that it would be the HHA's responsibility to notify the patient, representative (if any), caregivers, and the physician who is responsible for the HHA plan of care, when the individualized plan of care is updated due to a significant change in the patient's health status. We also proposed that, when the HHA makes updates related to plans for the patient's discharge, the HHA would communicate these changes with the patient and representative, caregivers, the physician who is responsible 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 (if any) to the patient after discharge from the HHA.

In § 484.60(d), "Coordination of care," we proposed in paragraph (d)(1) to require that the HHA must 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, the coordination of care provided by all disciplines, and communication with the physician. The proposed standard at § 484.60(d)(2) would also require the HHA to coordinate care delivery to meet each patient's needs, and to involve the patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care activities. Finally, under proposed § 484.60(d)(3), we proposed that the HHA ensure that each patient and caregiver, where applicable, receive ongoing training and education from the HHA regarding the care and services identified in the plan of care that the patient and caregiver are expected to implement. The HHA would be required to ensure that each patient and caregiver receives any training necessary for a timely discharge from the HHA. Each skilled professional would be expected to be responsible for educating the patient and/or caregiver about the care and services as appropriate to the discipline.

At § 484.60(e), "Discharge or transfer summary," we proposed that HHAs be required to compile a discharge or transfer summary for each discharged or transferred patient. The summary would be required to include the following:

- The initial reason for referral to the HHA;
- A brief description of the patient's HHA care;
- A description of the patient's clinical, mental, psychosocial, cognitive, and functional status at the start of care;
- A list of all services provided by the HHA to the patient;
- The start and end dates of HHA care;
- A description of the patient's clinical, mental, psychosocial, cognitive; and functional status at the end of care;
- The patient's most recent drug profile;
- Any recommendations for follow-up care;
- The patient's current individualized plan of care; and
- Any additional documentation that would assist in the continuity of post-discharge or transfer care, or that was requested by the receiving practitioner or facility.

6. QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI) (PROPOSED § 484.65)

As part of our effort to reduce medical errors, and improve the quality of health care in all settings, we propose to replace two current HHA CoPs, § 484.16, "Group of professional personnel," and § 484.52, "Evaluation of the agency's program," with a single, new CoP, at § 484.65, "Quality Assessment and

Performance Improvement” (QAPI). We have organized this new CoP into the following five standards: (1) Program scope; (2) Program data; (3) Program activities; (4) Performance improvement projects; and (5) Executive responsibilities.

In § 484.65(a), “Program scope,” we proposed that this data-driven QAPI program would be capable of showing measurable improvement in indicators for which there was evidence that the improvement led to improved health outcomes (for example, reduced hospitalizations and readmissions), safety, and quality of care for patients. The HHA would also have to measure, analyze, and track quality indicators, including adverse patient events, as well as other indicators of performance so that the agency could adequately assess its processes, services, and operations.

We proposed, at § 484.65(b), “Program data,” that an HHA's QAPI program utilize quality indicator data, including measures derived from the OASIS (CMS provided reports), where applicable, and other relevant data, to assess the quality of care provided to patients, and identify and prioritize opportunities for improvement. Quality assessment efforts, including data collection, should focus on high priority safety and health conditions, and other goals identified by an HHA. The tools, collected data, and associated quality measures would be used by the HHA to monitor the effectiveness and safety of its services, as well as the quality of its care. In addition, the HHA would use the quality measures that are calculated based on the data collected to identify opportunities for improvement. We also proposed that the HHA's governing body would be responsible for approving the frequency of, and level of detail to be used in data collection.

At § 484.65(c), “Program Activities,” we would require an HHA's QAPI program activities to focus on high risk, high volume, or problem-prone areas of service, and to consider the incidence, prevalence, and severity of problems in those areas. We also proposed that the HHA immediately correct any identified problems that directly or potentially threaten the health and safety of patients. Additionally, the HHA's QAPI activities would have to track incidents and adverse patient events, as well as analyze those events, so that preventive actions and mechanisms could be implemented by the HHA. We also proposed that after steps have been taken to improve an area of concern, the HHA would continue to monitor the area in order to assure that improvements were sustained over time. □

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Proposed § 484.65(d), “Performance improvement projects,” would require that the HHA's performance improvement projects, conducted at least annually, reflect the scope, complexity, and past performance of the HHA's services and operations. An agency would need to focus on those areas of past performance which have proven to be problematic for the HHA over time or areas where there was clear evidence of poor patient outcomes, as well as areas of high-risk and high-volume. Within this standard, we also proposed that the HHA document the QAPI projects undertaken, the reasons for conducting these projects, and the measurable progress achieved.

Finally, under proposed § 484.65(e), “Executive responsibilities,” we would require that the HHA's governing body assume responsibility for the agency's QAPI program. This subsection would require that the governing body assume the overall responsibility for ensuring that the QAPI program reflected the complexity of the HHA and its services, involved all services (including those provided under contract or arrangement), focused on indicators related to improved outcomes, and took actions that addressed the HHA's performance across the spectrum of care, including the prevention and reduction of medical errors. The governing body would be required to define, implement, and maintain a program for quality improvement and patient safety that was ongoing and agency-wide. The governing body would be required not only to ensure that performance improvement efforts were prioritized, but that they were also evaluated for effectiveness. We note that it is the governing body which would be ultimately responsible for establishing the HHA's

expectations for patient safety through an agency-wide QAPI program. Therefore, we proposed that the governing body establish clear expectations for patient safety. We also proposed that the governing body would appropriately address any findings of fraud or waste in order to assure that resources are appropriately used for patient care activities and that patients are receiving the right care to meet their needs.

7. INFECTION PREVENTION AND CONTROL (PROPOSED § 484.70)

We proposed to establish a new CoP at § 484.70, "Infection prevention and control," organized under the following three standards: (1) Prevention, (2) Control, and (3) Education. We proposed in § 484.70(a) that HHAs follow infection prevention and control best practices, which include the use of standard precautions, to curb the spread of disease. Under proposed standard § 484.70(b), "Control," we would expect the HHA to maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases. Additionally, under this proposal, the program would be expected to be an integral part of the agency's QAPI program. We proposed an education standard within this CoP at § 484.70(c). HHAs would be expected to provide education on "current best practices" to staff, patients, and caregivers.

8. SKILLED PROFESSIONAL SERVICES (PROPOSED § 484.75)

This proposed new condition would set forth the requirements for skilled professional services. Instead of specifically identifying tasks, we proposed to broadly describe the expectations of the skilled professionals who participate in the interdisciplinary team approach to home health care delivery. Skilled professionals, within this context, would provide services to HHA patients directly as employees of the HHA or under a contractual agreement. We proposed that skilled professionals actively participate in the coordination of all aspects of care where appropriate. We have organized this proposed condition into three areas: (1) Skilled professional services; (2) Responsibilities of skilled professionals; and (3) Supervision of skilled professional assistants. Skilled professional services, as proposed in § 484.75(a), include physician services, skilled nursing services, physical therapy, speech-language pathology services, occupational therapy, and medical social work services. Provision of services by skilled professionals, as proposed in § 484.75(b), would specify that skilled professional services may only be provided by health care professionals who meet the appropriate criteria spelled out in proposed § 484.115, "Personnel qualifications," and who practice according to the HHA's policies and procedures.

We proposed in § 484.75(b), "Responsibilities of skilled professionals," that skilled professionals who provide services to HHA patients directly, or under arrangement, participate in coordinating all aspects of care, including:

- Assuming responsibility for the ongoing interdisciplinary assessment and development of the individualized plan of care in partnership with the patient, representative (if any), and caregiver(s);
- Providing services that are ordered by the physician as indicated in the plan of care;
- Providing patient, caregiver, and family counseling;
- Providing patient and caregiver education;
- Preparing clinical notes;
- Communicating with the physician who is responsible for the home health plan of care and other health care practitioners (as appropriate) related to the current home health plan of care; and
- Participating in the HHA's quality assessment and performance improvement program and HHA-sponsored in-service training.

In addition to the requirements for licensed professional services described above, we proposed to include a requirement governing the supervision of skilled professional assistants at § 484.75(c). This would require an RN identified by the HHA to supervise the care provided by nurses such as licensed vocational nurses and licensed practical nurses. We also proposed that all rehabilitative therapy assistant services would be provided under the supervision of a physical therapist (PT) or occupational therapist (OT) who meets the appropriate requirements of § 484.115. Furthermore, we believe that it is essential for all medical social services to be provided under the overall supervision of a Master of Social Work (MSW) prepared social worker who meets the requirements of § 484.115.

9. HOME HEALTH AIDE SERVICES (PROPOSED § 484.80)

We proposed to organize the home health aide requirements as nine standards under § 484.80: (1) Home health aide qualifications; (2) content and duration of home health aide classroom and supervised practical training; (3) competency evaluation; (4) in-service training; (5) qualifications for instructors conducting classroom and supervised practical training; (6) eligible training and competency evaluation organizations; (7) home health aide assignments and duties; (8) supervision of home health aides; and (9) individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.

At proposed § 484.80(a)(1), we would specify the necessary requirements for an individual to be considered a qualified home health aide. A qualified home health aide would be an individual who has successfully completed one of the following: (1) A training and competency evaluation program that meets the requirements described in § 484.80(b) and § 484.80(c); or (2) a competency evaluation program that meets the requirements described in § 484.80(c); or (3) a nurse aide training and competency evaluation program that is approved by the state as meeting the requirements of § 483.151 through § 483.154 and is currently listed in good standing on the state nurse aide registry; or (4) a state licensure program that meets the requirements described in § 484.80(b) and § 484.80(c).

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Under proposed § 484.80(a)(2), we would specify when a home health aide is deemed to have completed a program (as specified in proposed § 484.80(a)(1)). This determination would be based on whether, since the most recent completion of a program, there was a period of 24 months or greater since completion of the last home health aide training during which none of the services furnished by the aide were for compensation. We would also stipulate that, if there had been a 24-month or greater lapse in furnishing services, the aide would need to complete another program before the home health aide can provide services, as specified in § 484.80(a)(1).

We proposed, at § 484.80(b), to set forth the requirements for training content and its duration, training methods (classroom and practical), and training documentation. At § 484.80(b)(4), we proposed to require the HHA to maintain documentation that the requirements for content and duration of home health aide classroom and supervised practical training have been met.

We proposed to address various requirements for the competency evaluation of home health aides in § 484.80(c). We proposed to retain the requirement currently found at § 484.36(b)(1), which states that an individual may furnish home health aide services on behalf of an HHA only after the successful completion of a competency evaluation program as described in that section. In accordance with proposed § 484.80(c)(2), the competency evaluation described in this paragraph may be offered by any organization, except an organization that falls under one of the exceptions specified in the regulation as described in proposed paragraph (f) of this section. Section 484.80(c)(3) would maintain the current requirement that an RN must perform the competency evaluation. In addition to the RN, we proposed that the competency evaluation be done in consultation with other skilled professionals, as appropriate. We proposed that, if a home health aide

is going to perform a task for which he or she was rated “unsatisfactory,” it must be performed under the supervision of a licensed nurse (either a licensed practical nurse or an RN) until he or she achieves an evaluation of “satisfactory.”

At § 484.80(d), we would retain 12 as the minimum number of hours of in-service training required for a 12-month period. The training could occur while an aide was furnishing care to a patient. Proposed § 484.80(b) would set forth the elements that must comprise home health aide classroom and supervised practical training, thus suggesting that those elements of training should form a basis for ongoing in-service training. We proposed that aide in-service training could be offered by any organization, and that the training would be required to be supervised by an RN.

We proposed to relocate the requirement that the RN that conducts training possess a minimum of 2 years of nursing experience, of which at least 1 year is in home health care, to standard (e), “Qualifications for instructors conducting classroom and supervised practical training.” We continue to believe that RNs with nursing experience in the home health field should be the principal instructors in the basic training of home health aides. While other individuals could provide instruction to home health aides, classroom and practical training would be required to be under the general supervision of an RN who possessed a minimum of 2 years nursing experience, at least 1 year of which would have to be in home health care.

We proposed to retain the current requirements regarding organizations that offer aide training at § 484.80(f), “Eligible training and competency evaluation organizations.” We proposed to retain the current requirement that home health aide training may be provided by any organization, except an organization that falls under one of the exceptions specified in the regulation. These exceptions include, but are not limited to, agencies that have been found out of compliance with the home health aide requirements any time in the last 2 years, agencies that permitted an unqualified individual to function as a home health aide, and agencies that have been found to have compliance deficiencies that endangered patient health and safety. The full list of exceptions are included in the regulatory text.

We proposed, at § 484.80(g), “Home health aide assignments and duties,” to set forth aide responsibilities and duties. Proposed § 484.80(g)(1) would provide that the home health aide would be assigned to a specific patient by the RN or other appropriate skilled professional (that is, physical therapist, speech-language pathologist, or occupational therapist). Proposed § 484.80(g)(2) would require that the home health aide provide services that are ordered by the physician in the plan of care, that the home health aide is permitted to perform under state law, and that are consistent with the home health aide training. In § 484.80(g)(3), we proposed to retain the inclusive listing of duties for home health aides currently under § 484.36(c)(2). At § 484.80(g)(4) we proposed a requirement that home health aides be members of the interdisciplinary team, must report changes in the patient's condition to an RN or other appropriate skilled professional, and must complete appropriate records in compliance with the HHA's policies and procedures.

On-going home health aide supervision, as described in proposed § 484.80(h), “Supervision of home health aides,” is a necessary component of quality care for HHAs, and ensures that services provided by home health aides are in accordance with the agency's policies and procedures and in accordance with state and federal law. In this proposed standard, we would differentiate the aide supervision requirements based on the skill level of the care required by the patient. In proposed § 484.80(h)(1), we proposed that if a patient is receiving skilled care, the home health aide supervisor (RN or therapist) must make an onsite visit to the patient's home no less frequently than every 14 days. The home health aide would not have to be present during this visit. If a potential deficiency in home health aide service was noted by the home health aide supervisor, then the supervisor would have to make an on-site visit to the location where the patient was

receiving care in order to observe and assess the home health aide while he or she is performing care. In addition to the regularly scheduled 14-day supervision visits and the as-needed observation visits, HHAs would be required to make an annual on-site visit to a patient's home to observe and assess each home health aide while he or she is performing patient care activities. The HHA would be required to observe each home health aide with at least one patient.

In proposed § 484.80(h)(2), we would require that if home health aide services are provided to a patient who is not receiving skilled care, the RN must make an on-site visit to the location where the patient is receiving care no less frequently than every 60 days in order to observe and assess each home health aide while he or she is performing care.

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At proposed § 484.80(h)(3), we would require that if a deficiency in home health aide services was verified by the home health aide supervisor during an on-site visit, then the agency would have to conduct, and the home health aide would have to complete, a competency evaluation in accordance with paragraph (c) of this section.

We also proposed to add a new paragraph at § 484.80(h)(4) to ensure that home health aide supervision visits focus on the aide's ability to demonstrate initial and continued satisfactory performance in meeting essential criteria. Supervision visits would be required to assess the home health aide's success in following the patient's plan of care; completing tasks assigned to the home health aide; communicating with the patient, representative (if any), caregivers, and family; demonstrating competency with assigned tasks; complying with infection prevention and control policies and procedures; reporting changes in the patient's condition; and honoring patient rights.

Proposed § 484.80(h)(5) would retain, with minor revisions, the current requirements found under § 484.36(d)(4) as they relate to the HHA's responsibilities for home health aides who are furnishing services under arrangement (that is, the aides are not employees of the HHA). The HHA would be required to ensure the quality of home health aide services, supervise aides as proposed in this section, and ensure that aides have met the training and competency evaluation requirements of this proposed part.

At proposed § 484.80(i), "Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit," we proposed to retain the requirements at current § 484.36(e), with some minor clarifying revisions. Under this provision, a Medicare-certified HHA that provides personal care aide services to Medicaid patients under a State Medicaid personal care benefit would be required to determine and ensure the competency of individuals for those Medicaid-approved services performed. In addition, the reference to § 440.170 in the current regulation at § 484.36(e)(2) is incorrect; it should read § 440.167. Therefore, we proposed to make the necessary correction.

D. Proposed Subpart C, Organizational Environment

1. COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAWS AND REGULATIONS RELATED TO HEALTH AND SAFETY OF PATIENTS (PROPOSED § 484.100)

We proposed that HHAs must be in compliance with all Federal, State and local laws related to the health and safety of patients, and that HHA services must be furnished in accordance with accepted professional standards and principles. We also proposed specific disclosure of ownership requirements. At § 484.100(a), we proposed to continue to require HHAs to comply with the requirements of part 420, subpart C by disclosing the names and addresses of all persons with an ownership or controlling interest, the name and

address of each officer, director, agent, or managing employee, and the name and address of the entity responsible for the management of the HHA along with the names and addresses of the CEO and chairperson of the board of that entity.

Under the provisions of proposed § 484.100(b), an HHA, its branches, and its staff would be licensed, certified, or registered, as applicable, by the state licensing authority if the state had established licensure requirements. If a state requires an HHA to have a license, then we would require that the provider be in compliance with that state's law or regulation.

Finally, we proposed at § 484.100(c), "Laboratory services," to require that HHAs engaged in certain types of lab testing, with an appliance that has been approved for that purpose by the Food and Drug Administration, conduct testing in compliance with the requirements of 42 CFR 493 (/select-citation/2017/01/13/42-CFR-493) (Laboratory Requirements). This section would also prohibit HHAs from substituting their own self-administered testing equipment in lieu of a patient's self-administered testing equipment when assisting a patient in administering the test. In addition, this section would provide that if the HHA chose to refer specimens for laboratory testing, the referral laboratory would have to be certified in accordance with the applicable requirements of part 493. The laboratory services standard is a federal requirement in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

2. ORGANIZATION AND ADMINISTRATION OF SERVICES (PROPOSED § 484.105)

We proposed at § 484.105(a), "Governing body," to require the governing body to be able to assess the HHA's financial needs and to assume responsibility for effectively managing its financial resources, as well as assume full legal authority and responsibility for the agency's overall management and operation, the provision of all home health services, the review of the budget and operational plans, and the agency's quality assessment and performance improvement program.

Proposed § 484.105(b), "Administrator," described the role of the administrator and provisions for when the administrator is not available. We proposed that the administrator be appointed by the governing body, be responsible for all day to day operations of the HHA, and be responsible for ensuring that a skilled professional as described in § 484.75 is available during all operating hours. We proposed that, any time when the administrator is not available, a pre-designated person, who is authorized in writing by the administrator and governing body, would assume the same responsibilities and obligations as the administrator, including the responsibility to be available during all operating hours.

In addition to the overall management of the HHA by the governing body and the administrator, we proposed a new clinical manager role at § 484.105(c). The clinical manager would be a qualified licensed physician or registered nurse, identified by the HHA, who is responsible for the oversight of all personnel and all patient care services provided by the HHA, whether directly or under arrangement, to meet patient care needs. The supervision of HHA personnel would include assigning personnel, developing personnel qualifications, and developing personnel policies.

In § 484.105(d), we proposed a new standard, "Parent-branch relationship," to focus on the ability of the parent HHA to demonstrate that it can monitor all services provided in its entire service area, furnished by any branch offices, to ensure compliance with the CoPs. We would require that HHAs report their branch locations to the state survey agency at the time of an HHA's initial certification request, at each survey, and at the time any proposed additions or deletions were made.

We proposed at § 484.105(e), “Services under arrangement,” to govern all services provided under arrangement with another agency or organization. The agency providing services under arrangement may not have been denied Medicare enrollment; been terminated from Medicare, another federal health care program, or Medicaid; had its Medicare or Medicaid billing privileges revoked; or been debarred from participating in any government program. We proposed to require that the primary HHA have a written agreement with another agency, with an organization, or with an individual, that it has contracted with to provide services to its patients, which stipulates that the primary HHA would maintain overall responsibility for all HHA care provided to a patient in accordance with the patient's plan of care, whether the care is provided directly or under arrangement. If the primary HHA chooses to furnish some services under arrangement, then it retains management, service oversight, and financial responsibility for all services that are provided to the patient by its contracted entities. All services provided by contracted entities would be authorized by the primary HHA, and furnished in a safe and effective manner by qualified personnel. In addition to this revision, we proposed to correct a typographical error in the cross-reference citation for the United States Code.

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As stated in proposed § 484.105(f)(1), skilled nursing and one of the therapeutic services must be made available on a visiting basis in the patient's home. At least one service would be required to be provided directly by the HHA.

We proposed a requirement for compliance with accepted professional standards and principles at § 484.105(f)(2). We would require that HHAs furnish all services in accordance with accepted professional standards of practice. We also proposed to require that all HHA services be provided in accordance with current clinical practice guidelines.

We proposed to relocate the requirements for outpatient physical therapy or speech pathology services to § 484.105(g), without change.

Finally, we proposed to retain the “Institutional planning” standard as required for HHAs under section 1861(z) of the Act at § 484.105(h). We did not propose any revisions to this content.

3. CLINICAL RECORDS (PROPOSED § 484.110)

We proposed to retain, with some additional clarification, many of the long-standing clinical record requirements. The primary requirement under the proposed clinical records CoP would be that a clinical record containing pertinent past and current relevant information would be maintained for every patient who was accepted by the HHA to receive home health services. We proposed to add the requirement that the information contained in the clinical record would need to be accurate, adhere to current clinical record documentation standards of practice, and be available to the physician who is responsible for the home health plan of care and appropriate HHA staff. The clinical record would be required to exhibit consistency between the diagnosed condition, the plan of care, and the actual care furnished to the patient.

Proposed § 484.110(a), “Contents of clinical record,” would retain the requirement that the record include clinical notes, plans of care, physician orders, and a discharge summary. We proposed to require that the clinical record include: (1) The patient's current comprehensive assessment, including all of the assessments from the most recent home health admission, clinical visit notes, and individualized plans of care; (2) all interventions, including medication administration, treatments, services, and responses to those interventions, which would be dated and timed in accordance with the requirements of proposed § 484.110(b); (3) goals in the patient's plan of care and the progress toward achieving the goals; (4) contact information for the patient and representative (if any); (5) contact information for the 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; and (6) a discharge or transfer summary note that would be sent to 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 within 7 calendar days, or, if the patient is discharged to a facility for further care, to the receiving facility within 2 calendar days of the patient's discharge or transfer.

We proposed to add a new standard at § 484.110(b) to require authentication of clinical records. We proposed that all entries be legible, clear, complete, and appropriately authenticated, dated, and timed.

At § 484.110(c), we proposed to require that clinical records be retained for 5 years after the discharge of the patient, unless state law stipulates a longer period of time. We would require, in § 484.110(c)(2), that HHA policies provide for retention of records even if the HHA discontinues operations. We also proposed that the HHA would be required to notify the state agency as to where the agency's clinical records would be maintained.

We also proposed at § 484.110(d) to require that clinical records, their contents, and the information contained therein, be safeguarded against loss or unauthorized use.

We proposed to add a new standard at § 484.110(e), "Retrieval of clinical records." We proposed that a patient's clinical records (whether hard copy or electronic) be made readily available to a patient or appropriately authorized individuals or entities upon request. The provision of clinical records must be in compliance with the rules regarding protected health information set out at 45 CFR, parts 160 and 164.

Finally, in the preamble material explaining § 484.110, we provided information regarding the HHS Policy Priority to Accelerate Interoperable Health Information Exchange, including Use of Certified Electronic Health Record Technology.

4. PERSONNEL QUALIFICATIONS (PROPOSED § 484.115)

We proposed a new "Personnel qualifications" CoP, with conforming amendments to the regulations for the other provider types that cross-reference the HHA personnel requirements. We proposed to retain the current personnel qualifications for the following professions: Audiologist, home health aide, licensed practical nurse, occupational therapist, occupational therapy assistant, physical therapist, physical therapist assistant, physician, registered nurse, social work assistant, and social worker. We also proposed to replace the term "practical (vocational) nurse," currently found in § 484.4, with the more widely used and accepted term, "licensed practical nurse."

We also proposed to revise the current personnel qualifications for HHA administrators. Specifically, we proposed that an HHA administrator would be required to be a licensed physician, or hold an undergraduate degree, or be a registered nurse. We also proposed that an administrator would have at least 1 year of supervisory or administrative experience in home health care or a related health care program.

Finally, we proposed at § 484.115(m) to revise the personnel qualifications for speech-language pathologists (SLP) in order to more closely align the regulatory requirements with those set forth in section 1861(l)(4)(A) of the Act. We proposed that a qualified SLP is an individual who has a master's or doctoral degree in speech-language pathology, and who is licensed as a speech-language pathologist by the state in which he or she furnishes these services. Should a state choose to not offer licensure at some point in the future, we proposed a second, more specific, option for qualification. In that □ circumstance, we would require that a SLP has

successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating supervised clinical experience); performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field; and successfully completed a national examination in speech-language pathology approved by the Secretary.

III. Home Health Crosswalk (Cross Reference of Former to New Requirements)

The table below shows the relationship between the former sections to the new regulations.

Current CoPs	Revised CoPs
§ 484.1, Basis and scope	Revised at § 484.1
§ 484.2, Definitions	Revised at § 484.2
§ 484.4, Personnel qualifications	Revised at § 484.115
Home health aide qualifications	Revised at § 484.80
§ 484.10, Patient rights	§ 484.50, Patient rights
§ 484.10(a)	Revised at § 484.50(a)
§ 484.10(b)	Revised at §§ 484.50(b), (c), and (e)
§ 484.10(c)	Revised at § 484.50 (c)
§ 484.10(d)	Revised at § 484.50(c)
§ 484.10(e)	Revised at § 484.50(c)
§ 484.10(f)	Revised at § 484.50(c)
	New standard at § 484.50(d), Transfer and discharge.
	New standard at § 484.50(e), Investigation of complaints.
§ 484.11, Release of patient identifiable OASIS information	§ 484.40, Release of patient identifiable OASIS information.
§ 484.12, Compliance with Federal, State, and local laws, disclosure and ownership information, and accepted professional standards and principles	§ 484.100, Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.
§ 484.12(a)	Revised at § 484.100 and § 484.100(b)
§ 484.12(b)	Redesignated at § 484.100(a).
§ 484.12(c)	Revised at § 484.60, § 484.70, and § 484.105(f)
§ 484.14, Organization, services, and administration	§ 484.105, Organization and administration of services.
§ 484.14(a)	Revised at § 484.105(f).
§ 484.14(b)	Revised at § 484.105(a).
§ 484.14(c)	Revised at § 484.105(b).
§ 484.14(d)	Revised at § 484.105(b), and § 484.105(c)
§ 484.14(e)	Revised at § 484.75(b) and § 484.115.
§ 484.14(f)	Revised at § 484.105(e).
§ 484.14(g)	Revised at § 484.60(d) and § 484.105(c).

Current CoPs	<i>Revised CoPs</i>
§ 484.14(h)	Revised at § 484.105(e).
§ 484.14(i)	Revised at § 484.105(h).
§ 484.14(j)	Revised at § 484.100(c).
§ 484.16, Group of professional personnel	Deleted, see § 484.65, Quality assessment and performance improvement (QAPI).
§ 484.18, Acceptance of patients, plan of care, and medical supervision	§ 484.60, Care planning, coordination of services, and quality of care.
§ 484.18(a)	Revised at § 484.60(a).
§ 484.18(b)	Revised at § 484.60(c).
§ 484.18(c)	Revised at § 484.60(b).
	New standard at § 484.60(e), Written information to the patient.
§ 484.20, Reporting OASIS information	§ 484.45, Reporting OASIS information.
§ 484.30, Skilled nursing services	§ 484.75, Skilled professional services.
§ 484.32, Therapy services	§ 484.75, Skilled professional services.
§ 484.34, Medical social services	§ 484.75, Skilled professional services.
§ 484.36, Home health aide services	§ 484.80, Home health aide services.
§ 484.36(a)(1)	Revised at § 484.80(b).
§ 484.36(a)(2)(i)	Revised at § 484.80(f).
§ 484.36(a)(2)(ii)	Revised at § 484.80(e).
§ 484.36(a)(3)	Revised at § 484.80(b).
§ 484.36(b)(1)	Revised at § 484.80(c).
§ 484.36(b)(2)(i)	Revised at § 484.80(c).
§ 484.36(b)(2)(ii)	Revised at § 484.80(h).
§ 484.36(b)(2)(iii)	Revised at § 484.80(d).
§ 484.36(b)(3)(i)	Revised at § 484.80(c) and (d).
§ 484.36(b)(3)(ii)	Revised at § 484.80(c) and (d).
§ 484.36(b)(3)(iii)	Revised at § 484.80(c).
§ 484.36(b)(4)	Revised at § 484.80(c).
§ 484.36(b)(5)	Redesignated at § 484.80(c).
§ 484.36(b)(6)	Deleted.
§ 484.36(c)	Revised at § 484.80(g).
§ 484.36(d)	Revised at § 484.80(h).
§ 484.36(e)	Revised at § 484.80(i).
§ 484.38, Qualifying to furnish outpatient physical therapy or speech pathology services	Revised at § 484.105(g).
§ 484.48, Clinical records	§ 484.110, Clinical records.
§ 484.48(a)	Revised at § 484.110(c).
§ 484.48(b)	Revised at § 484.110(d).

Current CoPs	<i>Revised CoPs</i>
<p>§ 484.52, Evaluation of the agency's program</p> <p>§ 484.55, Comprehensive assessment of patients</p>	<p>New standard at § 484.110(a), Contents of clinical record.</p> <p>New standard at § 484.110(b), Authentication.</p> <p>New standard at § 484.110(e), Retrieval of clinical records.</p> <p>Deleted, see § 484.65, Quality assessment and performance improvement and § 484.70, Infection prevention and control.</p> <p>§ 484.55, Comprehensive assessment of patients.</p>

IV. Analysis of and Responses to Public Comments

We received 199 letters of public comment from HHA industry associations, patient advocacy organizations, HHAs, and individuals. A summary of the major issues and our responses follow.

Effective Date

Comment: The vast majority of commenters made suggestions related to the effective date of the final rule. Commenters strongly expressed a need for a significant period of time to prepare for implementation of the new rules, noting that HHAs would need to adjust resource allocation, staffing, and potentially even infrastructure. Recommended implementation time frames ranged from 6 months to 5 years. The most frequent suggestion was to implement the final rule 1 year following its publication.

Response: We agree that it is appropriate to allow additional time to implement the final rule in order to allow HHAs adequate time to prepare for these changes. We believe that requiring HHAs to comply with the requirements of this rule on July 13, 2017 is sufficient to allow for appropriate HHA preparations to implement these changes. Therefore, we are finalizing an effective date of July 13, 2017.

Definitions

Comment: We received a few comments in support of the branch and parent office definition. One commenter strongly supported the change and emphasized with the automation age and web-based storage and access, the parent office can easily identify and investigate exceptions to standards of care for all patients and all employees, focusing administrative time on investigation, action and improvement. One commenter suggested CMS use the term of “Service Location” in lieu of “Branch Office.” Several commenters asked that CMS clarify some concerns regarding the branch office definition. The commenters asked that CMS provide guidance on what constitutes an adequate level of supervision on a “daily basis.” They specifically asked if there is a certain amount or type of communication between the branch and parent offices. In addition, one commenter asked whether a survey citation for a violation in a branch office would apply to the entire HHA.

Response: We appreciate the public comments regarding this issue. We will continue to use the term “branch location” because it has been in use for more than a decade, and both HHAs and surveyors are accustomed to the term. To change the terminology without a pressing reason to do so would risk unnecessary and unwanted confusion among HHAs and surveyors. The concept of an adequate level of supervision on a daily basis is longstanding, and refers to the parent HHA's ability to demonstrate administrative control over each branch. We did not propose, nor are we finalizing, any specific requirements for communication because our primary concern relates to the evidence of control rather than the process for achieving it. As stated in the

proposed rule, a violation that occurred in care and services being provided by a branch location would be considered a violation by the HHA as a whole. Therefore, it is essential for the parent to exercise adequate control, supervision, and guidance for all branches under its leadership.

Comment: We received several comments supporting the inclusion of the proposed definition of quality indicator. One commenter stated it is a much needed addition. Another commenter stated the addition of quality indicator as a definition would allow an HHA to take into account its patient population and unique characteristics while meeting the needs of the patients.

Response: We appreciate support from the public regarding this definition, and are finalizing it without change.

Comment: Several commenters submitted comments regarding the proposed definition of the term “representative.” Commenters supported our goal of creating a patient-centered definition that acknowledges the importance of patient choice, patient involvement in his or her care, and the role of family, friends, and caregivers. A commenter stated that this definition should facilitate more timely communication and cooperation between the HHA, patient, and representatives and family members. However, a few commenters expressed concern with the potential for confusion between legally designated representatives, such as a legal guardian, and patient-designated representatives. One commenter stated that HHAs may face questions of whom to listen to in situations where a patient has designated a representative who may not have legal status to make health care decisions. Another commenter stated that state laws regarding the rights and responsibilities of those with health care power of attorney can sometimes prevent an HHA from responding to communications and requests from a caregiver or loved one. The commenter suggested that the definition of “representative” should clearly acknowledge that legal limitations may exist that limit the HHA's ability to be responsive to communications and requests from patient-identified representatives at any given point in time. Recognition of this fact in the definition will assist agencies in managing those complex and conflicted situations that arise in the delivery of home health services. Similarly, another commenter suggested that the term “representative” be used only where the requirements include decision-making authority, while a different term, such as “caregiver” be used when the requirement is in relation to those individuals that provide support to the patient.

Response: We appreciate the broad-based support for this patient-centered definition of the term “representative.” We acknowledge that patients may have several different representatives, each serving a different support and/or decision making role in the patient's life. Although conflicts between representatives who have legal authority and those who do not do have legal authority exist, we believe that these situations are relatively uncommon. The resolution of such conflicts would be dependent upon the exact scope of the legal representation. For example, an individual may serve as a patient's representative solely for financial decision making, meaning that the individual would not have health care decision making authority, and would therefore be in no more significant of a position than any other individual chosen by the patient to serve as a patient-selected representative. If an individual was the legally designated or appointed health care decision maker, the HHA would be expected to act in accordance with the decisions made by that individual while still giving preference to patient choices within the boundaries of that legal representation relationship. As stated in the proposed rule (79 FR 61168 (/citation/79-FR-61168)), if an HHA has reason to believe that the representative is not acting in accordance with what the patient would want, is making decisions that could cause harm to the patient, or otherwise cannot perform the required functions of a representative, we would expect the HHA to make referrals and/or reports to the appropriate agencies and authorities to assure the health and safety of the patient. We do not believe that it would be appropriate to revise the definition of the term “representative” in an attempt to factor in the wide variety of legal

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relationships that may or may not exist; as such an attempt would inevitably fail to account for every possibility. We do agree that it is necessary to distinguish between those representatives that are chosen by a patient, but who may not have legal standing, and those representatives who are acting on legal authority to make health care decisions for a patient. While a commenter suggested that the term “caregiver” would be appropriate for those representatives that are chosen by a patient, but who do not have legally established decision making authority, we believe that the phrase “patient-selected representative” is a more appropriate way to express this concept. Likewise, when referring to those representatives who are acting on legal authority to make health care decisions for a patient, we will use the term “legal representative.” We believe that using the modifiers “patient-identified” and “legal” when referring to the types of “representatives” that a patient may have will help clarify the expectations for HHAs.

Comment: A commenter suggested that, if a representative is not following what the patient requests or is causing harm to the patient in any way, the HHA staff should report such disagreements or harm to HHA management so that HHA management can take appropriate steps to ensure the safety of the patient, including reporting harm to outside entities.

Response: We agree with this statement. As we stated in the proposed rule, “If an HHA has reason to believe that the representative is not acting in accordance with what the patient would want, is making decisions that could cause harm to the patient, or otherwise cannot perform the required functions of a representative, we would expect the HHA to make referrals and/or reports to the appropriate agencies and authorities to assure the health and safety of the patient.”

Comment: We received a few comments that directly asked for CMS to revise or clarify the requirements for verbal orders. The commenters stated that other licensed practitioners, such as physician's assistants and nurse practitioners, should be permitted to give verbal orders for treatment. Another commenter requested additional clarification of the word “spoken.”

Response: Section 1861(m) of the Act requires the HHA plan of care to be under the direction of a physician. We do not have statutory authority to allow other licensed practitioners to give verbal orders for treatment, as such an allowance would mean that the plan of care would no longer be under a plan established by a physician because pieces of that plan would be established by non-physicians. We intended a plain language meaning of the term “spoken” as meaning a communication that is said aloud or communicated by sign language.

Comment: One commenter stated that he or she disagrees with what appears to be another sub-regulatory process for the definitions of “in advance,” “quality indicator” and “supervised practical training.”

Response: The proposed rule included definitions for these terms within the regulation. Thus, we did not propose a “sub-regulatory” process for these definitions.

Comment: One commenter asked if CMS meant to remove the definition of “nonprofit agency” in the proposed rule.

Response: Removing the definition of the term “nonprofit agency” was intentional. This term is not used within the regulatory text; therefore it is not necessary to define a term that no longer exists.

Comment: One commenter stated they did not support the “subregulatory process” and deletion of the terms “bylaws” and “supervision” in the proposed rule because they feel the two definitions are important in the delivery of care and organizational structure.

Response: We proposed to delete a definition of the term “bylaws” because the term is not included in the regulatory text. It is not necessary to define a term that is not used. We proposed to delete the term “supervision” because a single definition of the term cannot adequately encompass the variety of ways in which the term is used in this rule. To set forth a single definition of the term would create more confusion rather than resolve it.

Comment: Several commenters asked CMS to amend § 484.14(a) to define “agency employee” by referencing common law definition of employee, or issue other guidance clarifying that CMS will interpret “agency employee” in accordance with the common law definition of employee. This guidance is utilized for payroll and accounting purposes for issuance of W-2 forms for the HHA. One commenter asked that CMS define the term “professional employment organization.”

Response: The regulation does not include the term “agency employee;” therefore we are not defining it. Where the term “employee” is used, CMS generally considers an employee someone for whom the facility issues a W-2. The regulation does not include the term “professional employment organization”; therefore it is unnecessary to set forth a definition for this term.

Comment: A commenter asked that CMS include the definition of “caregiver” in the final rule. They asked for CMS to clarify what the term “caregiver” is meant to encompass and how the term differs from “family.” They suggest CMS use the term “family caregivers,” which refers to any relative, partner, friend or neighbor of the patient who has a significant relationship with, and who provides a broad range of assistance to, the patient.

Response: The term “caregiver” refers to any individual who renders uncompensated care to a patient, whereas the term “family” refers to legal and/or blood relationships. We do not believe that it is necessary to define the term because it is not an HHA-specific term of art, nor is it being used to have a special meaning in this rule. Furthermore, we believe that adding a definition would run the risk of inadvertently excluding a type of caregiver, which would be detrimental to patients, caregivers, and HHAs alike. Many times “caregivers” are “family” members, but this is not a requirement. For example, a patient’s child may live out of state and be considered a “family” member, but would not render care to the patient as distance would preclude such an arrangement. Therefore, the daughter would be a “family” member, but not a “caregiver.” We do not believe that using the term “family caregivers” would bring greater clarity to our meaning, as such a term would inappropriately imply that only family members can be caregivers. Rather than being inclusive of neighbors, friends, church members, etc., the term “family caregivers” would imply that these individuals are not included in the broad category of “caregivers.”

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RELEASE OF PATIENT IDENTIFIABLE OUTCOME AND ASSESSMENT INFORMATION SET (OASIS) INFORMATION AND REPORTING OASIS INFORMATION

Comment: We received many supportive comments regarding the proposed OASIS data reporting requirements. Several of the commenters believe the changes are more consistent with electronic reporting technology and software that is currently being utilized for data transmission. One commenter stated they believe the proposed OASIS changes combine most of the current requirements and the language reflects current technological terms.

Response: We appreciate the support of the commenters, and are finalizing these sections as proposed, with one change. We originally proposed to change the transmission requirements for test OASIS data in a manner that would bring the regulation in line with current transmission guidelines that existed at the time when the proposed rule was published. Specifically, at § 484.45 we proposed to require that an HHA must, “Successfully transmit test data to the state agency or CMS OASIS contractor.” On January 1, 2015 CMS changed the OASIS transmission guidelines to require that an HHA must successfully transmit test data to the Quality Improvement and Evaluation System, Assessment Submission and Processing, (QIES ASAP) System or CMS OASIS contractor. We have revised the final rule at § 484.45 to reflect this change and maintain consistency between the transmission guidelines and the regulatory requirements.

Comment: One commenter encouraged CMS to address the potential implications and to coordinate its policies concerning data collection with the requirements of the IMPACT Act. They specifically mentioned the call for standardized post-acute care assessment data for quality, payment, discharge planning and other purposes.

Response: We agree that data collection should be coordinated, and have undertaken numerous efforts to align data elements across data sets, where appropriate. On November 5, 2015, we finalized the CY 2016 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements rule (80 FR 68623 (/citation/80-FR-68623)) that discusses implementation of the requirements of the IMPACT Act for HHAs. We will be taking steps to implement the IMPACT act over the next several years, in accordance with its statutory deadlines.

Comment: Several commenters cautioned CMS on over-reliance on OASIS to assess home health agency performance and for CMS to address shortcomings with the OASIS data collection tool. They recommended that CMS advise home health agencies to utilize available resources that provide guidance in managing complex health conditions.

Response: While we appreciate these suggestions related to the OASIS, the content of the OASIS and its use by CMS to assess the quality of care provided by HHAs are not within the scope of this rule. HHAs are encouraged to use all appropriate available resources to manage patient care, such as those available on the CMS OASIS Web site (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/index.html?redirect=/OASIS/o1_Overview.asp (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/index.html?redirect=/OASIS/o1_Overview.asp)).

PATIENT RIGHTS

Comment: Many commenters supported the proposed patient rights requirements, highlighting the patient-centered focus of the proposed requirements, and stating that such requirements will help achieve better health and better health outcomes. Conversely, a few commenters questioned the need for an expanded set of patient rights and stated that the new requirements would require too many forms. Others stated that the proposed requirements were repetitive.

Response: We appreciate the support for this requirement, and agree that it is a useful part of the overall goal to achieve better outcomes for patients. We do not agree that the new requirement will result in a greater number of forms per patient, as these changes can be incorporated into the current patient rights process that HHAs are already required to have. We also do not agree that the requirements are repetitive in that each standard addresses a distinct aspect of patient rights.

Comment: A few commenters suggested that CMS take an active role in assisting HHAs in complying with the patient rights requirements by requiring states to develop ombudsman services for home health care patients to help patients resolve complaints and assist patients who wish to appeal an HHA's decision to transfer or discharge them. Commenters also suggested that CMS should create a consumer Web site to provide information about patient rights in layperson's terms, and that this Web site should be available in multiple languages.

Response: We appreciate these suggestions; however, they are beyond the scope of this regulation. Therefore, we are precluded from acting upon them in this rule. We will retain this suggestion for future consideration.

Comment: A few commenters suggested that CMS develop standardized patient rights materials, translated into the languages most commonly used by Medicare beneficiaries. Commenters also suggested that CMS should provide the OASIS privacy notice in languages other than English and Spanish, and that the notice should be written in a way that is understandable to persons who have limited English proficiency.

Response: The content and format of the OASIS privacy notice are not within the scope of this rule; however we will retain this suggestion for future consideration. We do not agree that requiring a specific patient rights form would benefit HHAs or HHA patients, as the use of a specific form would reduce HHA flexibility to include additional HHA-specific information that may be relevant. In addition, mandating a specific form may interfere with or duplicate the patient rights information requirements established by states and accrediting organizations. Therefore, this rule does not require the use of a specific patient rights form. Rather, HHAs may use a means of their choosing that conveys the required information. We remind HHAs that where several regulatory bodies have established standards governing the same subject matter, we expect HHAs to adhere to the most stringent requirement. Absent a single mandated notice of patient rights, it is not possible for CMS to provide translations.

Comment: A commenter requested clarification regarding the provision of the notice of patient rights. The commenter asked whether the HHA would be required to deliver notices to (1) both the patient and the patient's representative, or (2) either the patient or the patient's representative.

Response: We proposed, and are finalizing a requirement that the notice of patient rights must be provided to both the patient and his or her representative. This is particularly necessary in situations where the representative legally possesses health care decision making authority. In situations where the representative is patient-selected and does not possess legal health care decision making authority, a patient may choose to decline the provision of the notice of rights to the patient-selected representative because the definition of the term "representative" explicitly states that the patient determines the role of the representative, to the extent possible. The patient may choose to involve or not involve the patient-selected representative regarding every interaction with the HHA. We would expect an HHA to document in the patient's record that a patient declined to have a copy of the notice of rights provided to the representative. We believe that explicitly allowing patients to choose whether or not the information is provided to the patient-selected representative will give patients greater control over their care.

Comment: A few commenters referenced existing statutes and regulations that relate to the proposed requirements. One commenter stated that it would be helpful if CMS expressly stated that these requirements are identical to the requirements under Title VI of the Civil Rights Act to ensure that there is no discrepancy related to the standard that will be applied. Another commenter referenced the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National

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CLAS standards, <https://www.thinkculturalhealth.hhs.gov/content/clas.asp> (<https://www.thinkculturalhealth.hhs.gov/content/clas.asp>), and stated that, under these standards, an agency may identify the dominant languages in its patient population and prepare written materials in the most frequently spoken languages. Individuals who speak less commonly encountered languages receive a description of the contents of the patient rights notice from an interpreter. The commenter asked whether adherence to the National CLAS standards will meet the intent of the proposed regulation. The commenter also suggested that we should revise the regulation requirements at § 484.50(a)(1)(ii) to specifically allow interpreters to be used to help individuals who speak a language not commonly found in the agency's service area to understand the notice of patient rights. Yet another commenter referenced the Office for Civil Rights (OCR) Guidance at <http://www.hhs.gov/ocr/civilrights/resources/specialtopics/lep/hhslepguidancepdf.pdf> (<http://www.hhs.gov/ocr/civilrights/resources/specialtopics/lep/hhslepguidancepdf.pdf>), which states, “. . . the starting point is an individualized assessment that balances the following four factors: (1) The number or proportion of limited English proficiency (LEP) persons eligible to be served or likely to be encountered by the program or grantee; (2) the frequency with which LEP individuals come in contact with the program; (3) the nature and importance of the program, activity, or service provided by the program to people's lives; and (4) the resources available to the grantee/recipient and costs.” The commenter suggested that this guidance should be used as the basis for the regulations.

Response: We appreciate the comments on this subject, but as stated in the proposed rule, the regulation requirements on this subject are already consistent with Department of Health and Human Services guidance regarding Title VI of the Civil Rights Act. We agree that the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS) is a good reference, but we are unable to say with certainty that adherence to CLAS guarantees full compliance with this rule because each situation is evaluated on its own merits. In addition, we would like to clarify that regulation requirements that state documents must be “understandable” does not require or suggest that documents must be written in every language.

Comment: While commenters expressed general support for the concept of effective communication with patients, a large number of commenters posed questions regarding the proposed requirement to communicate with patients in a language and manner that they understand. Commenters wanted to know if all patient rights documents would be required to be translated into the patient's preferred language both orally and in writing. Commenters also requested clarification regarding the responsibility of each HHA to have written notices in each possible language the agency may encounter in the community, and asked that CMS provide a more limited and nationally standardized set of languages in which such notice must be conveyed. Additionally, commenters suggested that we should differentiate between “vital” and “non-vital” patient rights information that would need to be provided, in writing, in a language and manner that a patient understands, limiting required written information to what is vital and permitting the communication of non-vital information to an oral translation. Commenters further noted the challenges associated with providing a written copy of the notice of rights in the preferred language at the time of the initial visit because there are times when an HHA is not aware of the referred patient's language preference until the visit is initiated. The commenter suggested that, in such situations, the HHA should be required to provide the written notice in a reasonable amount of time (for example, 72 hours). Similarly, a commenter questioned whether an unforeseen inability to orally inform a patient of his or her rights in understandable language and manner “in advance of providing care” would mean that the clinician performing the initial patient visit would be prohibited from admitting the patient to services.

Response: We appreciate these comments and realize the task of requiring agencies to communicate with patients in a language and manner in which they understand may cause confusion when trying to meet the regulations in a consistent manner to remain compliant. We do not have the expectation that HHAs will be presenting a translated patient rights document to every single patient in their native language when they are admitted and before they begin receiving care. We want to emphasize that the term “understandable” does not mean it is expected to be written in every language. A general understanding means that patients achieve a grasp of the explanation of something and not necessarily a verbatim written translation. We expect HHAs to utilize technology, such as telephonic interpreting services and any other available resources for oral communication in the patient's primary or preferred language prior to the completion of the second skilled visit. The flexibility that is built into this requirement, allowing the use of technology, remote interpretation services, and patient-selected interpreters should accommodate most situations, alleviating potential concerns regarding an “unforeseen inability” to communicate with patients in advance of furnishing services. Based on the HHA location, language needs will vary and often times a document will only have to be translated once and then can be utilized again as needed without extra translation burden. In addition, we have revised the requirements to allow additional time for HHAs to provide oral notification of rights, removing the requirement that oral notification be provided in advance of providing care. We believe that this change will also alleviate concerns regarding an unforeseen inability to orally inform a patient of his or her rights in understandable language and manner preventing the clinician performing the initial patient visit from admitting the patient to services.

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Comment: A commenter requested clarification of the term “preferred language.”

Response: The Department of Health and Human Services 2013 Language Access Plan described “Preferred Language” as the language that a limited English proficiency (LEP) individual identifies as the preferred language that he or she uses to communicate effectively.

Comment: Several commenters submitted comments regarding the role of patient-selected, rather than professional, interpreters. Specifically, commenters supported statements in the preamble that would permit a patient to select his or her own interpreter in lieu of a professional interpreter. Commenters noted that, even if a patient or representative does offer to provide an interpreter, she or he should still be informed of the availability of professional interpretation services. A commenter requested clarification of the preamble statement that an HHA “may wish to document” the refusal of a professional interpreter, stating that some surveyors may interpret this suggestion as a regulatory requirement.

Response: We appreciate these comments of support. We agree that a patient should be informed of the availability of professional interpretation services, regardless of whether the patient offers to provide an interpreter. Section 484.50(c)(12) requires HHAs to provide written notice, prior to the initiation of care, informing patients that they have the right to access auxiliary aids and language services, and how to access these services. Title VI of the Civil Rights Act does not require documentation, and we do not intend to require anything above and beyond what is currently required in Title VI. HHAs have the flexibility to document more information, but it is not a regulatory requirement.

Comment: A commenter disagreed with the idea that an HHA may communicate patient rights information to the patient's representative “if a patient is unable to effectively communicate directly with HHA staff.” The commenter asserted that this should only be true in situations where the patient is unable to participate, to any degree, in decision making regarding her or his health care. The commenter stated that if a patient can

participate in health care decision making, it is essential that HHAs offer auxiliary aids, professional interpretation services, and translated materials directly to the patient, rather than relying on the representative to serve as an interpreter.

Response: Our intent is to assure that HHAs communicate directly with the patient in all situations where the patient has the mental capacity to participate in and understand such communications. However, if a patient is unable to effectively communicate and participate in their care due to a compromised mental capacity as identified through information provided by referral sources, clinical observations, and/or clinical assessment, then the HHA is permitted to communicate with the patient's representative.

Comment: A commenter disagreed with the way we characterized the role of an interpreter in the preamble of the proposed rule. The commenter stated that, in addition to our original description, it is also an interpreter's role to facilitate two-way communication, so that the patient can describe changes in his or her condition or experience of care, ask questions, and articulate preferences and concerns.

Response: We agree that an interpreter's role also includes facilitating two-way communication and patient participation in his or her care. We encourage communication that will help the patient be an active participant in his or her care. We emphasize the interpreter's role in communications from the facility because the facility has a legal obligation to communicate effectively with the patient or his/her representative.

Comment: Some commenters agreed, while other commenters disagreed, with the requirement that the HHA must ensure that the communication via the interpreter of choice is effective. A commenter stated that this requirement is impracticable, as by nature of the fact that the HHA staff is using an interpreter means that staff member is unable to communicate in the patient's language, rendering the staff member incapable of ensuring the effectiveness of the communication. Another commenter recommended that minors should be prohibited from acting as patient-selected interpreters. This commenter stated that minors lack clinical knowledge to be effective interpreters, and that performing interpreter duties may result in minors being exposed to information that is confusing or frightening to them, especially if they are interpreting for a parent.

Response: The most reliable way to assure that communication is effective is to use the services of a professional interpreter who possesses appropriate training and certifications to perform his or her job duties as an interpreter. Even so, patients have the right to choose someone other than a professional interpreter. Absent a professional interpreter, either because the patient has expressly declined the use of one or the patient's language is so rare that an interpreter, whether in person or by communication device such as the telephone, cannot be located, the HHA may use a patient-selected interpreter, such as the patient's representative. The patient's representative, who could be a family member or friend, may act as a liaison between the patient and the HHA to help the patient communicate, understand, remember and cope with the interactions that take place during the visit, and explain any instructions to the patient that are delivered by the HHA staff. The HHA would be responsible for verifying that communication to the representative was effective and accurate communication, which could be accomplished by having the patient representative repeat back instructions. An HHA would be expected to observe the interactions between the patient-selected interpreter and the patient to determine whether the communication appears to be effective. For example, if a patient continues to look confused after the information is presented, then the HHA clinician may conclude that the communication was not effective in conveying the necessary information. This regulation is consistent with the current HHS guidance ("Guidance to Federal Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English

Proficient Persons,” 68 FR 47311 (/citation/68-FR-47311), August 8, 2003, (<https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/> (<https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/>)), and the HHA should respect patient preference to use someone other than a professional interpreter (even after being offered and denied). If the competency or accuracy of the patient-selected interpreter is in serious question, for example, the clinician speaks a paragraph of specific instructions and the interpreter “interprets” in a single sentence, the expectation would be to then bring in the services of a professional interpreter. We agree that the use of minors to serve as interpreters should be a last resort and only used in emergency circumstances.

Comment: Several commenters raised concerns about translators, particularly □ in relationship to less common languages. Commenters requested guidance on handling situations when an interpreter is not available in the community. Other commenters requested guidance on the appropriate use of available technologies that could be used to achieve compliance with the accessibility requirements in this rule.

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Response: We understand these concerns and agree that it is occasionally difficult to locate an interpreter for certain less common languages. Compliance with this requirement is achievable if the HHA takes all reasonable steps and actions to provide meaningful access to an interpreter as set forth by the HHA guidelines. HHAs are expected to exhaust all avenues of technology such as telephone translation, video conferencing, or online translation of written documents. All of those choices are acceptable options when a local interpreter cannot be located, provided that the chosen option meets the patient's communication needs.

Comment: A commenter asked whether the regulation requires HHA personnel to read the entire content of the notice of patient rights to the patient or whether it is acceptable to explain the overall intent and general content of the notice of patient rights without reviewing the rights verbatim.

Response: The intent of this requirement is for HHAs to thoroughly discuss the content of the notice of patient rights with the patient and representative, and to allow patients and representatives an opportunity to ask questions and otherwise seek clarification regarding the notice of patient rights. HHA staff members are not required to read the notice word-for-word to the patient. Rather HHA staff members have the flexibility to provide comprehensive and accurate summaries of each right in conversational language and tone in order to engage patients and representatives in this discussion.

Comment: A large number of commenters submitted comments regarding the proposed requirement to provide the notice of patient rights prior to the initiation of care. Commenters expressed concern about providing a large amount of information (both in paper form and in oral explanation) at a single visit, and all prior to initiating care. Commenters stated that this can be overwhelming for patients, and can result in patients not retaining important information (for example, how to make a complaint). The commenters suggested a multi-visit approach to providing information regarding patient rights. Some commenters suggested spreading the communications regarding patient rights across two visits, while others suggested a more extended approach. Commenters suggested that the first visit should include the information deemed to be essential prior to the initiation of care, with important, but not essential, information being reviewed during a subsequent visit. A commenter also suggested that HHAs should be required to provide the notice of rights whenever the plan of care is revised or updated, and should be required to obtain the patient's signature each time this is done.

Response: In accordance with the requirements of section 1891(a)(1)(F) of the Act, HHAs must provide notice in writing to each patient regarding his or her rights in advance of providing care. We agree that providing both written and oral notice in advance of providing care may not be in the best interest of all HHA patients. Therefore, we are revising the requirements at § 484.50(a) to require written notice in advance of providing care and oral notice by the end of the second skilled visit. HHAs must obtain the signature of the patient or the patient's legal representative to confirm that written information was received. HHAs may conduct a thorough conversation with the patient and representative regarding the content and meaning of the notice of patient rights over the first two visits by a skilled professional (nurse, therapist, and medical social worker). We believe that extending the time frame for the oral explanation of the notice of patient rights and responsibilities will foster greater patient understanding of those rights, as well as assure that the conversation does not inappropriately impede the delivery of patient care. HHAs would still need to document in the patient's clinical record that they have provided a complete oral explanation of the notice of patient rights, in addition to the written notice provided in advance of furnishing care. Documenting oral notice may be done by obtaining the patient's or representative's signature, or by a clinical note.

Comment: A commenter expressed concern with the proposed requirement that the HHA must provide the patient and the patient's representative (if any) with written and verbal notice of the patient's rights and responsibilities during the initial evaluation visit, in advance of care being provided to the patient. The commenter noted that a patient-selected representative may not be available or identified at the initial visit. Furthermore, the commenter stated that requiring the provision of written and verbal notice of patient rights to the representative in situations where a patient is competent may serve to postpone the initiation of patient care, and negatively impact patient health and safety. The commenter suggested that the requirements of § 484.50(a) should be clarified to allow for a patient's representative to receive a written notice of the patient's rights upon admission or as soon thereafter in situations when the patient is competent to make his or her own decisions.

Response: If a patient has a legally appointed or designated representative that has health care decision making authority, the HHA must provide notice of the patient's rights prior to initiating care. Notifying the individual with legal health care authority cannot be postponed. However, we agree that providing notice to patient-selected representatives that do not have legal health care decision making authority is not always necessary prior to the initiation of care. As stated previously, a patient may choose to decline the provision of the notice of rights to the patient-selected representative. We believe that HHAs would choose to document this in the patient's record in order to demonstrate compliance upon survey. If the patient does not decline to have the patient-selected representative be informed, and such representative is not present at the time of care initiation, an HHA may provide a copy to the patient-selected representative within 4 business days of initiating care. This information can be provided by mail or electronic means. We have revised the regulatory text at § 484.50(a) accordingly.

Comment: Some commenters strongly supported the proposed requirement to provide each patient with contact information for the HHA's administrator. A commenter stated that it would be appropriate to provide contact information for the administrator, as well as the administrator's designee, to meet the requirement. The administrator is not always available, so naming an alternate contact at the agency would facilitate more efficient and timely response to patient complaints or questions. However, a commenter suggested that an administrator should be responsible for receiving complaints, but not for answering routine patient questions that may be more appropriate for clinical staff and clinical managers. Other commenters suggested that it would be more appropriate to provide contact information for the HHA's 24-hour on-call service number or the HHA's general contact information.□

Response: We agree that routine patient questions may be more appropriate for clinical staff and clinical managers; therefore at § 484.50(a) we have removed from the regulation text the requirement for the administrator to receive questions. The requirement that the administrator receive complaints remains in the regulation because we believe this is an essential leadership function. We also agree that providing contact information for the 24 hour call line would be appropriate for answering patient questions; however we do not believe that this is necessary to require in regulation. HHAs may choose to incorporate this information, but would not be required to do so. Similarly, HHAs may choose to include contact information for the administrator's designee, but would not be required to do so.

Comment: A commenter questioned the necessity of requiring an HHA to provide each patient with a copy of the OASIS privacy notice, given that patients are also provided the Health Insurance Portability and Accountability Act (HIPAA) privacy statement. The commenter stated that, if the point of the OASIS privacy notice is to advise the patient why the OASIS is being collected, this information can be more simply stated and incorporated elsewhere.

Response: As stated in the June 18, 1999 notice related to the implementation of the OASIS data set (64 FR 32984 (/citation/64-FR-32984) through 32989), HHA patients whose data will be collected and used by the federal government must receive a notice of their privacy rights. These rights include: (1) The right to be informed that OASIS information will be collected and the purpose of collection; (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 Federal Privacy Act; (4) the right to refuse to answer questions; and (5) the right to see, review, and request changes on their assessment. The statements of patient privacy rights with regard to the OASIS collection (one for Medicare/Medicaid patients, one for all other patients served by the HHA) are included in the OASIS privacy notice. Many of the topics addressed in the OASIS privacy notice are not included in the HIPAA (Pub. L. 104-191 (<https://api.fdsys.gov/link?collection=plaw&congress=104&lawtype=public&lawnum=191&link-type=html>), 110 Stat. 1936, enacted August 21, 1996) privacy statement. Therefore, we do not believe that the HIPAA privacy statement is an appropriate substitution for the OASIS privacy notice, and we are maintaining the requirement that HHAs must provide patients with both the HIPAA privacy statement and the OASIS privacy notice.

Furthermore, we believe that the content of the OASIS privacy notice is understandable to patients. As explained in the June 1999 notice, consumer testing was undertaken to determine whether Medicare beneficiaries understood the overall message of the proposed Medicare notice. The findings indicated that beneficiaries understood that the notice was informing them about their rights relating to their personal health care information and that these protections were good. In addition, the majority of the beneficiaries found the notice's language to be clear and easy to understand.

Comment: Most commenters supported the patient-centered, patient-directed approach used in relationship to the role of the patient representative, and several commenters offered suggestions for ways to implement or clarify this role. A commenter suggested that HHAs should build a conversation focused specifically on patient representation into every admission visit. This conversation would allow the patient to identify those person(s) with whom the agency may discuss their care, or not discuss their care. The agency would document this in whatever format is most appropriate for them (for example, the electronic medical record (EMR)) and that would guide future conversations. In addition, the commenter suggested that HHAs should provide patients with written information, as part of the patient rights information, that would inform the patient that he or she can choose representatives, and make changes to that choice at any time by contacting HHA staff. Another commenter suggested that, in order to comply with the proposed requirement to allow patients to select their representatives, HHAs would need to create timeframes for contacting

representatives, maintain documentation of patient preferences, maintain documentation of contacts with representatives, and actually involve representatives in care planning. Another commenter suggested that HHAs should be required to establish a primary contact to which all communication will be directed concerning the patient. That person would receive all information regarding the patient's rights, plan of care, and discharge plan updates.

Response: We appreciate all of the suggestions, and believe that they are examples of best practices that an HHA may consider adopting in order to facilitate compliance with the written regulations and spirit of the rule.

Comment: A few commenters suggested changes to the wording used to describe competency as it relates to rulings under state law. Commenters stated that the regulation should include other designations made under state law short of adjudication of "incompetence." In place of the term "incompetence," commenters suggested that we use the phrase "lack legal capacity." Commenters also suggested that, if a state court has not adjudged a patient to lack legal capacity, the patient's representative should be permitted to exercise the patient's rights, but doing so must be in accordance with state law and with the patient's permission.

Response: While we believe that "incompetence" is a legally appropriate term, we agree that there are degrees of competence and incompetence, and that the term "incompetence" may not adequately express the exact degree that we originally intended to convey. For this reason, at § 484.50(b) we have replaced the term "incompetence" with the more precise phrase "lack legal capacity to make health care decisions as defined by state law." The extent to which patients who possess legal capacity to make their own health care decisions choose to delegate that decision making authority to others would be established by the patient, as recognized in the definition of the term "representative." The definition at § 484.3 states that, "the patient determines the role of the representative, to the extent possible." HHAs are encouraged to engage patients in a thoughtful discussion about the representative role that the patient desires. HHAs may find resources related to supported health care decision making agreements helpful in creating a framework for and documenting the results of these discussions. (See <http://autisticadvocacy.org/wp-content/uploads/2014/07/ASAN-Supported-Decisionmaking-Model-Legislature.pdf> (<http://autisticadvocacy.org/wp-content/uploads/2014/07/ASAN-Supported-Decisionmaking-Model-Legislature.pdf>) for one example of a supported health care decision making agreement.)

Comment: A commenter suggested that the patient or his or her representative should have the right, upon an oral or written request, to inspect all records pertaining to himself or herself including current clinical records within 48 hours (excluding weekends and holidays); and to receive copies of electronic records free of charge or to purchase, at a cost not to exceed the community standard, photocopies of the records or any portions of those records with 2 working days of the HHA receiving the request. □

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Response: We agree that patients and/or representative have the right to request a copy of their clinical record. Patients may access their records in accordance with § 484.110(e), which requires that a patient's clinical record (whether hard copy or electronic form) must be made available to the patient upon request, free of charge, at the next home visit, or within 4 business days (whichever comes first).

Comment: A commenter stated that it is redundant to require that HHAs must assure that patients receive services in a manner that is free from illegal actions, such as sexual abuse or physical abuse.

Response: We do not agree that it is redundant because the enforcement mechanisms for criminal statutes and these CoPs are very different. While certain actions, such as misappropriation of patient property (theft) are illegal, HHA surveyors do not enforce criminal statutes. However, we do believe that the HHA has a responsibility to ensure that no illegal activity takes place, and should be penalized if it does not take all necessary precautions to prevent its staff from engaging in criminal activity. If this requirement at § 484.50(c) were removed, an HHA surveyor would have no mechanism to cite an HHA for criminal acts committed by its staff. Therefore, we believe that it is in the best interest of HHA patients to include this requirement and enable an HHA surveyor to issue a deficiency citation for non-compliance.

Comment: A commenter stated that the patient's right to participate in, be informed about, and consent or refuse care in advance of and during treatment, where appropriate, with respect to factors that could impact treatment effectiveness is not a reasonable expectation in all cases.

Response: We disagree with this comment. A patient's right to be informed about care, and to consent or refuse any element of that care, is fundamental. Furthermore, where internal or external factors exist that may impact the effectiveness of a given treatment option, we believe that it is a reasonable expectation that they would be discussed with a patient in advance so that the patient can make an informed decision about the care they are set to receive.

Comment: A commenter opposed the proposed requirement that a patient has the right to participate in, be informed about, and consent or refuse care in advance of and during treatment, where appropriate. The commenter opposed the phrase "where appropriate," stating that there are no circumstances where it would not be appropriate for a patient to participate in, be informed about, and consent or refuse care in advance of and during treatment. The commenter also stated that the term "appropriate" is subjective and would be defined by the HHA, possibly resulting in limiting or even eliminating a patient's right to be involved in his or her care.

Response: While we agree that patients have these fundamental rights, and that those rights should be guaranteed in regulation, the phrase "where appropriate" is necessary. The patient has the right to determine the degree to which he or she wants to be involved in his or her care, and the use of this phrase reflects the fact that each patient will determine what is or is not appropriate in his or her own way. We believe that most patients will not want to be involved in every specific detail of care (for example, the type of supplies used). Thus, these decisions would likely not require full explanation to, and discussion with, the patient. To mandate the right to participate in, be informed about, and consent or refuse care in advance of and during treatment, for every single decision made by an HHA would be burdensome to patients that have no interest in such a degree of participation, and contrary to the goal of delivering care efficiently.

Comment: A commenter suggested that patients should have the right to participate in, be informed about, and consent or refuse care in advance of and during treatment with respect to the timing of visits and who provides services.

Response: These concepts are already included in § 484.55(c)(2), which requires the HHA to assess each patient's care preferences, and § 484.60, which requires that the individualized plan of care be based on the assessment of the patient.

Comment: A commenter suggested that, rather than requiring that a patient has the right to be informed about the patient-specific comprehensive assessment, the regulation should require that a patient has the right to be informed about all assessments throughout the course of care. The commenter stated that

patients and caregivers may want to know the findings of any given assessment, rather than just the comprehensive assessment, which is performed at specified periods of time.

Response: We agree that the HHA's patients should be informed about, and consent or refuse care in advance of and during treatment, where appropriate, with respect to all patient assessments, rather than just the "comprehensive assessment." We have revised the regulation text at § 484.50(c)(4)(i) to reflect this change.

Comment: A commenter recommended that a patient's right to be involved in establishing and revising the plan of care should be limited to involvement in major revisions to the plan of care, such as a change in the goal of care, the number of visits, or discharge date.

Response: The intent of this requirement is to assure that HHA patients can be informed about and involved in establishing and revising their plan of care as a whole. We believe the patient has a right to be involved with all facets of the care they receive. It is the HHA's responsibility to discuss the level of involvement that patients and their representatives want to have in the plan of care. This would include factors such as how much the patient is capable of understanding and the extent they wish to be involved with the development and updates to the plan of care. HHAs should make all reasonable attempts to respect patient wishes.

Comment: The majority of commenters expressed concern regarding the proposed requirement that an HHA must provide a patient with a copy of his or her plan of care. While some commenters agreed with our position that providing a patient with information about his or her plan of care would improve patient understanding and compliance, most stated that, as a clinically oriented document for use by medical personnel, the plan of care is not created in a manner that would make sense to a patient. Some commenters stated that patients would not want information about their plan of care, and noted that all patients already have a right to request copies of medical records, while other commenters stated that patients would prefer to receive this information. A few of these commenters suggested that the plan of care should be required to be provided if the patient desires it or specifically requests it. A single commenter sought reassurance that the copy of the plan of care would be provided at no charge to the patient. Still other commenters requested additional clarification regarding the meaning of the term "plan of care" as it is used in this section. These commenters stated that "plan of care" could mean general items the patient, home health clinicians, and physician agree the patient will be working on, or, it could mean all the physician orders, medications, etc. Some commenters suggested that HHAs should be required to provide each patient with an abbreviated plan of care, also referred to as a care plan summary, as a distinctive product specifically designed to engage □ patients, their caregivers, and representatives as partners in treatment and care. Commenters suggested the following elements for this product: Patient condition, goals of care and measurable outcomes that the agency and patient have identified, a list of homecare services to be provided, specific training and interventions designed to prevent the need for emergency department care and hospitalization, a visit calendar for each discipline involved in the patient's care, and any other information that is necessary to improve the patient's health.

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Response: We appreciate the many thoughtful comments that were submitted on this subject. We agree with the large majority of commenters that the plan of care (as set forth in § 484.60(a)) is a clinically oriented document that is written in medical terminology and in a manner that may not be comprehensible to the majority of HHA patients. For this reason, we agree that it is not appropriate to require HHAs to routinely provide each patient with a copy of his or her plan of care and we have removed this requirement from the regulation at § 484.50(c). However, HHAs are still required to provide any information contained in the clinical record, including the plan of care, free of charge, upon request from the patient, in accordance with

the requirements of § 484.110(e). While we see the potential benefit of requiring HHAs to prepare and provide a plan of care summary to each patient, and believe that patients should be able to easily access information pertinent to their care, we do not believe that the significant burden that would be imposed with such a requirement is justified at this time. Currently many HHAs do not possess the technology, such as electronic medical records with secure patient portals, to make implementation of a plan of care summary requirement feasible. We will consider a plan of care summary requirement in the future based on the evolving use of technology in the HHA environment. While the plan of care described in this rule is focused on services delivered by the HHA, we also note that the concept of a “plan of care” continues to evolve, and future “plans of care” are likely to be more comprehensive documents that reflect the care patients receive across settings. As plans of care become more comprehensive, the importance of ensuring patients have access to this document will also increase. It is important to note that HHAs are still required to involve patients in the actual development and updating of the plan of care as required by § 484.50(c) and § 484.60(c).

In addition, in response to comments requesting that CMS require that written clinical and educational information be made available to HHA patients and caregivers, we have added a new standard at § 484.60(e), “Written information to the patient.” The new provision, which partially replaces other requirements previously placed elsewhere, requires the HHA to provide written instructions to the patient and care giver outlining visit schedule including frequency of visits, medication schedule/instructions, treatments administered by HHA personnel and personnel acting on the behalf of the HHA, pertinent instructions related to patient care and the name and contact information of the HHA clinical manager. We believe that these requirements will ensure that patients are actively engaged in their own care. In addition, HHAs may use any form of communication (for example, typed summaries, checklists, calendars, handwritten notes, secure electronic communications, or orientation videos) to facilitate patient knowledge and understanding of the care being provided. Providing patients and caregivers written instructions that they may refer to between visits is critical to both the quality and safety of patient care.

Comment: Many commenters sought clarification regarding the format for providing a copy of the plan of care to each patient. Specifically, commenters questioned whether the plan of care could be provided via electronic means, such as a secure patient portal. A few commenters suggested that the regulations should only require information to be communicated to patients orally, rather than in written form. Commenters also sought clarification regarding the timing for providing a copy of the plan of care. Commenters questioned whether the plan of care needed to be signed by the physician before being provided to the patient. Commenters also stated that requiring that patients be immediately provided with a hard copy of their plan of care would be extremely difficult in the current system of electronic medical record (EMR) reliance, and urged that HHAs be allowed to mail a copy of the plan of care within 24 hours of any actions that necessitate the copy to be shared. Commenters also suggested that HHAs be permitted to deliver the copy of the plan of care either to the patient or to the patient's representative. Numerous commenters requested additional information about the proposed requirement to provide each updated version of the plan of care to each patient. Commenters questioned whether updates could be delivered electronically by email or other secure electronic means to the patient or to the patient's representative. Other commenters sought clarification about the types of updates that would be required to be communicated to patients. Specifically, one commenter stated that in the preamble to the proposed rule, we explained that an HHA would need to notify a patient when the individualized plan of care is updated due to a significant change in the patient's health status. However, the text of the proposed regulation did not include the word “significant,” making it appear as if slight changes in patient status that result in tweaks to the plan would require notice. The commenter stated that we should include the word “significant” in the final regulation.

Commenters offered suggestions regarding changes that would be significant, such as a change in therapy from physical to occupational therapy, with new caregivers coming to the home, or a change in medication, versus changes that would not, in the commenter's opinion, be significant, such as a change in visit frequencies or a change in medication dose. Commenters also requested flexibility in the format for providing notice, such as providing updates to the plan of care orally, with a notation in the patient's clinical record to document this oral communication. In addition to providing oral communication of changes to the plan of care, one commenter suggested that, if the change of plan of care involves teaching the patient skills to improve their medical treatment, the HHA should provide written information, such as flyers, that would help the patient remember and follow what they were taught. Another commenter suggested that HHAs should be required to manually update the copy of the first plan of care whenever there is a change or new order, and then furnish a clean, current copy of the plan of care upon request by the patient or representative, or whenever it is apparent that the patient's copy is missing, incomplete, inconsistent, or difficult to clearly read or follow.

Response: For the reasons set forth above, as well as in light of the many logistical concerns raised by commenters, we have revised the regulation at § 484.50(c) to remove the requirement that HHAs must routinely provide a copy of the plan of care to each patient. HHAs must involve patients in the development and updating of the plan of care to the degree that a patient chooses to be involved in this process. HHAs are permitted to use any form of communication (for example, typed summaries, checklists, calendars, handwritten notes, secure electronic communications, or orientation videos) to facilitate patient knowledge and understanding of the care being provided.

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Comment: A few commenters expressed concern regarding the information security of leaving a copy of a patient's plan of care in the home. The commenters were concerned that potentially sensitive information, such as substance use-related diagnoses, may be included on the plan of care, and potentially disclosed in the act of leaving a copy of the plan of care in the patient's home. A commenter also stated that it would be burdensome to require HHAs to educate patients and caregivers regarding the proper handling of sensitive information. The commenter stated that patients and caregivers, not HHAs, are in the best position to determine where this information should be kept and who sees it.

Response: We appreciate the thoughtful comments regarding sensitive patient information. For the reasons set forth above, we have revised the regulation at § 484.50(c) to remove the requirement that HHAs must routinely provide a copy of the plan of care to each patient. HHA patients retain the right to request a copy of any information contained in the patient's clinical record, including the plan of care. It is the HHA's responsibility to ensure proper and appropriate education is provided to the patient regarding protecting their own healthcare information. We do not agree that patient education regarding protection of the plan of care is any different than the patient education that is already provided regarding protection of other information that HHAs routinely leave in the patient's home (for example, aide visit calendars and patient rights information); therefore there would not be an additional burden for this activity. Rather, it is part of the cost of doing business. Teaching patients to secure their personal healthcare information is basic information that can be shared when giving the HHA contact information, policies and procedures and plan of care in the initial phase of care. Patients and their representatives have the ultimate responsibility to decide how and where information will be kept in the home.

Comment: Many commenters were concerned with the burden that would be placed upon HHAs in providing each patient with a copy of his or her plan of care, as well as updates to that plan of care.

Response: For the reasons set forth above, as well as in light of the many logistical and burden-related concerns raised by commenters, we have revised the regulation at § 484.50(c) to remove the requirement that HHAs must routinely provide a copy of the plan of care to each patient.

Comment: A few commenters asked for clarification about providing a copy of the plan of care in relation to the requirement to communicate with patients in a manner that they understand. Specifically, commenters wanted to know whether the plan of care would need to be provided in the language the patient is most comfortable with, whether it would need to be understood at a 6th grade level, and whether it would need to be provided in a format that accommodates individuals with disabilities.

Response: For the reasons set forth above, as well as in light of the many logistical concerns raised by commenters, we have revised the regulation at § 484.50(c) to remove the requirement that HHAs must routinely provide a copy of the plan of care to each patient. HHAs are permitted to use any form of communication (including, but not limited to, typed summaries, checklists, calendars, handwritten notes, secure electronic communications, and orientation videos) to facilitate patient knowledge and understanding of the care being provided. Should an HHA provide a written document to a patient, we would expect that document to be understandable to the patient in accordance with the requirements of § 484.50(f). As clarified above, the term “understandable” means that patients achieve a grasp of the explanation of something and not necessarily a verbatim written translation. We expect HHAs to utilize technology, such as telephonic interpreting services and any other available resources for timely oral communication in the patient's primary or preferred language.

Comment: While some commenters agreed with the proposed requirement that a patient would have the right to participate in establishing the goals of care, other commenters identified some concerns with this concept. Commenters observed that patients may not understand the concept of establishing measurable goals of care, may have unrealistic goals, or may have goals that are inconsistent with other goals of care. One commenter requested guidance on how to comply with this proposed requirement when the patient-identified goals are unclear or unrealistic, while another commenter suggested that in these cases an HHA should document the reason that the patient's goal cannot or should not be accommodated.

Response: We appreciate the thoughtful comments. Regardless of whether a patient can verbalize their goals, all patients have goals even if it is as basic as feeling better today than they did yesterday. It is part of the HHA's responsibility to help patients form and shape achievable goals that are relevant to the delivery of the HHA care they receive. There may be times when a patient's goal may be contrary to the HHA healthcare goals. For example, a patient may wish to walk outside unattended, but if the patient has serious cognitive impairment, they may be at risk for wandering. We believe the HHA is capable of discussing realistic goals with their patients and documenting why a specific goal may not be appropriate. As part of the re-directing process with the patient, the HHA is able to identify more appropriate goals that are achievable.

Comment: A few commenters sought clarification regarding the proposed patient right to refuse services. Commenters sought to understand the scope of this right, asking questions such as whether this right is meant to cover minor situations, such as refusing to have their hair washed on a particular day because of feeling ill, or more significant refusals such as the refusal of all services. Commenters stated that, if a patient's refusal relates to a significant part of the recommended care, the home health agency is faced with determining whether continued home care is reasonable and necessary for claims billing purposes or whether the home health patient should be discharged. Commenters stated that further guidance in this area would be appreciated.

Response: Patients have always had the right to refuse services. Although this is the first time that we are including such a right within the regulations, it is not a new concept. We expect HHAs to already have policies and procedures in place to address these situations. If a patient refuses something minor, such as declining a bath due to fatigue that day, we would expect the HHA to document this in the clinical record. If the patient or patient representative refuses large aspects of care (such as dressing changes or essential medications), then the HHA has the responsibility to document this in the clinical record and communicate with the patient regarding implications of the refusal. The HHA would also need to communicate with the physician(s) responsible for the plan of care regarding the refusal of one or more large aspects of care that have the potential to compromise the HHA's ability to safely and effectively deliver care to the extent that the HHA can no longer meet the patient's needs, and discuss the options with the physician(s). The HHA may need to consider discharge if the patient's refusal of services compromises the HHA's ability to safely and effectively deliver care to the extent that that the HHA can no longer meet the patient's needs. We would expect HHAs to advise the patient, the representative (if any), the physician(s) responsible for issuing orders related to the element(s) of the plan of care that are refused, 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 is being considered. HHAs should also provide the patient and representative (if any) with contact information for other agencies or providers who may be able to provide care in a manner that is consistent with the patient's preferences.

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Comment: A commenter suggested that the regulation should clearly state that representatives and caregivers have a right to be involved in establishing the goals of care and care preferences.

Response: This is an enumeration of the patient's rights. Legal representatives with health care decision making authority make decisions on behalf of the patient, and would therefore already have the right to establish the goals of care and care preferences on the patient's behalf. Additionally, if a patient has authorized a patient-selected representative to make decisions on his or her behalf, this individual would have the authority to establish the goals of care and care preferences. We believe that these flexibilities are sufficient to assure that representatives are able to represent the interests of patients. As an enumeration of the rights of the patient, we do not believe that it would be appropriate to set forth the distinct rights of the caregiver. It is a best practice for HHAs to take caregiver goals and preferences into account, but it is not a regulatory requirement.

Comment: A few commenters questioned the need for regulations that would enforce a patient's right to receive all of the services included in the plan of care. Additionally, a commenter expressed concern with this requirement in relation to specific service coverage limitations that may be imposed by payment sources.

Response: We believe it is absolutely necessary to include in regulations the right for the patient to receive all services outlined in the plan of care. Since HHAs and physicians are responsible for the items and services included in the plan of care, we presume they will only include those items and services that are covered by the patient's payment source or that the patient is willing to pay for.

Comment: A commenter suggested that HHAs should not be required to inform patients regarding the health hotline and patient liability for payment.

Response: These are statutory requirements for HHAs set forth at 1891(a)(1)(G) and (E), respectively, of the Act. Thus, it is appropriate and necessary to include these requirements in the HHA regulations.

Comment: Many commenters requested clarification regarding the proposed requirement that an HHA include contact information for local federally-funded and state-funded consumer information, protection, and advocacy agencies. Many of these commenters requested flexibility to determine, based on their patient population, which organizations would be most appropriate to meet this requirement. Commenters also stated that HHAs should not be required to assure that this list is exhaustive. Other commenters suggested that CMS should provide a set list of agencies to be included in the notice that is provided to patients. A commenter suggested that any organizations or agencies that are included on any list should be capable of substantive initial and follow-up services. Another commenter suggested that the list should include the local Center for Independent Living, transportation broker, and housing authority. Some commenters noted potential difficulties with this requirement, stating that it could be difficult to maintain the list as organizations and agencies continue and discontinue operations, relocate, etc. A commenter suggested that HHAs should be required to prepare and update the list annually. Furthermore, commenters noted that a universal list may not meet the needs of different patient populations. Commenters also stated that not all communities may be able to provide these types of services. Still other commenters stated that the requirement was unnecessary because nurses and social workers are available in HHAs to direct patients to the resources that suit their needs. Instead, commenters suggested that CMS should require that HHAs maintain accurate and up-to-date lists of local, state, and federal support and services agencies available to agency patients in the area where they reside.

Response: We agree that HHAs should have flexibility to include, at their discretion, those national, state and local resources that would appropriately meet the needs of their patient population. At the same time, we also agree that there needs to be a minimum set list of organizations and entities that all patients will receive. Therefore, we are finalizing a requirement at § 484.50(c) that an HHA must provide the names, addresses, and telephone numbers for the regional Agency on Aging (defined in section 102 of the Older Americans Act of 1965 (42 U.S.C. 3002 (<https://api.fdsys.gov/link?collection=uscode&title=42&year=mostrecent§ion=3002&type=usc&link-type=html>)), http://aoa.acl.gov/AoA_Programs/OAA/How_To_Find/Agencies/find_agencies.aspx (http://aoa.acl.gov/AoA_Programs/OAA/How_To_Find/Agencies/find_agencies.aspx)), Center for Independent Living (as defined in section 702 of the Rehabilitation Act of 1973 (29 U.S.C. 796 (<https://api.fdsys.gov/link?collection=uscode&title=29&year=mostrecent§ion=796&type=usc&link-type=html>))a), <http://www.ilru.org/projects/cil-net/cil-center-and-association-directory> (<http://www.ilru.org/projects/cil-net/cil-center-and-association-directory>)), Protection and Advocacy Agency (<http://www.ndrn.org/en/ndrn-member-agencies.html> (<http://www.ndrn.org/en/ndrn-member-agencies.html>)), Aging and Disability Resource Center (as defined in section 102 of the Older Americans Act of 1965 (42 U.S.C. 3002 (<https://api.fdsys.gov/link?collection=uscode&title=42&year=mostrecent§ion=3002&type=usc&link-type=html>)), <http://www.adrc-tae.acl.gov/tiki-index.php?page=ADRCLocator> (<http://www.adrc-tae.acl.gov/tiki-index.php?page=ADRCLocator>)), and Quality Improvement Organization (as set forth at sections 1152 through 1154 of the Social Security Act, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/index.html?redirect=/QualityImprovementOrgs/> (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/index.html?redirect=/QualityImprovementOrgs/>)) that serves the area where the patient resides. These federally- and state-funded community-based services and organizations provide care for patients who are returning home or who want to avoid institutionalization entities, and are required by federal statute to help connect individuals to community services and supports. HHAs that choose to provide the names, addresses, and telephone numbers of additional organizations and

entities may find the Eldercare Locator at <http://eldercare.gov/Eldercare.NET/Public/Index.aspx> (<http://eldercare.gov/Eldercare.NET/Public/Index.aspx>) to be useful, both as a reference for HHAs and as a reference to be provided to patients and their representatives.

Comment: A commenter stated that patients should be counseled on their right to access auxiliary aids and language services, and how to access those services.

Response: Section 484.50(c)(12) of the final rule states that patients have the right to be informed of the right to access auxiliary aids and language services, and of how to access these services. We believe that this information would be included in the written notice of patient rights that is understandable to the patient. Additionally, HHAs are required to orally discuss the content of the notice of rights, and we believe that this oral discussion is sufficient to meet patient needs.

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Comment: Some commenters requested clarification regarding the proposed requirement that an HHA provide a patient with information regarding the HHA's admission, transfer, and discharge policies. Specifically, commenters wanted to know whether the proposed requirement means that the policies must be provided to the patient, or that the HHA must notify the patient that such policies exist and are available upon request. Commenters also wanted to know if this information would be required to be provided orally or in writing. Finally, commenters requested clarification regarding how this requirement would be enforced in the survey process.

Response: HHAs are required to provide physical or electronic documents for the patient's keeping that outline the acceptable reasons for discharge or transfer, as set forth in 42 CFR 484.50 (/select-citation/2017/01/13/42-CFR-484.50)(d)(1) through (7). We agree that disclosure of admission policies is not necessary as the patient would already be admitted to the HHA before any such disclosure would take place, rendering the disclosure unnecessary. Therefore, we have revised the regulation at § 484.50(d) to clarify that only those discharge policies set forth in this rule need to be included in the notice. We expect that verification of distribution of this notice would be incorporated into a home visit made by a state surveyor.

Comment: A commenter suggested that we should add the following requirement to the patient rights CoP: An HHA must ensure that a patient is transferred or discharged to a setting in which he or she will receive the level and type of care needed and make every effort to honor a patient's preferences and choices. A transfer or discharge may not occur until care in an appropriate setting is obtained. The HHA must provide sufficient preparation and orientation to patients to provide for a safe and orderly transfer or discharge from the HHA.

Response: HHAs have the responsibility of coordinating the discharge and transfer plan to the greatest degree possible to assure a smooth transition in accordance with patient preferences. We agree that proper planning and thorough patient preparation is an important part of a smooth transfer and discharge process. The patient, representative, caregivers, follow-up care practitioner, etc. are required to be informed of changes to the transfer or discharge plans in accordance with the requirements of § 484.60(c)(3)(ii), and we believe this would be an appropriate time for HHAs to prepare patients for a transfer and discharge. However, we note that HHAs cannot control the availability and quality of post-discharge or post-transfer care and should not be held responsible for those elements that are beyond their control.

Comment: A few commenters submitted comments related to patient involvement in the discharge or transfer process. Some commenters suggested that the HHA should be required to provide written notice of potential discharge or transfer to the patient, as well as the caregiver or representative (as appropriate), at

least 30 days in advance of discharge or transfer. Furthermore, a commenter suggested that the written notice should be required to include the following:

- The reason for transfer or discharge;
- The effective date of transfer or discharge;
- The location to which the patient will be transferred or discharged;
- A statement that the patient has the right to appeal the HHA's decision to transfer or discharge him or her; and
- The address and telephone number of any agency/program that can represent the patient at a hearing, including but not limited to, the local office of the Legal Services Corporation; the state protection and advocacy system; and the local long-term care ombudsman if the state long-term care ombudsman program is authorized to serve home care clients.

Additionally, a commenter suggested that HHAs should be required to notify the State Survey Agency and Medicare contractor of its intention to discharge for cause. Another commenter requested clarification regarding whether patient consent is required for transfer. A commenter suggested that the regulation should include a specific process for patients to follow if they disagree with the HHA's decision to discharge or transfer.

Response: We believe the commenters' concerns are sufficiently addressed by § 484.60(c)(3)(ii), which requires that any revisions related to plans for the patient's discharge must be communicated to the patient, representative, and caregiver(s). This is sufficient to assure appropriate communications between the HHA and the patient, representative, and caregiver(s) regarding transfer or discharge plans. Specifically, we do not believe a thirty day notice of transfer or discharge is a practical requirement for HHAs at this time. HHA discharges can occur in much shorter timeframes for a variety of unavoidable reasons ranging from a patient's decision to transfer to another HHA to a patient's transfer to an acute care provider to a situation in which HHA personnel are unable to deliver care due to an unsafe home environment.

Comment: A few commenters suggested additional circumstances under which HHAs should be permitted to discharge a patient. The commenters suggested the following additions:

- The HHA experiences a staffing change (unexpected staffing shortage); and
- The coverage requirements (that is, the face-to-face encounter) have not been met.

Response: We do not agree that staffing changes would be an appropriate reason for patient discharge. HHAs are responsible for assuring adequate staffing at all times to consistently meet the needs of all patients under their care. Likewise, we do not agree that it is necessary to add a reason for discharge specifically related to coverage requirements. In the event that coverage requirements are not met, an HHA would be permitted to discharge a patient because the patient or payer will no longer pay for the care (§ 484.50(d)(2)). We believe that situations where an HHA patient does not meet Medicare coverage requirements due to a failure to complete the face-to-face encounter requirements should be exceptionally rare, as we have made considerable efforts to streamline the requirements related to the face-to-face encounter coverage requirement and there is ample time (a 120 day period) to complete this coverage requirement. We expect HHAs to facilitate and coordinate efforts of the patient and physician to ensure that the face-to-face encounter occurs timely. In the case where the face-to-face encounter requirement is not met, an HHA cannot hold a patient financially liable for services provided. Failure to meet a condition for payment is not one of the criteria where an HHA can hold a patient financially liable. Once a patient is admitted, an HHA

cannot abruptly discharge a patient unless the patient is properly notified and there is a valid reason for discharge. Ideally, a face-to-face encounter, as part of the □ certification process, would occur before the patient received services.

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Comment: A few commenters made suggestions regarding the entities to which patients are discharged. One commenter suggested that, in addition to requiring an HHA to discharge a patient to a suitable source of care, the regulation should also address situations where the patient refuses further placement or care from another entity. The commenter stated that patients have the right to refuse follow-up services. Another commenter suggested that HHAs should not be required to “ensure” a safe and appropriate transfer to another care entity because HHAs are not in control of other healthcare providers and cannot guarantee that another agency will take a patient under care.

Response: We appreciate these comments. All HHAs are required to ensure that appropriate arrangements for transfer are made for those patients whose acute care needs cannot be met by the HHA, and we have revised the final regulation at § 484.50(d)(1) to clarify this responsibility. The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113-185 (<https://api.fdsys.gov/link?collection=plaw&congress=113&lawtype=public&lawnum=185&link-type=html>)) requires HHAs to take into account patient goals and preferences in discharge and transfer planning. On November 3, 2015, we published a proposed rule, “Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies” (80 FR 68126 (/citation/80-FR-68126)), that would implement this section of the IMPACT Act. The HHA patient has the right to refuse a transfer to any provider or supplier, and the HHA would be expected to document the refusal and communicate with the patient and representative/care giver to help meet their healthcare needs to the best of the HHA's ability.

Comment: A commenter disagreed with the proposed regulation that an HHA would be permitted to discharge a patient when the patient or payer will no longer pay for the services provided by the HHA. The commenter stated that this regulation would conflict with the regulation in one state. Another commenter suggested that the regulation should be clarified with regard to what it means for a patient to no longer pay for services. Specifically, the commenter stated that discharge for non-payment should not be allowed in situations when a patient has submitted to a third party payer the paperwork necessary for the bill to be paid, and the bill is still pending.

Response: For those instances where state and federal laws overlap, the stricter regulation would prevail. For example, if a state regulation did not allow HHAs to discharge a patient due to a lack of payment, then the HHA would have to comply with state law, since state law prohibits discharge while federal regulations permit it. We agree that a discharge for non-payment is not to be considered until all payment source options have been fully explored and payment from a third party is no longer considered pending.

Comment: Some commenters opposed the proposal that an HHA be permitted to discharge a patient when the physician and HHA agreed that the patient no longer needed HHA services because the patient's health and safety had improved or stabilized sufficiently. The commenters stated that this regulation would, in certain cases, violate Medicare coverage law and regulations, as well as the settlement agreement in *Jimmo v. Sebelius* (see *Jimmo et al. v. Sebelius, D.Vt, No. 11-cv-17, October 25, 2011, 2011 WL 5104355*).

Response: The proposed rule stated that discharge or transfer would be permitted if it is appropriate because the patient's health and safety have improved or stabilized sufficiently, and the HHA and the physician who is responsible for the home health plan of care agree that the patient no longer needs the HHA's services. Our

intent was that, if the physician responsible for issuing orders related to the reason that HHA care was initiated and the HHA both agree that a patient has achieved the goals set forth in the plan of care (see § 484.60(a)(2)(xiv)), then discharge would be appropriate because the goals of care have been achieved. We have clarified this original intent in the regulation to assure that it is appropriately implemented. If the patient disagrees with a discharge or transfer, he or she has the right to appeal the decision. As set forth in § 484.50(c)(8), each patient has the right to 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 (/select-citation/2017/01/13/42-CFR-405.1200) through 405.1204. This written notice includes information related to patient appeals. Finally, the *Jimmo* settlement agreement pertains only to guidance, not to regulations, and does not prevent implementation of new regulations.

Comment: A few commenters submitted suggestions to clarify the proposed discharge requirements for situations when patients refuse HHA services. One commenter noted that there are various degrees of which a patient may refuse services. For example, a patient may refuse an IV antibiotic, but accept therapy services in lieu of such treatment. The commenter suggested that only a refusal of all HHA services would warrant discharge. Other commenters suggested that it is not the refusal of services in and of itself that would necessitate a discharge. Rather, it is the effect of that refusal that may make discharge appropriate. These commenters stated that HHAs should be allowed to discharge or transfer a patient at any time when the refusal of services or the refusal to follow the agreed upon plan of care results in the HHA being unable to effectively deliver care.

Response: As stated previously, patients have the right to decline services. If a patient declines something minor, such as declining a bath due to fatigue that day, we would expect the HHA to document this in the clinical record. If the patient or patient representative declines large aspects of care (such as dressing changes or essential medications) then the HHA has the responsibility to document this in the clinical record and communicate with the patient regarding implications of the decline. We would expect HHAs to explore alternative options for providing care that is both consistent with patient preferences that continues to meet the patient specific needs as identified in the comprehensive assessment, and the measurable outcomes and goals identified by the HHA and the patient. The HHA would also need to communicate with the physician regarding the decline of services that have the potential to compromise the HHA's ability to safely and effectively deliver care to the extent that that the HHA can no longer meet the patient's needs, and discuss the options. The HHA may consider discharge if the patient's decline of services compromises the HHA's ability to safely and effectively deliver care to the extent that that the HHA can no longer meet the patient's needs. We would expect HHAs to advise the patient, the representative (if any), the physician(s) issuing orders for the home health plan of care, and the patient's follow-up care professional (if any) that a discharge is being considered because the HHA can no longer meet the patient's needs. HHAs should also provide the patient and representative (if any) with contact information for other agencies or providers who may be able to provide care following discharge from the HHA.□

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Comment: Many commenters stated that HHAs should be explicitly permitted to discharge a patient for cause if the safety of the HHA's staff is threatened. In such situations, commenters suggested that reporting the danger to the proper authorities, such as law enforcement, protective services, etc., should suffice for documentation of the significant safety hazard that warranted a discharge. Other commenters suggested a broader list of reasons related to staff well-being that they believed would warrant discharging a patient from

services, such as sexual harassment or verbal abuse. A commenter also suggested that, if a patient is discharged for reasons related to HHA staff safety and well-being, the HHA should be permitted to conduct the discharge process via alternative means, such as by phone, mail or electronic communication.

Response: The proposed regulation text states that if “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,” then the HHA may discharge the patient after following certain intermediary steps to attempt to resolve the issue(s). We believe this requirement already includes situations where the HHA's staff feels threatened, as such situations would seriously impair the HHA's ability to operate effectively in the delivery of care. We also believe the proposed requirement for documenting the problem and efforts made to resolve the problem will be sufficient for documentation purposes. If HHA staff felt that re-entry to the patient's residence was unsafe for them, the discharge process could be handled by way of an alternative method (for example, phone or electronic mail) rather than face-to-face communication.

Comment: While many commenters suggested that HHAs should be permitted to discharge patients for cause at the discretion of the HHA, without any regulatory limitations, other commenters strongly opposed the concept of discharge for cause in its entirety, suggesting that a discharge for cause provision would be used to “dump” patients (or patients who have caregivers) who they could claim were being “difficult.”

Response: While we acknowledge that the discharge for cause provision may be subject to misuse in rare cases, we do not believe that the potential for abuse is appropriately counteracted by the complete removal of all discharge for cause options. Likewise, while we acknowledge that the discharge for cause provisions impose significant limits upon an HHA's ability to discharge patients who may be perceived as being “difficult,” we believe that these restrictions are essential in order to minimize the potential for inappropriate discharges. As part of the survey monitoring process, HHA's may be asked if there have been patients who have been discharged for cause. The surveyor may also request the patient(s) record as part of the clinical record review process during the survey. We believe that this type of monitoring may mitigate potential negative behaviors in an HHA.

Comment: A commenter opposed a statement in the preamble of the proposed rule that “it would be incumbent upon the HHA to take all reasonable steps to resolve safety and noncompliance issues prior to taking steps to discharge a patient.” The commenter stated that the word “all” is overly broad and implies that corrective action is entirely up to the agency.

Response: It appears that the intent of the statement was misunderstood. Rather than requiring that “all” steps be taken, this statement was intended to convey the message that “all reasonable” steps must be taken prior to discharging a patient for cause. HHAs would be expected to take every reasonable step that is available to them in order to resolve the issue(s) at hand prior to initiating a discharge for cause.

Comment: A few commenters requested clarification regarding the proposed requirement that HHAs investigate injuries of unknown source. Commenters sought guidance on how and to what extent HHAs should conduct such investigations. The commenters noted that patients are in the presence of HHA personnel for a very limited amount of time, and that HHAs should not be held responsible for minor injuries that occur in the course of everyday life, such as bruises and cuts.

Response: We appreciate the commenters' views and the opportunity to clarify the parameters an HHA should use when investigating an injury of an unknown source. An injury should be classified as an "injury of unknown source" when both of the following conditions are met: (1) The source of the injury was not observed by any person or the source of the injury could not be explained by the patient; and (2) The injury is suspicious because of the extent of the injury, or the location of the injury (for example, the injury is located in an area not generally vulnerable to trauma), or the number of injuries observed at one particular point in time, or the recurring incidence of injuries over time. The type, extent, process, and personnel involved for investigations would be left to the discretion of the HHA. HHAs are responsible for asking the questions necessary to determine whether minor injuries are indicative of more significant concerns. Furthermore, HHAs are responsible for complying with applicable state-specific reporting laws, in accordance with the requirements of § 484.50(e)(2).

Comment: While several commenters expressed strong support for the proposed requirement to investigate patient complaints regarding potential violations of patient rights, several other commenters offered suggested revisions to this requirement. While one commenter stated that CMS should recognize that investigations necessarily must vary in terms of intensity and duration, depending on the complaint alleged, and as such, any required investigation process should be flexible enough to allow for calibration to the circumstances, other commenters disagreed with the open-ended manner in which the standard was written, calling it "too vague." Some commenters sought specific parameters for what constitutes appropriate reporting and documentation. Others suggested that the regulation should include examples of authorities to whom patient rights violations should be reported, such as adult protective services, law enforcement, and the state licensure agency. Additionally, others suggested that the regulation should identify and delineate complaints into different categories by level of severity, and implement a clear process for investigation for each different level. Still another commenter suggested that we should create a robust and detailed complaint investigation standard that requires the following:

- HHAs must have a complaint process, complete with policies and procedures, that is provided, in writing, to the patient, the patient's representative, and the patient's caregivers at the time of admission and each time the plan of care is updated.
- HHAs must provide a written report to the patient, documenting the findings of the investigation and resolution of the complaint within 14 calendar days of its receipt.
- If the patient is not satisfied with the HHA's response, the patient should be permitted to request another review, and the HHA would be responsible for responding, in writing, within 30 days from the date it received the patient's request for review.
- The HHA's response to this second review would be required to include the

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telephone number and address of all agencies and programs with which a complaint may be filed, and the telephone number of the state home health hotline.

Response: We believe the proposed general language establishing an expectation for patient complaint investigation and reporting, without specifying details, is the most appropriate regulatory approach given the wide variety of situations that HHAs will likely encounter. We agree that HHAs will experience varying levels of intensity and duration when investigating patient complaints. These investigation and reporting suggestions from the commenters are all appropriate elements for HHAs to include in their internal policies and procedures for implementing this general requirement.

Comment: A few commenters sought clarification on the relationship between the proposed patient rights violation reporting requirements and existing state laws and regulations. One commenter stated that its state law requires HHAs, rather than HHA staff, to report misappropriation of patient property. Another commenter suggested that the reporting requirement should be qualified by the phrase “in accordance with state law” to assure that reporting meets current state requirements. A commenter also suggested that any HHA staff member 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, should be required to report said incidences or circumstances directly to law enforcement, in addition to reporting to the HHA management.

Response: We agree with the commenter that reporting should occur in accordance with state law, and have amended the regulations at § 484.50(e) to include this requirement. We note that, where these federal requirements are more stringent, HHAs are expected to comply with the more stringent federal requirement. We believe allowing each HHA to establish its own policies and precise chain of command for reporting incidents will give them the flexibility to meet the various levels of incidents and behavior, and to respond appropriately.

Comment: A commenter suggested that the regulation should state that a patient complaint may not be investigated by any HHA staff involved in the complaint.

Response: We agree that this is the appropriate policy for all HHAs, and would expect HHAs to exercise appropriate discretion in their investigations. However, we do not believe that this needs to be incorporated into the regulatory text, which establishes the broad goals for investigations rather than the specific mechanisms for them.

Comment: A commenter suggested that the regulation should clarify that complaints by a patient, representative, or caregiver may include, but are not limited to, complaints regarding treatment or care that is (or fails to be) furnished, is furnished inconsistently, or is furnished inappropriately. Another commenter suggested that the regulation should state that the patient has the right to make complaints “without discrimination, retaliation or fear of retaliation to the HHA and the state survey and certification agency.”

Response: We agree that the topics set forth in the proposed rule are not the only issues that a patient may make complaints about, and have revised regulatory text at § 484.50(e) accordingly. We also agree that patients have the right to exercise their right to complain without discrimination, retaliation or fear of retaliation. This concept is reflected in § 484.50(c)(11), which states that the patient has the right to be free from any discrimination or reprisal for exercising his or her rights or for voicing grievances to the HHA or an outside entity. This would include the right set forth in § 484.50(c)(3) to “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.”

Comment: A commenter suggested that the regulation should specifically state that an HHA must take action to prevent further potential violations, including retaliation, while the complaint is being investigated.

Response: We agree that HHAs should take all appropriate steps to prevent retaliation, and have incorporated this requirement into the regulatory text at § 484.50(e)(1)(iii).

Comment: A few commenters expressed concern regarding the proposed requirement to provide auxiliary aids to patients for the purpose of facilitating communication, citing the potentially large expense of certain auxiliary aids. Commenters stated that HHAs should be expected to make efforts to facilitate acquisition of auxiliary aids for patients, but not be required to provide more expensive equipment directly. Commenters also sought clarification of the proposed requirement to provide patient rights information in alternate formats. Specifically, the commenters stated that the term “alternate formats” is unclear.

Response: The provisions of the Americans with Disabilities Act and Section 504 of the Rehabilitation Act require facilities to provide equal access to individuals with disabilities. If the provision of auxiliary aids becomes an “undue burden,” the HHA may seek protection that is available under section 504 of the Rehabilitation Act. As we noted in the preamble of the proposed regulation, the alternate formats expectation includes, but is not limited to, the provision of qualified interpreters, large print documents, Braille, digital versions of documents, and audio recording.

Comment: Several commenters made suggestions regarding ways that CMS and HHAs could address the issue of health disparities. Comments ranged from providing a standardized notice of patient rights in multiple languages to requiring HHAs to employ personnel who are similar in age, gender, and background to the HHA's patient population to formulating a CMS-wide response to the results of the vulnerable care study mandated by the Affordable Care Act.

Response: We appreciate these suggestions that commenters submitted; however, they are beyond the scope of this rule. We will retain these suggestions for future consideration.

COMPREHENSIVE ASSESSMENT OF PATIENTS

Comment: A commenter stated that the requirement for each patient to have an initial and comprehensive assessment should only apply to those patients who are receiving skilled care. Another commenter asked whether the proposed content elements of the comprehensive assessment applied to patients from all payer sources, or only to a subset of patients with certain specified payer sources, such as Medicare and Medicaid.

Response: We do not believe that limiting the assessment requirements solely to those patients set to receive skilled care services or to those patients who have Medicare or Medicaid as a payment source would be in the best interest of patients. The patient assessment is designed to identify patient needs, and all patients will have needs to be assessed. Therefore we are maintaining the requirement that all patients must be assessed; otherwise they would not be receiving HHA services in the first place.

Comment: The majority of commenters who submitted comments on this section made suggestions regarding the professionals who are permitted to complete the initial and comprehensive patient assessments under various circumstances. Suggestions included allowing a therapy discipline to complete the assessments as long as that therapy is ordered, and allowing therapists to complete all assessments in all situations to allowing occupational therapists to complete the assessments in therapy-only, but not necessarily occupational therapy-only, situations.

Response: The suggestions made by commenters go far beyond our original intent to maintain the long-standing requirements that was proposed in the October 2014 rule. Since this would be a significant change to what was originally proposed, we believe that the most appropriate course of action would be to address this issue in separate notice and comment rulemaking at a future date. Therefore, we are finalizing the proposed requirements, which is a continuation of longstanding CMS policy.

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Comment: A commenter stated that the 5 day time frame within which HHAs must complete the comprehensive assessment may not be sufficient to capture the full extent of some of these proposed factors in the comprehensive assessment, such as psychosocial and cognitive status, for certain patients. The commenter stated that this is due, in part, to the nature of certain conditions—especially psychosocial conditions—and, in part, to the focus on stabilization that consumes much of the initial visit(s). The commenter recommended that CMS should acknowledge this limitation, and should provide for additional time to complete the comprehensive assessment in limited, necessary circumstances.

Response: We do not agree that a period of greater than 5 days is necessary to gather information regarding all elements of the patient assessment. HHAs are already accustomed to completing the current assessment requirements within 5 days, and there is no evidence that patient care has suffered because of the failure of additional conditions to manifest themselves within that timeframe. While we acknowledge that this rule will expand the content of the assessment, such expansion is in keeping with current best practices and can be incorporated into HHA assessment timelines without undue burden. We note that hospice care providers, who operate under similar conditions, and who are also required to complete a patient assessment of very similar content, have developed ways to successfully assess things such as psychosocial condition within the same 5 day period as we are finalizing in this rule. Given the success of another very similar provider type in meeting this timeline, we believe that it is appropriate to maintain the 5 day timeline for HHAs. The 5 day timeline to complete the comprehensive assessment begins upon the physician ordered start of care date. If an HHA is unable to begin care on that date for any reason, we would expect the HHA to decline the referral because it is unable to meet the patient's needs in a timely manner. It is not acceptable for an HHA to seek a new referral with a new start of care date that is more convenient for the HHA.

Comment: Several commenters expressed support for the proposed requirement that, when 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 occupational therapist. The commenters interpreted this requirement to mean that occupational therapy is now permitted to establish eligibility for the Medicare home health benefit.

Response: We appreciate the commenters' support. However, we did not propose to change the requirements for establishing eligibility for the Medicare home health benefit. Rather, we proposed that if occupational therapy established eligibility, which may occur for a non-Medicare home health benefit such as private insurance or for a subsequent episode of home health care when the continuing need for occupational therapy establishes Medicare eligibility for the home health benefit, then the occupational therapist may perform the assessment.

Comment: A commenter noted that the new requirements related to the content of the comprehensive assessment will require revisions to forms and electronic medical records in order to assure that all information is documented appropriately.

Response: Neither the proposed rule nor the final rule mandate the use of a specific assessment form or electronic medical records (EMRs), which may also be referred to as electronic health records (EHRs). The extent to which HHAs choose to revise their forms or EMRs is entirely left to their discretion.

Comment: A commenter suggested that information about caregivers should be gathered as part of the comprehensive assessment. The commenter noted that oftentimes caregivers play a significant role in care delivery, as indicated by the proposed rule's inclusion of specific requirements related to caregiver education and training. Given their important role in care delivery, the commenter suggested that the patient

assessment should include the following additional elements: caregiver willingness and ability to provide care; caregiver availability and schedules (for example, hours worked outside the home); the caregiver's current level of comfort in carrying out medical/nursing tasks or assisting with activities of daily living; and a brief screen for caregiver strain or depression. The commenter suggested that these elements are necessary in developing an understanding of a caregiver's particular situation in order to best provide appropriate and effective caregiver education and training.

Response: We agree that gathering certain key information about caregivers is essential for effective HHA care planning activities. HHAs cannot develop a schedule for turning a bed-bound patient, for example, without knowing the times when a caregiver would be available to perform the task. Thus, we are adding a requirement in this final rule that, as part of assessing patient caregivers (proposed and finalized at § 484.55(c)(6)), HHAs will be required to gather information regarding caregiver willingness, ability, availability, and schedules. We believe that the concept of “willingness and ability” adequately covers a caregiver's level of comfort in carrying out tasks. We believe that these concepts fit well with the finalized requirement at § 484.60(d)(5) that an HHA must ensure that each patient, and his or her caregiver(s), receive ongoing education and training provided by the HHA, as appropriate, regarding the care and services identified in the plan of care. However, screening for caregiver strain/depression is beyond the scope of HHA services as set forth in the Act. While these screenings are certainly a best practice that we encourage HHAs to incorporate on their own, we do not have the authority to expand the unit of care beyond the patient.

Comment: A commenter recommended that the comprehensive assessment regulation should address the use of standardized tests and measures by home health clinicians. The commenter stated that the use of standardized tests and measures early in an episode of care establishes the baseline status of the patient, assists in the development of the plan of care, and provides a means to quantify change in the patient's functioning. Outcome measures, along with other standardized tests and measures used throughout the episode of care, as part of periodic reexamination, provide information about whether predicted outcomes are being realized.

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Response: We fully support the use of standardized data elements, tools, and measures by HHAs. To that end, the OASIS already provides standardized data elements that HHAs may use to establish the baseline status of the patient, assist in the development of the plan of care, and provide a means to quantify change in the patient's functioning. For those aspects of the patient assessment that are not captured via OASIS data elements, we encourage HHAs to use standardized data elements, tools, and measures that are available from national sources. This may include measurement scales such as the Functional Independence Measure and Functional Assessment Measure (http://www.dementia-assessment.com.au/symptoms/fim_manual.pdf) and the Chedoke-McMaster Stroke Assessment (<http://www.rehabmeasures.org/pdf%20library/cmsa%20manual%20and%20score%20form.pdf>) to name a few.

Comment: While most commenters expressed general support for our proposal to expand the required elements of the comprehensive assessment, several commenters requested additional clarification regarding specific proposed elements of the comprehensive assessment as follows: Psychosocial status, and cognitive status. Specifically, commenters sought more information regarding the extent to which these proposed elements may or may not differ from similar OASIS items (M1700-M1750), the meaning and intent of the term “psychosocial,” and the goals that CMS wants to achieve as a result of requiring an HHA to assess psychosocial and cognitive status.

Response: We appreciate the opportunity to clarify the intent of these requirements. Assessing a patient's psychosocial status refers to an evaluation of his or her mental health, social status, and functional capacity within the community by looking at issues surrounding both a patient's psychological and social condition (for example, education and marital history). This provision is intended to be a screening for potential issues that may complicate or interfere with the delivery of HHA services and the patient's ability to participate in his or her own care. Based on the results of this screening, an HHA may need to make referrals to additional care sources and other outside entities. Assessing a patient's "cognitive status" refers to an evaluation of the degree of his or her ability to understand, remember, and participate in developing and implementing the plan of care. Numerous screening tools are available that HHAs may choose to use in order to implement this requirement (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2117747/> (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2117747/>)). We are not requiring the use of any particular tool, nor are we prescribing the extent of the cognitive status assessment. Our goal is to make cognitive assessment a routine practice in HHAs so that HHAs can use this information in developing and implementing the patient-specific plan of care, and so that HHAs identify potentially unmet patient needs that warrant follow-up care with another health care provider, with the HHA making appropriate referrals as needed. We agree that there is crossover between these assessment elements and those items already included in the OASIS. However, those items included in the OASIS may not be sufficient for all patients. That is to say, some patients may require additional assessment beyond what is required in the OASIS, and we expect HHAs to revise or expand their patient assessment, as needed, to assure that each patient's psychosocial and cognitive status are assessed. The goal of this requirement is to enable HHAs to develop a more complete and person-centered understanding of the patient.

Comment: A commenter requested additional information regarding the intent and meaning of the proposed requirement that an HHA would identify a patient's strengths and care preferences. Another commenter requested guidance on honoring patient care preferences in case-by-case situations, such as when a patient prefers a shower bath on a day that they are feeling well versus the bed bath that is scheduled for that day.

Response: Traditionally the home health plan of care has been developed with a focus on patient deficits that require treatment. The physician and the HHA decide how to treat these deficits, and patients are told what is going to be done. This model of care places patients in a passive recipient role that does not optimize the achievement of positive patient outcomes. First, this model does not take into account those patient-strengths that can be harnessed by the HHA staff and plan of care to facilitate patient well-being. Examples of patient strengths that HHAs may identify, through observation and directly asking the patient to identify his or her own strengths, may include things such as knowledge of medications, motivation and readiness for change, vocational interests/hobbies, interpersonal relationships and supports, and financial stability. HHAs need to look at a patient's deficits as well as their strengths in order to develop a complete understanding of the patient, and we believe that this requirement will facilitate this practice.

Second, the traditional model of home care tells patients what is going to be done rather than asking patients what their care preferences are. The requirement to gather information regarding patient care preferences and take them into account when developing and implementing the home health plan of care seeks to revise this approach. We would expect patients to be engaged as active participants in their own care, and this begins with gathering and taking into account patient preferences regarding their care. For example, if a patient prefers a shower on a day when a bed bath is scheduled, or, conversely, if a patient prefers a bed bath on a day when a shower is scheduled, we would expect the HHA to take this preference into account and accommodate it to the greatest degree possible. Patient care preferences may go beyond basic daily decisions. Some patients may prefer to have a greater degree of pain control requiring medications that impair the

ability to safely function independently while other patients may prefer to take less medication, even if that means a higher level of pain, to allow a greater degree of independence to safely function. Each patient has their own set of care preferences, and we would require HHAs to both identify and respect these care preferences to the greatest degree possible. Our goal is to assure that HHAs plan for and provide care that is both patient-directed and in accordance with the physician-ordered plan of care.

Comment: A few commenters requested clarification regarding proposed § 484.55(c)(8), which would require the comprehensive assessment to include data items collected at inpatient facility admission or discharge only. The commenters wanted to know what data items were being referred to in this requirement. The commenters asked if this requirement was in reference to the inpatient facility discharge/home health agency referral paperwork, or if there were other data items that we had in mind when developing this proposed requirement.

Response: The phrase “data items collected at inpatient facility admission or discharge only” is included in the regulations that HHAs have been required to comply with for more than a decade. This phrase refers to specific OASIS data elements (see <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-C1-DataSets.html>) [Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-C1-DataSets.html](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-C1-DataSets.html) [Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-C1-DataSets.html](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-C1-DataSets.html)). Specifically, in OASIS-C1/ICD 10, “data items collected at inpatient facility admission” is equivalent to those items that must be collected for “Transfer to an Inpatient Facility.” The data items collected at “discharge only” are equivalent to those items that must be collected for “Discharge from Agency—Not to an Inpatient Facility Death at home,” and “Discharge from agency.” No change to these data set items is being made at this time.

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Comment: A commenter requested clarification on the criteria HHAs should use to determine when a change in a patient's condition warrants an update to the comprehensive assessment. The commenter interpreted this requirement to mean that an update to the comprehensive assessment is required only in situations where the change in a patient's condition is significant enough that it warrants close monitoring by HHA staff or results in a revision to the plan of care.

Response: The proposed provisions do not reflect a change in our policy. Current policy requires each HHA to have a policy defining a significant change in condition that would trigger an update to the assessment. For example, an initiation or discontinuation of a service, or a significant improvement or worsening of a patient's condition not anticipated in the plan of care. It will be up to each individual HHA to determine how a significant change in condition is to be defined.

Comment: All commenters who submitted comments regarding the proposed allowance for a physician-ordered resumption of care date fully supported this proposed change. One commenter suggested that the requirement to update the comprehensive assessment within 48 hours of the patient's return to the home from a hospital admission should be reconsidered because a hospital stay is not the only marker of a change in condition that would warrant an update to the comprehensive assessment. The commenter noted that patients with extended emergency room stays, patients who are in the hospital on observation status, and patients who are accessing urgent care may all be appropriate candidates for a physician-ordered re-assessment.

Response: We agree that extended patients who experience extended emergency room stays, being kept in the hospital on observation status, and utilizing urgent care services for urgent concerns may be in need of an update to the comprehensive assessment. These situations are all examples of a “significant change in condition.” The regulation at § 484.55(d) requires that 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 the last 5 days of every 60 days beginning with the start-of-care date, unless there is a significant change in condition. Consistent with current CMS policy, HHAs are expected to develop policies and procedures that establish the parameters for what constitutes a “significant change in condition.” We believe that extended emergency room stays, patients who are in the hospital on observation status, and patients who are accessing urgent care are all experiencing a “significant change in condition” that would warrant a patient assessment. Therefore, we do not believe that it is necessary to explicitly incorporate these circumstances into the regulation because they are already captured under the broader heading of “significant change in condition.”

CARE PLANNING, COORDINATION OF SERVICES, AND QUALITY OF CARE

Comment: A commenter suggested that the requirement to develop an individualized plan of care should only apply to patients receiving skilled services. In other words, the plan of care requirements should not apply to those patients that only receive non-skilled (that is, homemaker) services.

Response: All patient care, regardless of the level of clinical skill involved, should be delivered in accordance with a plan of care. To do otherwise would create opportunities for uncoordinated care, duplication of services, and missing services.

Comment: A commenter stated that the use of the terms “plan of care” and “care plan” throughout the rule is confusing because some may interpret these two terms as being two separate documents. The commenter suggested that a single term be used consistently in order to avoid potential confusion.

Response: The use of “care plan” and “plan of care” were intended to mean the same thing. However, in order to avoid the potential for any confusion, we are using the term “plan of care” throughout to express this concept.

Comment: Most commenters expressed strong support for the overall concept of an HHA developing a patient-specific, patient-centered plan of care for each patient. The commenters stated that the revised requirement would better ensure that the patient will, indeed, receive all the services and education called for in the plan of care. One commenter suggested that the requirement should specify that each plan of care be individualized to the patient's needs, as reflected in the comprehensive assessment.

Response: We agree that the plan of care should be based on the assessment and that it is important for the plan to specify patient education and training. We understand that is standard of practice for the patient to receive written care information based off the individualize plan of care, from the HHA outlining the medication schedule/instructions, visit schedule and any other pertinent instruction related to the patients care and treatments that the HHA will provide. We believe that this is critical information to improve the patient and caregiver comprehension of diagnosis and treatment, improve compliance with medications and treatment schedules and promote high quality care for the patient. Therefore, in response to comments, we have revised our proposed rule to create a new standard at § 484.60(e), “Written information to the patient.” The new provision requires the HHA to provide written instructions to the patient and care giver outlining

visit schedule, including frequency of visits; medication schedule/instructions; treatments administered by HHA personnel and personnel acting on the behalf of the HHA; pertinent instructions related to patient care; and the name and contact information of the HHA clinical manager.

Comment: A commenter requested examples of effective interdisciplinary teams.

Response: Interdisciplinary teams work together, each member contributing their knowledge and skills, interacting with and building upon each other, to enhance patient care. The interdisciplinary team model is the foundation of care in other health care providers, such as hospices and complex chronic care management practices. HHAs may choose to develop interdisciplinary team models based on the experiences and knowledge developed by these similar care providers, or may develop their own strategies and structures to create effective interdisciplinary teams.

Comment: A commenter requested clarification of the term “social needs” in the context of the proposed requirement that 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.

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Response: Patients come from a variety of backgrounds and settings, each with their own social needs. Some patients require a more intense level of services based on their social needs, and not all HHAs have the staff (for example, social workers) or other capabilities to meet the needs of all patients. Patient social needs may include intrapersonal and interpersonal relationships in the immediate family, financial status, homemaker/household needs, vocational rehabilitation needs, family social problems, transportation needs, and recreational needs. This requirement assures that, if a patient has social needs that go beyond the capabilities of the HHA and/or they would interfere with the HHA's ability to safely and effectively deliver patient care, the HHA would not be expected to accept that patient for care.

Comment: A few commenters suggested that licensed practitioners, such as nurse practitioners and physician assistants, should be permitted to review, sign and order home health services for patients served by Medicare certified HHAs. Other commenters suggested that “physician extenders” should be authorized to provide verbal orders. The commenter stated that, as necessary, their orders could be co-signed by the physicians to whom they report for the purposes of billing.

Response: Section 1861(m) of the Act requires that the home health plan of care be established and maintained by a physician. Section 1861(r) of the Act defines “physician” in a manner that does not include other licensed practitioners, such as nurse practitioners and physician assistants. Therefore, pursuant to statute, other licensed practitioners may not establish and maintain the home health plan of care, including reviewing, signing, and ordering home health services.

Comment: A commenter suggested that the individualized plan of care should be required to identify caregiver needs.

Response: While the needs of caregivers are important, they are beyond the scope of the home health benefit as set forth in the Social Security Act. It would be inappropriate to require HHAs to identify caregiver needs in the home health plan of care, as HHAs would then be obligated to deliver care to meet those needs and such an obligation is beyond the scope of covered HHA services.

Comment: A commenter stated that the regulation should include more specificity regarding the proposed requirement that the plan of care would include safety requirements, functional limitations and nutritional requirements. The commenter stated that the regulation should specify the data elements and level of detail for these aspects of the plan of care because there are no industry standards for them.

Response: The intent of this final rule is to allow HHAs flexibility, where appropriate, to tailor their practices to the needs and preferences of their patients and staff, to the extent possible. Thus, specifying the data elements and exact level of detail for these aspects of the plan of care would not be in keeping with the intent of this rule. HHAs may identify data elements at a level of detail that meets the needs of patients and clinicians.

Comment: A small number of commenters requested clarification of the proposed requirement that each patient's plan of care be required to include the frequency and duration of visits to be made. One commenter stated that HHAs currently indicate visit frequency and duration in their plans of care, and questioned whether the proposed requirement is different from this current practice. Another commenter stated that some HHAs prescribe visit frequencies that span the entire 60 day certification period, while other HHAs prescribe visit frequencies and durations based on the patient's condition and best practices. The commenter wanted to know if the proposal would require HHAs to assure that visit frequencies and durations are based on assessment and plan of care findings, rather than on general episodes of care.

Response: The term "frequency" is used to refer to the frequency of services that are ordered by the physician (for example, nursing 2 to 4 times per week). Likewise, the term "duration" refers to the amount of time for a given frequency (for example, 5 weeks of nursing services, with nursing 2 to 4 times per week for the first 3 weeks, and 1 to 3 times per week for the last 2 weeks) and may, in the case of therapy services, also refer to visit lengths and/or intervention lengths (for example, 90 minute visit, 70 minutes therapeutic interventions and 20 minutes heat application). We expect the plan of care to contain visit frequencies and durations based on the patient-specific needs as assessed in the patient assessment. This may or may not mean that visit frequencies and durations will account for the entire 60 day certification period.

Comment: A small number of commenters suggested that HHAs should not be required to include a patient's rehabilitation potential in the plan of care because some patients receive home health services for skilled maintenance therapy and, therefore, this element may be unnecessary. Commenters also expressed concern regarding the presence of this element in the plan of care in relationship to the medical review process that is related to HHA payment policy. These commenters believe that including information related to rehabilitation potential in the plan of care may create problems for HHAs during medical review.

Response: We believe that including "rehabilitation potential" on the plan of care is appropriate for all patients, including those patients receiving skilled maintenance therapy. Assuming all other eligibility and coverage requirements are met, skilled maintenance therapy services are covered when an individualized assessment of the patient's clinical condition demonstrates that the specialized judgment, knowledge, and skills of a qualified therapist are necessary for the performance of a safe and effective maintenance program. "Rehabilitation potential" in the plan of care should include expected outcomes and the plan of care must also list measureable goals. The "rehabilitation potential" or the expected outcome of maintenance therapy can be to preserve and maintain the patient's current condition or to prevent or slow further deterioration. In addition, the home health record must specify the purpose of the skilled service required.

We remind the commenters that HHAs are required to report all services provided to the beneficiary during each episode, this includes reporting each visit in line-item detail. Therefore, it is expected that the home health records for every visit will reflect the need for the skilled care provided. In accordance with Chapter 7 of the Medicare Benefit Policy Manual (Pub. 100-02, section 40.2.1, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c07.pdf>) these clinical notes are also expected to provide important communication among all members of the home care team regarding the development, course and outcomes of the skilled observations, assessments, treatment and training performed. Taken as a whole then, the clinical notes are expected to tell the story of the patient's achievement towards his or her goals as outlined in the plan of care. In this way, the notes will serve to demonstrate why a skilled service is needed. Therefore, in accordance with Chapter 7 of the Medicare Benefit Policy Manual, the □ home health clinical notes must document as appropriate:

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- The history and physical exam pertinent to the day's visit, (including the response or changes in behavior to previously administered skilled services) and
- The skilled services applied on the current visit, and
- The patient/caregiver's immediate response to the skilled services provided, and
- The plan for the next visit based on the rationale of prior results.

Clinical notes should be written such that they adequately describe the reaction of a patient to his or her skilled care. Clinical notes should also provide a clear picture of the treatment, as well as “next steps” to be taken. When the skilled service is being provided to either maintain the patient's condition or prevent or slow further deterioration, Chapter 7 of the Medicare Benefit Policy Manual requires that the clinical notes must also:

- Include a detailed rationale that explains the need for the skilled service in light of the patient's overall medical condition and experiences,
- Describe the complexity of the service to be performed, and
- Describe any other pertinent characteristics of the beneficiary or home.

Finally, CMS requires the therapist to initially assess (and reassess at least every 30 calendar days) the patient using a method which allows for objective measurement of function and successive comparison of measurements. The therapist must document the measurement results in the clinical record.

Comment: All commenters who commented on the proposed requirement that each patient's plan of care must include patient and caregiver education and training to facilitate timely discharge expressed full support for this proposal. One commenter highlighted resources for caregiver education and training that are available from the Alzheimer's Association. The Association provides a wide variety of caregiver resources, which can be found at www.alz.org (<http://www.alz.org>), as well as through a 24/7 Helpline at 800-272-3900. A commenter also highlighted the Chronic Disease Self-Management Program (CDSMP) based at Stanford University's School of Medicine and the Skills2Care program, which helps caregivers to manage the challenges of dementia in the home.

Response: We appreciate the support from commenters, and agree that the resources noted in comments may be helpful to HHAs.

Comment: A single commenter requested guidance for handling situations in which it has been determined by clinical assessment that a patient is able to learn how to self-administer insulin but simply refuses to learn, and there is no able, willing and available caregiver to teach.

Response: Section 40.1.2.4 in Chapter 7 of the Medicare Benefit Policy Manual (Pub. 100-02) states that where a patient is either physically or mentally unable to self-inject insulin and there is no other person who is able and willing to inject the patient, the injections would be considered a reasonable and necessary skilled nursing service covered by the Medicare home health benefit. However, Medicare would not cover this service for a patient who is capable of learning and self-administering insulin, but refuses to do so, in which case the HHA may choose to discharge a patient because the payment source will no longer pay (see § 484.50(d)(2)). However, we believe that these situations are very rare. We would expect an HHA to explore all possible avenues to identify one or more individuals who could administer insulin to the patient as well as all possible options for convincing a patient to learn the proper self-administration techniques. We would also expect an HHA to thoroughly document all steps taken to resolve this issue, converse with the patient regarding the implications of this decision, communicate with the physician(s) involved in the patient's home health care and the practitioner who will be providing follow-up care, and provide the patient with information regarding other possible sources of care that may meet the patient's care preferences. For patients with other sources of payment that would continue to pay for insulin administration to a patient who is capable of learning self-administration, but refuses to do so, HHAs are permitted to continue providing services until such time as the patient is no longer in need of the HHA's services.

Comment: Several commenters supported the proposed requirement that the plan of care would be required to include measurable outcomes and goals identified by the HHA and the patient. One commenter stated that patients and caregivers need to feel their concerns matter in order to ensure their engagement. However, other commenters expressed concern and requested additional clarification regarding this proposed requirement. Commenters sought specific guidance regarding how to document patient goals, comply with patient-identified goals, and reconcile potential conflicts between patient-identified goals and the physician-ordered plan of care. One commenter suggested that HHAs should be required to establish the plan of care "in collaboration" with the patient, rather than "in partnership" because acting "in partnership" would increase the burden to HHAs. A single commenter asserted that patients don't know how to identify quantifiable, measurable goals.

Response: We appreciate the support of the commenters who submitted comments on this issue. We did not propose, nor are we finalizing, specific documentation or implementation requirements for this provision, as such requirements may impose unnecessary restrictions on HHAs in achieving the ultimate goal of delivering goal-concordant care. We acknowledge that patient established goals of care may be verbalized in a different fashion than those that are established by the physician(s) involved in the HHA plan of care. Nonetheless, we believe that patients are capable of establishing goals and that these goals can be successfully aligned with the goals established by the physician(s). Where there is direct conflict between a patient-established goal and a physician-established goal, we would expect the HHA to educate the patient about why the physician-established goal must be used to guide the care planning and delivery process. Patients should also be encouraged to discuss concerns regarding their care goals with their physician(s). We are finalizing this requirement as proposed, including use of the phrase "in partnership." We believe that the phrase "in partnership" is equivalent to the suggested phrase "in collaboration", and that there is no difference in burden based on the use of one phrase over another.

Comment: Some commenters agreed with the proposed requirement that the plan of care would include measurable outcomes, even suggesting that such outcomes should be supported by evidence based measures through the use of standardized test and measures when possible. However, a single commenter contested the necessity of including measurable outcomes in a patient's plan of care, stating that there is not sufficient evidence to support the requirement. Other commenters expressed concern with the potential implications of the proposed requirement. These commenters stated that requiring measurable outcomes may imply that the goal of helping patients safely and effectively manage their health conditions in a community setting is not sufficient in itself, and that home health services should be available to clients only so long as they demonstrate continued, quantifiable improvement from those services. Additionally, commenters expressed concern that working with the physician to establish such goals would be burdensome.

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Response: The concept of measurable outcomes is well established in health care. For example, measurable outcomes are used in physical therapy to assess the effectiveness of interventions and are used in medical social work to assess patient progress in mental health therapy. Measurable outcomes can be used in home health care to measure these elements, as well as outcomes related to nursing, patient safety, and effective self-management, to name just a few. Measurable outcomes jointly established by the patient, HHA, and physician(s) may include measures related to self-medication management, avoidance of unnecessary emergent care visits and hospital admissions, and more. We do not agree that the phrase “measurable outcomes” would in any way convey the message that the goal of helping patients safely and effectively manage their health conditions in a community setting is not sufficient of itself, and that home health services should be available to clients only so long as they demonstrate continued, quantifiable improvement from those services, as the commenter asserted. Furthermore, we do not agree that establishing measurable outcomes would be burdensome, as this should already be part of standard care planning activities. Without the pre-establishment of outcomes, it would be difficult to measure when a patient with a goal of rehabilitation (the primary population currently served by HHAs) has made sufficient progress to warrant discharge. Likewise, it would be difficult to assess whether maintenance services have, in fact, achieved their maintenance goals.

Comment: A commenter requested clarification of a statement in the preamble related to the development of measurable outcomes and goals. The preamble stated, “An evidence and outcome based approach to patient care that can be understood by the patient and caregivers, with specificity of orders, and adherence to best practice interventions to provide the basis for the development of an optimal plan of care and goals.” The commenter requested further explanation regarding evidence and outcome based approaches, as well as how adherence to best practices will be measured.

Response: The concept of evidence-based care, an approach to decision-making in which the clinician uses the best evidence available, in consultation with the patient, to decide upon the option which suits that patient best, is well established. For example, in 1997 the Agency for Healthcare Research and Quality launched an initiative to promote evidence-based patient care through its Evidence-based Practice Center Program. Among other things, the Program develops evidence reports on clinical topics and publishes those reports for public use (see <http://www.ahrq.gov/research/findings/evidence-based-reports/overview/> (<http://www.ahrq.gov/research/findings/evidence-based-reports/overview/>) for more details). We expect HHAs to use evidence-based care, often done through the implementation of best practices, to improve the experience of care and outcomes of individual patients and entire patient populations within an HHA's care.

Comment: One commenter requested examples of measurable outcomes, while another commenter noted that the National Quality Forum recently released recommendations on quality measurement and dementia that could be considered by HHAs as they develop outcomes for persons with dementia and their caregivers.

This commenter also urged that patient- or representative/caregiver-reported outcomes be included as measurable outcomes in the plan of care, stating that patient and caregiver perspective is often overlooked in favor of more quantifiable measures.

Response: Measurable outcomes may include anything from an improvement in ambulation to a stabilizing of blood pressure to an improvement in self-management. Measurable outcomes must be tailored to the specific patient, including his or her circumstances, goals, and condition. We believe that leaving the term as broad as possible is the most appropriate way to account for this high degree of variability. We believe that the suggestions provided by the commenter related to available resources are appropriate and may be of value to HHAs in implementing this requirement.

Comment: A commenter stated that, in addition to permitting the HHA and physician to add additional items to the plan of care, the patient should also be permitted to add items to the plan of care.

Response: HHAs are paid for their services based on a set of covered services and items that is established by each payment source, whether Medicare, a Medicaid state plan, private insurance, or the patient him/herself. While we agree that patients have the right to state their care preferences and goals (see § 484.50) and that those preferences and goals should be incorporated into the individualized plan of care (see § 484.60), we do not agree that patients should be permitted to add items to the plan of care. Because we require HHAs to provide all services set out in the plan of care, such additions could possibly place HHAs in the position of being required to deliver services and items that are not covered by the payment source. This would be an unreasonable burden on HHAs.

Comment: Commenters supported the concept of assessing a patient's risk for re-hospitalization, and several even suggested that the requirement should apply to all patients rather than be limited to those patients that are admitted to HHA services following a hospitalization. One commenter requested clarification regarding the exact patient population to which the requirement would apply, noting that not all home care begins immediately following a post-acute discharge. Commenters stated that identifying a patient's risk for re-hospitalization and emergency department visits will help improve patient care and reduce unnecessary and avoidable hospitalizations.

Response: We agree that, for the sake of patient safety and for the sake of establishing a requirement that can be clearly and equally applied by all HHAs, this requirement should be applied to all patients, as all patients have some level of risk for a hospital admission or emergency department visit. Therefore, we have made a change to the regulatory text at § 484.60(a)(2)(xii) to apply this requirement to all HHA admissions. This requirement is consistent with CMS's focus on reducing preventable re-admissions through a variety of efforts such as HHA quality measures and CMS payment reforms.

Comment: Commenters identified opportunities for improved clarity regarding the re-hospitalization risk assessment proposal. Commenters noted that using "low, medium, and high" to rank each patient's risk may result in significant variation among HHAs because these terms are subjective and are not defined. One commenter suggested that CMS should provide additional resources and training to facilitate compliance. A few commenters suggested that, in order to achieve consistency, there should be an instrument that has been validated for agencies to use. Another commenter suggested that this risk assessment should be based on a Patient Activation Measurement (PAM) score. The commenter stated that peer-reviewed studies, have identified a strong link between patient activation or having the knowledge, skills, and confidence needed to manage one's health and hospital readmissions. A study conducted at Boston Medical Center (Journal of Internal Medicine. February 2014; 29(2): 349-355. <http://www.ncbi.nlm.nih.gov/pmc/articles/>

PMC3912296/ (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3912296/)) found that patients with the lowest levels of activation had nearly twice the risk of returning to the hospital within 30 days, compared with patients with the highest levels of activation. Systematic assessment of a beneficiary's level of activation and self-management capability can guide more effective approaches to provider interactions with beneficiaries during in-home visits by skilled home healthcare professionals. Patients in the lower two levels of activation are often overwhelmed by their medical condition and struggle with health-related self-management tasks. Knowing a beneficiary's level of activation allows home health providers to tailor information, goals, and action steps to the abilities of the patient.

Response: We agree that the terms “low, medium, high” are not useful without further definition and standardized measurement tools that all HHAs would use. Our goal is to bring this issue to the forefront of patient care, and to assure that, within an HHA, it is consistently examined and addressed for each patient. While there may be benefits to establishing more inter-HHA consistency in the application of this requirement, we do not believe that those benefits would outweigh the cost of reducing HHA flexibility and innovation to determine the best possible way to achieve the overall goal of reducing unnecessary emergent care visits and hospital admissions. Therefore, at § 484.60(a)(2)(xii) we have removed the terms “low, medium, high”, and are not suggesting a specific tool or process at this time.

Comment: The proposed rule included a requirement that all patient care orders, including verbal orders, must be recorded in the plan of care. A commenter requested clarification regarding the need for, and benefit of, including ALL orders (including verbal orders) in the patient's plan of care. The commenter stated that including all orders may cause confusion in cases where orders have changed several times over the course of an episode.

Response: The plan of care is an evolving document that outlines the patient's journey throughout HHA care and treatment. It is essential that the plan of care be reflective of past orders and current orders that are actively ongoing. As new orders are given to initiate or discontinue an intervention, the plan of care is updated to reflect those changes. New versions of the plan of care are created as needed to assure that each clinician is working on the most recent plan of care, with older versions being filed away in the clinical record in any manner that meets the needs of the HHA.

Comment: Several commenters expressed concern with the proposed requirement that drugs, services, and treatments are administered only as ordered by the physician who is responsible for the home health plan of care. Commenters stated that patients often have multiple physicians who order treatments and medications, and that the physician responsible for the home health plan of care is often not the ordering physician for every drug and treatment included on the home health plan of care. According to commenters, the standard practice is that the HHA informs the physician responsible for the home health plan of care of all treatments, drugs and services that the patient is receiving, and if applicable, who the ordering physician is, without requiring that this physician actually orders all of them himself or herself. Another commenter stated that in certain situations one physician will not take responsibility for the orders of another. One commenter stated that the regulation should be revised to allow communication from the HHA to a physician group practice, noting that some HHAs provide services patients who receive care from a group of physicians, and these patients do not necessarily have a single physician who is responsible for the plan of care. Commenters suggested that the regulation should be revised to reflect that drugs, services, and treatments be administered only as directed by a physician who is responsible for the care of the patient, and that the physician responsible for the home health plan of care is made aware of all treatments that the patient is receiving from the HHA.

Response: We agree that situations may exist in which multiple physicians are directly involved in providing care for a patient at the same time, and would thus be in a position to give orders to the HHA related to the care of a single patient. Furthermore, we agree that it is appropriate to revise the regulations to permit this arrangement. To that end, we have revised the requirement specifically related to physician orders to allow HHAs to accept orders directly from multiple physicians who are involved in a patient's care at that point in time, regardless of whether those physicians are part of the same group practice or not. The physician that is responsible for care of the condition that led to the initiation of home health care, and is thus the main physician responsible for the home health plan of care would have the opportunity to review all orders because all orders from all physicians must be included in the plan of care (§ 484.60(a)(3)) and the plan of care must be reviewed and signed by the physician responsible for the HHA plan of care (§ 484.60(a)). We have also added new requirements within § 484.60(d), Coordination of care, to specifically address the role and responsibility of the HHA when it chooses to accept orders from more than one physician. Specifically, in addition to the proposed requirements that HHAs would be responsible for coordinating HHA services and ensuring patient education and training, we have added new requirements within § 484.60(d) that HHAs that choose to accept orders from multiple physicians are responsible for:

- (1) Assuring communication with all physicians involved in the plan of care.
- (2) Integrating orders from all physicians involved in the plan of care to assure the coordination of all services and interventions provided to the patient.

The purpose of assuring communication and integrating orders is to avoid duplicate or contradictory physician orders and to assure that all patient needs are being met (whether directly by the HHA or by the physicians). We would expect HHAs to have appropriate systems and processes in place to both identify and resolve conflicting or duplicative orders. We believe that these expectations are consistent with the role of the clinical manager at § 484.105(c). In particular, the clinical manager is responsible for assuring the development, implementation, and updates of the individualized plan of care. We believe that, in order to effectively assure the development, implementation, and updates of the individualized plan of care, there would have to be communication with all physicians involved in the plan of care and integration of orders from all physicians involved in the plan of care to assure the coordination of all services and interventions provided to the patient. The requirement to integrate orders from all physicians would include those orders related to medications. Medication orders may be for long-term maintenance issues (for example, cholesterol management medications) as well as shorter-term medications for temporary issues that may or may not be directly related to the reason that home health care was initiated (for example, pain management medications that may be used in the process of surgical recovery or may be used as part of a treatment plan for a strained back that the patient just happened to experience during the time that he or she receives HHA care). We would continue to expect that all services or interventions that are ordered are medically necessary, as supported by documentation in the patient's record, in accordance with the requirements of 42 CFR 409.44 (/select-citation/2017/01/13/42-CFR-409.44) and 409.45.

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Comment: One commenter requested clarification regarding the proposed requirements permitting HHAs to offer vaccinations to patients in accordance with HHA policy without obtaining a separate physician order for each patient. The commenter requested that CMS define what steps in the vaccination process it will hold providers accountable for, and how CMS will reimburse providers for the vaccine.

Response: The proposed provisions do not reflect a change in our policy. HHAs are permitted to, in consultation with a physician, develop a policy for the administration of influenza and pneumococcal vaccinations without a patient-specific physician order, such as in the form of a standing order. We would

expect that this policy would address topics such as obtaining patient consent and assuring that it is safe to administer a vaccination to a given patient prior to administration. As a medical treatment, this rule would require that any administered vaccines be documented in the patient's clinical record in accordance with the requirements of § 484.110(a).

Comment: A few commenters expressed confusion regarding the relationship between the concept of “verbal orders” and orders that are faxed or otherwise transmitted through other electronic methods. The commenters were unclear as to whether faxed or other HIPAA-compliant electronic orders are considered to be “verbal orders.” One commenter suggested that emailed and faxed orders would be followed up by a written order signed by the physician.

Response: In accordance with the definitions set forth in § 484.2, a verbal order means a physician 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. Faxed and other electronic orders are not considered verbal orders because they do not meet this definition. However, all orders need to be appropriately authenticated.

Comment: The proposed rule stated that, when services are provided on the basis of a physician's verbal orders, the clinician receiving the order(s) must document it in the patient's clinical record, and sign, date, and time the order(s). While a single commenter supported this proposal, the vast majority of commenters who submitted comments regarding this proposal disagreed with the requirement that verbal orders must be timed, questioning the relevancy and necessity of a requirement in the home health care setting. A commenter also stated that it is unclear whether the “timed” requirement applies to the time that the care was provided or activity occurred; when the verbal order was documented; or when the verbal order was signed by the physician.

Response: While we acknowledge that most HHA patients do not typically require rapidly changing orders, we nonetheless believe that timing the receipt of verbal orders is necessary for those infrequent occasions when such situations do arise. There are times when a patient's condition rapidly changes, and clinicians are not necessarily able to effectively predict when such situations are about to occur. Therefore, we believe that it is necessary and appropriate to proactively record the time of day that each verbal order is received by an HHA clinician from a physician. This requirement corresponds with the clinical record authentication requirements at § 484.110(b), which requires all entries in the clinical record to be timed.

Comment: The proposed rule stated that verbal orders must be authenticated and dated by the physician in accordance with applicable state laws and regulations, as well as the HHA's internal policies. Several commenters understood this provision to also require timing of the physician signature, and disagreed with that idea. One commenter suggested that the regulation should include a timeframe for physician signature, while other commenters strongly supported the proposed deferral to applicable state laws and regulations. One commenter cautioned states and HHAs against imposing 48 hour timeframes for physician countersignature of verbal orders, stating that strict deadlines could impose constraints on physicians' time and patient care schedules, and could also negatively impact patients and Medicare expenditures by leading to delays in receiving treatments.

Response: We appreciate the opportunity to clarify the proposed requirement. We believe that there was some confusion among commenters, and want to be clear that we did not propose, nor are we finalizing, a requirement related to a physician timing the signature for a verbal order. Rather, all verbal orders must be authenticated and dated by the physician in accordance with applicable state laws and regulations, as well as the HHA's internal policies. We do not believe that it is necessary to require a specific timeframe for

completing the authentication process, as in general, this is already effectively governed by existing state requirements. States and HHAs are permitted to establish timeframes that meet their needs. We remind HHAs that authentication must be completed in accordance with established billing requirements for those patients for whom Medicare is a payment source.

Comment: A commenter expressed concern about the requirement in § 484.60(b)(4) that a registered nurse or qualified therapist must document verbal orders. The commenter stated that state law allows others to receive verbal orders, and that the requirement included in the proposed regulation would limit an HHA's ability to employ licensed practical nurses (LPNs).

Response: We agree that there is no health and safety-related reason to prohibit a LPN from receiving and documenting verbal orders because LPNs have the necessary training and skill to perform this function. Therefore, we agree that it is appropriate to allow LPNs to receive verbal orders as long as the LPN is acting within his or her state licensure requirements and permitted in accordance with state scope of practice. This policy is consistent with the regulations for other providers, such as hospitals and hospice inpatient care facilities, both of which permit LPNs to receive verbal orders in accordance with state regulations and the organizations own policies and procedures. We have revised the regulation text at § 484.60(b)(4) to reflect this change.

Comment: A commenter requested clarification regarding the relationship between the requirements for care plan reviews and the timeframes for verbal order countersignature.

Response: All verbal orders must be authenticated and dated by the physician in accordance with applicable state laws and regulations, as well as the HHA's internal policies. This requirement applies to verbal orders that occur at any time during the plan of care development, implementation, and update cycle.

Comment: Commenters supported the proposed level of physician involvement in updating the plan of care, as well as the proposed □ requirement for an HHA to communicate with the physician as frequently as the patient's condition or needs require, when any significant changes in the patient's health care status occur, and at the time of discharge from the HHA.

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Response: We appreciate the support of these provisions, and are finalizing these requirements at § 484.60(c) with minor changes to reflect situations where more than one physician issues orders for patient care.

Comment: A few commenters suggested that the timeframes for updating the plan of care should be modified. Commenters suggested that the regulation should require a plan of care update when there is a significant change in patient condition, and upon the request of the patient or representative (if any), but no less frequently than once every 60 days, beginning with the start of care date.

Response: The HHA should be in regular communication with the patient and caregiver(s), and must assure that the plan of care is achieving the goals established by the patient and physician(s). However, we do not see a reason to explicitly state that the plan of care should be updated at the request of the patient or representative. The plan of care is not updated as long as it is meeting the goals established by the physician(s) and the patient.

Comment: A small number of commenters disagreed with the proposed requirement that a revised plan of care must reflect current information from the patient's updated comprehensive assessment. Commenters stated that a new assessment is not needed when there is a revised plan of care. Commenters also stated that the proposed requirement implies that any change in the plan of care, such as a "minor" change in orders that does not constitute a "significant change in condition" (for example adjusted medication dose, revised wound care procedure), requires an updated comprehensive assessment.

Response: The proposed provisions do not reflect a change in our policy. Current policy requires each HHA to have a policy defining a significant change in condition that would trigger an update to the assessment (for example, an initiation or discontinuation of a service, or a significant improvement or worsening of patient condition not anticipated in the plan of care). It will be up to each individual HHA to determine how a significant change in condition is defined.

Comment: A few commenters sought clarification regarding communications related to changes in the plan of care and the discharge plan. We proposed that, if the plan of care is revised due to a change in patient health status, an HHA must communicate the revisions to the patient, representative (if any), caregiver, and the physician who is responsible for the HHA plan of care. We also proposed that any revisions related to plans for the patient's discharge must be communicated to the patient, representative, caregiver, the physician who is responsible 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). Commenters asked the following questions:

- Does this mean that the care plan and discharge summary must be communicated to a specific provider or can be communicated to the patient's physicians' practice?
- What are the timeframes for when communication regarding revisions to the plan of care, including discharge planning, need to be completed and documented?
- Can these changes be communicated to the patient and the physician physically by mail or electronically by email or other secure electronic means?

Response: In the majority of cases where there is a specific physician or practitioner with whom to communicate, we would expect HHAs to communicate directly with that individual. In the small minority of cases where there is no designated practitioner, HHAs may communicate with the practitioner group. We are refraining from specifying timeframes and formats in order to afford HHAs flexibility in complying with these rules. Patient acuity and patient needs should drive the timeframes for various communications, with critical and/or time sensitive information being communicated as quickly as possible and less critical or time sensitive information being communicated on an as-needed basis. Likewise, the needs of the recipients should drive the format of the information and any associated documentation. We do not believe that it is necessary or appropriate to specify how information is communicated, provided that the patient's right to a confidential record is assured in accordance with § 484.50(c)(6).

Comment: Many commenters supported the proposed requirement that an HHA communicate changes in the plan of care to the patient, representative (if any), caregiver, and the physician who is responsible for the HHA plan of care, stating that, in order to successfully implement the plan of care, everyone involved must be aware of its contents. A few commenters suggested that the regulation should clarify that such communications must occur only when there is a significant change to the plan of care, such as when new orders are needed from the physician.

Response: We appreciate the support of the commenters for the requirement that an HHA communicate changes in the plan of care to the patient, representative (if any), caregiver, and the physician. HHAs are strongly encouraged to engage patients, representatives, and caregivers in a conversation about the level of involvement that these individuals prefer to have in developing and updating the plan of care, and to act in accordance with those preferences. Some individuals may prefer to have more involvement, desiring communication regarding every change, while others may prefer communications regarding changes to focus only on certain topics or occur no more than once a week. HHAs would document these preferences and structure their communications accordingly to meet them. In the absence of such patient-directed guidelines for communication of changes, the default expectation from CMS would be that all changes in the plan of care are communicated, even “minor” ones, such as visit frequencies. We remind HHAs that communications regarding updates to the plan of care to the patient, representative, or caregivers can be done via telephone or secure electronic means, with associated documentation in clinical record.

Comment: A commenter requested additional guidance regarding the manner in which HHAs should document that they communicated changes to the plan of care to patients, representatives, caregivers, and physicians. The commenter requested that CMS clarify whether all changes to the plan of care require the plan of care to be re-signed by the physician, and if not, explicitly when that would and would not be required. The commenter also suggested clarifying whether the HHA would also need the patient and/or the patient's representative to sign the plan of care to indicate that the HHA has communicated this information. If a patient signature is not required, the commenter requested information regarding how HHAs should provide evidence that the communication occurred.

Response: The signature of the physician who is responsible for issuing orders related to the condition(s) that led to the initiation of home health services should be on all iterations of the individualized plan of care for each patient in accordance with the requirements of § 484.60(a). We did not propose, nor are we finalizing, patient signature requirements for the plan of care. HHAs may document communications with the patient in regards to the patient's plan of care in any manner that demonstrates compliance with the communication requirements of § 484.60. This could include documentation in clinical notes, a specific section of the clinical record developed for this purpose, printouts or .pdf versions of secure electronic communications that are linked to or maintained within the clinical record, or any other method that could be used to demonstrate compliance.

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Comment: Several commenters submitted comments regarding the proposed care coordination requirements. Commenters supported the goals of care coordination, stating that communication between the HHA and other physicians and practitioners is essential for producing the best possible outcome of care. This is especially true with respect to issues that are not directly connected to the issues being addressed by the HHA. Commenters also stated that it was important to coordinate care with those managing the patient's care after the patient is discharged from the HHA. Commenters suggested that care coordination should be led by a clinician, and should be patient centered, goal oriented, and outcome based. Within the context of this broad support, a few commenters raised specific concerns and points for additional clarification. A commenter noted that carrying out these activities is growing increasingly complex with the emergence of new models of care. As managed care penetration grows, and new accountable care models gain traction, patients with complex needs are experiencing care management and care coordination on a number of fronts. There is a risk of duplication of effort, and confusing or inconsistent communications to patients and health care professionals. The commenter suggested that the regulations should support efforts to streamline requirements among various health care sources and increase flexibility in implementing them. Another commenter cautioned that, while it is important to involve family caregivers, as appropriate, in care

coordination and provide needed training, the coordination of care should also include appropriate continuity of care and referrals to accessible home and community-based services in the community, as needed. The commenter sought to assure that care coordination activities would not be delegated by an HHA to the caregiver.

Response: We agree with commenters that well implemented care coordination within an HHA has the potential to improve patient care and outcomes, and are finalizing this requirement. We note that the proposed care coordination requirements were specifically referring to coordinating care within an HHA. We expect HHAs to coordinate the nursing, therapy, aide, and medical social work services that they offer, whether these services are provided directly or under arrangement. In addition to these expectations, as discussed previously, in response to public comments we are finalizing a new requirement for HHAs to be in communication with all physicians who are writing orders related to the HHA plan of care. These activities are the inherent responsibility of the HHA, and it would not be appropriate for the HHA to delegate these tasks to a patient or caregiver under any circumstances. We do not expect HHAs to coordinate the care being provided by other entities beyond what is included in the HHA plan of care. For example, we would expect the HHA to coordinate all services and orders related to wound care for a patient receiving post-operative hip replacement HHA care. We would not expect the HHA to coordinate that patient's cardiac care with the patient's cardiologist and other specialists if this care coordination is already performed by the physician who is issuing the wound care orders, and if all orders for all care (wound and otherwise) are issued by that single physician who assumes the care coordinator role. It is only when HHAs choose to accept orders from multiple physicians to be included in the plan of care for a single patient that we would expect HHAs to coordinate the orders of those physicians. If an HHA chooses place itself in the role of a direct recipient of orders from multiple physicians, it is incumbent upon the HHA (as required by § 484.60(d)(2)) to assume the role of a care coordinator in order to assure that patient needs are continuously met and that there is no duplication or contradiction of services. While there may be HHAs that participate in care coordination programs where the HHA coordinates all aspects of a patient's care, care coordination programs are separate programs that have their own requirements, separate from the home health care requirements set forth in this rule. In these situations, HHAs would be expected to assume a care coordination role that meets the standards of the care coordination program in which it is participating, as well as meeting these HHA CoPs.

Comment: A commenter requested additional guidance on what constitutes an “adequate” level of coordination across all disciplines and the mechanism to conduct coordination. Another commenter suggested that the regulation should require HHAs to specifically document care coordination activities.

Response: Coordination of patient care entails assuring that patient needs are continually assessed, addressed in the plan of care, that care is delivered in a timely and effective manner, and that goals of care are achieved. HHAs may document these activities in a manner that suits their needs to demonstrate compliance.

Comment: Most commenters who submitted comments related to the “Care planning, coordination of services, and quality of care” requirement focused their comments on the proposed discharge summary requirements. Many of these commenters stated that the regulations should not include any requirements related to the discharge summary. Other commenters suggested a pared down list of content elements focused on the status of the patient at the time of discharge, such as a current reconciled medication list, a copy of the most recent plan of care, and recommendations for follow-up care.

Response: We appreciate the many suggestions that commenters submitted on this topic. Two days prior to publication of the proposed HHA CoPs, the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113-185 (<https://api.fdsys.gov/link?collection=plaw&congress=113&lawtype=public&lawnum=185&link-type=html>)) was signed into law. Section 2(a), which added new section 1899B(i) to the Act, requires hospitals of various types and HHAs to take into account quality measures, resource use measures, and other measures to assist patients and their families during the discharge planning process. We believe that this provision will encourage hospital patients and their families to become active participants in the planning of their transition to post-acute care settings (or between post-acute care settings). This requirement will allow patients and their families' access to information that will help them to make informed decisions about their post-acute care, while addressing their goals of care and treatment preferences. Due to the very close timing of this legislation in reference to publication of the HHA rule, the proposed HHA rule did not take into account the requirements of the IMPACT Act. In order to meet the requirements of the IMPACT Act for HHAs, we have decided to withdraw our proposals related to the content of the discharge summary. In its place, we are proposing a separate rule ("Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies," November 3, 2015 (80 FR 68126 (/citation/80-FR-68126))) that would implement the discharge planning provisions of the IMPACT Act and would address the content of the HHA discharge summary.

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Comment: Many commenters responded to the request for additional ways to increase and improve HHA-physician communication. Comments ranged from statements that it is not necessary or desirable to increase communications between HHAs and physicians to suggestions that HHAs should be required to have medical directors overseeing clinical operations. Additional suggestions included: The implementation of interoperable health records to facilitate timely information exchange; establishing a demonstration to test the use of licensed practitioners, such as nurse practitioners, to oversee the home health plan of care; and aligning physician financial incentives with the goal of reducing hospital admissions and re-admissions while improving patient outcomes.

Response: The only commenter suggestion that could be implemented through the CoPs is the suggestion that the regulations should require each HHA to have a physician medical director. This concept was not included in any manner in the proposed rule, and its inclusion would be a significant change. We believe that, should this policy be considered for implementation, it would be most appropriate to pursue separate notice and comment rulemaking at a future date. All other suggestions are beyond the scope of this rule.

QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI)

Comment: We received many comments regarding the proposed Quality Assessment and Performance Improvement (QAPI) requirements. The comments supported our understanding of data collection as a driving force in implementing evidence-based healthcare. The commenters stated that HHAs that are using data to drive organizational change can expect to improve the quality of care they provide to their patients. Many commenters appreciated the flexibility of the proposed requirement that allows HHAs to proactively identify risk areas and performance problems through the QAPI program. The commenters also supported the concept that each HHA would be expected to conduct its QAPI program in a way that best met its needs and the needs of the HHA's patients. However, we also received several comments that were not supportive of the QAPI CoP. One commenter stated that QAPI might not be appropriate for a home-based provider because the type of information collected through QAPI is geared toward facility-based patients and facility-based providers. In addition, this commenter stated that QAPI was too burdensome and too costly relative to any increased benefit it will provide. One commenter stated that the impact analysis for this provision was

far under their perceived estimate to implement a QAPI program and the cost proposed by CMS would not allow the HHAs to produce any credible results that would represent any fundamental quality improvement change.

Response: We appreciate the support of this proposed requirement, as it confirms our understanding of current HHA quality practices. We do not agree with the assertion that QAPI is not appropriate for home-based providers. Hospices and dialysis providers, both of which include home-based services within their scope of services, have been successfully complying with QAPI requirements since 2008. HHAs have an abundance of standardized data elements and quality measures to select from in order to facilitate compliance with this requirement. We note that the impact analysis is neither a minimum nor a maximum level of effort. It is merely an estimate of the time and associated costs for a statistically typical HHA to develop and implement a basic QAPI program. Each HHA, depending on its needs and circumstances, may need more or less resources than estimated in the impact analysis.

Comment: Several commenters asked for a phased-in implementation time frame beyond the other HHA regulations. The reasons for the increased implementation time frame were because many states align their licensure requirements with some of the federal CoP requirements and the fact many HHAs do not currently have a comprehensive QAPI program that meets the standards of the proposed CoP.

Response: We agree that a phased-in implementation time frame is appropriate for the requirement that HHAs must conduct performance improvement projects because it will take additional time to collect the data necessary to identify areas for improvement that are appropriate for performance improvement. We have added a phase-in to allow HHAs the time necessary to collect data prior to implementing performance improvement projects. This allows for a full 12 month time period between the time that this final rule is published and the time that HHAs must begin conducting performance improvement projects. All other QAPI requirements can be implemented within the standard time frame for implementation of the CoPs as a whole (by July 13, 2017).

Comment: One commenter suggested that CMS utilize the Patient Activation Measure (PAM) as part of the requirements for HHAs under the QAPI CoP. The commenter explained that PAM is a 10- or 13-item questionnaire that assesses an individual's knowledge, skill and confidence for managing their health and healthcare. They stated the measure has strong psychometric properties and is being used in clinical settings around the globe. In a related comment, a commenter suggested that HHAs should use the ASHA Functional Communication Measures, and should collect patient-level data related to speech, language, cognition, and swallowing as areas of focus within their QAPI programs.

Response: HHAs may choose to use data elements and measures that meet their quality needs and goals, provided that those data elements and measures meet the requirements of this final rule.

Comment: One commenter suggested it would be a good idea to have families or patients participate in a survey about the quality of service they are receiving from the HHA. They stated that having a survey like this would allow for CMS and HHAs to understand and receive feedback on the care they are providing.

Response: We agree that obtaining patient feedback is an important aspect of assessing the quality of care provided by an HHA. For this reason, in October 2009 HHAs began participating, on a voluntary basis, in collecting this information through the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Home Health Care Survey (HH CAHPS). The survey is designed to measure the experiences of people receiving home health care from Medicare-certified home health care agencies. HHA participation in

the survey became mandatory in late 2010. (<https://homehealthcahps.org/> (<https://homehealthcahps.org/>)) Information from the survey is publicly reported on Home Health Compare on the *Medicare.gov* Web site as of April 11, 2012. (<https://www.medicare.gov/homehealthcompare/search.html> (<https://www.medicare.gov/homehealthcompare/search.html>))

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Comment: Several commenters urged CMS to consider the development and use of tools that can be utilized by HHAs and shared with surveyors to provide additional guidance. Some suggested that OASIS data be used for QAPI, while others voiced concern over potential problems with Private Duty Nursing (PDN) patients versus traditional home health patients when utilizing OASIS data to measure HHA quality. Some commenters suggested incorporating information from HHA surveys by State Survey Agencies, and that quality measures should be differentiated by HHA size (small, large and more complex HHAs).

Response: Accreditation organizations, industry associations, universities, and other independent entities are all sources of quality measures, tools, guides, and other resources that HHAs may use to aid in the implementation of QAPI requirements. OASIS data and survey data may or may not be an appropriate source of information for specific quality measures, depending on the data needed. We believe that these various sources of quality measures and tools make it unnecessary for us to develop separate tools.

Comment: We received several comments that expressed concern over the QAPI requirements, suggesting that CMS was providing too much latitude to HHAs in designing and implementing their QAPI programs. The commenters stated that such flexibility would allow some HHAs to evade scrutiny or conveniently brush problems and violations under the rug. They stated that in the absence of clear expectations, parameters and standards for enforcement, less scrupulous providers will pay lip service to QAPI requirements without making a meaningful effort to address problem areas.

Response: While there may be a subset of providers that attempt to do the bare minimum to comply with all of the requirements in this rule, we do not believe that creating a more prescriptive requirement will enhance overall patient care. Indeed, a prescriptive requirement would likely lead to rote behaviors that lack the introspective analysis that QAPI is based on. HHAs would be more likely to just do something for the sake of compliance, rather than to think about ways to continually improve. We believe that the HHA survey process, which includes HHA surveys by State Survey Agencies or accreditation organizations at least every 36 months, is effective in identifying substandard providers and prompting the necessary corrections.

Comment: We received several general questions regarding the QAPI requirements. One commenter asked if an HHA could fulfill the QAPI requirements if it participated in a larger, system-based improvement program that was implemented by their parent hospital/health system. A second commenter asked about what would be considered to be an “effective” program. A third commenter stated they believed the requirements should hold HHAs accountable for complying with the requirement and not just require that the QAPI program be “capable of showing measurable improvement.” A fourth commenter asked if HHAs would be considered out of compliance if it chose an area that did not meet the criteria of high risk, high volume or problem-prone. A fifth commenter asked about what happens if improvements are not sustained.

Response: A QAPI program must be individualized to the HHA and must be designed in a manner that will result in improving patient care and HHA operations. We require that a program be “capable of showing measurable improvement” because, despite an HHA's best efforts, not all endeavors will result in actual improvements being made. Parts of quality improvement are trial and error, figuring out which interventions do and do not improve processes and outcomes. HHAs are responsible for making all reasonable efforts to collect and analyze data from a wide variety of sources (including, but not limited to, patient care records,

administrative records, and procurement records) to assess its operations and care delivery, and for using that data to develop and analyze performance improvement projects. For this reason, we believe that it remains appropriate to require that an HHA QAPI program be “capable of showing measurable improvement.” As stated previously, this rule requires the QAPI program to be individualized to the HHA. Participation in a larger, system-based improvement program may or may not satisfy the requirements of this rule, depending on whether the larger, system-based improvement program addresses the specific areas of concern or weakness within the HHA component of the system. HHAs are required to include, at a minimum, those areas that are high risk, high volume, or problem-prone, and that reflect the scope, complexity, and past performance of the HHA’s services and operations. If, for example, a system-based program focused on infection prevention and control, while the HHA’s historical area of weakness is the effectiveness of occupational therapy in achieving desired outcomes, then participation in the larger, system-based improvement program would not be considered sufficient to meet the requirements of this rule. Conversely, if an HHA chose to participate in the system-based program that focuses on infection prevention and control in addition to its own separate focus on occupational therapy, then it could be considered to be in compliance. HHAs may choose to focus on areas that are not high-risk, high-volume, or problem-prone in addition to their efforts related to areas that are high-risk, high-volume, or problem-prone. Regardless of the chosen focus areas, HHAs are required to implement performance improvement projects, to monitor their implementation, revise the projects as necessary to achieve success, and assure that improvements are sustained over time. If improvements are not sustained over time, we would expect HHAs to continue to revise their approach as needed until improvements are sustained.

Comment: We received several comments that suggested we remove or revise language in the regulations. Several comments asked that CMS remove or revise the language that used the term “medical errors.” They stated “medical errors” appears more applicable to hospitals and there is a legal definition of “medical error” now associated with liability insurance, so they cautioned CMS to use the term carefully. One commenter suggested the removal of “hospital admissions/re-admissions” and replace it with the terms “emergent care/re-hospitalization” because they pertain more to home health care. One commenter suggested we revise the requirement “immediate correction of any identified problem that directly or potentially threaten the health and safety of patients” because these types of situations indicate “immediate jeopardy” or emergency and should be corrected immediately and not necessarily as a result of data collection.

Response: We appreciate the suggestions related to “medical errors” and hospital admissions/re-admissions. In regards to the term “medical errors”, we are not associating this term with HHA liability insurance. While there may be liability insurance implications that may occur as a result of identifying a “medical error,” such insurance issues are not within the scope of this rule. Recognizing and responding to “medical errors” is an essential responsibility of all HHAs because medical errors are a significant quality and safety concern. As for hospital admission/re-admissions, we agree that using the term emergent/re-hospitalization is acceptable, however, all three of these areas (hospital admissions, re-admissions and emergent care) need to be considered by the HHA. We have revised the regulation at § 484.65 to include emergent care, in addition to admissions and re-admissions. Lastly, we agree that any immediate jeopardy situations that are identified, whether through an incident report, patient complaint, staff observation, or data collection should be corrected immediately. However, we do not agree that it is appropriate to revise the regulatory requirement that there must be an immediate correction of any problem that directly or potentially threatens the health and safety of patients. A problem that directly or potentially threatens the health and safety of patients should be immediately corrected, and we see no reason to change this requirement.

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Comment: We received several comments that asked who should work on QAPI. One commenter stated the preamble mentioned physician participation but did not include physicians specifically in the regulatory language. One commenter pointed out that patients, their representatives and caregivers are not included in the QAPI CoP requirements.

Response: We do not agree that it is necessary or appropriate to specify the persons that should be involved in QAPI. Each HHA may choose different individuals representing different areas of knowledge and experience in order to achieve their specific QAPI goals. HHAs may choose to solicit specific information from physicians, patients, representatives, and caregivers beyond the data that is already gathered from them to use in QAPI efforts.

Comment: One commenter asked if the elimination of the “Group of Professional Personnel” will eliminate physician involvement. The commenter stated that the current group of professional personnel requirement is the only factor that insures a physician has involvement with the operations of the agency. On the other hand, another commenter stated that maintaining the group of professional personnel “was more a troublesome administrative burden than a mechanism that yielded demonstrable benefits for patient care.” This commenter further stated the QAPI program, based on the concepts articulated in the proposed rules and prevailing QAPI accreditation standards, provides a better basis for achievement of patient-focused, performance-based outcomes. Another commenter stated that the previously-required 60 day summary of care statement should be part of an HHA's evidence-based program of quality improvement.

Response: HHAs may choose to involve physicians in their QAPI efforts, and may benefit from seeking the input of a variety of physicians, such as those who refer to home health care, those who manage HHA plans of care, and those who have expertise in quality measurement and improvement. However, we do not believe that it is necessary to mandate physician involvement, because this would be a significant cost to HHAs. Furthermore, HHAs may choose to assess the timeliness and completeness of HHA-physician communications, in their many forms, as part of their QAPI programs. We agree that this measurement and subsequent analysis may be valuable. However, we do not believe that it is appropriate to mandate such measures because they may not meet the specific needs of all HHAs.

Comment: One commenter suggested that CMS add a CoP that requires that every HHA receiving public dollars from Medicare and Medicaid programs must implement an electronic visit verification mechanism. They stated they believe this would provide electronic proof and record accountability that a visit had taken place. In addition, they stated this would be a common sense best practice approach to prevent fraud, waste and abuse that all HHAs must comply with in order to participate in the Medicare programs.

Response: While we agree that electronic visit verification software may be a helpful tool for HHAs to use, there are no uniform standards for the implementation of electronic visit verification. In the absence of these standards, we do not believe that it is appropriate to mandate the use of electronic visit verification software.

Comment: We received several comments asking for clarification and justification for the performance improvement projects. Several commenters asked that CMS be more specific in the requirement for performance improvement projects, specifically asking for a prescribed level of detail regarding their content and frequency. Commenters suggested that performance improvement projects may be warranted in response to a deficiency cited by a survey. In addition, commenters voiced concerns regarding the potential for inconsistent survey processes and outcomes related to this requirement because the requirement for QAPI is not prescriptive. One commenter asked why performance improvement projects are required and expressed concern that conducting performance improvement projects could distract and take away from

program activities that address critical problems. Additionally, a commenter observed that the proposed requirement does not call for the HHA to sustain these improvements. Absent such requirements, the commenter stated that the time and resources would be wasted on a short-lived effort whose effect does not last.

Response: The regulation already requires that performance improvement projects, as part of the overall QAPI program, be focused on indicators related to improved health outcomes, patient safety, and quality of care; focused on high risk, high volume, or problem-prone areas; and that the number and scope of distinct improvement projects conducted annually be reflective of the scope, complexity, and past performance of the HHA's services and operations. To be more specific than these requirements would restrict the flexibility that HHAs need in order to effectively and efficiently comply with these requirements. Of particular note, we believe that the requirement to focus on high-risk, high-volume, and problem-prone areas is the same as focusing on program activities that address critical problems. Rather than detracting from such efforts, the rule would require that they receive the data and resources necessary to develop effective solutions. Furthermore, the regulation at § 484.65(c)(3) requires that "The HHA must take actions aimed at performance improvement, and, after implementing those actions, the HHA must measure its success and track performance to ensure that improvements are sustained." We believe that this requirement will assure that HHAs sustain improvements over time.

Comment: We received various comments on the role of the governing body in the QAPI CoP. A few commenters stated that they supported the concept of "leadership from the top," and that the approval of data collection should be the role of the HHA leaders, not the governing body. We received comments that asked for clarification regarding the role of the QAPI Committee, the Professional Advisory Committee, the Interdisciplinary Record Review Committee and whether one takes the place of another, whether they could be combined, if there were expectations as to who served on what committee, how often each committee would need to meet, whether or not HHAs would need a medical director, and what role they would serve in meeting the QAPI CoPs.

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Response: The HHA governing body is responsible for approving data collection, leaving HHA management responsible for all of the research and decisions leading up to final approval by the governing body. Furthermore, these regulations do not require any particular committees to be used, so we are unable to clarify the roles, schedules, or compositions of committees that HHAs may choose to develop or maintain. Additionally, this regulation does not require an HHA to employ a medical director. If an HHA chooses to employ a medical director, the HHA would be allowed to incorporate the medical director into the QAPI program in a manner that it sees fit.

INFECTION PREVENTION AND CONTROL

Comment: We received many positive comments that supported our new infection control program requirements. Previously, the home health regulations only briefly addressed infection control procedures. One commenter stated they believed incorporating preventive care of infectious diseases is the best addition to the CoPs. Other commenters also agreed that infection control requirements will bring the focus of care back to the patient, and that it will promote and help to improve quality of care.

Response: We agree with commenters that the infection prevention and control requirements are an important addition to the HHA CoPs, and appreciate the support of the commenters.

Comment: Several commenters asked that CMS utilize a phased-in approach for the infection control program. The rationale for a phased-in approach was based on the fact that variation exists among home health agencies with regard to the infection control elements required, and will require additional resources for the agencies.

Response: This rule will be effective July 13, 2017. We believe that this time period will be sufficient for HHAs to develop and implement an infection prevention and control program that complies with these requirements.

Comment: One commenter suggested that CMS consider the requirement of an infectious disease specialist in implementing and maintaining such a program. The commenter believed that having an infectious disease specialist would help align the infection control efforts within the broader, integrated network and could be relied upon to lead the education programs for staff, patients and caregivers.

Response: The services of an infectious disease specialist may be valuable for HHAs in the development and refinement of infection prevention and control. However, we do not agree that the services of an infectious disease specialist are necessary for establishing a program that is capable of meeting the requirements of this rule. We believe that non-specialist physicians, advanced practitioners, nurses, and others have sufficient knowledge and training to create effective programs without the added cost and logistics of consulting an infectious disease specialist.

Comment: One commenter asked CMS to clarify the role of the Infection Control Committee. They asked if it was part of the QAPI or is it a separate committee.

Response: This rule does not require the use of an infection control committee. HHAs are permitted to create an infection prevention and control program using the expertise of all appropriate individuals.

Comment: Several commenters requested clarification on the method, plan and use of “standards of practice” when implementing an infection control program. They specifically asked for examples of surveillance activities, which guidelines or current standards of practice to use, and guidance on the type and amount of education and whether or not it can be provided verbally or if it must be in writing.

Response: Federal and state agencies such as the Centers for Disease Control and Prevention and state departments of health, as well as accreditation organizations and national professional organizations, have all developed infection prevention and control standards of practice. There is a wide variety of information on this subject available for HHAs to choose from in creating their own programs, and we do not believe that it is appropriate to specify which standards HHAs must use. We would expect an HHA to be able to identify the source of the standards it selects and be capable of explaining why those standards were chosen for incorporation into the HHA's infection prevention and control program. Similarly, we do not believe that it is appropriate to specify the form or content of patient and caregiver education regarding infection prevention and control. The education, both in content and format, must meet the needs of the patient and caregivers. This means different things for different individuals. Some understand better with written instructions while others understand better with in person demonstrations and still others understand better with video instructions. The form and content of the education efforts need to meet the needs of the individual being educated. We would expect HHAs to document these efforts in a manner that suits the workflow of the HHA and successfully demonstrate upon survey that the requirement was met.

SKILLED PROFESSIONAL SERVICES

Comment: One commenter suggested that this requirement should be renamed “Professional Services” because use of the term “skilled” may be confusing in relationship to coverage requirements. Additionally, the commenter recommended that CMS develop a more comprehensive title for § 484.75(b) by combining the language for a more inclusive responsibility.

Response: The professions included in this section are all “skilled”; therefore we believe that it is appropriate to maintain this element of the title. Furthermore, we do not agree that standard (b) should be re-named, as the content of the standard is directly related to the responsibilities of skilled professionals.

Comment: While several commenters supported the grouping of discipline-specific regulations under a single CoP, a small number of commenters disagreed with this regulatory text organizational structure. These commenters recommended retaining all of the current provisions as separate CoPs, and adding new regulatory requirements within each of those separate CoPs to support interdisciplinary participation. One commenter was concerned that grouping discipline-specific regulations under a single CoP would impede interdisciplinary care by diluting the roles of professionals within the team. One commenter also asked that “physician extenders” be recognized as part of the interdisciplinary team, while another suggested that physician services include those services provided by interns and residents.

Response: We appreciate the support for the reorganization of skilled professional services. We believe it is in the best interest of the HHA staff that each discipline be held to the same high standard, and that combining all discipline-specific requirements into a single standard will help assure that all disciplines are being equally held to the same expectations. Furthermore, applying the same expectations to all disciplines will facilitate HHA compliance with the regulations as well as facilitate survey consistency. We do not agree that holding all disciplines to the same expectations will dilute the roles of each discipline. In regard to the use of physician extenders, section 1861(m) of the Act specifically defines HHA services as skilled nursing, PT, OT, SLP, medical social services, and medical supplies. However, the Act does not include physician extenders. Therefore, we do not think that it is appropriate to include these professionals in the “skilled professional services” section. Lastly, there is only one place in section 1861(m)(6) of the Act that refers to HHA physician services. The Act states that “in the case of a home health agency which is affiliated or under common control of a hospital, medical services provided by an intern or resident-in-training of such hospital, under a teaching program of such hospital” are part of HHA services. Since we do not have a specific requirement for physician services in any part of this rule, they are otherwise not part of HHA services, and are exceedingly rare. Therefore, we do not believe that regulatory language is needed beyond what is already included in the Act to govern these situations.

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HOME HEALTH AIDE SERVICES

Comment: Several commenters offered support for the home health aide proposed requirements. One commenter states they are pleased CMS is proposing to enhance the current regulations to require HHAs to take action when there is a potential or verified deficiency in aide services. This new monitoring and oversight of aide performance would help ensure ongoing quality care. Another commenter strongly supports the incorporation of home health aides into the health care team process and supports the proposal to add a new home health aide skill requirement related to recognizing and reporting changes in skin condition, including pressure ulcers. Lastly, commenters strongly support the recognition of additional skilled professionals within the interdisciplinary team and urges CMS to adopt an immediate effective date for therapists and other appropriate skilled professionals to determine home health aide assignments.

Response: We appreciate the support of commenters in moving forward with these changes. While we acknowledge that some HHAs may wish to implement select changes as soon as possible, most commenters requested a significant period of time to implement the requirements of this final rule. To accommodate commenter concerns, we are finalizing a July 13, 2017 effective date. Therefore, the provision permitting therapists to determine home health aide assignments will be effective July 13, 2017.

We also appreciate the commenters' support for the new home health aide skill requirement related to recognizing and reporting changes in skin condition, including pressure ulcers. We believe that it is important for home health aides to be taught to recognize and report changes in skin condition; however, it has been brought to our attention that the skills involved in reporting changes in the condition of pressure ulcers are beyond the home health aide's normal scope of practice. Therefore, in light of this information, we are withdrawing our proposal to require home health aides to be taught to recognize and report changes in pressure ulcers. The revision will require only recognizing and reporting changes in skin condition.

Comment: One commenter stated that the regulations for education, training, competency evaluations, certification and supervisory requirements for certified home health aides are different in their state than what is proposed.

Response: We acknowledge that states often have more stringent aide requirements. In situations where a state has more stringent requirements for aide education, training, competency evaluations, certification and supervision, those state requirements would take precedence over these federal requirements. Likewise, in situations where the federal requirements are more stringent, those would take precedence over the more lenient requirements.

Comment: Several commenters expressed concern that the regulation's attention to home health aide service is excessive. Several other commenters suggested that the regulations should allow state nursing boards to set the standards.

Response: Many of the home health aide requirements, such as those for aide training and entities prohibited from offering training, are set forth in the Act and, as such, must be included in the regulation. We have streamlined the home health aide requirements to the greatest degree possible while still implementing the requirements of the Act and assuring that all essential components of aide services that lead to safe and effective patient care are addressed.

Comment: One commenter requested CMS to consider either not requiring home health aides to obtain CNA certification, or change the requirements to maintain CNA certification so a home health aide could maintain CNA certification without undue burden.

Response: To clarify, the proposed regulation does not require CNA training. Rather, the regulation proposed that CNA training (as opposed to home health aide training) may be considered as an appropriate qualification for an individual to be a home health aide.

Comment: A commenter disagreed with the proposed requirement that the individual complete another aide training program before providing services if, since the individual's most recent completion of the aide training program(s), there has been a continuous period of 24 consecutive months during which none of the services furnished by the individual were for compensation. Similarly another commenter recommended that flexibility be incorporated into this requirement. Another commenter stated that the aide 24-month lapse was not necessary.

Response: This regulatory requirement directly implements section 1891(a)(3)(A) of the Act and cannot be altered via regulation.

Comment: We received many comments requesting clarification on several different issues related to home health aides. A few commenters specifically requested clarification on home health aide employment/training. One commenter asked if a home health aide who had worked for an HHA for 10 years and then stopped working for the agency for 2 years to care for an aging parent, would then be required to complete a new aide training program prior to returning to work for the agency? Another commenter asked CMS to clarify what happens if an HHA aide completed another training program but had not furnished home health aide services for 24 months. This same commenter also requested a definition of the term “compensation.”

Response: We appreciate the opportunity to clarify the requirement related to home health aides. Part of our requirements for home health aides states, “A home health aide or nurse aide is not considered to have completed a training and competency evaluation program if, since the individual's most recent completion of the program(s), there has been a continuous period of 24 consecutive months during which no aide services (personal care services, simple dressing changes, assistance with medications that are ordinarily self-administered, assistance with activities that are directly supportive of skilled therapy services, and routine care of prosthetic and orthotic devices) were furnished for compensation.” In the examples from the commenters there was a 24-month lapse in furnishing services for compensation. This means the □ individual must complete another training and competency evaluation program, or a competency evaluation program, before providing services. If an individual has a 24 consecutive month lapse in furnishing aide services for compensation, regardless of the circumstances surrounding the lapse, he or she will be required to complete a new training and competency evaluation program, or a competency evaluation program, prior to providing aide services on behalf of the HHA. Compensation as it relates to home health aide means monetary compensation, as set forth in section 1891(a)(3)(A) of the Act.

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Comment: A commenter cautions CMS against using the word “clinical” in the standard relating to communication skills. It created a higher standard of clinical qualifications than may be required by the state. Instead of “verbally report clinical information,” the commenter suggested, “verbally reporting information relevant to the patient's clinical condition.” In addition, a commenter expressed concern about the possibility of increased expectation regarding the aide's capability in preparing documentation for the clinical record. The commenter asserted that HHA aides are not “certified” and so their level of documentation skills are not standardized. The commenter asked how a surveyor would assess the documentation developed by an aide when documentation standards do not exist for the aide. The commenter also stated that, unlike nurses, who must meet documentation standards by virtue of licensure, aides do not have such standards.

Response: We appreciate the opportunity to clarify the requirements related to HHA aide documentation. We do not agree that the language change to “verbally reporting information relevant to the patient's clinical condition . . .” is any clearer than what was proposed. Therefore, no changes will be made. The commenter also stated that HHA aides are not “certified” and so their level of documentation skills is not “standard.” To clarify, aides are expected to function within their existing state licensure requirements to the extent applicable, so no higher level of skill is expected than what is already established under a state's laws and regulations. As for documentation, this standard is related to the content of the aide training program. By including “documentation” as an element of the basic aide training program, training in documentation would become standardized, and both HHAs and surveyors would be able to assess the accuracy and effectiveness of aide documentation that is produced as a result of this training. HHAs will be held

responsible for the accuracy of information in the clinical record that is created by HHA aides, in accordance with the requirements of § 484.110. HHAs will also be held responsible for assuring that each aide completes, at a minimum, a competency evaluation to assure that an aide's documentation skills are sufficient.

Comment: We received several comments regarding HHA aide training. A few commenters requested clarification on currently employed HHA aides who have already been through basic training and competency assessment. Specifically the commenter asked if agencies will need to implement training regarding skin care, decubitus ulcers and communication and if that could be met through in-service training. Other commenters asked CMS to provide greater clarification as to the requirements regarding home health aide communication skills, including the required ability to read, write and verbally report clinical information to patients, representatives and caregivers as well as HHA staff. Several commenters suggested that the effective date for compliance be phased in to accommodate those aides currently employed by the agency to receive updated training in new areas through in-service training. A few commenters proposed that a certified nurse aide must successfully complete supplemental training in order to qualify as a home health aide. One of the commenters went on to suggest that the content of this training should be set by CMS and approved by the state.

Response: This rule will be effective on July 13, 2017. We do not believe that additional time for this provision is necessary because current HHA aides would only require training on new skills (for example, recognizing skin changes), which may be done through routine in-service training. In accordance with the requirements of § 484.80(a), individuals trained as nurse aides are already required to complete a competency evaluation to assure that they have the skills appropriate to furnish home health aide services to home health patients. In accordance with the requirements of § 484.80(c)(4), any skills for which a HHA aide is evaluated as unsatisfactory may only be done under the direct supervision of a registered nurse until such time as he or she successfully completes a subsequent evaluation. Retraining would be done as needed to assure competency in all required skill areas. We believe that this competency evaluation process will assure that nurse aides possess all necessary skills to furnish safe and appropriate care to home health patients.

Comment: A commenter requested clarification as to whether HHAs could use in-service education provided by another organization such as the HHQI national campaign, accompanied by a post test, adding that the HHA would still provide any educational needs or questions the aide may have.

Response: We appreciate the opportunity to clarify the requirements related to HHA aide in-service education. It would be permissible for HHAs to use in-service education through another organization, as long as it is under the supervision of an RN.

Comment: A commenter stated that the roles and responsibilities of the home health aide should be clarified. For example, the proposed language may be interpreted as allowing home health aides to provide clinical information to the patient, which the commenter did not support. In addition, the commenter recommends that this requirement provide specific direction as to how home health aides are to be involved on the interdisciplinary team.

Response: We appreciate the opportunity to clarify the requirements related to home health aide roles and responsibilities. The role of the aide is governed by the state licensure requirements. Therefore, CMS believes aides should be able to communicate clinical information to patients that is within the aide's licensure requirements (for example, blood pressure). While we understand the request for clarification related to the

home health aide's involvement in the interdisciplinary team, we believe that being prescriptive on how aides should be involved in the team could limit the HHA's own creativity, flexibility and innovation. It is up to the HHA to decide how it would like its aides to be involved in the interdisciplinary team.

Comment: A commenter stated that § 484.80(g)(3) could be misinterpreted to imply that the physician-signed plan of care must specifically identify each individual who would perform all of the duties set out in subparagraphs (g)(3)(i) through (iv).

Response: We appreciate the opportunity to clarify these requirements. We would expect the physician-established plan of care to authorize aide services in general. However, the aide-specific plan of care would be established by the RN or qualified professional, and would be expected to contain the level of detail set out at subparagraphs (g)(3)(i) through (iv).

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Comment: A commenter requested clarification on which professionals may give written instructions to aides. This commenter stated that many times OT is involved in preparing the plan of care, but is not involved for the duration of the care, and thus would not be supervising the aide.

Response: While written patient care instructions for the aide must be prepared by a licensed professional, preparing the written care instructions includes overseeing the contributions from all disciplines involved in the plan of care and synthesizing those contributions. As a result, a discipline that is involved in the patient's care for a portion of their time on service would contribute its information to the clinician responsible for developing the written instructions.

Comment: We received several comments related to HHA supervision. One commenter requested clarification on § 484.80, stating "please clarify 'professional'. Does this mean the actual professional (person) who completes the home health aide plan of care, or can any professional by discipline (for example, RN) perform the supervision?" A commenter suggested that an RN, PT, or OT should be permitted to supervise home health aides. One commenter requested clarification on the requirements for supervision of aides caring for skilled care and non-skilled care, specifically the 14-day versus the 60-day minimum supervision timeframe requirement. Another commenter asked CMS to clarify that the CoP requires the aide supervisor make at least one home visit for each non-skilled case every 60 days rather than one home visit per home health aide every 60 days. Some commenters were opposed to the 14-day supervisory aide visit, requesting that we remove the timeframe entirely, while others stated that phrasing the time frame as "every 2 weeks" provides the agency with more flexibility. Other commenters stated that it is more practical to allow home health aide supervision to be performed during a regularly scheduled skilled visit and/or to occur when the home health aide is actually present in the patient's home, while another commenter noted that skilled visits may occur on an infrequent basis, such as every 3 weeks. Some commenters stated that requiring the aide supervision to occur onsite, as opposed to being completed via a phone call, adds undue burden on the HHA in the form of non-billable nursing visits.

Response: We appreciate the opportunity to clarify the requirements related to home health aide supervision. As originally proposed, the requirement expected that written patient care instructions for the aide would be prepared by the same clinician who would supervise the aide. However, the proposed requirement generated significant confusion, and we believe that it should be revised to be simpler. To that end, we have removed the requirement that written patient care instructions for the aide would be prepared by the same clinician who would supervise the aide. In its place, we are finalizing a requirement that the skilled professional who supervises aide services must be familiar with the patient, the patient's plan of care, and the written patient care instructions described in § 484.80(g). This revision accomplishes the same goal

of assuring that the skilled professional responsible for supervision has all of the information necessary to effectively supervise the aide's services while removing the confusing regulatory language that was originally proposed.

We also appreciate the opportunity to clarify the aide supervision timeframes. If the patient is receiving skilled visits by an RN, PT, OT, SLP, then a supervisory visit is required at least once every 14 days. If the patient is receiving non skilled visits, meaning that RN, PT, OT, or SLP services are not being provided to that patient during that episode of care, then a supervisory visit is required every 60 days for each patient. While we acknowledge the request to change the "every 14 days" to "every 2 weeks," we disagree that this is an appropriate substitute. The 14-day requirement provides a more reliably frequent supervision schedule, whereas "every 2 weeks" creates the possibility for excessively long gaps between supervisory visits. Lastly, we believe that supervision by phone is not adequate. Without the supervisor actually seeing the patient in person, the onus is placed on the patient to report substandard care. The patient is not necessarily qualified to recognize when standards of practice are not followed. It is the responsibility of the HHA to ensure patient care is being delivered according to best practices, as well as agency policies and procedures. However, if a patient or representative report a problem related to the delivery of aide services, the expectation would be that the problem is noted by the supervisor and an onsite supervisory visit to observe aide serves would occur. We believe in-person supervision is in the best interest of the patient, ensuring quality health care in a safe environment.

Comment: A commenter stated that they did not agree that if an aide performed task(s) unsatisfactorily, only an RN could subsequently supervise (rather than a LPN), stating that both RNs and LPNs are qualified to supervise home health aides. The commenter proposes that CMS consider allowing for the RN or LPN to be able to assess the aide's proficiency of the task in a laboratory setting in addition to the patient's home. Another commenter recommended that remediation on the skill that was deemed deficient be required, rather than a complete competency evaluation.

Response: A registered nurse is responsible for overall aide supervision; therefore we believe that it is appropriate to require that a registered nurse must be responsible for supervising an aide in a task for which the aide's skills have been determined to be unsatisfactory. In addition to this level of supervision, a competency evaluation is necessary in situations where an aide's skill is noted to be unsatisfactory because a deficiency in one skill area may indicate higher likelihood of deficiencies in the aide's other skill areas. A competency evaluation would provide HHAs the opportunity to note any additional skill deficiencies, as well as the opportunity to retrain aides on unsatisfactory skills, thus assuring safer patient care.

Comment: One commenter requested clarification regarding the wording of § 484.80(h)(1)(iii), stating that this requirement may be interpreted as either requiring the HHA to provide an annual on-site visit to one of the home health aide's patients while the aide is working or that the HHA has to do an annual visit on each patient being seen by each home health aide. The commenter also expressed concern that in § 484.80(h)(1)(ii), the term "potential deficiency" is undefined and lacks a timeframe for what and when potential deficiencies would require a follow-up visit by the supervisor. They recommended that CMS change the term "potential deficiency" to a more solid term necessitating follow-up such as "identified deficiency." The commenter also requested further clarification of this requirement by including a time frame for the supervisor's site visit and adding this time frame requirement to § 484.80(h)(3).

Response: We appreciate the opportunity to clarify the requirements related to the aide supervisory visits. To clarify, the intent of this standard is to require supervision of each aide with at least one patient every year. We agree with the comments that the term "potential deficiency" may be misleading. Therefore we are

amending □ the language to state “area of concern”, which is also consistent with the way we express this same concept in the hospice CoPs. Lastly, we disagree with the commenters suggestion to include a time frame for the supervisor's site visit and adding this time frame requirement to § 484.80(h)(3). We want to ensure the necessary flexibility to account for variations in aide visit frequencies to the patient's home, as some patients have more frequent aide visits while others have less frequent aide visits. We also want to allow HHAs to tailor the timing of the direct supervision to the urgency of the area(s) of concern, with those that may affect patient safety or outcomes requiring a faster response time.

Comment: One commenter requested clarification on whether the supervision elements set forth in (h)(4)(i) through (vi) must be documented on each aide supervisory visit. Lastly, one commenter requested clarification on what is meant by “demonstrate specific communication skills”?

Response: All elements set forth in paragraph (h)(4) need to be accounted for in each and every supervisory visit. In other words, each supervisory visit would need to provide for and document supervision related to: Following the patient's plan of care for completion of tasks assigned to a home health aide by the registered nurse or other appropriate skilled professional; maintaining an open communication process with the patient, representative (if any), caregivers, and family; demonstrating competency with assigned tasks; complying with infection prevention and control policies and procedures; reporting changes in the patient's condition; and honoring patient rights. The phrase “demonstrate specific communication skills” was never used in the proposed rule, so we are unable to clarify its meaning or intent.

COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAWS AND REGULATIONS RELATED TO HEALTH AND SAFETY OF PATIENTS

Comment: We received several comments regarding lab services, specifically, the prohibition on substituting home health agency equipment for patient's equipment. Several commenters suggested that CMS allow HHAs the flexibility of using agency equipment based on individual patient need and with the patient's consent when assisting with self-testing. A few commenters requested clarification regarding situations when a patient could not afford equipment, or when testing would be for a short period of time. Commenters also asked if testing would be covered by a CLIA waiver, and, if an agency does not have a CLIA waiver, would they be covered to use their own equipment. Another commenter asked whether a patient's refusal to obtain equipment would be a reason to discharge for cause.

Response: We proposed and are finalizing a requirement that HHAs may not substitute HHA-owned self-administered testing equipment for patient-owned self-administered testing equipment. As stated in the preamble to the proposed rule, “Agencies may also use their own self-administered testing equipment for a short, defined period of time when the patient has not yet obtained his or her own testing equipment, such as in the days immediately following physician orders to obtain the testing equipment when a patient may not have the time and resources immediately available to complete the process. We would expect the HHA to use available resources to assist the patient in obtaining his or her own testing equipment as quickly as possible.” We believe that this establishes a reasonable expectation for the use of HHA owned self-administered testing equipment on a short-term basis while a patient obtains his or her own equipment. HHAs are expected to help patients identify and access existing resources that mitigate or alleviate any potential barriers to obtaining this essential equipment. We believe that enabling patients to use their own equipment will improve the quality of care management that they experience and will avoid the potential for a patient to not have access to any testing equipment in emergency situations when HHA staff may not be immediately available to provide it. In cases specifically related to the use of self-administered testing equipment for purposes of blood glucose monitoring, if, despite all HHA efforts to help patients identify and access existing resources that mitigate or alleviate any potential barriers to obtaining this essential equipment, a patient

refuses to obtain his or her own testing equipment, and if the patient is receiving the Medicare home health benefit, then the refusal to obtain self-administered testing could be grounds for patient discharge. Daily, and multiple daily visits for purposes of blood glucose monitoring over a long period of time would not meet the criteria for coverage of Medicare home health services under section 1861(m) of the Act, which prohibits payment for services that are more than part-time or intermittent. Therefore, an HHA would be permitted to discharge the patient because the payment source will no longer pay (see § 484.50(d)(2)). However, we believe that these situations are very rare. We would expect an HHA to thoroughly document all steps taken to resolve this issue, converse with the patient regarding the implications of this decision, communicate with the physician responsible for the home health plan of care and the practitioner who will be providing follow-up care, and provide the patient with information regarding other possible sources of care that may meet the patient's care preferences.

If the HHA is only assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the Food and Drug Administration (regardless of appliance ownership status), the testing self-administration assistance is not required to be in compliance with the applicable requirements of part 493 of this chapter. However, 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 Food and Drug Administration, then the testing must be in compliance with all applicable requirements of part 493 of this chapter.

ORGANIZATION AND ADMINISTRATION OF SERVICES

Comment: While one commenter strongly supported the proposed requirement that an HHA organize, manage and administer its resources to attain and maintain the highest practicable functional capacity for each patient's medical, nursing and rehabilitative needs as indicated by the plan of care, including overcoming those deficits that led to the patient's need for home health services, another commenter disagreed with this proposal. The commenter recommended revising the requirement from "overcoming those deficits that led to the patient's need for home health services" to "providing optimal care to meet patient's identified needs."

Response: We agree that revising this statement is appropriate to reflect the broad scope of HHA services that may be provided, including maintenance services. The revised is as follows, "The HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs."

Comment: A commenter recommended a total revision of the □ organization and administration requirements in a manner that removes established roles (for example, administrator and clinical manager) in favor of a structure that focuses on parent offices, where non-patient care administrative functions are performed and service locations from which patient care functions are performed.

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Response: A revision of this extent would be a significant departure from the original proposal. Thus, we believe that, should we choose to act upon this recommendation, such actions would be most appropriately undertaken in separate rulemaking to allow all interested parties the opportunity to comment on such changes.

Comment: Several commenters suggested that the regulations should require an HHA to have a physician that serves as the HHA medical director, similar to what is already required in the regulations for nursing homes and hospices. Commenters suggested that the medical director be responsible for the following:

- Implementation of patient care policies;
- Coordination of medical care within the HHA;
- Coordination and oversight of related practitioners;
- Clinical leadership regarding application of current standards of practice for patient care and new or proposed treatments, practices, and approaches to care;
- Promoting attainment of optimal patient outcomes;
- Serving as a clinical resource when attending physicians are unavailable to ensure that urgent matters are addressed;
- Diagnosing changes in patient condition;
- Linking the HHA to the physician community to improve HHA-physician relationships; and
- Providing input for the HHA's QAPI program.

Additionally, commenters requested that the relationship between the medical director and the governing body be defined.

Response: A new requirement of this magnitude, both in terms of potential effect on HHA daily operations and HHA costs, would be a significant departure from the original proposal. Thus, we believe that, should we choose to act upon this recommendation, such actions would be most appropriately undertaken in separate notice and comment rulemaking to allow all interested parties the opportunity to comment on such changes.

Comment: Commenters agreed with the proposed role of the governing body, but asked for clarification regarding the composition of the group. A commenter asked if the Professional Advisory Committee could be considered the governing body for purposes of this rule. Commenters also asked if there were specific disciplines that would be expected to be represented in the membership of the governing body and if there were specific requirements for how often the governing body would need to meet. Lastly, commenters asked for further explanation of the proposal that the governing body would assume “full legal authority” for the HHA.

Response: An HHA may establish a governing body composed of individuals of its choosing. The individuals that comprise the governing body are those who have the legal authority to assume responsibility for assuring that management and operation of the HHA is effective and operating within all legal bounds. Those individuals could be members of the previously-required Professional Advisory Committee, but that is not a requirement.

Comment: Many commenters submitted comments regarding the proposed requirements for HHA administrators. Of those commenters, many requested clarification on whether a single administrator would be permitted to oversee the operations of multiple HHAs. Commenters suggested that HHAs should be permitted to use this arrangement if it could be demonstrated that the administrator could fully meet the requirements of the duties set forth in the proposed rule. Commenters suggested that, in order to permit this arrangement, the regulation should be revised to clarify that the administrator be immediately available “in person or by telecommunications.”

Response: The HHA administrator is required, among other things, to be responsible for all day to day operations of the HHA (§ 484.110) and to be available to patients, representatives, and caregivers to receive complaints (§ 484.50(c)(3)). Our expectation is that the administrator will be actively involved in the daily responsibilities of running the HHA, and that HHAs will be able to demonstrate such involvement upon survey. We do not specify the manner in which this daily involvement must occur. We did not propose, nor

are we finalizing, a requirement that each HHA have a full-time administrator. Therefore, it is permissible within these regulations for an administrator to work part-time for more than one HHA. However, we believe that the expectation of active involvement in daily operations and regular availability to patients, caregivers, and representatives would be difficult, if not impossible, for an administrator to meet if he or she is responsible for operating numerous HHAs on any given day.

Comment: A commenter suggested that the role of the administrator should focus on the function of the HHA, assuring accountability to the governing body, and managing problems that cannot be resolved on a clinical level. Another commenter suggested that the role of the administrator should include responsibility for acting as liaison with the governing body, employing qualified personnel, ensuring adequate staff education, and conducting evaluations.

Response: We agree that the administrator should be accountable to and should report information to the governing body, and have added this requirement to the final rule. We also agree that assuring that the HHA employs qualified personnel is a responsibility of the HHA administrator, and have made this change. This is particularly important for the hiring and oversight of all management roles within the HHA. We believe that this concept includes assuring the proper education and training of those staff being hired. Furthermore, we agree that managing problems that cannot be resolved on a clinical level is part of the role of the administrator. However, we believe that this concept is already embodied in the requirement that the administrator must be responsible for all day-to-day operations of the HHA. We do not agree that an HHA administrator would be responsible for conducting staff evaluations, as directly evaluating all staff would be an inefficient use of administrator resources, and would likely be the appropriate responsibility of other managers within the organization.

Comment: A commenter suggested that the regulations should require an HHA to have a qualified professional clinician available to provide clinical oversight during all operating hours. The commenter noted that the current HHA regulations require a supervising physician or nurse, or equally qualified person, to be available at all times during operating hours. The proposed regulation requires the administrator (who may or may not be a clinician), or a pre-designated person who is a skilled professional, be available during operating hours. The proposed regulation did not require the clinical manager (who is a registered nurse or physician) to be available during operating hours, and did not require a designee in the clinical manager's absence. Therefore, the commenter stated that there exists the potential for a home health agency to be operating without the direction of a clinician during operating hours. For example, when the administrator is available, the proposed rule does not specify the need for any pre-designated skilled professional to be available as well. If the administrator is not a clinician, and the clinical manager is not on duty, the home health agency would be operating without a designated clinical manager.

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Response: We agree with the commenter that, as originally proposed, the regulations created the potential for a situation where a home health agency would be operating without a designated clinician serving in a manager role. This was not our intent, and we greatly appreciate the commenter's insight into this matter. We believe that a gap in clinical leadership would pose a threat to patient health and safety, as clinicians in the field would not necessarily have ready access to clinical management expertise and guidance when needed. In order to remedy this oversight, we have revised the regulatory text at § 484.105(b)(1)(iii) to require that a clinical manager, rather than a skilled professional, be available during all operating hours.

Comment: Many commenters requested additional information regarding the process for designating an individual to act on behalf of the administrator in his or her absence. Commenters asked whether the person designated to fill the role of the administrator, also referred to as the administrator designee, would need to

be registered with the State Survey Agency. Commenters also asked for information regarding the timing of the designation, wanting to know whether it could be done a few days prior to the administrator being on planned leave. In addition, commenters made suggestions regarding those responsible for authorizing the administrator designee. One commenter suggested that the administrator should be permitted to authorize the designee, while another commenter suggested that any one member of the governing body should be allowed to authorize the administrator designee.

Response: Section 484.100(a)(2), which implements section 1891(a)(2) of the Act, requires disclosure of certain specified information regarding an officer, a director, an agent, or a managing employee of the HHA. This statutory authority does not extend to individuals who may act in a management capacity on an episodic basis for a short period of time in the administrator's absence (for example, 2 weeks a year while the administrator is on vacation and on an occasional basis when the administrator is ill). However, if an individual were to act in a managing employee capacity as the administrator designee on a frequent or regularly scheduled basis (for example, 1 day a week every week, a few hours each day, or 2 weeks out of each month), then that individual would be a managing employee, and the HHA would be expected to disclose the required information in accordance with § 484.100(a). The timeframe for pre-designating the individual who will be responsible for fulfilling the role of the administrator in his or her absence should be established in each HHA's own policies and procedures. We note that pre-designation needs to be by both the administrator and the governing body as a whole. The time necessary to obtain governing body approval for the designation should be factored into the HHA's timeframe as established in its policies and procedures. The goal of this requirement is to provide management continuity within the HHA to the greatest degree possible. HHA staff should know and be able to verbalize upon interview whom the pre-designated individual(s) is/are for this role.

Comment: Several commenters made suggestions related to the number of administrator designees that an HHA should be permitted to have. Commenters agreed that having one administrator and one administrator designee may not be sufficient to allow for situations of illness, planned vacations, and various other factors. Some commenters suggested that three administrator designees may be appropriate, while others suggested having no limits to the number of designees that an HHA may select. One commenter suggested that, rather than have the governing body approve a single designated back up person to function in the absence of the administrator, the regulation should allow the governing body to approve the HHA's policy outlining how administrative oversight will be transferred in the absence of the administrator.

Response: The number of administrator designees should be determined by HHA needs and set forth in each HHA's policies and procedures. As stated previously, the goal is to provide continuity within the HHA to the greatest degree possible. HHA staff should know and be able to indicate to a surveyor whom the pre-designated individual(s) is/are for this role. We are retaining the requirement that the governing body must approve the pre-designated individual(s). The governing body is responsible for the administrator's appointment, and should be similarly responsible for the designee's appointment.

Comment: A commenter suggested that the regulation should clearly permit the clinical manager to serve as the administrator designee, as long as he or she meets the qualifications for the administrator as described in § 484.115(a).

Response: The clinical manager may be the designee, as long as he or she meets the personnel qualifications to do so. However, it would not be appropriate to specify this in the regulatory text, as such an addition may inaccurately imply that others within the HHA who also meet the personnel requirements would not be permitted to be the designee.

Comment: A commenter suggested that the term “equally qualified substitute” be used in place of “pre-designated person” to describe the individual who fills the administrator role in the absence of the administrator.

Response: We believe that both the “qualified” and “pre-designated” nature of the individual should be included in the regulation, and have added “qualified” to the regulatory text. An individual would be considered “qualified” to be the “pre-designated individual” by meeting the personnel qualifications for the administrator role as set forth in § 484.115(a).

Comment: A commenter requested clarification of the phrase “operating hours” as it was used in terms of the availability of the administrator. The commenter stated that HHAs typically have a nurse available to see patients 24 hours per day, and wanted to know if this availability would also mean that the administrator must be available 24 hours a day.

Response: As currently stated in the HHA interpretive guidelines (http://cms.hhs.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_b_hha.pdf (http://cms.hhs.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_b_hha.pdf)), the term “operating hours” means all hours that staff from the agency are providing services to patients. For the sake of consistency, we intend to maintain this understanding of the term.

Comment: We received many comments related to the proposed requirement that each HHA have a clinical manager who is responsible for several duties. Many of these commenters were supportive of the new requirement, stating that it more clearly articulates the responsibility of the former supervising physician or supervising nurse role, ensuring that patient needs are continually assessed, and ensuring coordination of care, coordination of referrals, and updating of plans, etc. While some commenters suggested that the role be eliminated altogether, other commenters sought clarification regarding its function, goals, and operational implementation. A commenter asked if this role was intended to be filled by the individual who would provide hands-on care in the field, or if it could be filled by a supervisor who may not be out in the field. Another commenter expressed a similar concern, asking whether the clinical manager would be responsible for oversight of certain agency functions (for example, making patient and personnel assignments, coordinating referrals, and assuring that patient needs were continually assessed) or whether the clinical manager would have to perform the functions himself. Some commenters asked whether multiple individuals would be permitted to fulfill the clinical manager role, noting that in large HHAs it may be difficult for one single individual to perform all of the proposed duties. Some suggested that multiple people could all do the same job, each for an assigned subset of the HHA's patient population, while others suggested that multiple people could divide the duties of the clinical manager role, such as one clinical manager is responsible for oversight of personnel and another clinical manager is responsible for patient care services. Other commenters suggested that the clinical manager should be permitted to delegate to other individuals, both clinical and non-clinical, to carry out the duties for which the clinical manager has oversight responsibility. Some commenters supported the idea that the clinical manager and the administrator should be separate roles filled by separate individuals, while other commenters stated that the roles should be permitted to be combined and filled by a single person.

Response: The clinical manager requirement is set forth as a list of responsibilities, such as coordinating patient care and referrals (§ 484.105(c)), in order to allow HHAs flexibility in its implementation. In a small HHA one clinical manager may fulfill all of these roles and for all patients. In a larger HHA, multiple clinical managers may divide up the HHA's caseload, and each clinical manager takes responsibility for assuring all of these functions for his or her caseload. Alternatively an HHA may have one clinical manager that delegates

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different aspects of the clinical manager role to different individuals, assuring that each individual performs the necessary duties and functions. The organizational structure for each HHA will vary, as set forth in each HHA's own policies and procedures. While we believe that it would be rare for a single individual to be capable of effectively fulfilling all of the responsibilities of the administrator and the clinical manager for an entire HHA, this rule would not prohibit this arrangement, provided that the individual meets the personnel qualifications for both roles as set forth in § 484.115 and the quality of care provided to patients is not compromised. However, we believe that in the vast majority of situations, HHAs will find it necessary to have at least two individuals fulfilling the administrator and clinical manager responsibilities separately.

Comment: Numerous commenters suggested that, in addition to permitting a registered nurse or a physician to fill the clinical manager role, the regulation should also permit a physical therapist, speech-language pathologist, occupational therapist, audiologist, or social worker to fill the clinical manager role.

Response: We agree that these skilled professionals may have the appropriate qualifications to fill this role. HHAs will be responsible for assuring that any skilled professional filling the role of the clinical manager has the necessary clinical, managerial, and communication skills needed to successfully fulfill his or her responsibilities as a clinical manager. The regulatory text regarding the qualifications for a clinical manager has been revised accordingly, and has been moved to the "Personnel Qualifications" section of the rule at § 484.115.

Comment: A few commenters opposed the proposal that the clinical manager be responsible for assuring the development of personnel qualifications and policies. Commenters stated that this is the role of the Human Resources staff, which has specialty knowledge regarding the legal rights and obligations of professionals relative to their employment with the organization. Commenters suggested that the development of personnel qualifications and policies should be the responsibility of the administrator and the human resources director, with approval from the governing body. Commenters also suggested that clinical managers should express the needs of the clinical program to the Human Resources staff so that those needs could be reflected in personnel policies (including, but not limited to, job duties, job knowledge, expectations relating to the submission of clinical notes, productivity expectations, and hours of work). These commenters suggested that it would be more appropriate to require that the clinical manager collaborate with the administrator regarding the development of personnel qualifications and policies.

Response: We agree that assuring the development of personnel qualifications, and policies and procedures, is a task more appropriately assigned to the administrator, rather than the clinical manager. We have revised the regulatory requirement at § 484.105(b)(1)(iv) accordingly. The administrator may choose to delegate these tasks to others, including the clinical manager, as appropriate, while retaining the responsibility for assuring that tasks are completed and duties performed.

Comment: A commenter recommended that the clinical manager be responsible for "supervision of staff."

Response: Both the proposed and final rule require that the clinical manager provide oversight of personnel. We believe that the broad concept of "oversight" already includes the narrower concept of "supervision." The extent to which the clinical manager directly supervises personnel or delegates such functions to others, while maintaining responsibility for assuring that supervision is done appropriately, would be left to the discretion of HHAs as established in their individual organization structures, as well as their own policies and procedures.

Comment: A few commenters suggested alternate phrasing for the clinical manager requirement in a way that avoids creating a specific management position. While the commenters supported the concept of HHA staff members performing the duties set forth in the proposed rule, they opposed establishment of a specific managerial role for those duties. Commenters suggested that the regulation should identify the functions that need to be performed without using the “clinical manager” title, and require that “a designated HHA staff member” who is a qualified licensed physician or registered nurse provide oversight. One commenter suggested that the regulation should be re-named “Oversight of Patient Care Services and Personnel.”

Response: As stated in the preamble of the proposed rule, our goal is to consolidate under the direct responsibility and authority of HHA management those areas that receive the most frequent deficiency citations. We believe that the clinical manager role is essential for managing the complex, interdisciplinary care of home health patients. Although the current HHA rule addresses these issues, it does so in a decentralized manner that has not consistently led to the patient care outcomes that we seek to achieve in this rule. Six of the twenty most frequently cited survey deficiencies center on the need for patient care coordination and implementation, including the most frequently cited deficiency related to ensuring that each patient has a written and updated plan of care. These frequent deficiency citations indicate that patient care, as structured under the current CoPs, is not being sufficiently planned, coordinated, and implemented to ensure the highest quality care for all HHA patients at all times. As such, we believe that a new approach is needed in order to consistently achieve improved patient outcomes, and that consolidating these frequently deficient areas under the overall responsibility of a designated management position will address this need. HHAs may choose to organize one or more clinical managers in a manner that meets their needs, but we believe that this designated position is essential.

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Comment: A few commenters expressed strong support for the proposed parent-branch relationship, particularly the proposal to remove distance between locations as a consideration in the branch approval process, stating that, distance should not be a consideration as long as the parent can demonstrate administrative control over the branch. Commenters also supported the proposed requirement that the parent office has direct day-to-day control and direct supervision of all activities performed and services provided by/from the branch office, including all contracts, personnel oversight, plans of care, services, quality control, etc. However, one commenter stated that the proposed rule did not go far enough in abandoning geography as an organizational consideration. The commenter stated that advancements in technology available to HHAs, including IT enhanced functions like clinical software (including, but not limited to, assessments, plan of care, and scheduling), IT support, payroll, communications, accounting/billing and many administrative functions, such as HR administration, insurance and strategic planning, are amenable to centralized configuration for multiple service locations, as opposed to decentralized provision of services and day-to-day supervision of services.

Response: We appreciate the support of most commenters, and believe that the proposed, and finalized, requirements strike an appropriate balance between the need for HHA flexibility in management and structure, and the need to assure accountability throughout an organization and its many possible locations in a manner that assures patient safety and high quality patient care.

Comment: While some commenters supported the proposal to discontinue the use of subunits, many commenters posed logistical questions regarding the conversion of existing subunits to branches or independent HHAs. One commenter indicated that its “branches” currently have their own provider number or NPI, and asked whether those “branches” that currently do have their own NPI will be required to be registered as a separate agencies. Other commenters noted that the current CMS Manuals indicate that there

is a process for the conversion of a branch to a subunit; however, those Manuals are silent on the process for the conversion of a subunit to a branch or to a parent HHA. In light of this, commenters posed the following questions:

- How will the transition need to occur for patients who span the conversion in terms of claim submission? Will agencies need to close the patient under the subunit provider number and re-open the patient's care under the parent provider number? Will that require a new start of care and associated face-to-face evaluation?
- Will a subunit converting to an independent HHA automatically be “recognized” as an independent parent HHA without any further application or formal conversion process? As a part of that recognition, will the subunits converting be permitted to maintain their current CMS certification numbers (“CCN”) so as not to interrupt treatment, billing and reimbursement for current patients?
- Will subunits undergoing the conversion process to branches be treated as new enrollees?
- Will subunits undergoing the conversion process be required to submit new CMS Form 855A applications?
- Will subunits undergoing the conversion process be subject to survey as a “new” HHA?
- Will subunits undergoing conversion be required to discharge current patients and readmit them to the parent HHA or an alternative HHA provider during the conversion process?
- Will billing and claims processing for subunits undergoing conversion to branch offices be interrupted, and how?
- How will subunits being converted to branch offices be added to their parent HHAs' CCNs?
- If an 855A is required for a subunit being converted, is there a way to streamline the process for approval if the subunit has a positive compliance record?
- How will subunits undergoing the conversion process to become a branch be held accountable for data transmission, billing, and compliance during the transition process?

Response: HHAs with subunits will need to work through a wide variety of questions and concerns. As the commenters indicated, guidance related to converting a branch to a subunit is set forth in CMS manuals in section 2182.3 of the State Operations Manual (<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf> (<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf>)). Similarly, we believe that the logistics of converting existing subunits to branches or independent HHAs is also more appropriately addressed in CMS manuals than in this regulation. Following publication of this final rule, we intend to issue a Survey and Certification letter to the states that will explain the change in terminology and revise the guidance to reflect the new terminology. Additionally, we will revise sections of Chapter 2 of the State Operations Manual that address branches and subunits to reflect the changes finalized in this rule.

Comment: Many commenters suggested that, in order to smooth the process of converting subunits to branches or independent HHAs, CMS should reprioritize approval of new branches and new HHAs from a tier 4 priority to a tier 1 priority in the State Survey Agencies and CMS Regional Offices.

Response: Subunits are already the equivalent of stand-alone HHAs and will be able to continue functioning as such, relieving the need to change to branches. Since there would be no threat to an HHA's ability to function and serve its patients, we do not agree that it would be appropriate for CMS to allocate survey resources to those HHAs that desire to, but do not need to, convert a subunit to a branch. Thus, the current process and priority levels will remain the same.

Comment: Numerous commenters stated that the final regulation should provide ample time for HHAs to convert a subunit to either a parent or a branch. Commenters stated that HHAs converting from subunits to independent parent HHAs may need to put into place a new governing body and/or appoint a new

administrator, meaning that HHAs may need time to recruit, hire, train and integrate these individuals. Commenters also stated that time may be needed for subunits to file new or amended state licensure applications and complete the processes necessary to obtain new or amended licenses. Lastly, commenters also stated that existing subunits in some states would have to seek and obtain permission from their respective state certificate of need agencies to convert to an independent parent HHA before they could even apply for the necessary state license. For these reasons, commenters requested a transition period of 6 to 12 months to ensure that HHAs have adequate time and preparation to come into compliance with the new parent-branch requirements that eliminate the use of subunits.

Response: All requirements set forth in this rule, including the removal of the subunit organizational structure, are effective July 13, 2017. We believe that this will provide HHAs with adequate time to make any adjustments for a subunit to begin operations as a stand-alone HHA.

Comment: One commenter suggested that the regulations related to HHA structure and parent-branch relationships could be streamlined by eliminating the requirement for bordering states to have reciprocal agreements in place in order to cross state borders. The commenter stated that this would negate the necessity of the separate provider number and resulting duplicative and unnecessary administrative costs. Agencies' offices in bordering states could then function under the revised branch definition, as proposed.

Response: This suggestion regarding reciprocal agreements between State Survey Agencies is related to the survey process, and is not within the scope of this rule, which sets forth the health and safety requirements for HHAs. Therefore, we are not addressing it in the rule.

Comment: A commenter requested reassurance that HHAs with existing subunits may choose to convert the subunit to either a parent or a branch at the HHA's discretion, subject to state-specific laws and regulations and the ability of the parent to demonstrate direct support and administrative control.

Response: The commenter is correct. A subunit may choose to be a distinct HHA (a parent) or go through the current approval process to become a branch.

Comment: A commenter expressed concern with the proposal that an HHA may not contract with an entity that has been denied Medicare or Medicaid enrollment; been excluded or terminated from any federal health care program or Medicaid; had its Medicare or Medicaid billing privileges revoked; or been debarred from participating in any government program. The commenter asked whether the entity's attestation that it meets these conditions as part of the written agreement would be sufficient to demonstrate compliance with this requirement. The commenter stated that it would be very difficult for an HHA to obtain this information directly.

Response: We appreciate the opportunity to clarify this requirement. Enforcement of these provisions will vary based on the specific provision to be verified. In order to identify whether or not an entity has been denied enrollment or had its billing privileges revoked, we agree that written and signed self-certification is the most appropriate method to assure compliance because this is not publicly available information that HHAs can check on their own. However, we expect that HHAs will routinely check the List of Excluded Individuals and Entities (<https://oig.hhs.gov/exclusions/> (<https://oig.hhs.gov/exclusions/>)). HHAs should also check the Special Advisory Bulletin (<https://oig.hhs.gov/exclusions/advisories.asp>) (<https://oig.hhs.gov/exclusions/advisories.asp>). In addition, in order to check whether or not an entity has been debarred, in accordance with the debarment regulations at 2 CFR 180.300 (/select-citation/2017/01/13/2-CFR-180.300), an HHA may check the System for Award Management

(<https://www.sam.gov/portal/SAM/#content> (<https://www.sam.gov/portal/SAM/#content>)) or obtain self-certification from the entity. HHAs are responsible for assuring a contracted entity's continued good standing, and would be expected to establish policies and procedures for doing so.

Comment: A small number of commenters suggested that the regulations should permit those individuals who are employed by a "Professional Employer Organization" (PEO) to be considered a direct employee for purposes of the proposed requirement that at least one HHA service must be provided directly.

Response: It is our longstanding policy to establish a "direct" relationship between an employer and employee through the issuance of a W-2 by an employer to an employee without intermediaries. We did not propose to revise our longstanding policy and the commenters did not provide any evidence to demonstrate that the use of PEOs would improve patient health and safety. Therefore, we are maintaining current CMS policy that providing a service "directly" means providing a service by employees who are issued a W-2 by the HHA.

Comment: A commenter suggested that the regulation should be clarified so that a service would be considered to be provided "directly" in situations when that service is temporarily provided by supplementary contracted staff. For example, an HHA may employ a large number of nurses to provide nursing services directly, but use contracted supplement nurses in situations such as a medical leave of absence of an employed nurse or to fill an employed nurse position while the HHA hires a new nurse. The commenter stated that having one or two temporarily contracted staff should not preclude the HHA from designating that service as being provide directly by the HHA.

Response: In order to assure compliance at all times with the requirement of 484.105(f), which states that a HHA "must provide at least one of the services described in this subsection directly," an HHA may not use contracted individuals to provide its chosen service directly.

Comment: A commenter suggested that the services of mental health professionals (Social Workers, Psychologists, Counselors, and Therapists) should be part of home health services.

Response: Medical social services are already part of the HHA benefit, as set forth in the Act. However, mental health services beyond those provided as medical social work services are not within the scope of HHA services as set forth in section 1861(m)(3) of the Act. For this reason, it would not be appropriate to include the services of other mental health professionals in this rule.

Comment: A commenter suggested that all regulations related to HHA financial planning should be removed or replaced by a regulation that focuses on the sufficiency of the HHA's operating budget to meet its needs and provide services to the patients in its care.

Response: The financial planning requirements for HHAs are set forth in section 1861(z) of the Act and these regulations implement those statutory requirements. Therefore, we are required to retain the financial planning requirements in this rule.

CLINICAL RECORDS

Comment: We received many comments on the content of the clinical record. A few commenters supported the requirement, stating that it would decrease duplication by no longer requiring certain information (for example, physician name and drug, treatment and activity orders) be included in a dedicated part of the clinical record since this information is also in the plan of care, which is a part □ of the total clinical record.

Other commenters requested clarification on what was meant by the term “current” comprehensive assessment. One commenter questioned the rationale for requiring that the home health clinical record contain the current assessment, including all of the assessments from the most recent home health admission. This commenter went on to say that assessments from prior admissions would have limited value in providing an accurate picture of a patient without all other components of the clinical record from that time frame. Furthermore, “most recent admissions” leaves home health agencies in the position of having to guess at the required time frame and the number of assessments needed to meet the requirement. The commenter recommended that CMS remove the requirement to include the assessments from prior admissions in the current clinical record since these assessments can be retrieved and viewed in the context of the total previous record for 5 years, in accord with record retention requirements.

Response: The current assessment would be the assessment that was completed with the most recent date. We did not propose, nor are we finalizing, that the record must include assessments from prior admissions. The patient's record is meant to provide a full history of that patient's care and status while he or she is under the care of the HHA. Therefore, it must contain all assessments ever related to the patient's current admission. HHAs may choose to keep the most current/recent assessment in a different part of the record to differentiate it from older, out of date assessments, if that would improve clarity for users of the clinical record.

Comment: One commenter urged CMS to require listing the inclusion of contact information for caregivers, not just the patient and any representative, in the patient's clinical record (§ 484.110(a)). The commenter goes on to say that while the comprehensive assessment identifies caregivers and itself is part of the clinical record, specifically including contact information for the caregivers is appropriate in light of the various responsibilities specified for HHAs with respect to a patient's caregivers throughout the CoPs.

Response: We agree that, in addition to the patient representative contact information (whether legal or patient-selected), it is important to include contact information for the primary caregiver(s) as well. We believe this would be helpful to the HHA staff as they coordinate and deliver care. Therefore, we amended the language at § 484.110(a)(4) by adding this requirement to the final rule.

Comment: One commenter expressed concern that it may be difficult for some organizations to obtain and keep contact information for the patient's primary care practitioner who will be responsible for providing the patient's care after discharge. The commenter also states that the requirement is very broad in scope, and in many cases the practitioner who will care for the patient after discharge may work within a practice in which one specific provider may not be identified for the patient. In addition, the practitioner who will care for the patient after discharge may not be the same as the physician(s) writing home health orders for the patient. The commenter continues on to say that this is often problematic for organizations to determine which practitioner will be providing care for the patient after they have completed their home health visits.

Response: We understand the commenter's concerns with obtaining contact information for the patient's follow-up care practitioner. However, we strongly believe this information benefits the patient by supporting continuity and transition of care between the HHA and the primary care or other practitioner. The practitioner(s) who will be responsible for providing post-discharge care need to be identified in the record so that HHAs know with whom to communicate regarding discharge planning, as required in § 484.60(c). We understand that the patient's practitioner(s) may be different than the physician(s) issuing orders for the HHA plan of care, which is why we strongly believe that requiring separate identification of the practitioner in the patient's clinical record is so important. Lastly, we understand it may not be possible to identify the

name and contact information for a specific practitioner where the practice as a whole furnishes care to the patient. In such cases it is acceptable for the HHA to include the contact information of the health care practice.

Comment: We received many comments regarding clinical records and the proposed discharge summary requirements. Some commenters supported the transfer/discharge requirement, with one commenter stating that they wanted to reinforce their belief that CMS was correct in assuming that most agencies do develop and send a discharge summary to the physician at the time of discharge. Many commenters stated that the 7 day and 2 day proposed timeframes to send the discharge or transfer summary was not enough time. Commenters stated that transfers and discharges could occur on weekends or holidays when staffing, specifically administrative staffing, is lower. Commenters suggested numerous alternative timeframes, as follows:

- 2 business (rather than calendar) days for transfer summaries.
- 7 business days for both discharge and transfer summaries.
- Transfer summaries on the day of transfer and discharge summaries in 2 calendar days.
- 5 business days for transfer summaries and 10 business days for discharge summaries.
- 7 to 14 business days for discharge summaries
- No timeframes for any summaries

Another commenter requested that if the HHA is not able to meet the timeframe requirements, CMS should permit the HHA to document the reason(s) in the medical record.

Response: We appreciate the wide array of comments. While most commenters believed that transfer and discharge summaries are important, the time frames suggested varied greatly. We believe both transfer and discharge summaries are important for care continuity and transitions. Transfer summaries prepared and sent on the day of transfer, and discharge summaries prepared and sent in 2 calendar days after discharge are ideal, and we strongly encourage all HHAs to meet these timeframes. However, we understand that this may not be feasible in all transfer and discharge situations. The CoP requirements are meant to establish maximum timeframes. Thus, we believe that 2 business days for a transfer summary and 5 business days for discharge summary are appropriate maximum standards, and have amended the regulatory language at § 484.110(a)(6)(i) and (ii) to reflect these new timeframes.

Comment: Some commenters stated that HHAs may not know that a patient was transferred to a facility for several days after that transfer has occurred, and therefore suggest starting the 2 day clock when the HHA becomes aware of the transfer. In addition, one commenter stated that no discharge/transfer summary for urgent/emergent admissions should be required, because HHAs usually do not know about these until several days later, and providing discharge/transfer summary days after the fact is not helpful to the receiving provider. One commenter suggested that the regulation should not require HHAs to send discharge or transfer summaries to hospitals; while another commenter requested CMS to consider allowing the HHA to develop their own policy on how to best communicate patient information at the time of transfer or discharge, which could include a verbal or written report. The commenter stated that in many cases, it is uncertain who at a hospital should receive the information. Additionally, the commenter stated that, generally, the discharge or transfer information would not be used in the diagnosis or treatment of the hospitalized individual.

Response: We understand the commenters' concerns regarding the issues surrounding an unplanned transfer to a facility, and agree that it would be difficult for the HHA to comply with the requirements if it was not aware that the transfer had occurred. Therefore, we have amended the regulatory requirement at § 484.110(a)(6)(iii) to require that the HHA sends a completed transfer summary within 2 business days of becoming aware of an unplanned transfer, only if the patient is still receiving care in the receiving health care facility at the time when the HHA becomes aware of the unplanned transfer. We believe that this revision strikes an appropriate balance between sharing information, when such sharing has the potential to be helpful because the patient is still under the care of the inpatient provider, and conserving HHA resources when the patient has been admitted and discharged from the inpatient care provider before the HHA is even aware of the situation. In the future, as the use of interoperable health records becomes widespread in the HHA industry, we may consider a shorter timeframe for sending a transfer summary in order to make the information exchange more timely and relevant to patient care.

Comment: One commenter suggested that transfers without an agency discharge, where the agency will be resuming care, should require that a transfer summary be provided only if a transfer summary was requested by the receiving facility. In addition, others stated that a transfer summary would only be needed if a patient was being discharged with no plan to return to the HHA. Another commenter suggested that an agency should be relieved of this requirement if the patient was admitted to home health from a facility and returned to that same facility.

Response: We appreciate these comments. While we understand that patients may be discharged for a period of time and then return to the HHA, we strongly believe that a transfer summary should be proactively sent, and that this information benefits the patient by supporting continuity and transition of care between the HHA and the receiving facility or practitioner. Therefore, no additional changes have been made to the transfer summary requirements at § 484.110(a)(6)(iii).

Comment: One commenter stated that CMS may want to consider including the requirement to send the discharge or transfer summary in § 484.60(e), Discharge or transfer, in addition to or instead of § 484.110(a), Contents of the clinical record. This requirement is more aligned with care coordination than clinical records, and moving its placement could make it easier to find for HHA staff working on discharge policies.

Response: While this requirement could also be grouped with those related to the content of the discharge or transfer plan, it is equally appropriate to include this requirement in the clinical record section because it addresses timeframes for distributing items that are maintained within the clinical record. In developing their own policies and procedures surrounding the discharge or transfer process, HHAs are free to gather information from all sections of the CoPs that are appropriate to inform the development of relevant HHA policies and procedures.

Comment: One commenter recommended that the regulation require the HHA to send a copy of the discharge or transfer summary to the patient, representative (if any) and the caregiver.

Response: Section 484.60(c)(3)(ii) requires that changes in the discharge plan must be communicated to the patient, representative and caregiver. We believe that this communication is appropriate and necessary for the patient, representative and caregivers. However, the discharge and transfer summary is written for medical professionals and is not necessarily appropriate for the patient's use. Therefore, we do not think that it is necessary to require HHAs to provide a copy of the discharge summary to each patient. Additionally,

HHAs are required to educate patients and caregivers regarding their roles in implementing the plan of care, so patients and caregivers should already have the knowledge and skills necessary to meet any ongoing care needs following cessation of home health services.

Comment: We received a few comments regarding the proposed clinical record authentication requirements. Some commenters supported the need to document the actual time of administration of treatments and/or medication administration, but were unsure as to why each entry into the record, which is not a time sensitive issue, must be timed. In addition, one commenter requested that CMS clarify “timed” in the sentence “dated and timed.” One commenter also went on to ask if this requirement would include all records of case conferences, phone calls, interdisciplinary communications, etc. be timed and dated; and if so, what would be the supporting reasoning as to the need to time such communications. An additional commenter also supported this requirement but noted that these requirements are often part of organizational policy. This commenter went on to state that some organizations will have difficulty meeting the requirements due to failure of staff to date and time their entries and encourages CMS to provide education for all home care organizations on these requirements.

Response: There seems to be confusion related to what we mean by the term “timed.” To clarify, “timed” means the actual time that an event occurred, which is not necessarily the time when the documentation was entered into the record. The date and time requirement applies to all entries in the record. We believe it is extremely important that the clinical record accurately reflects a clear account of the patient's entire course of care. The clinical record should tell a linear story of the course of the patient's care that is managed and delivered by the HHA. Without timing entries, there is the risk for a disjointed record and a possibility for the occurrence of avoidable medical errors.

Comment: We received a few comments on authentication. One commenter requested that the regulations be more specific about what is required for electronic signature, and require electronic audit trails which show if any changes were made in a patient's electronic health record, exactly what changes were made, who made those changes, and when those changes were made in all electronic health records. The commenter stated that HHAs experience problems with vendors when HHA surveys identify documentation problems. One commenter recommended that language relating to “signature and title” be replaced with the broader requirement for “authentication” without specifying how that authentication would be accomplished. Lastly, one commenter recommended that CMS allow providers that maintain clinical records electronically to scan the “signature” documents and then destroy the paper copies.□

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Response: We appreciate the comments received on the subject of record authentication. “Electronic signatures” may mimic paper signatures, complete with a signature and a title (occupation), or may be a secured computer entry by an identifier that is unique to the individual creating the entry. These requirements, particularly those for a “signature and title” are standard practice, and we see no reason to deviate from them at this time. While we understand that HHAs may desire to destroy paper copies of signature documents in order to reduce physical paper storage space, we believe that maintaining the original, signed paper documents is essential for purposes of authentication of the documents. Furthermore, while we agree that electronic audit trails may be a useful tool for some HHAs, we do not believe that they should be incorporated into the regulations as a minimum requirement for all HHAs because there is more than one way for an HHA to achieve the goals accomplished by electronic audit trails. Furthermore, electronic audit trails would not apply to those HHAs that choose to use paper records. HHAs bear ultimate responsibility for continuous compliance with the requirements of these regulations, and are expected to

manage all contracts, including those with software vendors, to assure such compliance. We urge HHAs to engage in due diligence to ensure that their vendors are providing them with EHR technology solutions that support patient health.

Comment: CMS received a few comments on record retention. One commenter recommended that retention of records mirror the timeframes in other federal law or regulation. For example, 5 years does not correlate with requirements for HIPAA or the look back periods for recovery audit contractors or zone program integrity contractors. While another commenter supported the 5 year time frame; stating it simplifies the timeframe during which the patient's records are kept (5 years from discharge as opposed to from filing of cost report) and for some states record retention regulations are stricter, requiring records be held for 6 years. Therefore this standard would not impose burdens on agencies in the state.

Response: We believe that retaining records for a period of 5 years is sufficient for health and safety purposes. We acknowledge that other rules may exist that contain different record retention or compliance documentation timeframes. HHAs need to develop their own agency-specific policies and procedures to assure that records are retained in accordance with the law, regulation, or policy that requires the longest retention period, which may exceed the 5 year period established here.

Comment: We received a few comments on the availability of clinical records. One commenter supports the standard, stating it facilitates access to records by patients, authorized individuals and entities to ensure transparency and continuity of care. Another commenter requested clarification on the timeframe for making records available, stating that, in cases where individuals are onsite awaiting information, HHAs should be allowed sufficient time to assemble records. In many HHAs, not all materials are electronic, including signed verbal orders, files from hospitals, and other content. HHAs may need several hours to compile the most up-to-date records. For other purposes, the commenter recommended that HHAs be allowed a minimum of 4 business days to make records available. Another commenter stated that this proposed condition will encourage more requests for copies of medical records which will increase costs. The commenters internal analysis indicates that as much as \$230,000 annually may be incurred on HHAs should there be a large increase in medical record requests and urges CMS to acknowledge the increase in costs of this requirement.

Response: We believe that all patients should have the right to receive information contained in the clinical record, including the plan of care, free of charge. We agree with the commenter that suggested HHAs be allowed a maximum of 4 business days to make records available. Additionally we understand that the HHA may have another scheduled visit with the patient before the 4-day mark and that it would be advantageous for the HHA to deliver the record at that next scheduled visit. Likewise, if a patient requests to have the plan of care emailed, the HHA would have a maximum of 4 business days to comply. Therefore, we are finalizing this requirement to state that “[a] patient's clinical record (whether hard copy or electronic form) must be made available to a patient, free of charge, upon request at the next home visit, or within 4 business days (whichever comes first).” HHAs may also be governed by state laws and regulations that pertain to this issue, and are expected to comply with such laws and regulations to the extent that they provide greater rights of patient access than HIPAA. We also understand and agree that it may take several hours to assemble a complete clinical record to be reviewed onsite, such as for state surveyor review. We do not think that this regulation is going to dramatically increase record requests. For additional information and guidance on the HIPAA requirements for patient access with which HHA's must also comply, please see guidance issued earlier this year from the OCR available at <http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html> (<http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html>).

Comment: We received several comments related to electronic health records (EHRs). A few commenters stated that incentives should be given to offset the costs and detailed training guidelines should be offered to HHAs who make the switch. One commenter offered support for EHRs, stating that they encourage the exchange of health information across all providers to improve the quality of care and care transitions. According to commenters, EHRs have been proven to reduce medical error rates and help improve the coordination of patient care. Therefore, according to commenters, assisting HHAs in making the leap to EHRs would be beneficial to improving the quality of patient care.

Response: We appreciate the commenter feedback related to EHRs. The Department of Health and Human Services is committed to accelerating health information exchange through the use of EHRs and other types of health information technology (health IT) across the broader care continuum through a number of initiatives including: (1) Alignment of incentives and payment adjustments to encourage provider adoption and optimization of health IT and health information exchange services through Medicare and Medicaid payment policies; (2) adoption of common standards and certification requirements for interoperable health IT; (3) support for privacy and security of patient information across all health information exchange-focused initiatives; and (4) governance of health information networks. These initiatives are designed to improve care delivery and coordination across the entire care continuum and encourage the electronic exchange of health information among all health care providers, including professionals and hospitals eligible for the Medicare and Medicaid EHR Incentive Programs and those who are not eligible for such programs. However, providing additional incentives to any provider, including HHAs, is beyond the scope of this rule and subject to the limitations of statutory authority.

Comment: One commenter believes that HIE, in theory, is an outstanding idea. The efforts nationwide, however, are scattered and of varying success. In the absence of ACA funding, some are failing. The commenter stated that he does not believe that use of an HIE should be addressed in the CoPs. With regard to interoperability, the commenter recommended consideration of the most recent ONC statement on interoperability, and stated that at this time full interoperability is too far in the future to make HIE an element of CoPs. Another commenter stated that a certification program, required or voluntary, cannot be successful without industry and provider commitment to the necessity of such a program and without participation requirements applicable to the provider community. The commenter also expressed concern that voluntary or required certification without the implementation of Meaningful Use Stage 3 will neither substantially improve the alignment of existing federal and state programs nor appropriately balance the required costs and benefits due to the current low adoption rates of Meaningful Use Stage 2 requirements by hospitals and other eligible providers.

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Response: We agree that this is not the appropriate time to require, in the CoPs, the use of HIEs or compliance with any stage of the Meaningful Use criteria. We will continue to monitor the voluntary use of certified record systems and HIEs, and would use the notice and comment rulemaking process to promulgate any future HHA regulations related to these issues.

Comment: One commenter stated that it was important to point out that as a result of the growing discussion related to the use of massive collections of data, an integrated information database that is aimed at improving quality standards in HHAs and aimed at a more comprehensive approach towards current and long term health care specifically designed for each individual patient could be a wonderful tool if used correctly. The commenter cautioned, however, that the amassing of data and the technology that is used to analyze it may be vulnerable to exploitation.

Response: We agree that it is incumbent upon HHAs to appropriately secure data, and the systems used to collect and analyze it, against inappropriate access and use. Section 484.110(d), Protection of records, requires that HHAs must be in compliance with the HIPAA Privacy and Security rules regarding protected health information set out at 45 CFR parts 160 (/select-citation/2017/01/13/45-CFR-160) and 164. We believe that this requirement establishes an appropriate expectation of security in the maintenance of patient data, and the systems used to collect and analyze it. In addition to the steps taken by HHAs to assure the confidentiality of data that they collect, CMS takes all appropriate steps to assure the security of all data that is submitted to CMS by HHAs.

PERSONNEL QUALIFICATIONS

Comment: We received many supportive comments regarding personnel requirements. One commenter supported the retention of the requirement that “social work assistants” be supervised by a qualified social worker. One organization strongly supports the proposal to retain personnel qualification requirements, including those for occupational therapy. This commenter stated that keeping the qualification requirements intact protects the public health, safety, and welfare of the patients served by occupational therapy practitioners and ensures that services are performed by trained and qualified providers.

Response: We appreciate the support of the commenters, and agree that establishing minimum personnel qualifications is an essential part of assuring the safety and quality of HHA care.

Comment: We received many comments on the personnel qualification of the administrator. A few commenters requested that CMS grandfather in the current administrators, with one commenter stating that there should be an exception policy in place that acknowledges years of experience in the Medicare certified home health field as an appropriate qualification for a home health administrator. One commenter stated that they applaud expanding the standard for eligibility for the administrator. The commenter added that they supported the role of administrator being provided by persons with skill sets that do not require medical or nursing degrees. A few commenters requested that CMS not require a degree and experience, stating that experience all on its own is good enough and requiring both is too burdensome. One commenter stated that an undergraduate degree and 1 year of experience does not seem adequate to fulfill the role of administrator, which requires knowledge in many areas. The commenter suggested that a graduate degree or specialized clinical certification and additional years of experience in management would be appropriate. Another commenter advised that CMS not have any qualification requirements.

Response: It was not our intent to disqualify any currently employed administrator from continuing to perform his or her job duties with his or her current employer. Therefore, we agree that administrators who do not meet these qualifications should be allowed to continue employment in their current position, and we have revised the regulation at § 484.115(a) to reflect this policy. In light of the various suggestions from the public regarding the appropriate qualifications for those administrators that begin working for an HHA after the effective date of this final rule (July 13, 2017), we have chosen to finalize the originally proposed requirement. An administrator who begins working for an HHA after the effective date of this final rule, even if he or she was previously employed as an administrator for a different HHA, is required to be a licensed physician, a registered nurse, or hold an undergraduate degree. A registered nurse would include a Nurse Practitioner or other advance practice nurse. Additionally, an administrator who begins working for an HHA after the effective date of this final rule is required to have experience in health service administration, with at least 1 year of supervisory or administrative experience in home health care or a related health care program. We believe that this combination of education and experience requirements strikes an appropriate balance between those commenters who sought to require that an administrator must possess a graduate

degree and those who sought to remove all personnel requirements for an administrator. Furthermore, we believe that adding these personnel requirements for all future administrators will serve as a disincentive to the creation of HHAs that are operated with fraudulent intent, as many of these entities are opened by individuals who would not meet these minimum qualifications. Such HHAs pose a significant threat to the health and safety of Medicare beneficiaries in need of HHA services. The personnel requirements set forth in this rule are the minimum requirements. HHA governing bodies may establish more stringent requirements that meet the needs of their organizations.

Comment: We received one comment on the personnel requirements for occupational therapists and one comment on occupational therapy assistants. The commenter stated that the qualifications for occupational therapists are almost identical to current regulation. However, the current regulations allow therapists educated abroad to meet part of the necessary criteria by successfully completing a program that is substantially equivalent to occupational therapist entry-level education in the U.S. offered by one of four categories of organizations. In the proposed rule, the therapist must have successfully completed a program that is substantially equivalent to occupational therapist assistant entry-level education in the U.S. by one of the four categories of organizations. The commenter questioned why the word “assistant” appears here, since there is a separate set of qualifications for occupational therapy assistants. The commenter who asked about occupational therapy assistants is requesting clarification stating that the qualifications outlined in the proposed rule for an occupational therapy assistant are almost exactly the same as those in current regulation. However, the proposed rule states that an occupational therapy assistant is a person who “[a]fter January 1, 2010, meets the requirements in paragraph (b)(6)(i) of this section.” There is no paragraph (b)(6)(i) in the proposed rule text.

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Response: Our intent was to maintain all of the current qualification options for occupational therapists and occupational therapy assistants, without change. We have revised the regulatory requirements to correct these technical errors.

Comment: We received a few comments on the personnel qualifications for physical therapists and physical therapy assistants. For physical therapists, one commenter requests clarification, stating that in the proposed rule, physical therapists must be licensed (if applicable) and must meet one of several additional categories of qualifications. In current regulations, the first category requires physical therapists to have successfully completed a physical therapist education program and passed an examination for physical therapists approved by the state. In the proposed rule, the word “and” is dropped, and the text is renumbered in a way that could imply that either education or passage of an exam is acceptable. An additional commenter requests clarification as to whether CMS intended to propose this change, stating that under current standards, the fifth category requires a physical therapist to have been admitted to membership by the American Physical Therapy Association (APTA); or admitted to registration by the American Registry of Physical Therapists; or have graduated from a physical therapy curriculum in a 4-year college or university approved by a state department of education. In the proposed rule, the fifth option includes the above mentioned membership, registration and graduation from a physical therapy curriculum. We received one comment on physical therapy assistants requesting that CMS consider clarifying and revising the qualifications for physical therapy assistants. This commenter stated that under the proposed rule, a physical therapy assistant is a person licensed, registered or certified as a physical therapy assistant, if applicable, by the state in which the assistant is practicing, unless licensure does not apply. In addition, the assistant must meet one of two other categories of criteria. In the first category, the assistant must meet the same specified education as listed in current regulations. In the second category, the assistant must have passed a national exam for physical therapist assistants before 2010, and he or she must meet one of the following criteria:

- Is licensed, or otherwise regulated in the state in which practicing; or
- In states where licensure or other regulations do not apply, graduated before 2010 from a 2-year college-level program approved by APTA and after January 1, 2010, meets the requirements of paragraph (b)(8) of this section.

The commenter stated that it was unclear what was meant by the reference to (b)(8) of this section, as there was no (b)(8) in the proposed regulations text.

Response: We did not intend to alter the content of the requirements for physical therapists and physical therapy assistants in any way. Any appearance of alteration is due to changes in numbering and/or the unintentional switching of the terms “and” and “or”, which we have revised accordingly in this final rule. We have also made other technical corrections, as described in this preamble.

Comment: We received several comments that noted the definition of Physician at 42 CFR 410.20 (/select-citation/2017/01/13/42-CFR-410.20)(b) is not consistent with the specialties of physicians who may certify and establish the plan of care for home health services in the regulation at 42 CFR 424.22 (/select-citation/2017/01/13/42-CFR-424.22)(a)(1)(iii). The commenter recommended the requirements for a physician should refer to 42 CFR 424.22 (/select-citation/2017/01/13/42-CFR-424.22)(a)(1)(iii).

Response: The personnel requirements for a physician refer only to those physicians who are employed by, or are under arrangement with, an HHA. These requirements would not apply to hospital and community-based physicians who are responsible for issuing orders that establish the home health plan of care, as they would function outside of the purview of the HHA. The requirements set forth at § 424.22(a)(1)(iii) are specific Medicare payment requirements for physicians who certify the eligibility of patients for the Medicare home health benefit. We do not believe that it would be necessary or appropriate to narrow down the group of physicians who are eligible for HHA employment to just those physician types set forth in the payment regulations because HHA physicians may perform many roles that do not relate to certification of HHA patients.

Comment: We received a few comments on the personnel qualifications for social workers. One commenter supported the addition of doctoral degree as a qualification option. Another commenter stated that baccalaureate (BSW), master's (MSW), or doctoral degree in social work is the only sufficient preparation for social work.

Response: We agree that a master's or doctoral degree is an appropriate qualification, and are finalizing this proposal without change. HHAs may choose to further restrict those individuals who are employed as social workers in order to meet their specific needs; however we do not agree that it is appropriate for these regulations to impose such a restriction, as it would disqualify many long time social workers who happen to have degrees in other related fields. Therefore we are maintaining the current requirement that a degree in a related field would be considered an appropriate qualification for a social worker.

Comment: We received one comment on the personnel qualifications for speech language pathologists. Specifically, this commenter states that CMS is correct in the assumption that all states now have licensing requirements for speech-language pathologists (SLPs). However, the commenter asserted that ASHA certification and completion of a degree from a Council on Academic Accreditation in Audiology and Speech-Language Pathology (CAA) approved program remains the standard and ensures that speech-language pathologists are participating in a minimum number of continuing education hours. Additionally, not all U.S.

Territories have licensure; therefore, continued use of ASHA certification is warranted. The commenter recommends that CMS continue to reference ASHA certification for minimum qualifications and requests that the revision maintain the ASHA certification.

Response: Section 1861(l)(4)(A) of the Act, on which the regulation is based, does not limit SLPs to only those individuals who meet the ASHA certification standards. Since this □ limitation does not exist in the Act, we do not believe it should exist in the regulations. Therefore, in order to align the regulatory requirements with those requirements set forth in the Act, we are not making the suggested change. States are free to require ASHA certification as part of their SLP licensure standards.

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Comment: We received one comment on the personnel requirements for the clinical manager. The commenter states that while they support the creation of the clinical manager position, they advise that CMS consider the inclusion of specific qualification requirements for the clinical manager, since there are frequent deficient practices related to reassessments, referrals, coordination of care and updating plans of care.

Response: We agree that it is appropriate to establish minimum personnel requirements for clinical managers. In the October 2014 proposed rule we proposed that a clinical manager be either a licensed physician or RN (79 FR 61164 (/citation/79-FR-61164), 61183). As stated previously, commenters also suggested a therapist or social worker could fill this role. We agree that those professionals may also be qualified to fulfill the duties of the clinical manager. Thus, we are finalizing a requirement at § 484.115(c), Clinical manager, requiring that a clinical manager be a licensed physician, physical therapist, speech-language pathologist, occupational therapist, audiologist, social worker, or a registered nurse. A registered nurse would include a Nurse Practitioner or other advance practice nurse.

Comment: We received a few comments related to criminal background checks. Specially, one commenter stated that background checks should be done for all staff members, especially those who plan to go to a patient's home to deliver health care. A few additional commenters advised that CMS should require reasonable and appropriate standards for criminal background screenings and that criminal background checks should be required for all owners, operators, or employees that have direct patient contact or access to patient records in order to validate competency according to minimum standards established by the Secretary.

Response: The National Background Check Program (NBCP), as established by the Affordable Care Act, aims to create a nationwide system for conducting comprehensive background checks on applicants for employment by the LTC facilities and providers. The term “long-term care facility or provider” means the following facilities or providers: Skilled nursing facility, nursing facility, home health agency, provider of hospice care, a long-term care hospital, a provider of personal care services, a provider of adult day care, a residential care provider that arranges for, or directly provides, long-term care services, including an assisted living facility, an intermediate care facility for the intellectually disabled, and any other facility or provider of long-term care services as the participating state determines appropriate. Prior to passage of this law and creation of the NBCP, many states already required background checks for LTC workers, but state requirements and programs varied. The intent of the NBCP is to set-up a standard, effective, and economical program to conduct background checks that also includes fingerprint-based criminal history checks. The U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) administers the NBCP. Since the start of the program in 2010, CMS has awarded nearly \$57 million in grant funds to a total of 25 states and U.S. Territories to design, implement, and operate background check programs that

meet CMS criteria. We believe that this comprehensive program that fosters consistency in implementation is a preferable way to improve the volume and scope of background checks that are conducted for HHA employees and contractors.

SUMMARY OF CARE

Comment: We received many comments on the removal of the 60-day summary of care requirement (79 FR 61166 (/citation/79-FR-61166)). A few commenters supported the elimination of the summary of care notification every 60 days. One commenter stated that their physicians did not see true value in having another document to review, but instead valued the verbal communication with them at pertinent times related to the care and treatment of their patient(s). Other commenters requested clarification as to whether it would be expected that the information typically contained in the summary of care notice would be provided to the physician by some other means or format. However, other commenters did not support the removal of the summary of care every 60 days. These commenters stated that, although immediate communication of timely events is undeniably important, it was not equivalent to summarizing the patient's status to the physician at the time of recertifying the plan of care because physicians do not always remember the relevant recent issues concerning a particular patient when asked to review and recertify a plan of care. Another commenter stated that CMS did not offer any other support or justification for this change. A commenter also stated that the Impact Analysis was unclear, specifically, the calculation that this requirement "imposes a burden of 3 minutes per patient" (it was unclear if CMS meant 3 minutes every 60 days or cumulatively for a year), and that removing the provision would amount to a savings of nearly \$17 million annually.

Response: Section 484.60(c)(1) requires that the HHA must promptly alert the physician(s) issuing orders for the HHA plan of care to any changes in the patient's condition or needs that suggest that outcomes were not being achieved and/or that the plan of care should be altered; the requirements at § 484.60(c)(3) requires that revisions to the plan of care due to a change in health status or a change in discharge plans be communicated to the physician issuing orders for the condition(s) that led to the initiation of home health care who was responsible for the HHA plan of care; and § 484.75(b)(7) requires that every skilled professional be responsible for communicating with the physician(s) issuing orders for the HHA plan of care. All three of these requirements in this final rule clearly establish the expectation that HHAs would apprise physicians of the information necessary to make appropriate decisions regarding the content of the plan of care at all times. We do not believe that a 60-day summary of care is a necessary regulatory requirement on top of the requirements referenced above. The burden imposed by the summary of care was originally estimated in the currently-approved PRA package (OMB control number 0938-0365), originally published in the **Federal Register** on July 12, 2013 (78 FR 41931 (/citation/78-FR-41931)).^[1] The burden estimate assumed a burden of 3 minutes per patient to develop the summary of care, and assumed that each patient would only be in HHA care long enough for a single 60-day summary of care to be prepared. We did not receive any public comments on this estimate at that time, and believe that they continue to be appropriate to use in this rule for purposes of estimating potential savings to HHAs. Savings to individual HHAs may be greater or lesser, depending on the HHA's average length of stay and technical capabilities to automate the production and distribution of the summary of care.



MISCELLANEOUS

Comment: We received a few comments related to home health agency surveys. One commenter stated that home health agencies should go through a health accreditation every year based on how their patients receive care. Other commenters strongly urge CMS to ensure that the interpretive guidelines provided to surveyors

are developed in collaboration with stakeholders across the industry, either through direct participation in their development or by providing an opportunity for stakeholders to comment on such guidelines before they are used for enforcement purposes. Other commenters encouraged CMS to share all such interpretive guidelines and surveyor training materials with HHAs prior to the start of enforcement.

Response: We appreciate the comments on this subject. However, the survey schedule, survey guidelines, and surveyor training materials are not within the scope of this rule.

Comment: One commenter asked if patients can receive care at their home if they are unable to go to a hospital. In addition, the commenter requested clarification on the kind of benefits patients can receive.

Response: The services covered under the Medicare home health benefit are set forth in section 1861(m) of the Act, as implemented in regulation at 42 CFR 409 (/select-citation/2017/01/13/42-CFR-409) subpart E. Medicaid and private insurers establish their own requirements for services, and we encourage the public to contact the relevant programs for any information that may be needed. HHA services are not meant to be a substitute for acute care providers, such as hospitals, in urgent and emergent situations. Rather, HHAs are expected to deliver part-time or intermittent skilled care to homebound patients who would otherwise receive care in an outpatient setting such as a physician office or physical therapy office, but who are confined to the home.

Comment: A few commenters suggested ways CMS could improve patient engagement. One commenter suggested that providing Medicare beneficiaries with materials similar to the annual update to *Medicare & You* that offer more details on the home health benefit and its requirements would be a place to begin. The commenter also suggested that a YouTube segment explaining the benefit would help beneficiaries, their families, and other caregivers. A few commenters stated that it would also help to hear from home health agency patients and their families to gather information about the quality of service they were observing, the necessity of certain procedures, and how they thought the quality of care was meeting the standards set out in the proposed rule.

Response: We appreciate these suggestions for additional Medicare outreach options. However, Medicare outreach to beneficiaries is beyond the scope of this rule. We will retain these suggestions for future consideration. We agree that a patient care survey is a valuable tool for quality of care purposes, and implemented the Home Health Consumer Assessment of Healthcare Providers and Systems survey in October 2009 (<https://homehealthcahps.org/> (<https://homehealthcahps.org/>)).

Comment: We received many comments on referrals. One commenter suggested that CMS should educate other providers about the value of home health care. One commenter urged CMS to clarify, in regulation, that care referrals to HHAs by emergency departments and other care settings are appropriate. The commenters also suggested that we publish guidance on appropriate care coordination pathways that would encourage referrals to HHAs, making them more likely and possible. Another commenter encouraged CMS to help HHAs educate emergency departments and other providers to make more frequent and appropriate use of home health care for a growing volume of beneficiaries with complex health conditions. Lastly, one commenter recommended that CMS consider updating the number of paid medical consultants, medical directors, and physicians who are permitted to refer patients to home health services.

Response: We appreciate these suggestions for referral source outreach. However, this topic is beyond the scope of this rule. We will retain these suggestions for future consideration.

Comment: We received multiple comments related to HHA payment policy issues. Some commenters stated the CMS should increase Medicare/Medicaid rates for home health services. Another commenter suggested that CMS should grant greater flexibility in the coverage and reimbursement of home monitoring for oral anticoagulation therapy, including CMS coverage for home visits by nurses to patients who find it difficult to do their own home monitoring or travel to get tested. One commenter requested that CMS provide funding to HHAs so that they can develop the computer and related systems needed to share data with physicians, hospitals and other providers.

Response: We appreciate these suggestions related to Medicare home health coverage policy and Medicare payment rates. Medicare home health coverage policy and payment rates are addressed in separate annual rulemaking, and comments related to this topic can be submitted during that process. This topic is beyond the scope of this rule therefore, we are not addressing these suggestions at this time.

Comment: Numerous commenters made suggestions for ways to revise Medicare home health coverage policy. One commenter requested that CMS consider permitting non-physician practitioners to perform face-to-face encounters and to sign a patient's plan of care, to the extent permitted by the licensing authority in the state in which the practitioner is licensed. Another organization urged CMS to re-examine the Medicare homebound requirement for Medicare home health services eligibility. One commenter shared that the home health industry advocates have long argued that case or care management is a natural activity for home health agencies, particularly for elderly individuals with multiple co-morbidities. However, in order for agencies to be successful care managers, the focus of the Medicare home health benefit must shift from exclusively short-term, skilled, post-acute intervention for the homebound patient to include a chronic care management and oversight function for patients who may not need skilled care or be homebound at any given point in time. Additionally, one commenter stated the inclusion of maintenance therapy guidelines is greatly needed, and that they agree with the new Medicare Benefit Policy Manual update that the maintenance of the patient's current condition and prevention or slowing of further deterioration of the patient's condition may both warrant the use of skilled care provided under the Medicare home health benefit. Another commenter suggested that the social determinants of health should be considered as relevant variables in the prospective payment system.

Response: We appreciate these suggestions related to Medicare home health coverage policy. Medicare home health coverage policy is addressed in separate annual rulemaking, and comments related to this topic can be submitted during that process. As this topic is beyond the scope of this rule, we are not addressing these suggestions at this time.

Comment: We received a few comments related to OASIS. Commenters urged CMS to update the OASIS instrument to:

- Allow HHAs to indicate when referrals come from EDs and other health care providers and settings; and
- Reflect the social determinants of health.

Response: We appreciate these suggestions related to the content of the OASIS; however, this topic is beyond the scope of this rule, therefore we are not addressing these suggestions at this time. We will retain these suggestions for future consideration.

Comment: A commenter stated that under the Patient Protection and Affordable Care Act, CMS was required specifically to assess and document the needs of vulnerable individuals accessing home health services, and that this should be implemented in the CoPs.

Response: Section 3131(d) of the Affordable Care Act directed the Secretary to conduct a study on HHA costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas, and in treating beneficiaries with high levels of severity of illness. A Report to Congress on this home health study was released at the end of 2014, and is available to view at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/HH-Report-to-Congress.pdf> (<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/HH-Report-to-Congress.pdf>). We awarded a follow-on contract to Abt Associates to further explore possible payment methodology changes as a result of the home health study. The work is ongoing at this time.

Comment: A commenter expressed confusion with the “reimbursement rates” described in the Collection of Information and Regulatory Impact Analysis sections. The commenter stated that “there seems to be a discrepancy with how services will be reimbursed. According to the 2014-2015 outlook, the hourly rate for physicians, nurses, clinical managers and administrators is \$180, \$63, \$85, and \$98; respectively. There are asterisks near job titles and hourly rates performed by nurses. For example, the clinical manager and administrator roles have asterisks. Clarification is needed regarding the reimbursement rate for other health care providers, including physicians, performing these administrative roles.”

Response: The impact analysis does not set forth reimbursement rates for any HHA services. Rather, as stated in the title of Table 1, “Assumptions and estimates used throughout the information collection and impact analysis section”, the impact analysis presents a set of assumptions regarding how much a typical HHA pays in terms of the salary, benefits, and overhead associated with a single hour of employment for a given employee class. What an HHA chooses to pay an individual fulfilling an administrative role is entirely up to the discretion of the HHA. For purposes of our analysis, we assumed that a typical HHA would pay a typical administrator \$98 per hour (including salary, benefits, and overhead). A given HHA may pay more or less than this amount.

Comment: We received a few comments related to CMS data collection and one comment related to emergency preparedness. Specifically, one commenter encouraged CMS to consider collecting data on the quality of the HHA's respective training/education programs. The commenter stated that data should measure the impact of the training/education program from the patient's, family caregiver's, and, as appropriate, from the direct care staff's perspectives. CMS should consider whether a quality measure in this area is appropriate and feasible. Another commenter wrote that CMS's proposed rule, “Medicare and Medicaid Programs: Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers” (78 FR 79082 (/citation/78-FR-79082), 79111, December 27, 2013) would require the home health agency to develop an emergency preparedness plan and conduct training and a mock drill or table top exercise annually, and that these requirements should be included as a standard under the organization and administration CoP.

Response: We appreciate suggestions related to the development of additional CMS data collection items and quality measures. Furthermore, we appreciate the suggestion related to the placement of future emergency preparedness requirements. However, these topics are not within the scope of this rule and are addressed in separate rule (Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 81 FR 63859 (/citation/81-FR-63859)).

Comment: One commenter expressed concern on the economic impact to rural communities will lead to barriers to access in some areas due to a combination of negative margins, new standards, and limited referral sources.

Response: As its measure of significant economic impact, HHS uses a change in revenue of more than 3 to 5 percent. We estimate that the cost of this rule on a per-HHA basis is minimal (approximately a \$30,000 net increase in burden per non-accredited HHA in the 1st year, and a \$15,000 savings increase for accredited HHAs in the 1st year). Furthermore, many of the burdens occur on a one-time basis as HHAs update their forms, and policies and procedures to conform to the updated requirements. We believe that this rule offers sufficient implementation flexibility to be adapted to the operations of a wide variety of HHAs, including those in rural areas.

Comment: One commenter encourages CMS to think creatively about how to leverage HHAs and home health services to improve health outcomes and quality of care, and avoid unnecessary hospitalizations and other institutional admissions. For example, the commenter suggested that if HHA personnel were providing services to an individual, and while, in the course of working with the family caregiver, saw that the family caregiver had health needs, the HHA staff could offer advice, make referrals, or provide a simple service to the caregiver that could improve their health (indirectly assisting the home health patient), especially if the caregiver is receiving Medicare or Medicaid services. Another commenter suggested that CMS ensure the operational capability of providers by requiring those agencies with new provider numbers to demonstrate proof of sufficient capital to operate for 1 year, and by requiring that existing agencies provide a \$100,000 surety bond. Additionally, one commenter suggested that CMS establish a 2-year moratorium on the entry of new home health agencies into counties with demonstrable over-penetration (subject to certain exceptions). Another commenter suggested CMS identify and withhold payment for aberrant episodes and LUPA claims. Another commenter suggested that CMS consult with the Inspector General of the Department of Health and Human Services to establish a claims validation process by screening each claim (or a sample of claims) so that, before payment is made, the Secretary would validate claims on the basis of an HHA's submission of OASIS assessments (or some other data set approved for home health agencies).

Response: We appreciate the commenters' suggestions. However, we believe these comments are outside the scope of this rule.

V. Provisions of the Final Regulations

We are adopting as final the provisions set forth in the proposed rule published in the **Federal Register** on October 9, 2014 (79 FR 61164 (/citation/79-FR-61164)), with the following changes:

- Revised the definition of “representative” at § 484.2 for additional clarity.
- Revised 484.45(c)(2) to align the regulatory text with the current CMS guidelines for data transmission by replacing the requirement that test data

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be transmitted to the “state agency” with a requirement that test data be transmitted to the “QIES ASAP system.” We proposed to require that an HHA must, “Successfully transmit test data to the state agency or CMS OASIS contractor.” On January 1, 2015, CMS changed the OASIS transmission guidelines to require that an HHA must successfully transmit test data to the QIES ASAP System or CMS OASIS contractor. We have revised the final rule at § 484.45 to reflect this change and maintain consistency between the transmission guidelines and the regulatory requirements. We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposal. This procedure can be waived, however, if an agency finds good cause to do so. In section VI of this preamble, we have provided our rationale for finalizing these provisions without prior notice and comment.

- Revised § 484.50(a)(1) to clarify that it is the patient's legal representative that must be informed of the patient rights information prior to the start of care.
- Revised § 484.50(a)(1)(i) to require that an HHA must provide each patient with written notice regarding the HHA's transfer and discharge policies. This requirement was originally proposed at 484.50(d).

- Redesignated proposed § 484.50(a)(1)(ii) as § 484.50(a)(3).
- Redesignated proposed § 484.50(a)(2) as § 484.50(a)(1)(ii) and removed the requirement that HHA administrators are expected to receive patient questions.
- Redesignated proposed § 484.50(a)(3) as § 484.50(a)(1)(iii).
- Redesignated proposed § 484.50(a)(4) as § 484.50(a)(2), and clarified that a signature confirming receipt of the notice of patient rights is only required from a patient or a patient's legal representative.
- Revised § 484.50(a)(3), requiring that the HHA must provide verbal notice of the patient's rights no later than the completion of the second visit from a skilled professional.
- Added new § 484.50(a)(4), requiring that the HHA provide written notice of the patient's rights and the HHA's discharge and transfer policies to a patient-selected representative within 4 business days after the initial evaluation visit.
- Revised 484.50(b) to replace the term "incompetence" wherever it appears with the more precise term "lack legal capacity to make health care decisions."
- Revised § 484.50(c)(4)(i) to clarify that patients have the right to participate in and be informed about all assessments, rather than just the comprehensive assessment.
- Removed the requirement at § 484.50(c)(4)(iii) regarding providing a copy of the plan of care to each patient.
- Revised § 484.50(c)(10) to require HHAs to provide contact information for a defined group of federally-funded and state-funded entities.
- Revised § 484.50(d) to remove the requirement for HHAs to provide patients with information regarding HHA admission policies and clarified that the "transfer and discharge policies" are those set forth in paragraphs (1) through (7) of this standard.
- Revised § 484.50(d)(1) to clarify that HHAs are responsible for making arrangements for a safe and appropriate transfer.
- Revised § 484.50(d)(3) to clarify that discharge is appropriate when the physician and the HHA both agree that the patient has achieved the measurable outcomes and goals established in the individualized plan of care.
- Revised § 484.50(e)(1)(i) to clarify that the subject matter about which patients may make complaints is not limited to those subjects specified in the regulation. HHAs must investigate all such complaints.
- Revised § 484.50(e)(1)(iii) to specify that HHAs must take action to prevent retaliation while a patient complaint is being investigated.
- Revised § 484.50(e)(2) to specify that circumstances of mistreatment, neglect, abuse, or misappropriation of patient property must be reported in accordance with the requirements of state law.
- Added a requirement at § 484.55(c)(6)(i) and (ii) that the comprehensive assessment must include information about caregiver willingness and ability to provide care, and availability and schedules.
- Added a requirement at § 484.60 that patient and caregiver receive education and training including written instructions outlining medication schedule/instructions, visit schedule and any other pertinent instruction related to the patients care and treatments that the HHA will provide, specific to the patient's care needs.
- Moved proposed § 484.60(a)(3) to § 484.60(a)(2)(xii), making it applicable to all patients, and removed the terms "low," "medium," and "high."
- Revised § 484.60(b)(1) to permit drugs, services and treatment to be ordered by any physician, not just the one responsible for the patient's plan of care.
- Revised § 484.60(b)(4) to permit any nurse acting in accordance with state licensure requirements to receive verbal orders from a physician.
- Added requirements at § 484.60(d)(1) and (2) that HHAs must assure communication with all physicians involved in the plan of care, and integrate orders from all physicians involved in the plan of care to assure the coordination of all services and interventions provided to the patient.
- Redesignated proposed § 484.60(d)(1) through (3) as § 484.60(d)(3) through (5).
- Added a requirement at § 484.60(e), Written information to the patient.
- Revised § 484.65 to require that QAPI program indicators include the use of emergent care services.

- Revised § 484.75(b)(7) to require skilled professionals to communicate with all physicians involved in the plan of care.
- Revised § 484.80(b)(3)(xiii) by withdrawing part of the provision under home health aide training requirements for aides to recognize and report changes in pressure ulcers. We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposal. This procedure can be waived, however, if an agency finds good cause to do so. In section VI of this preamble, we have provided our rationale for finalizing these provisions without prior notice and comment.
- Revised § 484.80(g)(1) by removing the requirement that the skilled professional who is responsible for the supervision of a home health aide must be the individual who prepares written patient care instructions for the home health aide.
- Revised § 484.80(h)(1)(i) by adding a requirement that the registered nurse or other appropriate skilled professional who conducts supervision of a home health aide must be familiar with the patient, the patient's plan of care, and the written patient care instructions described in § 484.80(g).
- Revised § 484.80(h)(1)(ii) by removing the word "potential deficiency" and replacing it with "area of concern."
- Redesignated § 484.22—Emergency Preparedness under subpart B as § 484.102 under subpart C to align with CoP's related to "Organizational Environment." Section 484.22 was implemented as part of the Emergency Preparedness final rule published on September 16, 2016 (81 FR 63859 (/citation/81-FR-63859)).
- Revised the requirement at § 484.105 to clarify that an HHA must

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organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs.

- Added a requirement at § 484.105(b)(1)(i) that the administrator must report to the governing body.
- Revised § 484.105(b)(1)(iii) to require that the administrator assures that a clinical manager is available during all operating hours.
- Added a requirement at § 484.105(b)(1)(iv) that the administrator must ensure that the HHA employs qualified personnel, including assuring the development of personnel qualifications and policies.
- Revised § 484.105(b)(2) to clarify that an individual that is pre-designated to fill the administrator role in the absence of the administrator (including the clinical manager) must be qualified to do so.
- Revised § 484.105(c) to specify that one or more qualified individuals must provide oversight of all patient care services and personnel.
- Revised § 484.105(c) Clinical manager by retaining a description of the clinical manager's duties while relocating the personnel specifications for this role to new § 484.115(c), which sets for the specific personnel requirements for the clinical manager.
- Removed § 484.105(c)(6).
- Added a requirement at § 484.110(a)(4) that the clinical record must include contact information for the patient's primary caregiver(s).
- Revised § 484.110(a)(6)(i) by changing the discharge summary deadline for completion from 7 calendar days to 5 business days.
- Revised § 484.110(a)(6)(ii) by changing the transfer summary deadline for completion from 2 calendar days to 2 business days of a planned transfer, if the patient's care will be immediately continued in a health care facility.
- Added § 484.110(a)(6)(iii), requiring that a completed transfer summary must be sent within 2 business days of becoming aware of an unplanned transfer, if the patient is still receiving care in a health care facility at the time when the HHA becomes aware of the transfer.
- Revised § 484.110(e), requiring that a patient's clinical record (whether hard copy or electronic form) must be made available to a patient, free of charge, upon request at the next home visit, or within 4 business days (whichever comes first).
- Revised the personnel qualification requirements for HHA administrators at § 484.115(a) to grandfather in currently employed HHA administrators.

- Added § 484.115(c) to specify personnel qualifications for clinical managers.
- Redesignated paragraphs § 484.115 (c) through (m) as (d) through (n).
- Revised the proposal at § 484.115(e) licensed practical nurse to utilize existing regulatory language regarding vocational nurses, and align the requirement with state practice acts. We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposal. This procedure can be waived, however, if an agency finds good cause to do so. In section VI of this preamble, we have provided our rationale for finalizing these provisions without prior notice and comment.
- Made technical changes to the requirements at § 484.115(f) through (i) to align with current personnel qualification requirements for occupational therapists, occupational therapy assistants, physical therapists, and physical therapy assistants.

VI. Good Cause To Waive Notice and Comment Rulemaking

As discussed in section IV of this preamble, at § 484.45 we proposed to require that an HHA must, “Successfully transmit test data to the state agency or CMS OASIS contractor.” However, on January 1, 2015, CMS changed the OASIS transmission guidelines to require that an HHA must successfully transmit test data to the QIES ASAP System or CMS OASIS contractor. We have revised the final rule at § 484.45 to reflect this change and maintain consistency between the transmission guidelines and the regulatory requirements.

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposal. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. We believe that finalizing the previously proposed language is contrary to the public interest because it conforms our rules to transmission guidelines that have changed since this rule has been proposed. We wish to waive notice and comment for rulemaking because waiting until a future rulemaking to resolve this inconsistency would create unnecessary confusion within the HHA community. Such confusion would likely lead to inconsistent compliance with either the regulations or the transmission guidelines, potentially leading to information gaps in CMS databases that could negatively impact HHA payments and the accuracy of quality measure information that is reported to the public. Because this change is operational, non-controversial, and has already been implemented at the sub-regulatory level, we find good cause to waive the notice of proposed rulemaking related to this change, and to issue this provision of the final rule.

In section IV of this preamble, at § 484.80 “Condition of participation: Home Health Aide Services,” we proposed to add a requirement under home health aide training at § 484.80(b)(3)(xiii) to require home health aides to be trained on “Recognizing and reporting changes in skin condition, including pressure ulcers.” We believe that it is important for home health aides to be taught to recognize and report changes in skin condition; however, during the process of developing this final rule, CMS stakeholders identified concerns that this requirement is beyond the aide's scope of practice and possibly the aide's ability to report changes in pressure ulcers. Out of an abundance of caution, we are withdrawing the proposal for the aide to be taught to recognize and report changes in pressure ulcers. The revision will require only recognizing and reporting changes in skin condition.

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposal. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-

comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. We believe that finalizing the previously proposed language is contrary to the public interest because requiring home health aides to perform skills that are inconsistent with their state scope of practice requirements would create a direct conflict between state and federal requirements. This direct conflict would impede the ability of home health aides to do their jobs efficiently and effectively, and would negatively impact patient care and outcomes. Therefore, we find good cause to waive the notice of proposed rulemaking related to this change, and to withdraw this provision from the final rule.

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In section IV of this preamble, at § 484.115 “Condition of participation: Personnel qualifications,” we proposed to remove the word “vocational” from the current CFR at § 484.4, “Personnel qualifications.” During a meeting of state leaders that occurred outside of the public comment process we were notified that two states currently use the term “licensed vocation nurse.” We believe that there are no significant substantive differences that exist between LPNs and LVNs other than the geographical locations and local variants in nomenclature; there are no major differences in educational preparation, licensure, roles, or skill sets. Therefore, after discussions with the states and an internal review we have amended § 484.115(e). We have withdrawn our proposal to delete the word “vocational” from the position title, and have amended the proposed definition to utilize existing regulatory language inclusive of both LVNs and LPNs. The final provision states: *Licensed Practical (vocational) Nurse*. A person who has completed a practical (vocational) nursing program, is licensed in the state where practicing, and who furnishes services under the supervision of a qualified registered nurse.

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposal. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. We believe that finalizing the previously proposed language is contrary to the public interest because the only significant difference between LPNs and LVNs is the geographical locations in which these terms are used. The terms are used interchangeably, and continuing the use of both terms, as has been required in the HHA CoPs for more than a decade, will have no impact on patient care or HHA operations. Therefore, we find good cause to waive the notice of proposed rulemaking related to this change, and to withdraw this provision from the final rule.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs) during the proposed rulemaking.

Assumptions and Estimates

We have made several assumptions and estimates in order to assess both the time that it would take for an HHA to comply with the new provisions as well as the costs associated with that compliance. We have detailed these assumptions and estimates in Table 1, and have used these assumptions as the basis for both the Collection of Information and the Regulatory Impact Analysis sections of this rule.

Table 1—Assumptions and Estimates Used Throughout the Information Collection and Impact Analysis Sections

Number of Medicare participating HHAs nationwide in 2015	12,602
Number of Medicare participating HHAs that are accredited in 2015	4,972
Number of HHA patients in Medicare participating HHAs nationwide in 2014	17,751,840
Number of HHA patients in Medicare participating in 2015, accredited HHAs	7,005,548
Number of Medicare beneficiaries in HHAs in 2015	3,475,730
Average number of new HHAs per year (based on growth in the number of HHAs from 2010-2015)	455
Average number of new, non-accredited HHAs per year (based on growth in the number of HHAs from 2010-2015)	14
Average number of patients per HHA per year	1,409
Hourly rate of registered nurse *	\$63
Hourly rate of HHA office employee *	\$26
Hourly rate of administrator *	\$98
Hourly rate of home health aide *	\$20
Hourly rate of clinical manager *	\$85
Hourly rate of QAPI coordinator **	\$63
Hourly rate of physician *	\$180
Hourly rate of therapist (average of PT, OT, SLP) *	\$72
Hourly rate of clinician (average of Nurse, Aide, Therapist) *	\$60

* Estimate from the Bureau of Labor Statistics Occupational Outlook Handbook, 2014-2015 edition; includes 100 percent benefit and overhead package.

** Based on a registered nurse fulfilling this role.



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Collection of Information Requirements—Discussion and Summary

A. ICRs Regarding Condition of Participation: Reporting OASIS Information (§ 484.45)

Section 484.45 states that HHAs must electronically report all OASIS data in accordance with § 484.55. Specifically, an HHA would have to encode and electronically transmit each completed OASIS assessment to the state agency or the CMS OASIS contractor within 30 days of completing an assessment of a beneficiary. The burden associated with this requirement is the time and effort necessary to conduct the OASIS assessment on a beneficiary and encode and transmit the information to the state agency or the CMS OASIS

contractor. We did not make any changes to the OASIS data set, so the time to conduct the OASIS assessment on a beneficiary has stayed the same. We did change the destination of transmitted data; however, this does not change the time necessary to encode and transmit the data. While this requirement is subject to the PRA, the burden is currently approved under OMB control number 0938-1279.

B. ICRs Regarding Condition of Participation: Patient Rights (§ 484.50)

Section 484.50 implements the patient rights provisions of section 1891(a)(1) of the Act, which are currently specified in § 484.10. The purpose is to recognize certain rights that home health patients are entitled to, and protect their rights. HHAs are required to inform each patient of their rights. In § 484.50, we require HHAs to inform patients about the expected outcomes of treatment and the factors that could affect treatment. The HHAs are asked to devote efforts to improve patient's health literacy which lead to an increased comprehension of diagnosis and treatment for both patients and family. Increased comprehension allows patients to remain active and make the best possible decisions for their medical care. The requirements currently specified in § 484.10, that are retained in the final rule include:

- An HHA must provide the patient and representative (legal or patient-selected) with an oral and a written notice of the patient's rights in a manner that the individual can understand. The HHA must also document that it has complied with the requirements of this section.
- An HHA must document the existence and resolution of complaints about the care furnished by the HHA that were made by the patient, representative, and family.
- An HHA must advise the patient in advance of the disciplines that will furnish care, the plan of care, expected outcomes, factors that could affect treatment, and any changes in the care to be furnished.
- An HHA must advise the patient of the HHA's policies and procedures regarding the disclosure of patient records.
- An HHA must advise the patient of his or her liability for payment.
- An HHA must advise the patient of the number, purpose, and hours of operation of the state home health hotline.

In addition to the retained requirements, we require that HHAs must also advise the patient of the following:

- The names, addresses, and telephone numbers of specified State-funded and federally-funded entities.
- The right to access auxiliary aids and language services, and how to access these services.

We foresee that HHAs will develop a standard notice of rights to fulfill the requirements contained in § 484.50(a) of this section. A copy of the signed notice would serve as documentation of compliance. We estimate that a home health agency will utilize an administrator to develop the patient rights form. All newly established HHAs would need to develop a notice of patient rights document. In order to speed up the process of becoming Medicare-approved, the majority of new HHAs are choosing to become accredited by a national accrediting organization for Medicare deeming purposes. The patient rights standards and patient notification requirements of the national accrediting organizations would meet or exceed those included in this rule; therefore this rule does not impose a burden upon those new HHAs that choose to obtain accreditation status for Medicare deeming purposes. We estimate that it would take 8 hours for each new non-accredited home health agency to develop the form. The total annual burden for new HHAs is 112 hours (8 hours per HHA × 14 HHAs). The estimated cost associated with this requirement is \$784 per HHA and \$10,976 for all new non-accredited HHAs, annually. In addition, we estimate that it would take each existing HHA 1 hour to update its existing patient rights form, for a one-time total of 12,602 hours and a cost of \$1,234,996.

The burden associated with § 484.50(e), which requires an HHA to document both the existence of a patient complaint regarding care provided (or not provided) or inappropriate treatment by HHA staff and those working on behalf of the HHA, and the resolution of the complaint, would be the time and effort necessary to document a patient complaint and its resolution. We estimate that, in a 1 year period, an HHA would need to document complaints involving about 5 percent (70) of its patients. We estimate that the documentation would require 5 minutes per investigation. HHAs accredited by the Joint Commission, the Community Health Accreditation Partner, and the Accreditation Commission for Health Care are already required by their accrediting bodies to adhere to stringent patient rights violation investigation and record-keeping standards; therefore accredited HHAs are not be burdened by this new standard. The total annual burden per non-accredited HHA (7,630) would be 6 hours (70 investigations × 5 minutes per investigation/60).

We believe that the requirements of standard (f), "Accessibility," related to providing information to patients in a manner that can be understood would not impose a burden because all HHAs have already attested to CMS that they are in compliance with the requirements of Title VI of the Civil Rights Act of 1964, the Americans With Disabilities Act, and section 504 of the Rehabilitation Act (see 42 CFR 489.10 (/select-citation/2017/01/13/42-CFR-489.10), as implemented by form HHS-690, currently approved under OMB control number 0938-1279, current expiration August 31, 2017). Since HHAs have already attested that they are in compliance with these longstanding requirements, and since the requirements of this rule are not intended to go beyond these statutes, no new burden would be imposed.

C. ICRs Regarding Condition of Participation: Comprehensive Assessment of Patients (§ 484.55)

Section 484.55 requires the HHA to conduct, document and update, within a defined timeframe, a patient-specific comprehensive assessment that identifies the patient's need for HHA care and services, and the patient's need for physical, psychosocial, emotional and spiritual care. Although we have included additional areas of focus within the patient assessment requirements, these areas are already addressed in the OASIS data set that HHAs have been required to collect since 1999. Therefore, no new burden has been added with these changes. The information collection burden associated with the OASIS data set is currently approved under OMB control number 0938-1279. The current expiration date is December 31, 2019.

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D. ICRs Regarding Condition of Participation: Care Planning, Coordination of Services, and Quality of Care (§ 484.60)

The requirements in this section reflect an interdisciplinary, coordinated approach to home health care delivery. Section 484.60 requires that each patient's written plan of care specify the care and services necessary to meet the patient specific needs identified in the comprehensive assessment. Additionally, the written plan of care will be required to contain the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. This section incorporates several of the requirements under former § 484.18. Section 484.18 consists of longstanding requirements that implement statutory provisions found in sections 1835, 1814, and 1891(a) of the Act. While these requirements are subject to the PRA, the associated collection is currently approved under OMB control number 0938-0365. [2] Additionally the plan of care must also specify the patient and caregiver education and training specific to the patient's care needs. A typical HHA patient will have one original plan of care, and we believe compliance with the new plan of care requirements, such as addressing each patient's psychosocial status and interventions to address readmission risk factors, will impose a new burden of 10 minutes per patient, per plan of care. We believe that most HHAs are already addressing these areas during the care planning process, so for purposes of this analysis only, we assume that 90 percent of HHAs are already complying with these requirements and that 10 percent will need to comply. We estimate that the 1,260 HHAs that are not

already addressing these new factors in their care planning process will use 296,482 hours (1,409 patients per HHA \times 0.167 hours per patient \times 1,260 HHAs) at a cost of \$18,678,366 for a nurse to document the new required information in the plan of care.

Section 484.60(a) requires that each patient's written plan of care be established and periodically reviewed by a doctor of medicine, osteopathy, or podiatry. While HHAs average 1,409 home health patient admissions per year, on average 276 of those are Medicare patients. Having a doctor of medicine, osteopathy, or podiatry establish and periodically review the HHA plan of care is also a requirement for Medicare payment; therefore HHAs do this in the absence of this requirement. Thus this requirement will not impose a burden with respect to those 276 Medicare patients. The anticipated burden associated with this requirement involves a member of the office support staff who would facilitate interaction with the physician with regard to non-Medicare patients. We estimate that this would take 5 minutes per admission for a total estimated burden of 94 hours per HHA ([1,133 non-Medicare admits per year \times 5 minutes]/60 minutes per hour).

Section 484.60(a)(4) and (b)(1) requires HHAs to conform and fulfill all medical orders issued in writing or telephone (and later authenticated) by a patient's physician or qualified medical professional. We believe compliance with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3 (/select-citation/2017/01/13/5-CFR-1320.3) (b)(2). Issuing orders for patient care is one of the most fundamental tasks performed by physicians. Likewise, documenting and adhering to physician orders is one of the most fundamental tasks performed by the physician and all other clinicians within a patient's health care team, including the nurses, therapists, and social workers that are involved in home health care.

Section 484.60(c) requires an HHA to review, revise and document the plan on a timely basis. The burden associated with these requirements is the time and effort associated with reviewing, revising, and maintaining the plan of care. We believe compliance with the new plan of care requirements, such as addressing each patient's psychosocial status and interventions to address readmission risk factors, will impose a new burden of 5 minutes per patient, per updated plan of care. Assuming that a typical HHA patient will have one update to the plan of care, we estimate that all HHAs will use 147,353 hours (1,409 patients per HHA \times 0.083 hours per patient \times 1260 HHAs) at a cost of \$9,283,329 for a nurse to document the new required information in the plan of care.

Section 484.60(e) is a new provision that was added based on comments and which partially replaces other requirements previously placed elsewhere. This provision requires the HHA to provide written instructions to the patient and care giver outlining visit schedule including frequency of visits, medication schedule/instructions, treatments administered by HHA personnel and personnel acting on the behalf of the HHA, pertinent instructions related to patient care, and the name and contact information of the HHA clinical manager. Giving written instruction to the patient and care giver outlining the medication schedule/instructions, visit schedule, pertinent instruction related to the patient's care and treatments and contact information of the HHA has been a long standing practice in the home health industry and is one of the most fundamental elements in patient education. For purposes of this analysis only, we assume that 90 percent of HHAs are already providing this information and 10 percent are not. We estimate that it would take 20 minutes to provide a patient with this written information and that each patient will receive written information twice while under the HHA's care. Based on these assumptions, we estimate that this provision will impose 1,182,376 hours of burden at a cost of \$74,489,688 for a nurse to provide the written information.

E. ICRs Regarding Condition of Participation: Quality Assessment and Performance Improvement (QAPI) (§ 484.65)

Section 484.65 requires HHAs to develop, implement, maintain and evaluate an effective, data driven quality assessment and performance improvement program. We have not prescribed the structures and methods for implementing this requirement and have focused the condition toward the expected results of the program. This provides flexibility to the HHA, as it is free to develop a creative program that meets the HHA's needs and reflects the scope of its services. This new provision replaces the former conditions at § 484.16, "Group of professional personnel," and § 484.52, "Evaluation of an agency's program."

The first standard under § 484.65 requires that an HHA's quality assessment and performance improvement program must include, but not be limited to, the use of objective measures to demonstrate improved performance. The second standard requires the HHA to track its performance to assure that improvements are sustained over time. The third standard requires that the HHA must set priorities for performance improvement, consider prevalence and severity of identified problems, and give priority to improvement activities that affect clinical outcomes. Lastly, the fourth standard requires the HHA to conduct performance improvement projects that reflect the scope, complexity, and past performance of the HHA's services and operations, and document these projects.

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We believe the writing of internal policies governing the HHA's approach to the development, implementation, maintenance, and evaluation of the quality assessment and performance improvement program, as described in § 484.65, will impose a new burden. We want HHAs to utilize maximum flexibility in their approach to quality assessment and performance improvement programs. Flexibility is provided to HHAs to ensure that each program reflects the scope of its services. We believe that this requirement provides a performance expectation that HHAs will set their own QAPI plan and goals and use the information to continuously strive to improve their performance over time. Given the variability across HHAs and the flexibility provided, we believe that the burden associated with writing the internal policies governing the approach to the development, implementation, and evaluation of the quality assessment and performance improvement program will reflect that diversity. We estimate that the burden associated with writing the internal policies would be an average of 4 hours annually per HHA, for an industry-wide total of 30,520 hours. (4 hours per HHA × 7,630 non-accredited HHAs), and an industry-wide cost of \$1,922,760 (30,520 hours × \$63/hour).

HHAs accredited by the Joint Commission, the Community Health Accreditation Partner, and the Accreditation Commission for Health Care are already required by their accrediting bodies to undertake and document performance improvement projects. In the absence of accreditation requirements, we believe that most HHAs already document the quality projects that they have undertaken as part of standard business practice. For purposes of this analysis only, we assume that 10 percent of non-accredited HHAs would use additional resources to document their quality projects. We estimate that the affected HHAs would use 1 hour per quarter to document performance improvement project activities and that the QAPI coordinator would perform this function, for a total of 3,052 hours (0.1 × 7,630 non-accredited HHAs × 1 hour per quarter × 4 quarters per year) at a cost of \$192,276.

F. ICRs Regarding Condition of Participation: Infection Prevention and Control (§ 484.70)

Section 484.70 requires an HHA to maintain and document an infection control program with the goal of preventing and controlling infections and communicable diseases. Specifically, § 484.70(b) states that the HHA must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the HHA's

QAPI program. Section 484.70(c) requires that each HHA provide infection control education to staff, patients, and caregivers. All aspects of the infection prevention and control CoP, from teaching patients and caregivers about proper prevention practices to monitoring infectious disease occurrences within an HHA's population to cooperating with outside bodies during disease outbreaks, are current standards of practice. Since health care-acquired infections have been a source of significant research, education, and training efforts by both the public and private health care sectors for more than a decade, we believe that all HHAs already have infection prevention and control programs. The burden associated with the infection prevention and control program would be the time necessary to document the program. We estimate that each HHA will spend 1 hour per quarter documenting its infection prevention and control program, for a total of 50,408 hours at a cost of \$3,175,704 for a nurse to complete the documentation.

G. ICRs Regarding Condition of Participation: Skilled Professional Services (§ 484.75)

We consolidated former provisions governing skilled nursing services at § 484.30, therapy services at § 484.32, and medical social services at § 484.34, under one new condition, § 484.75. Section 484.75 requires skilled professionals who provide services to HHA patients as employees or under arrangement to participate in all aspects of care. This includes, but is not limited to, participation in the on-going patient assessment process; development and maintenance of the interdisciplinary plan of care; patient, caregiver, and family counseling; patient and caregiver education; and communication with other health care providers. Section 484.75 also requires skilled professionals to be actively involved in the HHA's QAPI program and participate in HHA in-service trainings. Furthermore, § 484.75 requires skilled professional services to be supervised. In the proposed rule that published on October 9, 2014 (79 FR 61114 (/citation/79-FR-61114)), we incorrectly stated that these requirements would be exempt under the implementing regulations of the PRA at 5 CFR 1320.3 (/select-citation/2017/01/13/5-CFR-1320.3)(b)(3). We still maintain that the burden associated with these requirements would be exempt; however, the correct exemption is located at 5 CFR 1320.3 (/select-citation/2017/01/13/5-CFR-1320.3)(b)(2). These are usual and customary business practices. Clinician involvement in patient care, quality improvement efforts, and continuing education are all commonly accepted as good medical practice and are typically part of state licensure requirements. The supervision of clinician services is also standard medical practice to ensure that patient care is delivered in a safe and effective manner.

H. ICRs Regarding Condition of Participation: Home Health Aide Services (§ 484.80)

This section governs the requirements for home health aide services. Many requirements in this section directly mirror the statutory requirements of sections 1891 and 1861 of the Act and include the following requirements: (1) The HHA must maintain sufficient documentation to demonstrate that training requirements are met; (2) The HHA's competency evaluation must address all required subjects; (3) The HHA must maintain documentation that demonstrates that requirements of competency evaluation are met; and (4) a registered nurse or appropriate skilled professional prepares written instructions for care to be provided by the home health aide.

We retained, for the most part, the requirements at previous § 484.36, but place them in a new condition of participation at § 484.80. We also added the provisions from previous § 484.4 concerning the qualifications for home health aides. All home health aide services must be provided by individuals who meet the personnel requirements and training criteria as specified. An HHA is required to maintain documentation that each home health aide meets these qualifications as specified in § 484.80(a). The burden associated with these standards is the time required to document that each new aide meets the qualification requirements. We estimate that it will take 5 minutes per newly hired home health aide per year to document the information. We assume that the average home health agency would replace 30 percent of its home health aides in a given

year, or roughly two home health aides a year based on an average of six home health aide FTEs (Basic Statistics About Home Care Updated 2010, National Association for Home Care, http://www.nahc.org/facts/10HC_Stats.pdf (http://www.nahc.org/facts/10HC_Stats.pdf)). Based on an estimate of 5 minutes per newly hired aide and two newly hired aides per agency, per year, we estimate that there will be 2,100 annual burden hours ($[5 \text{ minutes per aide} \times 2 \text{ aides per HHA}] / 60 \text{ minutes per hour} \times 12,602 \text{ HHAs}$) for the home health industry. We assume, based on our experience with a similar requirement in the hospice environment, that an office employee (\$26/hour) would perform this function at a cost of \$4 per HHA per year. The total cost for all HHAs is \$54,600 ($2,100 \text{ hours} \times \$26/\text{hour}$).

Section 484.80(b)(1) through (3) sets forth the content and duration of the home health aide classroom and supervised practical training. With respect to the recordkeeping requirements, § 484.80(b)(4) states that an HHA is required to maintain documentation that demonstrates that the requirements of this standard have been met. The burden associated with this requirement would be the time and effort necessary to document the information and maintain the documentation as part of the HHAs records. We estimate that it would take each of the 12,603 HHAs 5 minutes per newly hired aide per year to document that the requirements of this standard have been met. The estimated annual burden is 2,100 hours ($[5 \text{ minutes per aide} \times 2 \text{ aides per HHA}] / 60 \text{ minutes per hour} \times 12,602 \text{ HHAs}$). The cost burden associated with this requirement is \$54,600, based on an office employee completing the documentation ($\$26/\text{hour} \times 2,100 \text{ hours}$).

Section 484.80(c) contains the standard for competency evaluation. An individual could furnish home health services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this section. With respect to the recordkeeping requirements, § 484.80(c)(5) states that an HHA is required to maintain documentation that demonstrates that the requirements of this standard have been met. The burden associated with this requirement would be the time and effort necessary to document the information and maintain the documentation as part of the HHAs records. We estimate that it would take each of the 12,602 HHAs 5 minutes per newly hired aide per year to document that the requirements of this standard have been met. The estimated annual burden is 2,100 hours ($[5 \text{ minutes per aide} \times 2 \text{ aides per HHA}] / 60 \text{ minutes per hour} \times 12,602 \text{ HHAs}$). The cost burden associated with this requirement is \$54,600, based on an office worker completing the documentation ($\$26/\text{hour} \times 2,100 \text{ hours}$).

Section 484.80(d) states that a home health agency is required to maintain documentation that all home health aides have received at least 12 hours of in-service training during each 12-month period. The burden associated with this requirement would be the time and effort necessary to document and maintain records of the required in-service training. We assume that it would require 5 minutes per aide to document the in-service training, and that these trainings would be conducted on a quarterly basis, for a total of approximately 2 hours per HHA, annually, to meet this requirement ($[0.083 \text{ hours (aka 5 minutes) per aide per training} \times 4 \text{ trainings per year} \times 6 \text{ aides}] / 60 \text{ minutes per hour}$). The estimated total annual burden for this requirement is 25,103 hours ($0.083 \text{ hours (aka 5 minutes) per aide per training} \times 4 \text{ trainings per year} \times 6 \text{ aides per HHA} \times 12,602 \text{ HHAs}$).

Section 484.80(g) states that written patient care instructions for a home health aide must be prepared by a registered nurse or other appropriate skilled professional who is responsible for the supervision of a home health aide. The burden associated with this requirement would be the time and effort necessary for a registered nurse or other skilled professional to draft written patient care instructions for a home health aide. Providing written patient care instructions is a usual and customary business practice in accordance with the implementing regulations of the PRA at 5 CFR 1320.3 (/select-citation/2017/01/13/5-CFR-1320.3)(b)(2).

Home health aide licensure standards require aides to practice under the direction of a nurse or other qualified medical professional. Likewise, the scope of practice for nurses and other qualified medical professionals includes the preparation of patient care instructions.

This rule at § 484.80(h) also requires HHAs to document the supervision of home health aides in accordance with specified timeframes. Supervising employees to ensure the safe and effective provision of patient care is standard business practice throughout the health care community. Likewise, documenting that this supervision has occurred for internal personnel, accreditation, and state and federal compliance purposes constitutes a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulation of the PRA at 5 CFR 1320.3 (/select-citation/2017/01/13/5-CFR-1320.3)(b)(2).

I. ICRs Regarding Condition of Participation: Compliance With Federal, State, and Local Laws and Regulations Related to the Health and Safety of Patients (§ 484.100)

We are retaining most of the provisions of former § 484.12, “Compliance with Federal, State and local laws, disclosure of ownership information and accepted professional standards and principles” with minor changes, now set forth at § 484.100. As stated in § 484.100(a), the HHA is required to disclose to the state survey agency at the time of the HHA's initial request for certification the name and address of all persons with an ownership or control interest in the HHA, the name and address of all officers, directors, agents, and managers of the HHA, as well as the name and address of the corporation or association responsible for the management of the HHA and the chief executive and chairman of that corporation or association. This requirement directly implements section 1891 of the Act. This provision expands upon a similar requirement currently contained in § 405.1221(b). It would impose a minimal burden of adding the necessary additional information to the current disclosure used by HHAs as required by former § 484.12(b), which further reference the requirements of 42 CFR part 420 (/select-citation/2017/01/13/42-CFR-420), subpart C related to Medicare Program Integrity requirements. We estimate that modifying the current disclosure would require 5 minutes (0.083 hours) per HHA, for a total of 1,046 hours for the HHA industry as a whole on a one-time basis (0.083 hours per modification × 12,602 existing agencies). Additionally, we estimate that it would require new HHAs 1 hour to develop a disclosure statement, for a total of 455 annual hours industry wide each year (1 hour per new HHA × 455 new HHAs).

J. ICRs Regarding Condition of Participation: Organization and Administration of Services (§ 484.105)

This section sets forth the organization and administration of services provided by an HHA. It states that the HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity for each patient regarding medical, nursing, and rehabilitative needs as indicated by the plan of care. Although there are reporting and documentation requirements associated with the requirements, these activities are □ standard business practice and would not impose a burden on HHAs. For example, § 484.105(d)(1) states that the parent HHA is responsible for reporting all branch locations of the HHA to the state survey agency at the time of the HHA's request for initial certification, at each survey, and at the time the parent proposes to add or delete a branch. Similarly, § 484.105(e)(2) states that an HHA must have a written agreement with another agency, with an organization, or with an individual when that entity or individual furnishes services under arrangement to the HHA's patients. We believe the burden associated with the aforementioned will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3 (/select-citation/2017/01/13/5-CFR-1320.3)(b)(2). Paragraph (h) of this section, “Institutional planning,” imposes a minimal burden of the time required by new HHAs to develop the initial plan and by existing HHAs to review and revise the existing plan. We estimate the burden for developing a new plan at 11/2 hours (90

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minutes) and the burden for reviewing and revising an existing plan at 30 minutes. Accredited HHAs are required by their accrediting bodies to engage in institutional planning efforts that exceed these minimum federal requirements; therefore this requirement would not impose a burden upon accredited agencies. In addition, the vast majority of new HHAs are entering the Medicare program via accreditation from a national accrediting body; therefore this provision would not be imposing a burden upon new agencies as well. The estimated annual burden for existing HHAs is 3,815 hours ($[7,630 \text{ existing non-accredited HHAs} \times 30 \text{ minutes}] / 60 \text{ minutes per hour}$). The estimated annual burden for anticipated new HHAs is 21 hours ($1.5 \text{ hours per HHA} \times 14 \text{ new HHAs}$).

K. ICRs Regarding Condition of Participation: Clinical Records (§ 484.110)

This section sets forth the requirements that clinical records contain pertinent past and current findings, and are maintained for every patient who is accepted by the HHA for home health services. A clinical record containing pertinent past and current findings would be maintained for every patient receiving home health services. All entries in the clinical record must be authenticated, dated and timed, which is usual and customary clinical practice and does not impose a burden. Clinical records must be retained for 5 years after the month the cost report for the records is filed with the intermediary. HHAs are required to have written procedures that govern the use and removal of records, and the conditions for release of information. This section contains longstanding provisions that are specifically required in section 1861(o) of the Act, and are necessary to preserve the patient's privacy and the quality of care. The aforementioned documentation and record retention requirements are considered usual and customary business practices; therefore the burden associated with those requirements will not be subject to the PRA in accordance with the implementing regulation of the PRA at 5 CFR 1320.3 (/select-citation/2017/01/13/5-CFR-1320.3)(b)(2). At § 484.110(a)(5) HHAs are required to send a copy of a patient's discharge or transfer summary to 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, or the facility, if the patient leaves HHA care to enter a facility for further treatment. We estimate that an HHA would spend 5 minutes per patient sending the discharge or transfer summary to the patient's next source of health care services, for a total of 117 hours per average HHA annually ($[5 \text{ minutes per patient} \times 1,409 \text{ patients}] / 60 \text{ minutes per hour}$) at a cost of \$3,042 for an office employee to send the required documentation ($\$26 \text{ per hour} \times 117 \text{ hours}$).

Furthermore, a patient's clinical record (whether hard copy or electronic form) must be made available to a patient, free of charge, upon request at the next home visit, or within 4 business days (whichever comes first). The burden associated with this requirement is the time and effort required to disclose a clinical record to an appropriate authority. Making clinical records available to the appropriate authority is part of the survey and certification process, and we believe compliance with this requirement will constitute a usual and customary business practice. Therefore, the burden associated with this requirement will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3 (/select-citation/2017/01/13/5-CFR-1320.3)(b)(2). Furthermore, we do not believe that this requirement would alter the frequency or scope of requests stemming from other appropriate authorities such as law enforcement.

L. ICRs Regarding Personnel Qualifications (§ 484.115)

In § 484.115, we defer to state certification or state licensure requirements in cases where personnel requirements are not statutory or do not relate to a specific payment provision. As defined in the implementing regulations of the PRA at 5 CFR 1320.3 (/select-citation/2017/01/13/5-CFR-1320.3)(b)(2), these requirements are usual and customary business practices. In accordance with the implementing

regulations of the PRA at 5 CFR 1320.3 (/select-citation/2017/01/13/5-CFR-1320.3)(b)(3), we believe this state requirement would exist even in the absence of the federal requirement; therefore, the associated burden is not subject to the PRA.

Table 2—Burden and Cost Estimates Associated With Information Collection Requirements

Regulation section	OMB control No.	Respondents	Responses	Burden per response (in hours)	Total annual burden (in hours)	Hourly labor cost of reporting (\$)	Total cost of reporting (\$)
§ 484.50(a)*	0938-New	14	14	8	* 112	98	10,976
§ 484.50(a)*	0938-New	12,602	12,602	1	* 12,602	98	1,234,996
§ 484.50(e)	0938-New	7,630	534,100	0.083	44,330	63	2,792,790
§ 484.60(a)	0938-New	12,602	14,276,110	0.083	1,184,917	26	30,809,662
§ 484.60(a)	0938-New	1260	1,775,340	0.167	296,482	63	18,678,366
§ 484.60(c)	0938-New	1260	1,775,340	0.083	147,353	63	9,283,239
§ 484.60(e)	0938-New	1260	3,550,680	0.333	1,182,376	63	74,489,688
§ 484.65(e)*	0938-New	7,630	7,630	4	* 30,520	63	1,922,760
§ 484.65(d)	0938-New	763	3,052	1	3,052	63	192,276
§ 484.70	0938-New	12,602	50,408	1	50,408	63	3,175,704
§ 484.80(a)	0938-New	12,602	25,204	0.083	2,100	26	54,600
§ 484.80(b)	0938-New	12,602	25,204	0.083	2,100	26	54,600
§ 484.80(c)	0938-New	12,602	25,204	0.083	2,100	26	54,600
§ 484.80(d)	0938-New	12,602	302,448	0.083	25,103	26	652,678
§ 484.100(a)	0938-New	12,602	12,602	0.083	1,046	98	102,508
§ 484.100(a)*	0938-New	455	455	1	* 455	98	44,590
§ 484.105(h)		7,630	7,630	0.5	3,815	98	373,870
§ 484.105(h)	0938-New	14	14	1.5	21	98	2,058
§ 484.110(a)	0938-New	12,602	17,751,840	0.083	1,473,403	26	38,308,478
Total		140,189	40,135,877	19	4,462,805	1,185	182,350,264

* Denotes a one-time information collection requirement.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 2. In addition, the column for the total costs is also represents the total cost of reporting; therefore, we have removed the total cost of reporting column from Table 2 as well.

VIII. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 ([/executive-order/13563](#)) on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4 (<https://api.fdsys.gov/link?collection=plaw&congress=104&lawtype=public&lawnum=4&link-type=html>)), Executive Order 13132 ([/executive-order/13132](#)) on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804 (<https://api.fdsys.gov/link?collection=uscode&title=5&year=mostrecent§ion=804&type=usc&link-type=html>)(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year).

This final rule is a revision of the Medicare and Medicaid CoPs for HHAs. The CoPs are the basic health and safety requirements that an HHA must meet in order to receive payment from the Medicare and Medicaid programs. This final rule incorporates advances and current medical practices in caring for home health patients while removing unnecessary process and procedure requirements contained in the current CoPs. This is a major rule because the overall economic impact for all of the new CoPs is estimated to be \$293.3 million in year 1 and \$290.1 million in year 2 and thereafter.

B. Statement of Need

As the single largest payer for health care services in the United States, the federal government assumes a critical responsibility for the delivery and quality of care furnished under its programs. Historically, we have adopted a quality assurance approach that has been directed toward identifying health care providers that furnish poor quality care or fail to meet minimum federal standards, but this problem-focused approach has inherent limits. Ensuring quality through the enforcement of prescriptive health and safety standards, rather than improving the quality of care for all patients, has resulted in our expending much of our resources on dealing with marginal providers, rather than on stimulating broad-based improvements in the quality of care delivered to all patients.

This final rule adopts a new approach that focuses on the care delivered to patients by home health agencies while allowing HHAs greater flexibility and eliminating unnecessary procedural requirements. As a result, we are revising the HHA requirements to focus on a patient-centered, data-driven, outcome-oriented process that promotes high quality patient care at all times for all patients. We have developed a set of fundamental requirements for HHA services that encompasses patient rights, comprehensive patient assessment, and

patient care planning and coordination by an interdisciplinary team. Overarching these requirements is a QAPI program that builds on the philosophy that a provider's own quality management system is key to improved patient care performance.

These regulations contain two critical improvements that support and extend our focus on patient-centered, outcome-oriented surveys. First, the regulations are designed to enable surveyors to look at outcomes of care, because the regulations specify that each individual receives the care which his or her assessed needs demonstrate is necessary, rather than focusing simply on the services and processes that must be in place. Second, the addition of a strong QAPI requirement not only stimulates the HHA to continuously monitor its performance and find opportunities for improvement, it also affords the surveyor the ability to assess how effectively the provider was pursuing a continuous quality improvement agenda. All of the changes are directed toward improving patient-centered outcomes of care. We believe that the overall approach of the final CoPs will increase performance expectations for HHAs, in terms of achieving needed and desired outcomes for patients and increasing patient satisfaction with services provided.

C. Public Comments

As discussed in section III, "Analysis of and Responses to Public Comments," of this rule, we received several public comments related to the estimates presented in the RIA section of the proposed rule. As a general summation, commenters stated that the estimates did not fully account for the burdens that HHAs will encounter in implementing this rule. However, by and large, commenters did not provide suggestions for estimates that should be used or evidence to guide the development of new estimates. Responses to particular comments are included under the relevant subject matter headings. That is to say, comments regarding the RIA estimates related to patient rights, for example, are located in the discussion of all other patient rights comments. Those who submitted comments on particular burden estimates made general, vague statements that the estimates for the time and cost associated with compliance were understated. With one exception, commenters did not provide suggestions of more appropriate estimates. We received one specific comment, which asserted that requiring HHAs to notify patients of their right to access their own medical records would cost the HHA and additional \$230k, annually, because many more patients would be accessing their records. However, notifying each patient of his right to receive a copy of information contained in his medical record is already included in the standard HIPAA notice that HHAs are required to provide (see 45 CFR 164.520 (/select-citation/2017/01/13/45-CFR-164.520), as accounted for by OMB Control Number 0945-0003). Therefore, we are not creating a new right, nor are we creating a new notice of this right. Thus, we do not believe that this requirement will create the exponential increase in record requests that the commenter claims.

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D. Summary of Impacts

Section VII of this rule, Collection of Information Requirements, provides a detailed analysis of the burden hours and associated costs for all burdens related to the collection of information by HHAs that is required by this rule. That section, in tandem with this regulatory impact analysis section, present a full account of the burdens that will be imposed by this rule. Because the burdens have already been assessed in the Collection of Information Requirements section, we will not recount them in this RIA section. All estimates presented in this RIA section are based on the assumptions presented in Table 1, located at the beginning of the Section VII of this rule, Collection of Information Requirements.

Although we endeavor to provide the most accurate account of the burdens that will be imposed by this rule that is possible, we acknowledge that such analysis is inevitably imprecise. We believe that many of the tasks set forth in this final rule are already being done by the majority of HHAs as part of good business and health

care practice. We have identified several activities, such as developing and updating a written plan of care for each patient, as usual and customary practices that would occur in the absence of regulation. While we believe that these identifications are an accurate reflection of current HHA practices as a whole, uncertainty remains regarding whether such usual and customary practices occur in all HHAs in all appropriate circumstances. Additionally, there are some estimates for which we lack information regarding implementation in the HHA environment because we have not previously regulated those activities. Following implementation of this final rule, we will monitor HHA practices to assess the impact of these new regulations.

Where appropriate, we have differentiated between the burdens that this rule would impose on accredited versus non-accredited HHAs in recognition of the fact that current accreditation standards established by the three main HHA accreditation entities will meet or exceed the minimum standards that are established in this rule. Accredited HHAs will experience less burden when implementing new the patient rights, QAPI, infection prevention and control, and organization and administration of services requirements.

In addition to analyzing the burden hours and associated costs for all burdens related to these requirements, we have also assessed the potential savings associated with our removal of certain outdated, burdensome requirements that exist in the current HHA CoPs.

Table 3—Summary of Estimated Burden for All CoPs

CoP	Total time (hours)	Total cost in year 1	Annual cost in year 2 and thereafter
Burden and Cost Estimates Associated with Information Collection Requirements	4,462,805	\$182,350,264	\$179,136,942
Patient rights	2,398,446	147,326,970	147,326,970
QAPI	618,030	29,070,300	25,316,340
Infection prevention and control	595,140	37,493,820	37,493,820
Removal of 60 day summary requirement	887,592	-16,864,248	-16,864,248
Removal of Group of professional personnel requirement	203,620	-16,924,452	-16,924,452
Removal of Evaluation of the agency's program	1,335,073	-69,111,119	-69,111,119
Total	5,648,136	293,341,535	290,128,213

1. BURDEN ASSESSMENT

REPORTING OASIS INFORMATION (§ 484.45)

We are making one change to replace the requirement that an HHA has a “direct telephone connection” to transmit the OASIS data with a requirement that an HHA must 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. The FIPS 140-2 applies to all federal agencies that use cryptographic-based security systems to protect sensitive information in computer and telecommunication systems (including voice systems) as defined in section 5131 of the Information Technology Management Reform Act of 1996, Public Law 104-106 (<https://api.fdsys.gov/link?collection=plaw&congress=104&lawtype=public&lawnum=106&link-type=html>), including CMS. Therefore, this requirement does not impose a new burden upon HHAs.

PATIENT RIGHTS (§ 484.50)

The final rule requires that an HHA must provide a patient with a written notice of rights. The final rule requires that an HHA must provide a patient's representative (legal) with a written notice of rights, and must provide a patient's representative (patient-selected) with a written notice of rights in accordance with patient preferences. Communicating with patients and representatives, including the provision of a written notice of rights, is a standard practice in the health care industry and would impose no additional costs. Similar requirements already exist for many other health care provider types, including hospice providers, long term care facilities, ambulatory surgery centers, and end-stage renal disease facilities. □

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Verbal notification of rights in a language and manner that the individual understands, however, may create a new burden for some HHAs. The national accrediting organizations already require their accredited HHAs to orally apprise their patients of their rights in situations where patients cannot read or understand the written notice. We assume, for purposes of this analysis only, that accredited HHAs are providing oral notification to the 25 percent of their patients that cannot read or understand the written notice. Based on this assumption, 1,751,387 patients are already orally notified of their rights each year; therefore, we are excluding these patients from this analysis. For the remaining 75 percent of patients receiving care from an accredited HHA, we estimate that it would take approximately 5 minutes per patient to describe the content of the notice of rights and obtain the patient's signature confirming that he or she has received a copy of the notice. We assume that patients would be informed of their rights by a registered nurse at a cost of \$5 per patient (5 minutes × \$63/hour). The total number of hours per accredited HHA would be 88 hours (1,057 patients × 5 minutes per patient/60 minutes), at a cost of \$5,285 (1,057 patients × \$5 per patient).

For non-accredited HHAs, the requirement to provide this verbal notice is a new requirement for all 1,409 patients served in an average HHA each year. The total cost of this provision per non-accredited HHA would be \$7,045 (1,409 patients × \$5 per patient). The total number of hours per non-accredited HHA would be 117 hours (1,409 patients × 5 minutes per patient/60 minutes). The total cost for all HHAs would be \$80,030,370 ([\$7,045 per non-accredited × 7,630 HHAs] + [\$5,285 per accredited HHA × 4,972 HHAs]). The total number of hours for all HHAs would be 1,330,246 hours ([117 hours per non-accredited HHA × 7,630 HHAs] + [88 hours per non-accredited HHA × 4,972 HHAs]).

We note that the requirement to communicate with patients in a language and manner that the patient understands is not a new expectation for Medicare-approved HHAs, as they are already required to be in compliance with the current civil rights requirements and guidance (see 42 CFR 489.10 (/select-citation/2017/01/13/42-CFR-489.10)(b)). Specifically, HHAs are already required to comply with the requirements of Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, section 1557 of the Affordable Care Act and “other pertinent requirements of the Office for Civil Rights of HHS.” HHS guidance, issued in 2003, further explains the expected role of interpreters in communications with patients (“Guidance to Federal Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons,” August 8, 2003, 68 FR 47311 (/citation/68-FR-47311)). As such, the requirement to communicate with patients in a language and manner that the patient understands would not impose a new burden on HHAs.

Standard 484.50(e) requires that all patient/family complaints be investigated. We estimate that, in a 1 year period, an HHA would need to investigate complaints involving about 5 percent (70) of its patients, and that each investigation would take 2 hours to complete. The total annual burden per HHA would be 140 hours (70 investigations × 2 hour per investigation). All national accrediting organizations already require their accredited HHAs to document, investigate, and resolve patient complaints; therefore all 4,972 accredited

HHAs would not be burdened by this requirement. The total annual burden hours for the industry would be 1,068,200 (140 hours per HHA × 7,630 non-accredited HHAs). The total annual cost for the QAPI coordinator to complete all investigations would be \$8,820 per HHA (\$63/hour × 140 hours), and \$67,296,600 for all non-accredited HHAs (\$63/hour × 1,068,200 hours).

Table 4—Patient Rights

Standard	Time per HHA (hours)	Total time (hours)	Cost per HHA	Total cost
Providing notice of rights (annual, non-accredited/accredited HHAs)	117/88	1,330,246	\$7,045/5,285	\$80,030,370
Investigations (annual, non-accredited HHAs)	140	1,068,200	\$8,820	\$67,296,600
Total (annual, non-accredited/accredited)	257 or 88	2,398,446	\$15,865 or \$5,285	\$147,326,970

COMPREHENSIVE ASSESSMENT OF PATIENTS (§ 484.55)

We are retaining the requirements of current § 484.55, with a reorganization of several sections related to the content of the comprehensive assessment and the addition of several broad focus areas. We believe that the new focus areas (for example, cognitive status and patient goals) are standard practice and would not impose an additional burden. In addition, we are making a minor change to allow for the completion of an OASIS update upon the physician-ordered resumption of care date. Allowing for a physician to order the resumption of care date increases HHA flexibility; therefore there is no new burden associated with this retention.

CARE PLANNING, COORDINATION OF SERVICES, AND QUALITY OF CARE (§ 484.60)

The current regulations at § 484.12(c), “Compliance with accepted professional standards and principles”; § 484.14(g), “Coordination of patient services”; and § 484.18 “Acceptance of patients, plan of care, and medical supervision,” are reorganized and revised at § 484.60.

The change in § 484.18, “Acceptance of patients, plan of care, and medical supervision,” requires each patient to receive an individualized written plan of care, including any additions or revisions. The plan of care includes all orders, specifies the care and services necessary to meet the patient-specific needs and the measurable outcomes that the HHA anticipates would occur as a result of implementing and coordinating the plan of care with the patient and physician, and includes all patient and caregiver education and training. The intent of the current standard at § 484.12(c) is retained under this CoP with the requirement that services be furnished in accordance with accepted standards of practice. No burden is associated with this part of the CoPs, as these requirements constitute current industry practices regarding plans of care.

Standard 484.60(a), “Plan of care,” codifies current industry standards of practice through the revision of current § 484.18(a), “Plan of care,” including references to the identification of patient-specific needs and measurable outcomes that are already currently required under current § 484.55, □ “Comprehensive assessment of patients.” Therefore, this requirement does not present a new burden.

Proposed § 484.60(b), “Conformance with physician orders,” retains the provision of the current regulation at 42 CFR 484.18 (/select-citation/2017/01/13/42-CFR-484.18)(c) that allows HHAs to administer influenza and pneumococcal vaccinations without specific physician orders, provided that certain requirements are adhered to. As an allowance of flexibility, rather than an imposition of a specific requirement, we believe that this provision does not impose a burden upon HHAs.

This standard also retains many of the current requirements regarding verbal orders with the exception of the requirement at § 484.60(b)(5), “Conformance with physician orders,” which requires the physician to countersign and date all verbal orders. Although this requirement is not in the current regulations, this and similar physician order practices are consistent with current standards of practice and with many state laws. Therefore, we expect no new burden with this provision.

Standard 484.60(c), “Review and revision of the plan of care,” incorporates some current requirements. Although there has been some revision to current § 484.18(b), “Periodic review of plan of care,” to include mention of measurable outcomes for patients, the intent of this requirement already exists at § 484.55, “Comprehensive assessment of patients.” Section 484.55 requires an HHA to demonstrate patient progress toward the achievement of desired outcomes. Therefore, the current standard remains essentially intact in this final rule and the new standard does not constitute any new burden.

Standard 484.60(d), “Coordination of care,” revises current § 484.14(g), “Coordination of patient services,” and some elements of current § 484.18(a), “Plan of care.” The intent of the current standards remains intact, and these revisions do not generate new burden.

Standard 484.60(e), “Written information to the patient,” requires the HHA to provide written instructions to the patient and care giver outlining visit schedule including frequency of visits, medication schedule/instructions, treatments administered by HHA personnel and personnel acting on the behalf of the HHA, pertinent instructions related to patient care and the name and contact information of the HHA clinical manager. Giving written instruction to the patient and care giver has been a longstanding practice in the home health industry and is one of the most fundamental elements in patient education. Patient education practices are fundamental to patient care and are consistent with current standards of practice. Therefore, we expect no new burden with this provision.

QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI) (§ 484.65)

The quality assessment and performance improvement (QAPI) requirement replaces the current quality-related requirements of § 484.16, “Group of professional personnel,” and § 484.52, “Evaluation of the agency’s program.” Quality assessment is already part of standard HHA practice through annual evaluations of an agency’s total program using both administrative reviews and a quarterly review of a sample of clinical records. Furthermore, HHAs are already familiar with the basic concept of measuring quality on both a patient and aggregate level. This rule further refines current HHA quality efforts and brings HHA quality programs in line with their counterparts in a variety of other settings, such as hospitals and hospices. Likewise, this rule brings non-accredited HHA quality practices in line with those of their accredited counterparts. The national accrediting organizations have spent a decade or more enhancing, expanding, and refining their quality-related standards, and those standards far exceed the current Medicare regulations. Indeed, many of the current quality-related standards established by the accrediting organizations, we believe, exceed those that we require in this rule. Since accredited HHAs already have QAPI programs that should meet the requirements of this rule by virtue of meeting the already existing accreditation standards,

we are not including accredited HHAs in our analysis of the impact of this requirement. This rule provides a basic outline of what QAPI is and how we expect it to function in the HHA environment. Each HHA is free to decide how to implement the QAPI requirement in a manner that reflects its own unique needs and goals.

For purposes of this impact analysis we have described the impact in three general phases that we believe an average HHA will go through. These phases are based on our experience in implementing the QAPI requirements in hospices, another home-based provider type with a similar operating structure and patient population. While we have outlined these phases below, we stress that an HHA is not be required to approach QAPI in this manner. The QAPI requirement does not stipulate that an HHA must collect data for a specific domain; use specific quality measures, policies and procedures, or forms; submit QAPI data to an outside body; or conduct a specified number of performance improvement projects. An HHA may choose to implement a data-driven, comprehensive QAPI program that meets the requirements of this rule in any way that meets its individual needs. These phases described below simply provide a framework for assessing the potential impact of the QAPI requirement upon an average non-accredited HHA. In phase one, we believe that an HHA will—

- Identify quality domains and measurements that reflect its organizational complexity; involve all HHA services; affect patient outcomes, patient safety, and quality of care; focus on high risk, high volume, or problem-prone areas; and track adverse patient events;
- Develop and revise policies and procedures to ensure that data is consistently collected, documented, retrieved, and analyzed in an accurate manner; and
- Educate HHA employees and contractors about the QAPI requirement, philosophy, policies, and procedures. In phase two, we believe that an HHA will—
- Enter data into patient clinical records during patient assessments;
- Aggregate data by collecting the same pieces of data from patient clinical records and other sources (for example, human resource records);
- Analyze the data that is aggregated through charts, graphs, and various other methods to identify patterns, anomalies, areas of concern, etc. that may be useful in targeting areas for improvement; and
- Develop, implement, and evaluate major and minor performance improvement projects based on a thorough analysis of the data collected. In phase three, we believe that an HHA will—
- Identify new domains and measures that may replace or be in addition to the domains and measures already being monitored by the HHA;
- Develop and/or revise policies and procedures to accommodate the new domains and measures; and
- Educate HHA employees and contractors on the new domains and measures, as well as the policies and procedures for them.

In addition to these three phases, an HHA will likely allocate resources to an individual responsible for the general overall coordination of its QAPI program. For simplicity, we refer to this individual as the QAPI coordinator; however, an HHA is not required to use this title. For purposes of this analysis only, we assume that an HHA would □ choose a QAPI coordinator who has a clinical background, such as a nurse.

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Based on these three phases, we have anticipated the impact of the QAPI requirement on an HHA's resources. In phase one, we anticipate that an HHA will use 9 hours to identify quality domains and measures. HHA quality domains and measures are readily available. Indeed, HHAs already collect data for a wide variety of domains and measures each year as part of the OASIS patient assessment data collection tool, and this data is already used to calculate quality measures as presented in OBQI, OBQM, and PBQI reports and the home health compare Web site. These sources provide a robust starting point for HHAs in the quality measurement efforts. We expect that these hours will be distributed among the three members of the HHA's QAPI committee. While we do not require an HHA to have a QAPI committee, we believe that most

HHAs would choose to do so to ensure a variety of perspectives are represented in the QAPI decision-making process. We believe that the QAPI committee will include the QAPI coordinator, the HHA administrator, and a clinical manager. We estimate that the QAPI committee will meet three times per year for 1 hour each meeting to identify appropriate quality domains and measures. We estimate that, in total, the QAPI committee will need 9 hours annually to identify appropriate quality domains and measures (3 staff hours per meeting \times 3 meetings per year). The total annual cost for an average HHA to identify the domains and measures is \$738 (\$189 per QAPI coordinator + \$294 per administrator + \$255 per clinical manager). The total cost for all HHAs is \$5,630,940 (\$738 per HHA \times 7,630 non-accredited HHAs).

In addition to selecting measures and developing policies and procedures for QAPI activities, we anticipate that HHAs will train appropriate staff in data collection for any new data elements necessary to calculate quality measures, as well as the overall QAPI philosophy and efforts within the agency. For purposes of this analysis, we assume HHAs will train all clinical staff in the basic concept of QAPI, the agency's implementation of this requirement, and any agency-specific policies and procedures. We estimate that an HHA will spend 1 hour per staff member to provide this training, as many staff are already familiar with data collection and its role in quality measurement and improvement through the OASIS, OBQI, and PBQI instruments. For purposes of our analysis we are including patient care clinicians because they are the staff members that are most likely to be performing data collection. In 2009, Medicare-certified HHAs had 242,020 clinician FTEs, for an average of 24 clinical FTEs per HHA. The cost per HHA is \$1,824. (1 hour per clinical staff member \times 24 clinical staff members \times \$76 per hour per clinical staff member) The total hour for non-accredited HHAs is 183,120 (24 hours per average HHA \times 7,630 non-accredited HHAs) and the total cost is \$13,917,120 (183,120 hours \times \$76/hour).

Phase two is related to gathering, entering, and analyzing data for quality assessment and performance improvement purposes. Thoroughly assessing a patient and collecting patient data in a standardized manner is already standard practice due to the OASIS regulations. The presence of the OASIS data set and quality reporting measures has been in place for several years and the concepts of each are fully integrated into standard HHA practices. Therefore, we do not believe that it would be a burden for HHAs to incorporate new data gathered for dual patient care planning and QAPI purposes into their current systems and processes.

We believe that any additional burden will arise from the act of entering, aggregating, and analyzing other types of available data that HHAs already collect for other purposes (for example, staffing productivity, staff vacancy rates, timeliness of delivery of services). We estimate that, in order to ensure that the volume of gathered data is manageable, an HHA will gather its data once a month. An HHA may choose to gather data on a more or less frequent basis to suit its needs and circumstances. Some HHAs may choose to gather all patient-level data, but we believe that most HHAs will choose to gather data from a sample of clinical records. Likewise, some HHAs may choose to gather data from a wide variety of administrative files, while others may choose to select only a few administrative data sources. There are many combinations that an HHA may choose to use when it comes to gathering data, and no single approach is considered preferable to another. Given this variability, it is difficult to estimate how long an average HHA may spend gathering and organizing data. For purposes of this analysis only, we assume that an average HHA will use 4 hours per month to gather data, for a total of 48 hours a year. We believe that an office employee would perform the data aggregation and organization at a cost of \$1,248 (4 hours \times 12 months \times \$26/hour) per HHA. The total cost is \$9,522,240 (\$1,248 per HHA \times 7,630 HHAs). Following data gathering and organization, an HHA will analyze the data to identify trends, patterns, anomalies, areas of strength and concern. We believe that this data analysis will be done by the QAPI committee described previously. In order to identify trends and patterns, the committee will need to examine several months of data at the same time. Therefore, we assume

that the committee will meet once every quarter to examine the data and make decisions based on the analysis. Meeting to discuss quality measure data is standard practice in the HHA industry. HHAs are well versed in quality measure reports due to the OBQI and PBQI reports produced by CMS, and the quality measure reports available to the public on the Home Health Compare Web site. Since HHAs already meet to discuss and analyze quality measure results, we do not believe that this requirement will impose a new burden.

Performance improvement projects follow all of the data entry, gathering, organization, and analysis. An HHA must conduct projects to improve its performance in areas where a weakness was identified. Performance improvement projects must reflect the HHA's scope, complexity, and past performance. They must also be data-driven, and affect patient outcomes, patient safety, and quality of care. Although this rule more clearly describes a performance improvement project, its basis, and its purpose, it is based on the same concept as the current requirement at § 484.52, "Evaluation of the agency's program," which requires that "Results of the evaluation are reported and acted upon by those responsible for the operation of the agency. . . ." Since an HHA already takes action to ensure that its program is appropriate, adequate, effective, and efficient, and since providing safe and effective care at all times for all patients is the essential charge of all health care providers, we believe that conducting both major and minor performance improvement projects is already a standard of practice within the HHA industry. Therefore, there will be no additional burden associated with this provision. Although we do not believe that the requirement to conduct performance improvement projects will require additional time and resources, we do believe that the required focus of such projects, and their data-driven nature, will help HHAs improve the efficiency and effectiveness that they achieve in these projects. We believe that the improved project efficiency and effectiveness may result in improved patient outcomes, □ avoidance of future adverse events, more appropriate resource allocation, and a wide variety of other beneficial outcomes, based on the projects selected by each HHA.

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Phase three of the QAPI process builds upon the QAPI program that an HHA already has in place. We estimate that an HHA will use 3 hours a year to identify new domains and quality measures, and we believe that the QAPI committee will perform this task, at a total cost of \$246 (1 hour × \$63/hour for QAPI coordinator + 1 hour × \$98/hour for administrator + 1 hour × \$85/hour rate for clinical manager). The total annual cost for non-accredited HHAs in updating domain and measures is \$1,876,980 (\$246 per HHA × 7,630 HHAs) in year 2 and thereafter.

Table 5—Quality Assessment and Performance Improvement

Standard	Time per HHA (hours)	Total time (hours)	Cost per HHA	Total cost
Identify domains and measures (1st year)	9	68,670	\$738	\$5,630,940
Train staff (1st year and on-going)	24	183,120	1,824	13,917,120
Aggregate data (1st year and on-going)	48	366,240	1,248	9,522,240
Update domains and measures (on-going)	3	22,890	246	1,876,980
Total 1st year	81	618,030	3,810	29,070,300
Total yearly on-going	75	572,250	3,318	25,316,340

INFECTION PREVENTION AND CONTROL (§ 484.70)

There is no specific current requirement addressing infection control in the current HHA CoPs. However, current § 484.12(c), “Compliance with accepted professional standards and principles,” requires an HHA and its staff to comply with accepted professional standards and principles that apply to professionals furnishing services in an HHA. Given this broad requirement, we believe that HHA personnel are already using well-documented infection control practices and well-accepted professional standards and principles in their patient care practices. This regulation reinforces positive infection control practices and addresses the serious nature, as well as the potential hazards, of infectious and communicable diseases in the home health environment. This rule also brings non-accredited HHA quality practices in line with those of their accredited counterparts. The national accrediting organizations have spent a decade or more developing and refining their infection prevention and control standards in the absence of specific Medicare regulations. Indeed, the current infection prevention and control standards established by the accrediting organizations would, we believe, even exceed those that we require in this rule.

Specifically, the regulation requires HHAs to have an organized, agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the HHA's quality assessment and performance improvement (QAPI) program. The agency's program is required to include the following:

- The use of accepted standards of practice, including standard precautions, to prevent the transmission of infections and communicable diseases;
- A method for identifying infectious and communicable disease problems;
- A plan for the appropriate actions that are expected to result in improvement and disease prevention; and
- Education to staff, patients, and caregivers about infection prevention and control issued and practices.

We believe that developing this organized program will require HHA resources, and estimate that an HHA will use 1.5 hours of staff time each week, or 78 hours per year (1.5 hours × 52 weeks), to develop and maintain the infection prevention and control program. At a cost of \$63 per hour for a nurse to provide program leadership, the cost will be \$4,914 per HHA (78 hours × \$63/hour)

While we cannot quantify the benefits of having an organized program for the prevention and control of infections or the costs of replacing current infection control practices with practices conducted under an organized program, we believe a program should produce benefits for HHAs and their patients. For example, a program may improve the manner in which HHAs identify to HHA staff those patients who are infected or colonized with antibiotic resistant bacteria so that staff may take additional precautions in order to protect themselves during interactions with patients, thereby reducing the amount of sick leave used by HHA staff. We do not have adequate data from which to create accurate estimates of the potential benefits or ongoing costs of this requirement, but we believe that they are substantial.

Table 6—Infection Prevention and Control

Standard	Time per HHA (hours)	Total time (hours)	Cost per HHA	Total cost
Develop and maintain program	78	595,140	\$4,914	\$37,493,820
Total	78	595,140	4,914	37,493,820

SKILLED PROFESSIONAL SERVICES (§ 484.75)

We consolidated provisions previously located at § 484.30, “Skilled nursing services”; § 484.32, “Therapy services”; and § 484.34, “Medical social services,” into this new requirement. We added a requirement that skilled professionals participate in the QAPI program. Involvement in patient care and patient care-related activities is a professional responsibility, and therefore we believe involvement in the □ agency's QAPI program imposes little or no additional burden. We also added a requirement, somewhat similar to the requirement at § 484.14(d), regarding the supervision of nursing assistants, therapy assistants, and medical social service assistants. We require that all nursing services be provided under the supervision of a registered nurse; all rehabilitative therapy assistant services be provided under the supervision of a physical therapist or occupational therapist; and all medical social services be provided under the supervision of a social worker. These supervision requirements codify current HHA supervision practices, and therefore do not impose a new burden upon HHAs.

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HOME HEALTH AIDE SERVICES (§ 484.80)

Home health aide services are an integral part of home health care, and the CoP retains many of the current longstanding requirements. However, in an effort to make the current requirements for home health aides more consistent throughout, improve overall clarity, and reflect current standards of practice more accurately, we have reorganized and revised the requirements in this CoP. The burdens associated with this section are described in the Collection of Information section of this rule. Therefore, we are not repeating those burdens in this section. Other changes, such as requiring HHAs to supervise aides when performing skills for which the aides have not passed a competency evaluation or requiring aides to report changes in a patient's condition to a registered nurse or other appropriate skilled professional, constitute standard practice within the HHA industry. Therefore, no new burdens are imposed by these changes.

COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAWS AND REGULATIONS RELATED TO HEALTH AND SAFETY OF PATIENTS (§ 484.100)

The current regulations at § 484.12(a), “Compliance with Federal, State, and local laws and regulations”; § 484.12(b), “Disclosure of ownership and management information”; and § 484.14(j), “Laboratory services,” have been reorganized with only minor clarifying revisions to the language of each standard. The current condition statement is modified slightly for clarification purposes. However, the current regulation regarding compliance with all applicable laws and regulations related to patient health and safety, state licensing of HHAs, and laboratory services, essentially remains intact under this rule. The burden associated with this provision is the disclosure of certain information, which was discussed in the Collection of Information section of this rule, and there are no other burdens associated with this provision.

ORGANIZATION AND ADMINISTRATION OF SERVICES (§ 484.105)

Several of the requirements currently found at § 484.14, “Organization, services, and administration,” have been reorganized and revised under this condition.

In order to facilitate compliance with § 484.60(d) and to ensure that each patient's care is coordinated, we have combined, revised, and elaborated on former § 484.14(d) and (e) at § 484.105(c), “Clinical manager.” This standard requires one or more qualified individuals to provide oversight of all patient care services and HHA personnel. Oversight includes making patient and personnel assignments; coordinating patient care; coordinating referrals; and assuring the development, implementation, and updates of the individualized plan of care. The clinical manager role in the regulations is a further refinement of the former “Supervising physician or registered nurse” role found in regulation at § 418.14(d); therefore the general duties described above are already required of home health agencies. The complex, multi-disciplinary nature of home health

care necessitates both personnel supervision and patient care coordination to ensure the effective delivery of patient care and positive patient outcomes. The clinical manager position does not constitute any new functions within an HHA; rather, it provides a more structured approach for patient care coordination and personnel supervision tasks. Since the various patient care coordination functions already in existence are consolidated under the clinical manager position and are thus be a realignment of current resource allocations, we do not believe that this requirement poses a new burden.

CLINICAL RECORDS (§ 484.110)

The former regulation at § 484.48, "Clinical records," is revised, and reorganized under this CoP. We believe that the majority of the revisions to the former clinical record requirement reflect contemporary professional standards already in place in the home health industry. Therefore, no additional burden is imposed. In addition, the requirements allow HHAs to maintain and send a patient's clinical record in electronic form. This flexibility may result in a reduction in burden for many HHAs with systems of electronic record keeping already in place.

PERSONNEL QUALIFICATIONS (§ 484.115)

We reorganized the personnel qualification requirements formerly found at § 484.4, "Personnel qualifications," in a new CoP dedicated to personnel qualification standards. Within this new condition we use the term "licensed practical (vocational) nurse" instead of the current term of "practical (vocational) nurse" since state practice acts vary and both of these terms are accepted and typically used interchangeably. We also require that the possession of any undergraduate degree would be sufficient for a newly-hired administrator. In addition, we are expanding the qualifications for social workers to include those individuals who possess either a master's (M.S.W.) or a doctor's degree (D.S.W.) in social work. Furthermore, we are deferring to state licensure requirements as the basis for determining the qualifications of SLPs. This expansion of the qualifications for administrators, social workers, and SLPs could provide an agency more flexibility in hiring these professions if it chose, and could provide a potential reduction in burden, though we are not able to quantify what this reduction might be at this time. These changes create no new burden for HHAs.

2. DELETED REQUIREMENTS

We deleted three requirements of the former HHA regulations in their entirety. First, we deleted § 484.14(g), removing the requirement that an HHA must send a written summary report for each patient to the attending physician every 60 days. This requirement imposes a burden of 3 minutes per patient, and 887,592 hours, annually, for all HHAs at a cost of \$16,864,248, as indicated by the currently-approved PRA package (OMB control number 0938-0365). Therefore, removing this requirement saves HHAs \$16,864,248 each year.

Second, we deleted § 484.16, "Group of professional personnel," because the QAPI requirements address the same goals as are currently required of the group of professional personnel. This requirement imposes a documentation burden of 10 minutes per HHA, and 1,988 hours, annually, for all HHAs at a cost of \$37,772, as indicated by the currently-approved PRA package (OMB control number 0938-0365).

In addition to the burden related to documentation, we believe that eliminating this requirement also alleviates the burden of holding meetings with the group of professional □ personnel for the sole purpose of complying with this regulatory requirement. The regulation requires that the group must consist of at least one physician, one registered nurse, and representation from other professional disciplines, with at least one member who is not employed by or an owner of the HHA. Since the regulations at § 484.14(a) require HHAs to provide skilled nursing services as well as the services of at least one other discipline, not including

physician services, we know that the group of professional personnel is required to have at least three members. For purposes of this analysis, we assume that the group of professional personnel would include a physician (\$180), a registered nurse (\$63), a therapist (\$72), and a home health aide (\$20). The regulation also requires that the group of professional personnel must meet “frequently.” For purposes of this analysis, we assume that the frequency requirement would be met by holding quarterly meetings of the group. Furthermore, we assume that most quarterly meetings would require 1 hour of each member’s time, for a total of 4 labor hours per meeting, or 16 labor hours per year per HHA. We estimate the cost associated with this requirement to be \$335 per meeting, or \$1,340 per HHA per year (\$335 per meeting × 4 meetings per year), for a total of 201,632 hours (16 hours per HHA × 12,602 HHAs) at cost of \$16,886,680 (\$1,340 per HHA × 12,602 HHAs) per year. Therefore, we estimate that the total reduction of burden is 203,620 hours (201,632 hours + 1,988 hours) and \$16,924,452 (\$16,886,680 + \$37,772).

Third, we deleted § 484.52, “Evaluation of the agency’s program,” because the prescriptive quarterly review of clinical records is outdated and unnecessary. This requirement currently imposes a documentation burden of 11,863 hours, annually, for all HHAs at a cost of \$304,199, as indicated by the currently-approved PRA package (OMB control number 0938-0365).

In addition to the documentation burden imposed by this requirement, we believe that there is a burden associated with the time necessary to complete the quarterly clinical record reviews. The regulation requires that appropriate health professionals, representing at least the scope of the program, review a sample of both active and closed clinical records to determine whether established policies are followed in furnishing services directly or under arrangement. There is a continuing review of clinical records for each 60-day period that a patient receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care. Each professional may review the records separately, at different times. For purposes of this analysis, we assume that an HHA would review a 5 percent sample of its clinical records, or an average of 70 clinical records per year per facility. Furthermore, for purposes of this analysis, we assume that a registered nurse (\$63/hour), a therapist (\$72/hour), and a home health aide (\$20/hour) reviews each clinical record, and that each review would require 30 minutes per discipline, for a total of 90 minutes per record review. We estimate that each HHA uses 105 hours per year to meet this requirement, for a total of 1,323,210 hours for all HHAs. The total cost per record review is \$78, or \$5,460 per HHA per year, for a total of \$68,806,920 for all HHAs. Therefore, we believe that removing this requirement alleviates a total burden of 1,335,073 hours and \$69,111,119.

3. IMPACT ON PATIENT CARE

Although the positive effects of these changes cannot be quantified, we note that the changes are focused on improving the delivery of care to each and every patient. For example, the QAPI standard encourages HHAs to use their own internally-generated data to proactively identify patient care inefficiencies, contradictions, lapses, and other issues in the care delivery system so that HHAs can rapidly implement performance improvement projects designed to remedy the issue(s) at hand. Proactively identifying care issues and implementing projects to correct those issues will ultimately lead to more effective and efficient patient care and improved patient outcomes. However, as previously indicated, we cannot quantify the impact on patients.

E. Alternatives Considered

We considered finalizing the proposed requirement that HHAs must proactively provide each patient with a copy of his or her plan of care. We considered multiple options for implementing the originally proposed requirement.

Option 1—Require HHAs to provide each patient with a copy of only the initial plan of care. No written updates would be required in this option. We estimate that this requirement would create approximately 600,000 annual burden hours, at a cost of \$15.6 million, annually.

Option 2—Require HHAs to provide each patient with a copy of only the initial plan of care, and require HHAs to translate key elements of the plan of care into layman's terms. No written updates would be required. We estimate that this requirement would create approximately 3 million annual burden hours at a cost of \$189 million annually (based on the assumption of a nurse using 10 minutes to translate the clinical plan of care into layman's terms).

Option 3—Require HHAs to provide each patient with a copy of plan of care for each 60-day episode of care. We estimate that this requirement would create approximately 11 million annual burden hours at a cost of \$285 million, annually.

Option 4—Require HHAs to provide each patient with a copy of plan of care and translate key elements of the plan of care into layman's terms for each 60-day episode of care. We estimate that this requirement would create approximately 55 million annual burden hours at a cost of \$3.5 billion, annually.

Option 5—Require HHAs to provide each patient with a copy of plan of care and require it to be updated for significant changes. Assuming 4 plans of care per 60 day episode for complex patients and 1 plan of care per 60 day episode for non-complex patients, we estimate that this requirement would create approximately 31 million annual burden hours at a cost of \$799 million, annually.

Option 6—Require HHAs to provide each patient with a copy of plan of care and translate key elements into layman's terms. Also require the plan of care to be updated for significant changes. Assuming 4 plans of care per 60 day episode for complex patients and 1 plan of care per 60 day episode for non-complex patients, we estimate that this requirement would create approximately 153.6 million annual burden hours at a cost of \$9.7 billion, annually.

Option 7—Do not require HHAs to provide patients with written information regarding the plan of care under any circumstances. Removing this concept from the regulations entirely would be consistent with current requirements, and would signal to HHAs, states, and accreditation organizations that such written communication is unnecessary. We believe that most HHAs are already providing certain written information to patients. Removing this concept from the rules entirely may encourage those entities to stop providing such written information, thus reducing their self-imposed burden.

We also considered retaining the broad requirement from the proposed rule that HHAs provide patients with the names, addresses, and telephone numbers of pertinent, Federally-funded and State-funded, State and local consumer information, consumer protection, and advocacy agencies. Commenters stated that such a broad requirement would impose a significant burden due to the volume of entities to be identified and the need to assure updated contact information for such entities at all times. Although commenters did not provide an estimate of the burden, we believe that HHAs may have expended one hour per quarter, or approximately 50,000 hours annually at a cost of \$1.3 million, annually.

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F. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4 (http://www.whitehouse.gov/omb/circulars_a004_a-4)), we have prepared an accounting statement in Table 7 showing the classification of the transfers and costs associated with the provisions of this rule for

Calendar Year (CY) 2017 to 2021.

Table 7—Accounting Statement: Classification of Estimated Net Costs From CY 2017 to CY 2021

[In millions]

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Costs:				
Annualized Monetized (\$million/year)	291	2015	7	2017-2021
	291	2015	3	2017-2021

Although the benefits and some of the costs of these changes cannot be quantified, we note that the changes are focused on improving the delivery of care to each and every patient. An increased focus on identifying and proactively addressing risk factors for emergency department visits and hospital re-admissions has the potential to reduce both, leading to improved patient health and decreased payer expenditures. Likewise, requiring HHAs to educate and teach patients the necessary self-care skills to facilitate a timely discharge may lead to more and better patient engagement in managing chronic health conditions such as diabetes, ultimately leading to improved patient health and reduced payer expenditures. However, as previously indicated, we cannot quantify the impact on patients.

G. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Individuals and states are not included in the definition of a small entity. For the purposes of the RFA, most HHAs are considered to be small entities, either by virtue of their nonprofit status or government status, or by having revenues less than \$15 million in any 1 year (for details, see the Small Business Administration's (SBA) Web site at https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf (https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf) (refer to the 620000 series). There are 12,602 Medicare-certified HHAs with average annual patient census of 1,409 patients per HHA. An average Medicare-participating HHA in 2010 had annual revenues (all payment sources) of \$6.55 million. Therefore, the vast majority of these Medicare-certified HHAs would be considered small entities under the SBA's NAICS.

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this final rule because the cost of this rule on a per-HHA basis is minimal (approximately a \$15,100 net increase in burden per typical non-accredited HHA in the 1st year, and a small net savings of approximately \$700 for accredited HHAs in the 1st year). There are a small number of HHAs that will experience a larger increase in burden than a typical HHA, ranging anywhere from an additional \$500 to \$59,000 per year, depending on which aspects of the rule constitute a significant departure from their current practices. We believe that these HHAs account for up to 10 percent of the entire HHA population. An HHA tht would need to come into compliance with the most costly provision (providing specified written

information to patients per the requirements of 484.60(e), approximately \$59,000 per affected HHA) would still only experience a change in revenue equal to 1.13 percent (\$15,100+ \$59,000). Therefore, we certify that this rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We believe that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals because there are few HHAs in those facilities. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

H. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2016, that is approximately \$146 million. It includes no mandates on state, local, or tribal governments. The estimates presented in this section of the final rule exceed this threshold and, as a result, we have provided a detailed assessment of the anticipated costs and benefits in RIA section as well as other parts of the preamble.

I. Federalism

Executive Order 13132 (/executive-order/13132) establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct □ requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This rule has no Federalism implications.

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J. Congressional Review Act

This regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 (<https://api.fdsys.gov/link?collection=uscode&title=5&year=mostrecent§ion=801&type=usc&link-type=html>) *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 409 (/select-citation/2017/01/13/42-CFR-409)

- Health facilities
- Medicare

42 CFR Part 410 (/select-citation/2017/01/13/42-CFR-410)

- Health facilities
- Health professions
- Kidney diseases
- Laboratories

- Medicare
- Reporting and recordkeeping requirements
- Rural areas
- X-rays

42 CFR Part 418 (/select-citation/2017/01/13/42-CFR-418)

- Health facilities
- Hospice care
- Medicare
- Reporting and recordkeeping requirements

42 CFR Part 440 (/select-citation/2017/01/13/42-CFR-440)

- Grant programs—health
- Medicaid

42 CFR Part 484 (/select-citation/2017/01/13/42-CFR-484)

- Health facilities
- Health professions
- Medicare
- Reporting and recordkeeping requirements

42 CFR Part 485 (/select-citation/2017/01/13/42-CFR-485)

- Grant programs—health
- Health facilities
- Medicaid
- Medicare
- Reporting and recordkeeping requirements

42 CFR Part 488 (/select-citation/2017/01/13/42-CFR-488)

- Administrative practice and procedure
- Health facilities
- Medicare
- Reporting and recordkeeping requirements

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

1. The authority citation for part 409 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 (<https://api.fdsys.gov/link?collection=uscode&title=42&year=mostrecent§ion=1302&type=usc&link-type=html>) and 1395hh).

2. In the table below, for each section and paragraph indicated in the first two columns, remove the reference indicated in the third column and add the reference indicated in the fourth column:

Section	Paragraphs	Remove	Add
§ 409.43	(a)	§ 484.18(a)	§ 484.60(a)
§ 409.43	(c)(1)(i)(C)	42 CFR 484.4 (/select-citation/2017/01/13/42-CFR-484.4)	42 CFR 484.115 (/select-citation/2017/01/13/42-CFR-484.115)
§ 409.43	(d)	§ 484.4	§ 484.115
§ 409.44	(b)(1) introductory text and (c)(2)(ii)	§ 484.4	§ 484.115
§ 409.45	(c)(4)	§ 484.4	§ 484.115
§ 409.46	(b)	§ 484.36(d)	§ 484.80(h)
§ 409.47	(b) introductory text	§ 484.14(h)	§ 484.105(e)

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

3. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302 (<https://api.fdsys.gov/link?collection=uscode&title=42&year=mostrecent§ion=1302&type=usc&link-type=html>)). 1395m, 1395hh, and 1395ddd.

§ 410.62 [Amended]

4. In § 410.62(a) introductory text, remove “§ 484.4” and add in its place “§ 484.115”.

PART 418—HOSPICE CARE

5. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 (<https://api.fdsys.gov/link?collection=uscode&title=42&year=mostrecent§ion=1302&type=usc&link-type=html>) and 1395hh).

6. In the table below, for each section and paragraph indicated in the first two columns, remove the reference indicated in the third column and add the reference indicated in the fourth column:

Section	Paragraphs	Remove	Add
§ 418.76	(f)(1)	§ 484.36(a) and § 484.36(b)	§ 484.80
§ 418.76	(f)(2)	§ 484.36(a)	§ 484.80(a)

PART 440—SERVICES: GENERAL PROVISIONS

7. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302 (<https://api.fdsys.gov/link?collection=uscode&title=42&year=mostrecent§ion=1302&type=usc&link-type=html>)).

§ 440.110 [Amended]

8. In § 440.110(a)(2) and (b)(2), remove “§ 484.4” and add in its place “§ 484.115”.

PART 484—HOME HEALTH SERVICES

9. The authority citation for part 484 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 (<https://api.fdsys.gov/link?collection=uscode&title=42&year=mostrecent§ion=1302&type=usc&link-type=html>) and 1395(hh)) unless otherwise indicated.

10. Part 484 is amended by revising subparts A through C to read as follows:

Subpart A—General Provisions [□]

484.1 Basis and scope.

484.2 Definitions.

Subpart B—Patient Care

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

484.45 Condition of participation: Reporting OASIS information.

484.50 Condition of participation: Patient rights.

484.55 Condition of participation: Comprehensive assessment of patients.

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

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

484.70 Condition of participation: Infection prevention and control.

484.75 Condition of participation: Skilled professional services.

484.80 Condition of participation: Home health aide services.

Subpart C—Organizational Environment

484.100 Condition of participation: Compliance with Federal, State, and local laws and regulations related to health and safety of patients.

484.102 Condition of participation: Emergency preparedness.

484.105 Condition of participation: Organization and administration of services.

484.110 Condition of participation: Clinical records.

484.115 Condition of participation: Personnel qualifications.

Subpart A—General Provisions

§ 484.1 **Basis and scope.**

(a) *Basis.* This part is based on:

(1) Sections 1861(o) and 1891 of the Act, which establish the conditions that an HHA must meet in order to participate in the Medicare program and which, along with the additional requirements set forth in this part, are considered necessary to ensure the health and safety of patients; and

(2) Section 1861(z) of the Act, which specifies the institutional planning standards that HHAs must meet.

(b) *Scope.* The provisions of this part serve as the basis for survey activities for the purpose of determining whether an agency meets the requirements for participation in the Medicare program.

§ 484.2 **Definitions.**

As used in subparts A, B, and C, of this part—

Branch office means an approved location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The parent home health agency must provide supervision and administrative control of any branch office. It is unnecessary for the branch office to independently meet the conditions of participation as a home health agency.

Clinical note means a notation of a contact with a patient that is written, timed, and dated, and which describes signs and symptoms, treatment, drugs administered and the patient's reaction or response, and any changes in physical or emotional condition during a given period of time.

In advance means that HHA staff must complete the task prior to performing any hands-on care or any patient education.

Parent home health agency means the agency that provides direct support and administrative control of a branch.

Primary home health agency means the HHA which accepts the initial referral of a patient, and which provides services directly to the patient or via another health care provider under arrangements (as applicable).

Proprietary agency means a private, for-profit agency.

Public agency means an agency operated by a state or local government.

Quality indicator means a specific, valid, and reliable measure of access, care outcomes, or satisfaction, or a measure of a process of care.

Representative means the patient's legal representative, such as a guardian, who makes health-care decisions on the patient's behalf, or a patient-selected representative who participates in making decisions related to the patient's care or well-being, including but not limited to, a family member or an advocate for the patient. The patient determines the role of the representative, to the extent possible.

Subdivision means a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets 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.

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 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.

Subpart B—Patient Care

§ 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.

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(3) Provide verbal notice of the patient's rights and responsibilities in the individual's primary or preferred language and in a manner the individual understands, free of charge, with the use of a competent interpreter if necessary, no later than the completion of the second visit from a skilled professional as described in § 484.75.

(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 (/select-citation/2017/01/13/45-CFR-160) and 164.
- (7) Be advised 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 (/select-citation/2017/01/13/42-CFR-411.408)(d)(2) and 42 CFR 411.408 (/select-citation/2017/01/13/42-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 (/select-citation/2017/01/13/42-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.
- (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 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 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 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.

§ 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-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, 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 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-ordered resumption date;

(3) At discharge.

§ 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.

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(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 acting within the scope of his or her state license, certification, or registration. If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan.

(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 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 orders.* (1) Drugs, services, and treatments are administered only as ordered by a physician.
- (2) Influenza and pneumococcal vaccines may be administered per agency policy developed in consultation with a physician, 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'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 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 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) 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.

(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 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 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 involved in the plan of care.

(2) Integrate orders from all physicians 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.

§ 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.

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(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.

(2) The HHA must use the data collected to—

(i) Monitor the effectiveness and safety of services and quality of care; and

(ii) Identify opportunities for improvement.

(3) The frequency and detail of the data collection must be approved by the HHA's governing body.

(c) *Standard: Program activities.* (1) The HHA's performance improvement activities must—

(i) Focus on high risk, high volume, or problem-prone areas;

(ii) Consider incidence, prevalence, and severity of problems in those areas; and

(iii) Lead to an immediate correction of any identified problem that directly or potentially threaten the health and safety of patients.

(2) Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions.

(3) The HHA must take actions aimed at performance improvement, and, after implementing those actions, the HHA must measure its success and track performance to ensure that improvements are sustained.

(d) *Standard: Performance improvement projects.* Beginning January 13, 2018 HHAs must conduct performance improvement projects.

(1) The number and scope of distinct improvement projects conducted annually must reflect the scope, complexity, and past performance of the HHA's services and operations.

(2) The HHA must document the quality improvement projects undertaken, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(e) *Standard: Executive responsibilities.* The HHA's governing body is responsible for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety is defined, implemented, and maintained;

(2) That the HHA-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness;

(3) That clear expectations for patient safety are established, implemented, and maintained; and

(4) That any findings of fraud or waste are appropriately addressed.

§ 484.70 Condition of participation: Infection prevention and control.

The HHA must maintain and document an infection control program which has as its goal the prevention and control of infections and communicable diseases.

(a) *Standard: Prevention.* The HHA must follow accepted standards of practice, including the use of standard precautions, to prevent the transmission of infections and communicable diseases.

(b) *Standard: Control.* The HHA must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the HHA's quality assessment and performance improvement (QAPI) program. The infection control program must include:

(1) A method for identifying infectious and communicable disease problems; and

(2) A plan for the appropriate actions that are expected to result in improvement and disease prevention.

(c) *Standard: Education.* The HHA must provide infection control education to staff, patients, and caregiver(s).

§ 484.75 Condition of participation: Skilled professional services.

Skilled professional services include skilled nursing services, physical therapy, speech-language pathology services, and occupational therapy, as specified in § 409.44 of this chapter, and physician and medical social work services as specified in § 409.45 of this chapter. Skilled professionals who provide services to HHA patients directly or under arrangement must participate in the coordination of care.

(a) *Standard: Provision of services by skilled professionals.* Skilled professional services are authorized, delivered, and supervised only by health care professionals who meet the appropriate qualifications specified under § 484.115 and who practice according to the HHA's policies and procedures.

(b) *Standard: Responsibilities of skilled professionals.* Skilled professionals must assume responsibility for, but not be restricted to, the following:

- (1) Ongoing interdisciplinary assessment of the patient;
- (2) Development and evaluation of the plan of care in partnership with the patient, representative (if any), and caregiver(s);
- (3) Providing services that are ordered by the physician as indicated in the plan of care;
- (4) Patient, caregiver, and family counseling;
- (5) Patient and caregiver education;
- (6) Preparing clinical notes;
- (7) Communication with all physicians involved in the plan of care and other health care practitioners (as appropriate) related to the current plan of care;
- (8) Participation in the HHA's QAPI program; and
- (9) Participation in HHA-sponsored in-service training.

(c) *Supervision of skilled professional assistants.* (1) Nursing services are provided under the supervision of a registered nurse that meets the requirements of § 484.115(k).

(2) Rehabilitative therapy services are provided under the supervision of an occupational therapist or physical therapist that meets the requirements of § 484.115(f) or (h), respectively.

(3) Medical social services are provided under the supervision of a social worker that meets the requirements of § 484.115(m).

§ 484.80 Condition of participation: Home health aide services.

All home health aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section.

(a) *Standard: Home health aide qualifications.* (1) A qualified home health aide is a person who has successfully completed:

- (i) A training and competency evaluation program as specified in paragraphs (b) and (c) respectively of this section; or
- (ii) A competency evaluation program that meets the requirements of paragraph (c) of this section; or

(iii) A nurse aide training and competency evaluation program approved by the state as meeting the requirements of § 483.151 through § 483.154 of this chapter, and is currently listed in good standing on the state nurse aide registry; or

(iv) The requirements of a state licensure program that meets the provisions of paragraphs (b) and (c) of this section.

(2) A home health aide or nurse aide is not considered to have completed a program, as specified in paragraph (a)(1) of this section, if, since the individual's most recent completion of the program(s), there has been a continuous period of 24 consecutive months during which none of the services furnished by the individual as described in § 409.40 of this chapter were for compensation. If there has been a 24-month lapse in furnishing services for compensation, the individual must complete another program, as specified in paragraph (a)(1) of this section, before providing services.

(b) *Standard: Content and duration of home health aide classroom and supervised practical training.*

(1) Home health aide training must include classroom and supervised practical training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing services to an individual under the direct supervision of a registered nurse, or a licensed practical nurse who is under the supervision of a registered nurse. Classroom and supervised practical training must total at least 75 hours.

(2) A minimum of 16 hours of classroom training must precede a minimum of 16 hours of supervised practical training as part of the 75 hours.

(3) A home health aide training program must address each of the following subject areas:

(i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff.

(ii) Observation, reporting, and documentation of patient status and the care or service furnished.

(iii) Reading and recording temperature, pulse, and respiration.

(iv) Basic infection prevention and control procedures.

(v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.

(vi) Maintenance of a clean, safe, and healthy environment.

(vii) Recognizing emergencies and the knowledge of instituting emergency procedures and their application.

(viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the HHA, including the need for respect for the patient, his or her privacy, and his or her property.

(ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks that include—

- (A) Bed bath;
- (B) Sponge, tub, and shower bath;
- (C) Hair shampooing in sink, tub, and bed;
- (D) Nail and skin care;
- (E) Oral hygiene;
- (F) Toileting and elimination;
- (x) Safe transfer techniques and ambulation;
- (xi) Normal range of motion and positioning;
- (xii) Adequate nutrition and fluid intake;
- (xiii) Recognizing and reporting changes in skin condition; and
- (xiv) Any other task that the HHA may choose to have an aide perform as permitted under state law.
- (xv) The HHA is responsible for training home health aides, as needed, for skills not covered in the basic checklist, as described in paragraph (b)(3)(ix) of this section.

(4) The HHA must maintain documentation that demonstrates that the requirements of this standard have been met.

(c) *Standard: Competency evaluation.* An individual may furnish home health services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this section.

(1) The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (iii), (ix), (x), and (xi) of this section must be evaluated by observing an aide's performance of the task with a patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient.

(2) A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (f) of this section.

(3) The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate.

(4) A home health aide is not considered competent in any task for which he or she is evaluated as unsatisfactory. An aide must not perform that task without direct supervision by a registered nurse until after he or she has received training in the task for which he or she was evaluated as

“unsatisfactory,” and has successfully completed a subsequent evaluation. A home health aide is not considered to have successfully passed a competency evaluation if the aide has an “unsatisfactory” rating in more than one of the required areas.

(5) The HHA must maintain documentation which demonstrates that the requirements of this standard have been met.

(d) *Standard: In-service training.* A home health aide must receive at least 12 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient.

(1) In-service training may be offered by any organization and must be supervised by a registered nurse.

(2) The HHA must maintain documentation that demonstrates the requirements of this standard have been met.

(e) *Standard: Qualifications for instructors conducting classroom and supervised practical training.* Classroom and supervised practical training must be performed by a registered nurse who possesses a minimum of 2 years nursing experience, at least 1 year of which must be in home health care, or by other individuals under the general supervision of the registered nurse.

(f) *Standard: Eligible training and competency evaluation organizations.* A home health aide training program and competency evaluation program may be offered by any organization except by an HHA that, within the previous 2 years:

(1) Was out of compliance with the requirements of paragraphs (b), (c), (d), or (e) of this section; or

(2) Permitted an individual who does not meet the definition of a “qualified home health aide” as specified in paragraph (a) of this section to furnish home health aide services (with the exception of licensed health professionals and volunteers); or

(3) Was subjected to an extended (or partially extended) survey as a result of having been found to have furnished substandard care (or for other reasons as determined by CMS or the state); or

(4) Was assessed a civil monetary penalty of \$5,000 or more as an intermediate sanction; or

(5) Was found to have compliance deficiencies that endangered the health and safety of the HHA's patients, and had temporary management appointed to oversee the management of the HHA; or

(6) Had all or part of its Medicare payments suspended; or

(7) Was found under any federal or state law to have:

(i) Had its participation in the Medicare program terminated; or

(ii) Been assessed a penalty of \$5,000 or more for deficiencies in federal or state standards for HHAs;
or

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- (iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled; or
- (iv) Operated under temporary management that was appointed to oversee the operation of the HHA and to ensure the health and safety of the HHA's patients; or
- (v) Been closed, or had its patients transferred by the state; or
- (vi) Been excluded from participating in federal health care programs or debarred from participating in any government program.

(g) *Standard: Home health aide assignments and duties.* (1) Home health aides are assigned to a specific patient by a registered nurse or other appropriate skilled professional, with written patient care instructions for a home health aide prepared by that registered nurse or other appropriate skilled professional (that is, physical therapist, speech-language pathologist, or occupational therapist).

(2) A home health aide provides services that are:

- (i) Ordered by the physician;
- (ii) Included in the plan of care;
- (iii) Permitted to be performed under state law; and
- (iv) Consistent with the home health aide training.

(3) The duties of a home health aide include:

- (i) The provision of hands-on personal care;
- (ii) The performance of simple procedures as an extension of therapy or nursing services;
- (iii) Assistance in ambulation or exercises; and
- (iv) Assistance in administering medications ordinarily self-administered.

(4) Home health aides must be members of the interdisciplinary team, must report changes in the patient's condition to a registered nurse or other appropriate skilled professional, and must complete appropriate records in compliance with the HHA's policies and procedures.

(h) *Standard: Supervision of home health aides.* (1)(i) If home health aide services are provided to a patient who is receiving skilled nursing, physical or occupational therapy, or speech-language pathology services, a registered nurse or other appropriate skilled professional who is familiar with the patient, the patient's plan of care, and the written patient care instructions described in § 484.80(g), must make an onsite visit to the patient's home no less frequently than every 14 days. The home health aide does not have to be present during this visit.

(ii) If an area of concern in aide services is noted by the supervising registered nurse or other appropriate skilled professional, then the supervising individual must make an on-site visit to the location where the patient is receiving care in order to observe and assess the aide while he or she is performing care.

(iii) A registered nurse or other appropriate skilled professional must make an annual on-site visit to the location where a patient is receiving care in order to observe and assess each aide while he or she is performing care.

(2) If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy, or speech-language pathology services, the registered nurse must make an on-site visit to the location where the patient is receiving care no less frequently than every 60 days in order to observe and assess each aide while he or she is performing care.

(3) If a deficiency in aide services is verified by the registered nurse or other appropriate skilled professional during an on-site visit, then the agency must conduct, and the home health aide must complete a competency evaluation in accordance with paragraph (c) of this section.

(4) Home health aide supervision must ensure that aides furnish care in a safe and effective manner, including, but not limited to, the following elements:

(i) Following the patient's plan of care for completion of tasks assigned to a home health aide by the registered nurse or other appropriate skilled professional;

(ii) Maintaining an open communication process with the patient, representative (if any), caregivers, and family;

(iii) Demonstrating competency with assigned tasks;

(iv) Complying with infection prevention and control policies and procedures;

(v) Reporting changes in the patient's condition; and

(vi) Honoring patient rights.

(5) If the home health agency chooses to provide home health aide services under arrangements, as defined in section 1861(w)(1) of the Act, the HHA's responsibilities also include, but are not limited to:

(i) Ensuring the overall quality of care provided by an aide;

(ii) Supervising aide services as described in paragraphs (h)(1) and (2) of this section; and

(iii) Ensuring that home health aides who provide services under arrangement have met the training or competency evaluation requirements, or both, of this part.

(i) *Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.* An individual may furnish personal care services, as defined in § 440.167 of this chapter, on behalf of an HHA. Before the individual may furnish personal care services, the individual

must meet all qualification standards established by the state. The individual only needs to demonstrate competency in the services the individual is required to furnish.

Subpart C—Organizational Environment

§ 484.100 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.

The HHA and its staff must operate and furnish services in compliance with all applicable federal, state, and local laws and regulations related to the health and safety of patients. If state or local law provides licensing of HHAs, the HHA must be licensed.

(a) *Standard: Disclosure of ownership and management information.* The HHA must comply with the requirements of part 420 subpart C, of this chapter. The HHA also must disclose the following information to the state survey agency at the time of the HHA's initial request for certification, for each survey, and at the time of any change in ownership or management:

(1) The names and addresses of all persons with an ownership or controlling interest in the HHA as defined in § 420.201, § 420.202, and § 420.206 of this chapter.

(2) The name and address of each person who is an officer, a director, an agent, or a managing employee of the HHA as defined in § 420.201, § 420.202, and § 420.206 of this chapter.

(3) The name and business address of the corporation, association, or other company that is responsible for the management of the HHA, and the names and addresses of the chief executive officer and the chairperson of the board of directors of that corporation, association, or other company responsible for the management of the HHA.

(b) *Standard: Licensing.* The HHA, its branches, and all persons furnishing services to patients must be licensed, certified, or registered, as applicable, in accordance with the state licensing authority as meeting those requirements. □

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(c) *Standard: Laboratory services.* (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 Food and Drug Administration, the testing must be in compliance with all applicable requirements of part 493 of this chapter. The HHA may not substitute its equipment for a patient's equipment when assisting with self-administered tests.

(2) If the HHA refers specimens for laboratory testing, 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.

§ 484.102 Condition of participation: Emergency preparedness.

The Home Health Agency (HHA) must comply with all applicable Federal, State, and local emergency preparedness requirements. The HHA must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The HHA must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

- (1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.
 - (2) Include strategies for addressing emergency events identified by the risk assessment.
 - (3) Address patient population, including, but not limited to, the type of services the HHA has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.
 - (4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the HHA's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.
- (b) *Policies and procedures.* The HHA must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:
- (1) The plans for the HHA's patients during a natural or man-made disaster. Individual plans for each patient must be included as part of the comprehensive patient assessment, which must be conducted according to the provisions at § 484.55.
 - (2) The procedures to inform State and local emergency preparedness officials about HHA patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment.
 - (3) The procedures to follow up with on-duty staff and patients to determine services that are needed, in the event that there is an interruption in services during or due to an emergency. The HHA must inform State and local officials of any on-duty staff or patients that they are unable to contact.
 - (4) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.
 - (5) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(c) *Communication plan.* The HHA must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

- (1) Names and contact information for the following:
 - (i) Staff.
 - (ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, or local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the HHA's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the HHA's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510 (/select-citation/2017/01/13/45-CFR-164.510)(b)(4).

(6) A means of providing information about the HHA's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The HHA must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The HHA must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(ii) Demonstrate staff knowledge of emergency procedures.

(2) *Testing.* The HHA must conduct exercises to test the emergency plan at least annually. The HHA must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the HHA experiences an actual natural or man-made emergency that requires activation of the emergency plan, the HHA is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the HHA's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the HHA's emergency plan, as needed.□

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(e) *Integrated healthcare systems.* If a HHA is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the HHA may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

§ 484.105 Condition of participation: Organization and administration of services.

The HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs. The HHA must assure that administrative and supervisory functions are not delegated to another agency or organization, and all services not furnished directly are monitored and controlled. The HHA must set forth, in writing, its organizational structure, including lines of authority, and services furnished.

(a) *Standard: Governing body.* A governing body (or designated persons so functioning) must assume full legal authority and responsibility for the agency's overall management and operation, the provision of all home health services, fiscal operations, review of the agency's budget and its operational plans,

and its quality assessment and performance improvement program.

(b) *Standard: Administrator.* (1) The administrator must:

(i) Be appointed by and report to the governing body;

(ii) Be responsible for all day-to-day operations of the HHA;

(iii) Ensure that a clinical manager as described in paragraph (c) of this section is available during all operating hours;

(iv) Ensure that the HHA employs qualified personnel, including assuring the development of personnel qualifications and policies.

(2) When the administrator is not available, a qualified, pre-designated person, who is authorized in writing by the administrator and the governing body, assumes the same responsibilities and obligations as the administrator. The pre-designated person may be the clinical manager as described in paragraph (c) of this section.

(3) The administrator or a pre-designated person is available during all operating hours.

(c) *Clinical manager.* One or more qualified individuals must provide oversight of all patient care services and personnel. Oversight must include the following—

(1) Making patient and personnel assignments,

(2) Coordinating patient care,

(3) Coordinating referrals,

(4) Assuring that patient needs are continually assessed, and

(5) Assuring the development, implementation, and updates of the individualized plan of care.

(d) *Standard: Parent-branch relationship.* (1) The parent HHA is responsible for reporting all branch locations of the HHA to the state survey agency at the time of the HHA's request for initial certification, at each survey, and at the time the parent proposes to add or delete a branch.

(2) The parent HHA provides direct support and administrative control of its branches.

(e) *Standard: Services under arrangement.* (1) The HHA must ensure that all services furnished under arrangement provided by other entities or individuals meet the requirements of this part and the requirements of section 1861(w) of the Act (42 U.S.C. 1395 (<https://api.fdsys.gov/link?collection=uscode&title=42&year=mostrecent§ion=1395&type=usc&link-type=html>))x (w)).

(2) An HHA must have a written agreement with another agency, with an organization, or with an individual when that entity or individual furnishes services under arrangement to the HHA's patients. The HHA must maintain overall responsibility for the services provided under arrangement, as well as

the manner in which they are furnished. The agency, organization, or individual providing services under arrangement may not have been:

- (i) Denied Medicare or Medicaid enrollment;
- (ii) Been excluded or terminated from any federal health care program or Medicaid;
- (iii) Had its Medicare or Medicaid billing privileges revoked; or
- (iv) Been debarred from participating in any government program.

(3) The primary HHA is responsible for patient care, and must conduct and provide, either directly or under arrangements, all services rendered to patients.

(f) *Standard: Services furnished.* (1) Skilled nursing services and at least one other therapeutic service (physical therapy, speech-language pathology, or occupational therapy; medical social services; or home health aide services) are made available on a visiting basis, in a place of residence used as a patient's home. An HHA must provide at least one of the services described in this subsection directly, but may provide the second service and additional services under arrangement with another agency or organization.

(2) All HHA services must be provided in accordance with current clinical practice guidelines and accepted professional standards of practice.

(g) *Standard: Outpatient physical therapy or speech-language pathology services.* An HHA that furnishes outpatient physical therapy or speech-language pathology services must meet all of the applicable conditions of this part and the additional health and safety requirements set forth in § 485.711, § 485.713, § 485.715, § 485.719, § 485.723, and § 485.727 of this chapter to implement section 1861(p) of the Act.

(h) *Standard: Institutional planning.* The HHA, under the direction of the governing body, prepares an overall plan and a budget that includes an annual operating budget and capital expenditure plan.

(1) *Annual operating budget.* There is an annual operating budget that includes all anticipated income and expenses related to items that would, under generally accepted accounting principles, be considered income and expense items. However, it is not required that there be prepared, in connection with any budget, an item by item identification of the components of each type of anticipated income or expense.

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(2) *Capital expenditure plan.* (i) There is a capital expenditure plan for at least a 3-year period, including the operating budget year. The plan includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure of more than \$600,000 for items that would under generally accepted accounting principles, be considered capital items. In determining if a single capital expenditure exceeds \$600,000, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, modernization, expansion, or replacement of land, plant, building, and equipment are included. Expenditures directly or indirectly related to capital expenditures, such as grading, paving, broker commissions, taxes assessed during the construction period, and costs involved in demolishing or razing structures on land

are also included. Transactions that are separated in time, but are components of an overall plan or patient care objective, are viewed in their entirety without regard to their 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 Services Block Grant) 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. 1320 (<https://api.fdsys.gov/link?collection=uscode&title=42&year=mostrecent§ion=1320&type=usc&link-type=html>)a-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.

(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.

(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.

§ 484.110 Condition of participation: Clinical records.

The HHA must maintain a clinical record containing past and current information for every patient accepted by the HHA and receiving home health services. Information contained in the clinical record must be accurate, adhere to current clinical record documentation standards of practice, and be available to the physician(s) issuing orders for the home health plan of care, and appropriate HHA staff. This information may be maintained electronically.

(a) *Standard: Contents of clinical record.* The record must include:

(1) The patient's current comprehensive assessment, including all of the assessments from the most recent home health admission, clinical notes, plans of care, and physician orders;

(2) All interventions, including medication administration, treatments, and services, and responses to those interventions;

(3) Goals in the patient's plans of care and the patient's progress toward achieving them;

(4) Contact information for the patient, the patient's representative (if any), and the patient's primary caregiver(s);

(5) Contact information for the 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; and

(6)(i) A completed discharge summary that is sent to the 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) within 5 business days of the patient's discharge; or

(ii) A completed transfer summary that is sent within 2 business days of a planned transfer, if the patient's care will be immediately continued in a health care facility; or

(iii) A completed transfer summary that is sent within 2 business days of becoming aware of an unplanned transfer, if the patient is still receiving care in a health care facility at the time when the HHA becomes aware of the transfer.

(b) *Standard: Authentication.* All entries must be legible, clear, complete, and appropriately authenticated, dated, and timed. Authentication must include a signature and a title (occupation), or a secured computer entry by a unique identifier, of a primary author who has reviewed and approved the entry.

(c) *Standard: Retention of records.* (1) Clinical records must be retained for 5 years after the discharge of the patient, unless state law stipulates a longer period of time.

(2) The HHA's policies must provide for retention of clinical records even if it discontinues operation. When an HHA discontinues operation, it must inform the state agency where clinical records will be maintained.

(d) *Standard: Protection of records.* The clinical record, its contents, and the information contained therein must be safeguarded against loss or unauthorized use. The HHA must be in compliance with the rules regarding protected health information set out at 45 CFR parts 160 (/select-citation/2017/01/13/45-CFR-160) and 164.

(e) *Standard: Retrieval of clinical records.* A patient's clinical record (whether hard copy or electronic form) must be made available to a patient, free of charge, upon request at the next home visit, or within 4 business days (whichever comes first).

§ 484.115 Condition of participation: Personnel qualifications.

HHA staff are required to meet the following standards:

(a) *Standard: Administrator, home health agency.* (1) For individuals that began employment with the HHA prior to July 13, 2017, a person who:

(i) Is a licensed physician;

(ii) Is a registered nurse; or

(iii) Has training and experience in health service administration and at least 1 year of supervisory administrative experience in home health care or a related health care program.

(2) For individuals that begin employment with an HHA on or after July 13, 2017, a person who:

(i) Is a licensed physician, a registered nurse, or holds an undergraduate degree; and

(ii) Has experience in health service administration, with at least 1 year of supervisory or administrative experience in home health care or a related health care program.

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(b) *Standard: Audiologist.* A person who:

(1) Meets the education and experience requirements for a Certificate of Clinical Competence in audiology granted by the American Speech-Language-Hearing Association; or

(2) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

(c) *Standard: Clinical manager.* A person who is a licensed physician, physical therapist, speech-language pathologist, occupational therapist, audiologist, social worker, or a registered nurse.

(d) *Standard: Home health aide.* A person who meets the qualifications for home health aides specified in section 1891(a)(3) of the Act and implemented at § 484.80.

(e) *Standard: Licensed practical (vocational) nurse.* A person who has completed a practical (vocational) nursing program, is licensed in the state where practicing, and who furnishes services under the supervision of a qualified registered nurse.

(f) *Standard: Occupational therapist.* A person who—

(1)(i) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing, unless licensure does not apply;

(ii) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and

(iii) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(2) On or before December 31, 2009—

(i) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing; or

(ii) When licensure or other regulation does not apply—

(A) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and

(B) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc., (NBCOT).

(3) On or before January 1, 2008—

(i) Graduated after successful completion of an occupational therapy program accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or

(ii) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.

(4) On or before December 31, 1977—

(i) Had 2 years of appropriate experience as an occupational therapist; and

(ii) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(5) If educated outside the United States, must meet both of the following:

(i) Graduated after successful completion of an occupational therapist education program accredited as substantially equivalent to occupational therapist entry level education in the United States by one of the following:

(A) The Accreditation Council for Occupational Therapy Education (ACOTE).

(B) Successor organizations of ACOTE.

(C) The World Federation of Occupational Therapists.

(D) A credentialing body approved by the American Occupational Therapy Association.

(E) Successfully completed the entry level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing.

(g) *Standard: Occupational therapy assistant.* A person who—

(1) Meets all of the following:

(i) Is licensed or otherwise regulated, if applicable, as an occupational therapy assistant by the state in which practicing, unless licensure does apply.

(ii) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education, (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or its successor organizations.

(iii) Is eligible to take or successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(2) On or before December 31, 2009—

(i) Is licensed or otherwise regulated as an occupational therapy assistant, if applicable, by the state in which practicing; or any qualifications defined by the state in which practicing, unless licensure does not apply; or

(ii) Must meet both of the following:

(A) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association.

(B) After January 1, 2010, meets the requirements in paragraph (f)(1) of this section.

(3) After December 31, 1977 and on or before December 31, 2007—

(i) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association; or

(ii) Completed the requirements to practice as an occupational therapy assistant applicable in the state in which practicing.

(4) On or before December 31, 1977—

(i) Had 2 years of appropriate experience as an occupational therapy assistant; and

(ii) Had achieved a satisfactory grade on an occupational therapy assistant proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(5) If educated outside the United States, on or after January 1, 2008—

(i) Graduated after successful completion of an occupational therapy assistant education program that is accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by—

(A) The Accreditation Council for Occupational Therapy Education (ACOTE).

(B) Its successor organizations.

(C) The World Federation of Occupational Therapists.

(D) By a credentialing body approved by the American Occupational Therapy Association; and

(E) Successfully completed the entry level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

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(ii) [Reserved]

(h) *Standard: Physical therapist.* A person who is licensed, if applicable, by the state in which practicing, unless licensure does not apply and meets one of the following requirements:

(1)(i) Graduated after successful completion of a physical therapist education program approved by one of the following:

(A) The Commission on Accreditation in Physical Therapy Education (CAPTE).

(B) Successor organizations of CAPTE.

(C) An education program outside the United States determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or an organization identified in 8 CFR 212.15 (/select-citation/2017/01/13/8-CFR-212.15)(e) as it relates to physical therapists.

(ii) Passed an examination for physical therapists approved by the state in which physical therapy services are provided.

(2) On or before December 31, 2009—

(i) Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or

(ii) Meets both of the following:

(A) Graduated after successful completion of an education program determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified in 8 CFR 212.15 (/select-citation/2017/01/13/8-CFR-212.15)(e) as it relates to physical therapists.

(B) Passed an examination for physical therapists approved by the state in which physical therapy services are provided.

(3) Before January 1, 2008 graduated from a physical therapy curriculum approved by one of the following:

(i) The American Physical Therapy Association.

(ii) The Committee on Allied Health Education and Accreditation of the American Medical Association.

(iii) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

(4) On or before December 31, 1977 was licensed or qualified as a physical therapist and meets both of the following:

(i) Has 2 years of appropriate experience as a physical therapist.

(ii) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(5) Before January 1, 1966—

(i) Was admitted to membership by the American Physical Therapy Association;

(ii) Was admitted to registration by the American Registry of Physical Therapists; or

(iii) Graduated from a physical therapy curriculum in a 4-year college or university approved by a state department of education.

(6) Before January 1, 1966 was licensed or registered, and before January 1, 1970, had 15 years of fulltime experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy.

(7) If trained outside the United States before January 1, 2008, meets the following requirements:

(i) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(ii) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

(i) *Standard: Physical therapist assistant.* A person who is licensed, registered or certified as a physical therapist assistant, if applicable, by the state in which practicing, unless licensure does not apply and meets one of the following requirements:

(1)(i) Graduated from a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association; or if educated outside the United States or trained in the United States military, graduated from an education program determined to be substantially equivalent to physical therapist assistant entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified at 8 CFR 212.15 (/select-citation/2017/01/13/8-CFR-212.15)

(e); and

(ii) Passed a national examination for physical therapist assistants.

(2) On or before December 31, 2009, meets one of the following:

(i) Is licensed, or otherwise regulated in the state in which practicing.

(ii) In states where licensure or other regulations do not apply, graduated before December 31, 2009, from a 2-year college-level program approved by the American Physical Therapy Association and after January 1, 2010, meets the requirements of paragraph (h)(1) of this section.

(3) Before January 1, 2008, where licensure or other regulation does not apply, graduated from a 2-year college level program approved by the American Physical Therapy Association.

(4) On or before December 31, 1977, was licensed or qualified as a physical therapist assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(j) *Standard: Physician.* A person who meets the qualifications and conditions specified in section 1861(r) of the Act and implemented at § 410.20(b) of this chapter.

(k) *Standard: Registered nurse.* A graduate of an approved school of professional nursing who is licensed in the state where practicing.

(l) *Standard: Social Work Assistant.* A person who provides services under the supervision of a qualified social worker and:

(1) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or

(2) Has 2 years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that the determinations of proficiency do not apply with respect to persons initially licensed by a state or seeking initial qualification as a social work assistant after December 31, 1977.

(m) *Standard: Social worker.* A person who has a master's or doctoral degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.

(n) *Standard: Speech-language pathologist.* A person who has a master's or doctoral degree in speech-language pathology, and who meets either of the following requirements:

(1) Is licensed as a speech-language pathologist by the state in which the individual furnishes such services; or

(2) In the case of an individual who furnishes services in a state which does not license speech-language pathologists:

(i) Has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating supervised clinical experience);

(ii) Performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field; and

(iii) Successfully completed a national examination in speech-language pathology approved by the Secretary.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

11.The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 (<https://api.fdsys.gov/link?collection=uscode&title=42&year=mostrecent§ion=1302&type=usc&link-type=html>) and 1395(hh)).

12.In the table below, for each section and paragraph indicated in the first two columns, remove the reference indicated in the third column and add the reference indicated in the fourth column:

Section	Paragraphs	Remove	Add
§ 485.58	Introductory text	and 484.4	and 484.115.
§ 485.70	(c) and (e)	§ 484.4	§ 484.115.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

13.The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102, 1128l, 1864, 1865, 1871 and 1875 of the Social Security Act, unless otherwise noted (42 U.S.C 1302 (<https://api.fdsys.gov/link?collection=uscode&title=42&year=mostrecent§ion=1302&type=usc&link-type=html>), 1320a-7j, 1395aa, 1395bb, 1395hh) and 1395ll.

§ 488.805 [Amended]

14.In § 488.805, in the definition of “temporary management”, remove “§§ 484.4 and 484.14(c)” and add in its place “§§ 484.105(b) and 484.115”.

Dated: December 8, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: December 9, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

Footnotes

1. This collection will be discontinued when a new collection is approved which will better align the PRA package with new regulations.

Back to Citation

2. This collection will be discontinued when a new collection is approved which will better align the PRA package with new regulations.

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