January 7, 2015

Marilyn Tavenner
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS 3819P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted Electronically

Re: CMS 3819-P, Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies; Proposed Rule October 9, 2014

Dear Ms. Tavenner,

The National Association for Home Care & Hospice (NAHC) is the nation’s largest trade association representing home health and hospice agencies including Visiting Nurse Associations, government-based agencies, multi-state corporate organizations, health system affiliated providers, and freestanding proprietary agencies. NAHC members serve over 3 million Medicare home health and hospice beneficiaries each year.

NAHC appreciates and supports CMS’ efforts to modernize the home health Conditions of Participation (CoPs) by developing standards that are data driven, patient centered and outcome based. Many of the proposed changes will result in improved patient care by allowing agencies to focus their efforts on processes and initiatives that have a direct impact on high quality care.

However, we urge CMS to consider the significant time and effort required to invest in training, education and software and systems changes to comply with the new CoPs. NAHC requests that CMS allow agencies 12 -18 months to implement and comply with the changes following the issuance of the final rule.

That lead time will provide CMS with the opportunity to issue any needed interpretive guidelines and conduct training of state surveyors and providers. It will also permit providers to make the changes necessary to achieve compliance, including full staff education and revisions to policies, protocols, and operations. Further, to the extent that the final changes affect the standards applied
by accrediting bodies, it will provide time for those organizations to adjust as well. As these new CoPs are not intended to address any serious shortcomings in the quality of care provided by home health agencies, there is no need for an immediate institution of the changes. Instead, CMS and home health agencies working in partnership can bring about the improvements that these new standards intend in a consistent and comprehensive manner. We wish to offer the following comments and recommendations.

§484.2 Condition of Participation: Personnel Qualifications

(i) Standard: Physician. A person who meets the qualifications and conditions specified in section 1861(r) of the Act and implemented at 42 CFR 410.20(b) of this chapter.

Issue: Section 1861(r) of the Act and the regulation at 42 CFR 410.20(b), provides a definition of a physician that is inconsistent with the types of physicians who may certify, establish and review the plan of care for home health services in the current and proposed CoPs and the regulations at §424.22(a)(1)(iii). The proposed definition includes doctors of dental surgery, doctors of optometry, and chiropractors, while other sections of the regulations limits the definition of a physician to a doctor of medicine, osteopathy, or podiatric medicine.

§410.20(b) By whom services must be furnished. Medicare Part B pays for the services specified in paragraph (a) of this section if they are furnished by one of the following professionals who is legally authorized to practice by the State in which he or she performs the functions or actions, and who is acting within the scope of his or her license.

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized in section 1101(a)(7) of the Act.
(2) A doctor of dental surgery or dental medicine.
(3) A doctor of podiatric medicine.
(4) A doctor of optometry.
(5) A chiropractor who meets the qualifications specified in §410.22

§424.22 Requirements for home health services.

Medicare Part A or Part B pays for home health services only if a physician certifies and recertifies the content specified in paragraphs (a)(1) and (b)(2) of this section, as appropriate.

(a) Certification—(1) Content of certification. As a condition for payment of home health services under Medicare Part A or Medicare Part B, a physician must certify as follows:

(i) The individual needs or needed intermittent skilled nursing care, or physical or speech therapy, or (for the period from July through November 30, 1981) occupational therapy. If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician will include a brief narrative describing the clinical justification of this need. If the narrative is part of the certification or recertification form, then the narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must sign immediately following the narrative in the addendum.

(ii) Home health services were required because the individual was confined to the home except when receiving outpatient services.

(iii) A plan for furnish the services has been established and is periodically reviewed by a physician who is a doctor of medicine, osteopathy, or podiatric medicine, and who is not precluded from performing this
function under paragraph (d) of this section. (A doctor of podiatric medicine may perform only plan of
treatment functions that are consistent with the functions he or she is authorized to perform under State law.)

**Recommendations:** Revise the definition of a physician throughout the proposed CoPs and at
§424.22(a)(1)(iii) to be a person who meets the qualifications and conditions specified in section
1861(r) of the Act and implemented at 42 CFR 410.20(b).

§484. 50 Condition of Participation: Patient rights

NAHC has long supported comprehensive and appropriate patient rights as a means of assuring
high quality home health services. In fact, we view home health care as the leader of patient
rights in the spectrum of health care services. The proposed refinements continue that legacy and
we fully support CMS’s interest in instituted any useful changes in the existing patient rights
condition of participation.

As a general comment, it would be very helpful if CMS could clearly indicate in the rule, what
actions required of home health actions must be communicated in writing. While there are a
number of standards that specifically reference written or verbal notice, there are others that
leave it open to interpretation. For example, is the information required under 484.50(c)(4)
permitted to be communicated verbally?

**(c)Standard: Rights of the patient.**

*The patient has the right to—*

(4)(iii) Establishing and revising the plan of care, including receiving a copy of it;

**Issue:** The proposed standard would require that the home health agency (HHA) provide the
patient with a copy of their home health plan of care (HH POC), including the initial plan and
any revisions to the plan. Although CMS no longer requires a specific format for the HH POC ,
the contents of the POC are specified in the proposed 484.60(a) to include all diagnoses, mental
status, orders for care and services, medications, nutritional requirements, safety measures and
teaching necessary to meet the patient-specific needs and the measurable outcomes that the HHA
anticipates would occur.

Providing patients with a copy of the initial POC and at each revision would be burdensome for
the agency to track and maintain, particularly for patients that have frequent changes; not to
mention the additional cost of coping every POC and revision for every patient. This
requirement is in addition to agencies having to provide a written notice whenever services are to
be reduced or terminated and prior to discharge. When multiple written notices are provided to
patients they become overwhelming and lose their intended purpose.

In addition, a HHA POC is written from a clinical perspective and in discipline specific parlance.
In order to comply with this requirement, agencies would need to rewrite the POC in a manner
the patient understands. Also, it is unclear whether the agency is required to provide the written
POC and revisions in the patient’s preferred language, if so, it would be unwieldy to implement this requirement.

**Recommendation:** NAHC urges CMS to review the requirement in terms of the magnitude and complexity it will be to implement. As an alternative, permit the agency to inform the patient of the plan of care and revisions verbally in a manner the patient understands. Require that the agency document in the medical record that the information was provided. The written POC could be provided when requested by the patient.

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

**Issue:** Patients may not always identify treatment goals or may have unrealistic goals.

**Recommendation:** Clarify what is required for compliance with meeting patient identified goals when those goals are unclear or unrealistic.

**(10) Be advised of the names, addresses, and telephone numbers of pertinent, Federally-funded and State funded, State and local consumer information, consumer protection, and advocacy agencies.**

**Issue:** Providing a patient with all pertinent, Federally-funded and State funded, State and local consumer information, consumer protection, and advocacy agencies would be impossible to manage. How will a provider know which agencies to include or what surveyor expectations will be? “Pertinent” is subjective as well as patient-specific.

**Recommendation:** The agency should have the flexibility to determine, based on their patient population, which organizations are appropriate to be included in order meet this requirement. In addition, CMS could require that state surveyors develop a comprehensive list and make it available to patients and their families on line.

**(d) Standard: Transfer and discharge** patient and representative (if any), have a right to be informed of the HHA’s policies for admission, transfer, and discharge in advance of care being furnished. 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 services agree that the HHA can no longer meet the patient’s needs, based on the patient’s acuity. The HHA must ensure a safe and appropriate transfer to other care entities when the needs of the patient exceed the HHA’s capabilities

**Issue:** A decision as to the capabilities of an HHA to meet a patient’s needs should be made by the HHA exclusively. Requiring physician agreement when a physician does not have first hand knowledge creates a roadblock to proper patient action. If an HHA finds it does not have the resources to safely meet a patient needs, transferring the patient to a safe care setting ASAP is of paramount importance.
Also, the proposed rule limits the standard of “can no longer meet the patient’s needs” to situations related to the patient’s acuity. However, HHAs can find that they can no longer meet patient needs for many other reasons such as insufficient staff, changes in service area, and loss of a care discipline needed by the patient.

Finally, the proposed rule requires that HHAs assure a safe and appropriate transfer. This standard needs some definition. That definition must account for circumstances where continued home health care is unsafe for the patient, but an alternative care setting is not readily available.

**Recommendations:** The rule should be revised to require that an HHA inform the patient’s physician that it cannot adequately meet the patient’s needs, not that it secure the physician’s agreement. Upon notice, the physician can then become actively involved in discharge planning and transfer. In terms of assuring a safe and appropriate transfer, the proposed rule should be revised to state that the HHA should take reasonable steps to assist the patient to transfer to appropriate care setting by providing information regarding the patient’s needs and recommendations as to appropriate care settings. HHAs should be allowed to discharge such patients when the continuation of home health services would put the patient at risk even though the patient has refused to consider a more appropriate care setting.

The rule should also be revised to delete the restricting phrase “based on the patient’s acuity.” As noted above, there are other reasons why an HHA may no longer be able to meet a patient’s needs.

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 (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:

**Issue:** The proposed standard identifies reasons for an acceptable transfer or discharge of a patient. CMS defines cause as a patient or other person in the home exhibiting behavior that is “disruptive, abusive, or uncooperative.” These three behaviors limit the reasons an agency may transfer or discharge for cause and are up to interpretation as to when a patient may be exhibiting the behaviors. Patients may exhibit other behaviors or have extenuating circumstances that are not clearly defined as disruptive, abusive, or uncooperative that prevents an agency from effectively caring for the patient or might be a threat to the agency staff. Depending on the severity of the patient’s behavior and the threat to staff, complying with all sections (i-iv) above may not be appropriate. For example, when the agency believes their staff is at risk or in imminent danger. That risk can be caused by the patient, other household members, the environment, or other circumstances beyond the control of the HHA.

**Recommendation:** Reasons for cause should not be limited to the three listed behaviors. Rather, the rule may these as examples for when it would be appropriate for agency to transfer or discharge a patient, but not represent a complete list of causes justifying discharge or transfer. Agencies should be permitted to transfer or discharge a patient for any reason related to cause
that affects their ability to provide adequate care and/or threatens the safety of the staff. The agency would be required to document the reason for discharge and to comply with sections i-iv of the standard, when appropriate, ensuring that the agency has made every effort to resolve the problem, provide information on other resources for care, and notify the patient and representative and all health care professionals responsible for the patient’s care of the anticipated transfer or discharge.

We also strongly recommend that the rule provide the flexibility in terms of the HHA’s actions to initiate a discharge immediately, prior to the steps set out in (5)(1) through (iv). For example, where staff are at imminent risk of harm, the HHA should not need to first advise the patient that a discharge for cause is being considered followed by efforts to resolve the problems presented. HHAs have faced circumstances where patients or household members directly threaten the life of the caregiver with a weapon. In such types of circumstances, pre-termination procedural steps should be waived.

§484.50(e)(2) Standard: Investigation of complaints

(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.

Issue: This provision requires definitive action from HHA staff or contractors that may be beyond the control of the HHA. Also, it sets a standard that needs to be integrated with like or potentially conflicting state law requirements. Finally, it provides no protection to the HHA staff from reprisal nor does it permit anonymous reports.

Recommendation: The proposed rule should be revised to require that HHAs establish policies and procedures for staff reporting of incidents in a manner and means consistent with state laws. In the absence of such state law, the HHA policies should permit an anonymous report.

§484.55 Condition of Participation: Comprehensive assessment of the patients

(a) 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.

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.

**Issue:** CMS maintains the requirement for the registered nurse (RN) to conduct the initial and comprehensive assessment, except in therapy only cases. However, this seems contrary to CMS’ overarching goal of promoting an integrated model of care delivery. Revisions throughout the proposed rule reflect this philosophy. For example, revisions to the standard under §484.75-Skilled services, combines the provision of services for all skilled professionals into one, and the revisions to the standards under §484.80- Home health aide services, allows either the RN or therapist to assign, develop the plan and supervise home health aides, not just the RN. In addition, the requirement for the RN to conduct the initial and comprehensive assessments when nursing and therapy are both ordered results in the waste of valuable resources (extra RN visits that are not reimbursable) in cases where the plan of care requires that the therapist visit prior to the RN.

Further, a therapist may currently conduct the initial and comprehensive assessment if therapy is the only discipline ordered. Therefore, there has always been precedent for a therapist to conduct the initial and comprehensive assessments.

A separate concern is the requirement that the assessing clinical professional “determine eligibility for the Medicare home health benefit, including homebound status.” Medicare eligibility assessments are the responsibility of the HHA and should not be assigned to a clinical professional. An HHA should be able to decide who in its organization takes on that responsibility. While an eligibility determination may benefit from inputs from the clinical professional who conducts the patient clinical assessment, the eligibility determination should ultimately lie with the HHA rather than such staff member. However the determination is made, the important part is that it be communicated to the patient as is required under the patient rights ruler.

**Recommendations:** (1) Permit either the RN or the therapist to conduct the initial and comprehensive assessment, as required by the POC, when both disciplines are ordered at the initiation of care.

(2) delete the requirement that the clinical professional who responsible for the comprehensive clinical assessment is also responsible for a Medicare eligibility assessment.

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

(a) **Standard: Plan of care.**

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

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(xiii) Patient-specific interventions and education; measurable outcomes and goals identified by the HHA and the patient;
**Recommendation:** Similar to the requirement under the standard for patient rights, clarify what is required for compliance with patient identified goals.

**(b) Standard: Conformance with physician orders.**

(4) When services are provided on the basis of a physician’s verbal orders, a registered nurse, 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.

**Issue:** CMS proposes to require the RN or qualified practitioner who documents the verbal order sign, date, and time the orders. The rationale for the agency to include the time a verbal was received is unclear, and does not seem relevant for home health care. The date a verbal order is received by a home health agency should be sufficient.

**Recommendation:** Maintain the current standard that verbal orders to be signed and dated with the date of receipt by the RN and or qualified therapist.

**Methods to maximize physician involvement in the patient’s care**

**Issue:** CMS is soliciting comments regarding methods to engage physicians caring for patients prior to admission to home health service.

“Specifically, we are interested in ways to maximize the level of involvement of the physician who is most involved in the patient’s care prior to admission to the home health agency, and who is responsible for overall treatment of the condition(s) that led to the need for home health care.”

**Recommendations:** CMS should use their demonstration authority to develop a care delivery model that would test the use of Nurse Practitioners (NPs) as primary care practitioners for home health patients.

NPs often function as the primary care practitioner for patients in the community and play a significant role in providing care for patients, including Medicare beneficiaries, who use home health services. Therefore, any initiative aimed at engaging physicians who care for home health patients will necessitate recognizing and engaging the NPs that care for these patients.

NAHC realizes that the current statute prohibits NPs from certifying patients for home health services or writing orders while patients are under a home health plan of care. However, the statute is archaic and counter to facilitating the continuity of care, particularly for patients with co-morbidities and chronic conditions that often use home health services.

**(e) Standard: Discharge or transfer summary**

The discharge or transfer summary must include—

1. A summary of the patient’s stay, including the reason for referral to the HHA, the patient’s clinical, mental, psychosocial, cognitive, and functional condition at the time of the start of services by the HHA, all services provided by the HHA, the start and end date of care by the HHA, the patient’s clinical, mental, psychosocial, cognitive, and functional condition at the time of discharge from the HHA, an updated reconciled list of medications at the time of discharge or transfer, and any recommendations for ongoing care (for example, outpatient physical therapy);

2. The patient’s current plan of care, including the latest physician orders; and
(3) Any other documentation that will assist in post-discharge or transfer continuity of care, or that is requested by the health care practitioner who will be responsible for providing care and services to the patient after discharge from the HHA or receiving facility.

**Issue:** The standard requires that the agency provide a summary which contains elements that go beyond what would typically be included in, or needed, for an effective discharge or transfer summary. To require that the agency include the amount of information as proposed on a summary report, whether at discharge or transfer, creates an unnecessary burden for the agency and may be of little value to the recipient. The information proposed for the summary report is more than what might be needed for every patient in order to facilitate an effective transfer of care. However, if any element is missing it could be the basis for a deficiency citation that may have no bearing on the quality of care.

It is unclear whether CMS proposes to require a summary report be provided whenever a patient is transferred from the agency to an inpatient setting, even to include transfers where the patient will not be discharged from the agency.

**Recommendation:** Allow professional standards of practice to dictate what should be communicated in a discharge/transfer summary to health care professionals assuming care of the patient. Any additional information will be provided as requested by the receiving health care professional or facility.

Require that a transfer summary only be required if the agency is discharging a patient to a facility. For transfers without an agency discharge, where the agency will be resuming care, require that a transfer summary be provided if requested by the receiving facility.

**§484.65 Quality Assessment and Performance Improvement**

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 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.

**Issue:** CMS believes agencies will be able to implement a QAPI program with little commitment of additional resources.

“We believe small and mid-size HHAs would be able to effectively implement this condition as easily as larger HHAs. The proposed QAPI CoP would provide HHAs with enough flexibility to implement the quality assessment and performance improvement process without inordinate expenditure of capital or human resources”

Although NAHC supports CMS’ proposal to require agencies implement a comprehensive QAPI program we believe the proposed CoP may require considerable investment in additional resources by home health providers. Many agencies do not have a QAPI program that meets all the proposed requirements. The CoP consists of five standards with very specific activities and expectations.
**Recommendations:** Given the time, effort and investment required to implement the new CoP, we urge CMS to provide ample time for all agencies to comply with the new CoP and consider phasing in the requirements of the proposed QAPI Program.

§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.

**Issue:** NAHC supports the requirement that all agencies have an effective infection control program. Although many agencies currently have some type of infection control program, they may not meet all the required elements CMS proposes.

**Recommendations:** Similar to our recommendations related to the proposed QAPI program, NAHC urges CMS to provide ample time for agencies to comply with the proposed infection control standards.

§ 484.80 Condition of participation: Home health aide services.
(b) Standard: Content and duration of home health aide classroom and supervised practical training.

**Issue:** CMS has added several new requirements under home health aide training requirements. For example, under (b) (3) (i) the aid must demonstrate specific communication skills, and under (b) (3) (xiii) must be able to recognize and report changes in the patient’s skin condition. For home health aides currently employed by the agency additional training will be required to meet the new requirements.

**Recommendation:** Allow the effective date for compliance to be phased in to accommodate those aides currently employed by the agency. Permit the agency to provide the training through in-service training.

§ 484.100 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.

(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-testing.

**Issue:** Patients with financial constraints may not be able to afford self-testing equipment or may choose not to obtain the equipment. Also, self-testing may be required for a limited period of time and therefore it would not be practical for these patients to purchase the equipment.
Recommendation: Allow the agency the flexibility to use their own equipment as determined by the patient’s needs and choice when assisting with self-testing.

§ 484.105 Condition of participation: Organization and administration of services.
Issue: Current 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 does not require the clinical manager (who is a registered nurse or physician) to be available during operating hours and does not require a designee in the clinical manager’s absence. Therefore, there exists the potential for a home health agency to be operating without direction of a clinician person. For example, when the administrator is available during operating hours, the proposed rule does not specify the need for the pre-designated skilled professional to be available. 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.

Recommendation: Revisit and revise, as necessary, these standards to ensure that a qualified professional is available to provide clinical oversight during all operating hours. Allow therapists to be a designated clinical manager

b) Standard: Administrator. (1) The administrator must: (i) Be appointed by the governing body; (ii) Be responsible for all day-to-day operations of the HHA; (iii) Ensure that a skilled professional as described in § 484.75 is available during all operating hours. (2) When the administrator is not available, a 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 skilled professional as described in paragraph (b) (1) (iii) of this section. (3) The administrator or pre-designated individual is available during all operating hours.

Issue: The duties the Administrator are expanded to include responsibilities of the day to day operations of the organization and to be available during all operating hours.

Recommendations: Permit the administrator to be shared among commonly owned organizations if they can demonstrate that the administrator is able to fulfill all the proposed requirements

c) Clinical manager. A qualified licensed physician or registered nurse 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; (5) Assuring the development, implementation, and updates of the individualized plan of care; and (6) Assuring the development of personnel qualifications and policies.
**Issue:** The clinical nurse manager is a new designation with responsibilities that are extensive and diverse. It is unclear how CMS expects the agency to operationalize this new position. In a large agency some duties may need to be delegated to other staff members. Conversely, in a very small agency one individual may be able to serve as both the administrator and the clinical manager.

**Recommendations:** Permit the agency to determine how they can best meet the requirements for the clinical nurse. This might require delegating tasks to others, including therapists or non-skilled personnel, for a large agency or combining the duties with the administrator in a small agency.

(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.

**Issue:** This standard has been interpreted to mean that an HHA must provide at least one of the qualifying services directly through agency employees, but may provide the additional services under arrangements with another agency or organization. This inhibits contract arrangements even when needed for emergencies or staffing shortages. Home health shows that subcontracting is necessary when temporary staffing shortages exist, community demands result in increased referrals, and patients require the skills of specialty nurses and therapists. The current health care environment has resulted in an increase in managed care and numerous organizational relationships. In order to remain competitive for managed care contracts, providers must contract for services to control costs while enabling patients to receive specialty services. Mergers, acquisitions, and joint ventures are taking place at a rapid pace, resulting in the need for greater flexibility in the provision of services to ensure HHA and hospice survival. Finally, HHPPS requires HHAs to contract for therapy services when their patients need special equipment not available in the home, leaving nursing, aides and social workers as the only possible direct service providers. Beyond extraordinary circumstances, there has been no evidence that the use of contracted services compromises quality of care.

**Recommendations:** HHAs should be permitted to provide unlimited services under arrangements both by individuals or other agencies or organizations. CMS should enforce the home health regulations that require oversight and control of services by the certified providers regardless of whether the persons providing care are employees or contractors. This requirement does not fit within the current health care service economy and workforce market. The “service directly requirement” is a proxy for establishing quality assurance in the provision of care. Medicare maintains an outdated and unfounded belief that an employed caregiver is more capable of providing high quality services to patients than a contracted caregiver. Arbitrary staffing/contractor ratios do not ensure quality of care. Existing and proposed quality, coordination, and supervision regulations and guidelines, if enforced, can serve to ensure quality of care to Medicare beneficiaries.
§484.110 Condition of participation: Clinical records.
(a) Standard: Contents of clinical record. The record must include:
(6) A completed discharge or transfer summary, as required by § 484.60(e), 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 7 calendar days of
the patient’s discharge; or, if the patient’s care will be immediately continued in a health care
facility, a discharge or transfer summary is sent to the facility within 2 calendar days of the
patient’s discharge or transfer.

Issue: Requiring the summary be provided using calendar days could limit the real time frame
the agency has to provide the information since many health care professionals and facilities are
not available or limit operations during non-business times, and the lack of electronic record
inoperability in health care often requires that information be shared through less efficient
methods.
Similar to a previous comment, it is unclear when the transfer summary would need to be
provided. If the requirement is to be applied any time a patient transfer to a facility, the agency
may not be aware of the transfer for several days.

Recommendation: Replace “calendar days” with “business days”. Also, require that a transfer
summary be required only if the agency is discharging a patient to a facility. If the requirement is
to be applied to any facility transfer, allow the transfer summary to be provided within 2 business
days of the notification of the transfer to accommodate when a patient may have transferred to a
facility without the agency’s knowledge.

Elimination of subunit designation
Issue: CMS proposes to eliminate the subunit distinction upon finalization of the rule. Any
existing subunit will either have to apply to become a branch or operate as a parent. However,
CMS does not address a transition plan to convert subunits to a parent or a branch. This could be
problematic for agencies located in states where the Medicare state survey agency is not
approving branches or initial certifications due to workload prioritizations. Since only the
Medicare state survey agency is authorized to approve home health branches, branch approval
may not be delegated to accrediting organizations. In addition, claims processing issues could
occur when a subunit changes to a branch. The branch will be submitting claims under the parent
agency billing numbers.

Recommendation: NAHC urges CMS to provide ample time for agencies to convert a subunit
to either a parent or a branch. CMS should required the Medicare state survey agencies
reprioritize to a Tier 1 any approvals related to a subunit transitioning to a parent or a branch.
Also, efforts must be coordinated among all affected departments within CMS to ensure that
claim processing related to a subunit transition is uninterrupted.
Thank for the opportunity to submit these comments. If you need further information, please do not hesitate to contact me.

Very truly yours,

Mary K. Carr,
Vice President for Regulatory Affairs