



January 7, 2015

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

**Re: Comments on Conditions of Participation for Home Health Agencies, Proposed Rule
79 Fed. Reg. No. 196 (October 9, 2014)**

**Submitted Electronically through www.regulations.gov;
CMS-3819-P**

Dear Administrator Tavenner:

The National Consumer Voice for Quality Long-Term Care (Consumer Voice) is a national non-profit organization that advocates on behalf of long-term care consumers across care settings. Our membership consists primarily of consumers of long-term care and services, their families, long-term care ombudsmen, individual advocates, and citizen advocacy groups. Consumer Voice has almost 40 years' experience advocating for quality care.

We thank you for the opportunity to submit comments on CMS's proposed Conditions of Participation (CoPs) for home health agencies.

Consumer Voice commends CMS for proposing to hold home health agencies (HHAs) to a higher standard of care by requiring them to attain and maintain a patient's highest practicable functional capacity. We support the new provisions that focus on individualized and person-centered care, such as a patient-centered assessment and care planning process, as well as a more holistic and interdisciplinary approach to care. We are also pleased that the proposed rules call for greater consumer involvement, participation and engagement and include additional patient rights that better protect patient health and well-being.

Nevertheless, Consumer Voice opposes CMS's proposal to eliminate "administrative process requirements" unless they are "predictive of either achieving clinically relevant outcomes for patients or preventing harmful outcomes for patients" (Federal Register/Vol.79, No. 196, Thursday, October 9, 2014/Proposed Rules, p 61166). First, an outcome should not have to be clinically-based to be positive. Secondly, and even more important, such an approach has

The National Consumer Voice for Quality Long-Term Care (formerly NCCNHR) is a 501(c)(3) nonprofit membership organization founded in 1975 by Elma L. Holder that advocates for quality care and quality of life for consumers in all long-term-care settings.

resulted in the failure to include numerous patient rights regarding receipt of critical information in writing. For example, the proposed rule does not require:

- written notice to patients about payment for services, services that are covered/not covered by Medicare, Medicaid, and charges for non-covered services;
- written information to patients about the toll free state home health telephone hotline and the names, addresses, and telephone numbers of consumer information, consumer protection and advocacy agencies; and
- written notice to patients of a proposed transfer/discharge.

Consumer advocates have found such information to be essential in protecting residents in the nursing home setting. This information is even more important in the home care setting where the majority of patients do not have advocates such as long-term care ombudsmen to help support their rights and are more isolated than nursing home residents.

We also fundamentally disagree with CMS's view that the current CoPs' "problem-oriented, external, after the fact (occurrence) approach" must be replaced with the proposed Quality Assessment and Performance Improvement (QAPI) CoP that would require "proactive performance monitoring through an effective, ongoing, agency-wide, data-driven QAPI program" (Federal Register/Vol.79, No. 196, Thursday, October 9, 2014/Proposed Rules, p. 61175). Consumer Voice believes that both approaches are necessary - one to look "after the fact" at problems that have occurred, and the other to work to avoid problems. The two are not mutually exclusive. While we support HHAs having an internal quality improvement system, it is our view that CMS is relying too heavily on such a process to ensure quality care and not enough on regulatory oversight.

Our detailed comments and recommendations are outlined below. We have italicized and used bold to indicate our suggested language changes.

§484.50 Condition of Participation: Patient rights

§484.50(a) Standard: Notice of rights.

§484.50(a)(1) Proposed change:

*Provide the patient and the patient's representative (if any) the following information during the initial evaluation visit, in advance of furnishing care to the patient **and whenever the care plan is reviewed and/or revised:***

We strongly support providing the patient and representative (if any) with a written notice of rights at the time of the initial evaluation visit and in advance of furnishing care. It is essential that patients know of their rights from the very beginning of home health services. However, we urge CMS to also require home health agencies to provide patients with a written and verbal notice of their rights at each care plan meeting. The initial evaluation visit can be a stressful time for patients. There is a great deal of information being presented to them and numerous documents to sign. They may also not be feeling well. It is not realistic to expect that an individual will remember receiving a written copy of patient rights, particularly if the copy has been tucked away in a folder with many other forms and papers. Reviewing this information at each care plan meeting would better ensure that patients are fully informed and aware of their rights.

§484.50(a)(1)(i) and (ii)

Consumer Voice is pleased to see that the proposed rule would require notice to be provided in a way that is understandable to the patient and that interpreter services must be furnished if necessary at no charge to the patients. This new provision would assist individuals in better understanding their rights, which is necessary in order to exercise those rights.

§484.50(a)(4) Proposed change:

*Obtain the patient's or representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities **during the initial visit and whenever the care plan is reviewed and/or revised.***

Without such documentation it is not possible to know whether the HHA has provided this notice of rights at these times.

§484.50(b) Standard: Exercise of rights

§484.50(b)(1) Proposed change:

(1) The patient has the right to exercise his or her rights as a patient of the HHA.

(2) If a state court has not adjudged a patient to lack legal capacity, the patient's representative may exercise the patient's rights in accordance with state law and with the patient's permission.

(3) If a patient has been adjudged to lack legal capacity under 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.

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

While the intent of this section is to define who has the right to exercise patient rights, the right of an individual to exercise his/her own rights is not acknowledged, and the language and flow of the proposed rule is unclear and confusing. Further, the original language in the proposed rule at (b)(2) could be interpreted as giving a patient's representative the right to exercise the patient's rights even when the individual is quite capable of exercising his/her own rights and wishes to do so. For these reasons, we recommend that this standard be rewritten as suggested above.

§484.50 (c) Standard: Rights of the patient

§484.50 (c)(3) Proposed change

*Make complaints, **including those** 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, **without discrimination, retaliation or fear of retaliation to the HHA and the state survey and certification agency.***

*(i) The patient must be advised **orally and in writing** of:*

- a. 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.*
- b. the names, addresses and telephone numbers of pertinent, Federally-funded and State-funded, State and local consumer information, consumer protection, and advocacy*

agencies, including the state long-term care ombudsman program in states where the program is authorized to advocate in the home care setting.

Below are descriptions of and reasons for these recommendations:

- We urge CMS to broaden the extent of complaints that can be filed. Patients should be able to make complaints about a wide range of issues that fall within the jurisdiction of the HHA. They should not be restricted to complaints related to treatment/care or respect for property and/or person.
- Our second recommended change would add to this provision protections against discrimination and reprisal. We understand that these protections are put forth in (11). However, consumers and advocates report that one of the top concerns of patients is the fear of retaliation if they voice a grievance or speak up in any way. Because this fear cannot be overemphasized, putting this language in (b)(3) and (b)(11) sends a message to both HHAs and consumers that CMS takes retaliation seriously.
- Consumer Voice believes information about the hotline and consumer protection and advocacy agencies should be given both verbally and in writing. Receiving this information in both formats promotes greater clarity and understanding.
- Finally, we suggest reorganizing the proposed rule so that requirements related to making complaints are together in one place. This will help consumers better understand their rights and the range of options they have for voicing complaints.

§484.50 (c)(4) Proposed change:

Participate in, be informed about, and consent or refuse care in advance of and during treatment, ~~where appropriate~~, with respect to -

We can think of no circumstance in which it would not be appropriate for the patient to participate in, be informed about, and consent or refuse care. Moreover, 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/her care.

§484.50 (c)(4)(iii) Proposed change:

*Establishing and revising the plan of care, including receiving a copy of it **at no charge***

Patients should have a copy of their plans of care in order to know what care and services they should be receiving and to more fully participate in their care. However, charging for this copy could prevent many individuals from obtaining their care plans.

§484.50 (c)(4)(v) Proposed change:

*The frequency **and timing** of visits **and who provides services***

Consumer Voice asks CMS to also give patients the right to have a say both in the timing of visits and the personnel assigned to provide services during those visits. Consumers have informed us that visits are often conducted at times that are convenient for the HHA, but not for the patient. In addition, they report that they may have a different paid caregiver every time. If the goal of these rules is to support individualized and person-centered care, these visits must take place

at times and be conducted by staff that reflect the patient's needs and preferences. In addition to promoting person-centered care, honoring a patient's preference for who provides services and when can help achieve a better patient outcome. For instance, an individual who is not a "morning" person will be much more likely to actively engage in physical therapy if that therapy is provided in the afternoon and not first thing in the morning. Similarly, if the same home health aide consistently cares for the patient, the aide will be better able to identify a change in condition and alert the appropriate nurse or therapist.

§484.50 (c)(6) Proposed change:

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

- (i) **The patient or his or her representative has the right—**
- a. **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**
 - b. **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 advance notice to the HHA.**

While the proposed rule would address release of patient information and clinical records, it does not cover the patient's access to his or her own information/records. Ensuring that patients can access and review their information and records promotes greater involvement in their own care and supports person-centered care. In addition, individuals should have easy access to information that concerns them. Patients can use the health information to better communicate with providers, better understand their health and treatment options, and make sure health information about them is as accurate and complete as possible.

§484.50 (c)(9) and (10) Proposed change:

See recommendations for §484.50 (c)(3) above.

§484.50 (c)(12) Proposed change:

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

As noted above, receiving this information in both formats promotes greater clarity and understanding on the part of the patient and representative.

§484.50 (d) Standard: Transfer and discharge

General comment:

Consumer Voice supports and thanks CMS for the establishment of a standard that addresses transfers and discharges. The lack of such a standard has led to some home health agencies terminating services arbitrarily, with little or no advance notice and inadequate arrangements for continued care of the patient.

We agree with CMS that identifying criteria by which an HHA could discharge or transfer a patient would help prevent the untimely discharge of home health patients and ensure that patients are discharged or transferred only under appropriate circumstances. However, we disagree with permitting a HHA to discharge for “cause” based on the agency’s own policy of what constitutes cause. This gives the agency too much discretion and latitude to craft this term in such a way that it becomes a “catch-all” that allows the agency to stop serving patients that it may perceive as complaining too much or taking too much time.

We also disagree with leaving it up to each HHA to create its own policies for transfer and discharge, including how and when notice is given. Each home health patient should be entitled to the same protections regardless of what agency provides care and services. If CMS does not set forth more specific parameters as we suggest below, this rule could easily result in some patients having fewer protections than others, which would be unacceptable.

§484.50 (d)(1) Proposed change:

*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, and **only after the home health agency has attempted to resolve the situation and documented the attempts in the patient’s clinical record.** The HHA must ensure a safe and appropriate transfer to other care entities when the needs of the patient exceed the HHA’s capabilities. **A patient whose acuity is such that the HHA cannot meet his or needs may only be transferred to a care entity that provides a higher level of care, such as a hospital or nursing facility.***

Consumer Voice supports allowing such a transfer only when the needs cannot be met due to acuity. Simply permitting a transfer because a provider states that a patient’s needs cannot be met is too broad and subject to abuse. Based on advocate and consumer experience in the nursing home setting, not being “able to meet a patient’s needs” can become a cover for discharging for other reasons.

When a discharge/transfer does occur due to patient acuity, there should be no reason for an HHA to transfer the patient to another HHA since all Medicare-certified HHAs are held to the same standards.

§484.50 (d)(2) Proposed change:

*The patient or payer will no longer pay for the services provided by the HHA. **A patient cannot be transferred for non-payment if he or she has submitted to a third party payer the paperwork necessary for the bill to be paid. Non-payment would occur if a third party payer, including Medicare or Medicaid, denies the claim and the patient refused to pay for services.***

An HHA should not be permitted to draw its own conclusion about a patient’s eligibility for third party payment, nor move to discharge a patient before an official determination has been made.

§484.50 (d)(3) Proposed change:

The transfer or discharge 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

Under *Jimmo v. Sebelius*, it would not be legal to discharge a patient simply because he or she has stabilized if the patient continues to need skilled nursing and/or therapy services to maintain function or prevent or slow his or her decline.

§484.50 (d)(4) Proposed change:

*The patient refuses **all** services, or elects to be transferred or discharged. **Prior to any transfer or discharge due to refusal of all services, the HHA must assess the reasons for the patient's refusal, advise the patient about the consequences of refusal, and offer pertinent alternative treatments.***

The term "refusal of services" is too broad as 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. An HHA should not be permitted to transfer or discharge patients for refusing some, but not all, services since patients have the right to refuse care. When all care is refused, the HHA should try first to determine what is causing the refusal and work to address the cause or explore alternative treatments. The patient may respond if a different approach is used or the cause of his or her refusal is addressed.

§484.50 (d)(5) Proposed change:

~~**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, 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 patient, primary caregiver or other person in the home has exhibited behavior that is a safety risk to agency staff, such as physical abuse, sexual harassment, threatening behavior or verbal abuse. The HHA must do the following before it discharges a patient **due to a safety risk**:**~~

- ~~(i) Advise the patient, representative (if any), the physician who is responsible 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 **due to a safety risk** is being considered~~

As noted above, permitting an HHA to discharge for "cause" based on the agency's own policy of what constitutes cause gives the agency too much discretion and latitude to craft this term in a way that becomes a "catch-all" and a way to discharge patients the agency no longer wants to serve. For some agencies, cause could mean that a patient's care takes too much time or the patient and/or their family are "too demanding" or complain "too much." Our suggested change would give the HHA the ability to discharge if behavior is abusive without allowing an agency to use the idea of "cause" as a way to inappropriately discharge a patient.

§484.50 (d)(8) Proposed change: (new provision)

The patient has the right to appeal the HHA's decision to transfer or discharge him or her.

Patients must have the right to appeal if they choose to dispute the HHA's decision to discharge/transfer them. Without due process, patients are at the mercy of the HHA, which can claim it is discharging due to one of the permitted reasons without ever having to show how the criteria for discharge are being met. Given the enormous impact a discharge/transfer can have on patients, patients must have recourse when they disagree with the agency's decision.

§484.50 (d)(9) Proposed change: (new provision)

The HHA shall provide both a verbal and written notice to the patient and representative (if any) prior to transfer or discharge. Notice must be made at least 30 days in advance and include:

- i. The reason for transfer or discharge;***
- ii. The effective date of transfer or discharge;***
- iii. The location to which the patient will be transferred or discharged;***
- iv. A statement that the patient has the right to appeal the HHA's decision to transfer or discharge him or her; and***
- v. 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.***

The proposed rule does not provide patients with adequate protections. The rule fails to require the provision of a written notice of transfer or discharge; does not ensure the patient has sufficient time prior to the end of services; and does not provide notice to patients about appeal rights or give them information about where they may turn to for help.

- Without adequate advance notice, patients could abruptly lose care and services with little to no advance notice. The sudden termination of services could severely impact their health and safety. Sufficient notice is also important because transfer or discharge means the end of receiving care from caregivers who have become familiar to the patient and with whom the patient may have developed close relationships. It takes time for a patient to adjust to this major change in his or her life.
- Few patients and family members will realize they have the right to appeal if they are not informed again in the notice of transfer/discharge.
- If a patient decides to file an appeal, he or she will almost certainly need representation at the hearing. Hearings can be extremely daunting for consumers, particularly since the HHA controls the medical records and staff witnesses and is frequently represented by legal counsel. However, patients and their families seldom know where to turn for assistance. The notice must provide patients with this information.

§484.50 (d)(9) Proposed change: (new provision)

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.

We urge CMS to adopt this language for all transfers/discharges regardless of the reason. Our proposed language would protect the patient from suddenly losing all care and services, being transferred to an inappropriate provider or care setting, or from being hurriedly transferred to the care of another provider without being consulted or given sufficient time to prepare for such a major change. Each of these scenarios could cause physical and/or psychological harm to patients.

Finally, while outside the scope of this rule, we urge CMS to require states to develop ombudsman services for home health care patients. Ombudsmen would promote patients' rights, help patients resolve complaints and assist patients who wish to appeal an HHA's decision to transfer or discharge them.

§484.50 (e) Standard: Investigation of complaints

§484.50 (e)(1) and(2) Proposed change:

(1) *The HHA must –*

- (i) ***Develop and implement policies and procedures for an internal complaint process that permits the patient, the patient's representative (if any), and the patient's caregivers, and family to file a complaint orally or in writing. A summary of the complaint process must be provided to the patient, the patient's representative (if any) and family upon admission to services and whenever the care plan is reviewed and revised.***
- (ii) ***Investigate complaints made by a patient, the patient's representative (if any) and the patient's caregivers and family including, but not limited to, complaints regarding***
 - 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.*
 - 1. ***The complaint may not be investigated by any HHA staff involved in the complaint.***
- (iii) *Document both the existence of the complaint and the resolution of the complaint.*
- (iv) ***Provide a written report to the complainant documenting the findings of the investigation and resolution of the complaint within 14 calendar days of its receipt.***
- (v) ***If the patient is not satisfied with the response, he or she may request that the complaint be reviewed by the HHA. The patient must request such a review within 10 days of receiving the response. The HHA must respond in writing within 30 days from the date it received the patient's request for review. The response must***

include the 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.

*(vi) 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 the findings immediately to the HHA, **law enforcement** and other appropriate authorities **in accordance with State law.***

Consumer Voice supports the creation of a new standard for complaint investigations and agrees that it is essential given the vulnerability of home health patients. As noted above, patients should be able to make complaints about a wide range of issues as long as they fall within the jurisdiction of the HHA. They should not be restricted to complaints related to treatment/care, mistreatment, neglect, abuse and misappropriations of patient property. We ask CMS to adopt the recommendations we have presented in order to create a more robust and transparent internal complaint process. Such a process is critical for quality care and patient safety. It is also more responsive to patient needs and concerns and better ensures that concerns are addressed promptly before care is compromised. Our recommendations stress the provision of information to patients so they know what the complaint process is, what the results of their complaint are, and what they can do if not satisfied with the HHA's response to their complaint.

In addition, our suggested requirements would create more consistency and standardization across home health agencies so that all patients have the same rights related to complaint investigations. While we do not oppose giving HHAs the flexibility to establish their own policies and procedures for documenting and resolving complaints, we object to agencies being allowed to decide for themselves how long they will take to investigate a complaint and whether or not they will report the findings to the complainant.

§484.55 Condition of Participation: Comprehensive assessment of patients

Consumer Voice applauds CMS for enhancing the content of the comprehensive assessment by including an assessment of psychosocial and cognitive status; patient strengths, goals and care preferences; and the patient's progress toward achievement of the goals identified by the patient. This language would make the assessment more holistic by recognizing the importance of psychosocial well-being and the impact that cognitive impairment can have on a patient's health. It also supports individualized and person-centered care by identifying patient goals and care preferences rather than only the "desired outcomes of the HHA."

Furthermore, we are pleased to see the inclusion in the assessment of information about the primary caregiver(s), which often will be a patient's

family member. This recognizes the critical importance of the family caregiver to the patient’s health and well-being.

Proposed change:

We ask CMS to consider including a family caregiver assessment in the proposed CoPs when patient care is dependent on family caregivers. With individuals being discharged “quicker and sicker” from hospitals, family members are increasingly required to carry out complex medical tasks. An AARP report found that 46 percent of family caregivers have performed medical or nursing tasks for patients with multiple physical and chronic conditions. Of these individuals, 78 percent were in charge of managing the patient’s medications, administering fluids and doing injections.¹

As another AARP report notes, family support is often essential for helping older people and adults with disabilities continue to live at home and in the community. Yet, the work of family caregivers can be demanding—physically, emotionally, and financially. If caregiver needs are not assessed, their own health and well-being may be at risk, which may, in turn, lead to burnout—jeopardizing their ability to continue providing care at home.²

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

We commend CMS for proposing a person-centered approach to care planning and for focusing on “each” patient, an “individualized” plan of care and “patient-specific needs.” The proposed CoPs, unlike the current rules, stress the need to look at every patient as an individual with different needs and goals. As we discussed in the assessment section above, family support is often critical for helping older people and adults with disabilities remain at home, yet the work of family caregivers can be very difficult. Family caregiver needs must not only be assessed, they must be addressed. We urge CMS to explore including the identified family caregiver needs in the patient’s care plan.

§484.60(a) Standard: Plan of care

§484.60(a)(1)

Consumer Voice believes it is important to explicitly state that each patient must receive the home health services that are written in an individualized plan of care. Such language better ensures that the patient will indeed receive all the services called for in the care plan.

§484.60(a)(2)

We support the addition of new components to a patient’s plan of care, including the patient’s mental, psychosocial and cognitive status; patient and

¹ Home Alone: Family Caregivers Providing Complex Chronic Care. Susan C. Reinhard, RN, PhD, FAAN, Senior Vice President and Director, AARP. Carol Levine, MA, Director, Families and Health Care Project, United Hospital Fund & Sarah Samis, MPA, Senior Health Policy Analyst, United Hospital Fund, [Public Policy Institute](#), October, 2012.

² http://www.aarp.org/content/dam/aarp/research/public_policy_institute/lrc/2013/the-need-to-include-family-caregiver-assessment-medicare-hcbs-waiver-programs-report-AARP-ppi-lrc.pdf

caregiver education and training; patient-specific interventions and education; and measurable outcomes and goals identified by the HHA and the patient. These elements underscore the importance of viewing the patient as a unique individual whose needs and goals differ from those of others. We are also pleased that CMS acknowledges the importance of and need for patient and caregiver education and training.

§484.60(a)(2)(xv) Proposed change:

*Any additional items the HHA, physician **or patient** may choose to include.*

To be truly patient-centered and reflect what the patient wants, patients should also be permitted to add to the care plan.

§484.60(a)(3)

Consumer Voice is pleased to see a proposed requirement to identify a patient's risk for emergency department visits and hospital readmission and interventions to address those risks. This will help improve patient care and reduce unnecessary and avoidable hospitalizations.

§484.60(b) Standard: Conformance with physician orders

§484.60(b)(4)

Consumer Voice agrees with CMS's proposal that verbal orders should be authenticated, dated and timed by the physician and believes such measures would better protect patient safety. However, we encourage CMS to require a timeframe for physician signature. Allowing each agency or state to determine this timeframe could result in instances where too much time elapses before authentication by the physician. In such situations, problems with authenticity would not be found quickly enough and could endanger the health and welfare of patients.

§484.60(c) Standard: Review and revision of the plan of care

§484.60(c)(1) Proposed change:

*The individualized plan of care must be reviewed and revised by the physician who is responsible for the home health plan of care, the HHA, **the patient, representative (if any), and caregiver** as frequently as the patient's condition or needs require, **including when there is a significant change; 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.*

While §484.50 (c)(4) calls for the patient to participate in, be informed about, and consent or refuse care with respect to establishing and revising the plan of care, the language in this section calls for the care plan to be reviewed and revised only by the physician and the HHA. It does not include the patient. Our suggested language would encourage patient participation and make the proposed requirement more person-centered. We also ask CMS to require that the care plan be reviewed 1) upon patient request since the patient may have concerns and should not be forced to wait to the end of a 60 day period for review; and 2) when there is a significant change to provide more clarity to the proposed rule.

§484.60(c)(3) Proposed change:

Consumer Voice supports this proposed provision that would require revisions to the plan of care to be communicated to the patient, representative – if any – and caregiver. In order to successfully implement the plan of care, everyone involved must be aware of what it calls for. To further enhance communication and make certain it is timely, we recommend requiring that such information be conveyed within a certain period of time.

§484.60(d) Standard: Coordination of care

This proposed standard would improve care delivery and more fully involve the patient, representative (if any) and the caregiver. At the same time, we disagree with CMS's statement in the preamble that it should be the agency's responsibility to determine the most appropriate and effective way to provide evidence during a survey that care coordination activities are occurring on a continual basis and that the agency is assessing the impact of these activities on patient care. Such total flexibility fosters inconsistency in the survey process that can, in turn, result in inconsistent compliance with the proposed rule. Consumer Voice urges CMS to require HHAs to specifically document these activities so surveyors across the country will be evaluating compliance using the same approach.

§484.60(e) Standard: Discharge or transfer summary.

We support the elements that the proposed CoP would include in the discharge or transfer summary and believe that detailing what must be included in the summary will result in more effective follow-up care planning and smoother transitions. Please see *§484.110 Condition of participation: Clinical records* for additional comments about the discharge or transfer summary.

§484.65 Condition of Participation: Quality Assessment and Performance Improvement (QAPI)

Consumer Voice believes that the quality assessment and performance improvement process is important and agrees that each HHA should be required to establish such a program. QAPI is a way for an HHA to identify ways to improve care and patient safety outside of the survey process. It should be an internal agency process that supplements, but does not replace, CMS oversight and monitoring.

We have several questions and concerns about the proposed QAPI CoP:

- What is considered to be an “effective” QAPI program? This should be defined so that HHAs know to what standards they will be held.
- We are very troubled by the language in §484.65 (a)(1) stating that the program must be “at least capable of showing measurable improvement.” Given CMS's focus on outcome, an HHA should be required to show actual improvement in order to comply with the QAPI requirement, and not just that it is capable of doing so.
- Will an HHA be considered compliant with the proposed QAPI CoP if it sets a goal for improvement - no matter how low - and meets that goal, or must it achieve a certain level of improvement? If the latter, how much improvement must an HHA show?

- The proposed CoP lacks clarity and should provide examples about what is meant by: “indicators for which there is evidence that improvement in those indicators will improve health outcomes, patient safety, and quality of care” [(a)(1)] and “quality indicators” [(a)(2)].
- Although HHA performance improvement activities must focus on high risk, high volume or problem-prone areas [(c)(1)(i)], there is no requirement for HHAs to justify why they chose a particular area. Will an HHA be considered to be out of compliance if it chooses an area that does not meet those criteria?
- According to the proposed rule at (c)(3), an HHA must “ensure that improvements are sustained.” What happens if improvements are not sustained? Will an HHA be considered to have failed to comply with the QAPI regulation under those circumstances?
- Why are performance improvement projects required? These could distract and take away from the program activities that address critical problems. Moreover, the proposed requirement does not call for the HHA to sustain these improvements. Without such a requirement, HHAs could end up devoting time, energy and resources for a short-lived effort to make an improvement that does not last. In addition, the language in (d)(1) is extremely vague and would be difficult for surveyors to assess.
- The proposed QAPI CoP does not require that patients, their representatives and caregivers be part of the QAPI program. Patients are the ones most impacted and with the most at stake, yet there is no mention of including them or those who represent and/or provide care to them in any aspect of the QAPI program.

We urge CMS to address these questions and concerns and to further develop this section before finalizing this proposed CoP.

In addition, Consumer Voice disagrees with completely eliminating two current HHA CoPs – sections §484.16, “Group of professional personnel” and §484.52, “Evaluation of the agency’s program” and replacing them with the proposed QAPI CoP. The role and purpose of QAPI is not the same as these two CoPs. As described in the preamble and proposed rule, QAPI is focused on quality indicators and improved outcomes. It does not look at the HHA’s total program to determine the extent to which it is appropriate, adequate, and effective; nor does it include a review of agency admission and discharge policies, medical supervision and plans of care, clinical records, etc. If sections §484.16 and §484.52 were deleted, HHAs would not have to evaluate areas such as patient rights to see if rights are being upheld and promoted, or review personnel qualifications to determine if the appropriate skills, education, and experience are being required of employees. We ask CMS to continue to require HHAs to conduct some type of overall and comprehensive agency evaluation at least annually.

§484.75 Condition of participation: Skilled professional services

We support an interdisciplinary approach to care and services and agree with CMS that skilled professionals should participate in the coordination of all aspects of care. We also see how identifying the common expectations of skilled professionals across disciplines can be helpful and foster a coordinated, interdisciplinary approach to care and services. However, while there are commonalities, there are also significant differences in the roles of registered nurses, licensed practical nurses, physical and occupational therapists, speech language pathologists, medical social workers and physicians. Completely consolidating the Conditions of Participation for each of these disciplines blurs the important distinctions between them and why they each are needed. We recommend that the *Standard: Responsibilities of skilled professionals* remain in the proposed rule, but that specific tasks that do not fall into those categories be listed for each type of professional. For instance, the role of the medical social worker to assist the physician and other team members in understanding the significant social and emotional factors related to the patient's health problems is a unique duty of the social worker that should continue to be required under the proposed CoPs.

§484.80 Condition of participation: Home health aide services

§484.80 (a) Standard: Home health aide qualifications

§484.80 (a) (1)(ii) Proposed change:

~~A competency evaluation program that meets the requirements of paragraph (c) of this section~~

The training outlined in (b): *Standard: Content and duration of home health aide classroom and supervised practical training* is essential for a home health aide. While an aide may be able to successfully complete the tasks, that does not mean that he or she has the necessary knowledge to provide care and services in a way that best promotes a patient's quality of life and care. We do not believe, for instance, that it is possible to adequately assess through a competency evaluation a prospective aide's understanding of physical, emotional and developmental needs and ways to work with the populations served by the HHA or the need for privacy and respect. In our view, this knowledge is best provided and evaluated in a classroom setting.

§484.80 (a)(iii) Proposed change:

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, a state approved supplemental training in the clinical and communication skills and competencies necessary for working in the home environment and being a part of the interdisciplinary team in a home health setting, and is currently listed in good standing on the state nurse aide registry; or

In order to give workers greater flexibility, Consumer Voice agrees that certified nurse aides should qualify as home health aides, but only with additional training. We support PHI's comments that individuals who complete the nurse aide training and competency evaluation program may not receive training in

duties specific to home and community-based care. PHI points out that, while the duties are similar, the environments are different, and the home environment lacks the support of additional personnel, on-site supervision or, equipment available in a facility. Because the job of the home health aide is more independent by nature, she or he has a greater need for training in the clinical and communication skills and competencies necessary for working in the home environment and being a part of the interdisciplinary team in a home health setting. To address that need, we propose that a certified nurse aide must successfully complete supplemental training in order to qualify as a home health aide. The content of this training should be set by CMS and approved by the state.

§484.80 (b): Standard: content and duration of home health aide classroom and supervised practical training

§484.80 (b)(1) Proposed change:

*Classroom and supervised practical training must total at least **120** hours.*

Over the past few decades, the acuity level of individuals receiving home health care has increased. Home care is no longer just about talking to patients, giving baths and taking their blood pressure. Home health patients now include critically ill individuals who are being discharged from hospitals and sent home with a need for complex and skilled care. While it is questionable whether 75 hours has ever been sufficient, Consumer Voice believes it certainly is inadequate in today's home health care setting and urges CMS to adopt the 2008 Institute of Medicine recommendation to increase the training requirement to at least 120 hours.³

§484.80 (b)(3) Proposed change: (new provision)

Patients' rights

Home health aides, like other home health staff, must promote and protect patients' rights. To do so, they must be taught what those rights are, why they are important and how they can support patients in exercising their rights.

§484.80 (b)(3) Proposed change: (new provision)

Dementia care

The number of individuals with dementia is growing, and home health aides will increasingly be caring for patients with Alzheimer's disease or other dementias. Consumer Voice frequently hears from family members that far too often the aides assigned to care for their loved ones with dementia are ill-equipped and lack the necessary knowledge and skills. This can compromise the quality of care and be a safety risk for aides who do not understand how to work with

³ Retooling for an Aging America: Building the Health Care Workforce. Institute of Medicine report. 2008.

individuals with dementia. Including dementia-specific education as part of the classroom training will help aides better meet the needs of their patients.

§484.80 (d) Standard: In-service training:

§484.80 (d) Proposed change

Increase the number of hours of in-service training per year.

The number of in-service hours, like the hours of initial training, should be increased for the reasons noted above in (b)(1).

§484.80 (g) Home health assignments and duties

§484.80 (g)(4)

We strongly support this proposed new language that would require home health aides to be members of the interdisciplinary team. A home health aide is frequently the staff person who knows the patient the best. He or she can contribute important information and ideas and should be a full partner in the care planning and delivery process. We also appreciate that the proposed CoPs would require home health aides to report changes in the patient's condition to a registered nurse or another appropriate skilled professional.

§484.80(h) Standard: Supervision of home health aides

Consumer Voice is pleased that 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. The current regulations do not address this situation, which can result in continued problems. This new monitoring and oversight of aide performance would help ensure ongoing quality care.

§484.105 Condition of participation: Organization and administration of services

Consumer Voice commends CMS for requiring that an HHA must 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. This new language would greatly benefit patients since HHAs would have to meet a higher standard of care.

§484.105 (c) Standard: Clinical manager

Under current regulation, the administrator is permitted to also serve as the "supervising physician or registered nurse." Given the important responsibilities of these two positions, Consumer Voice does not believe that one person can adequately perform both roles. We support eliminating the current rule and replacing it with a clinical manager who is a physician or registered nurse, but not the administrator. We agree with CMS that a clinical manager is needed to manage the complex, interdisciplinary care of home health patients. The proposed duties of the clinical manager would expand upon those previously

required of the supervising physician or registered nurse and would improve the planning, coordination and implementation of patient care.

§484.105 Proposed change: (new provision)

The HHA must designate a physician to serve as medical director. The medical director is responsible for –

(i) Implementation of patient care policies; and

(ii) The coordination of medical care within the agency.

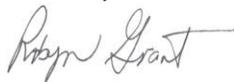
Consumer Voice urges CMS to require each HHA to have a medical director. Although the clinical manager may be a physician, the role of this physician is different from that of a medical director. A medical director would serve as a leader in helping HHAs to provide quality care. He or she would coordinate and oversee related practitioners; provide clinical leadership regarding application of current standards of practice for patient care and new or proposed treatments, practices, and approaches to care; and promote attainment of optimal patient outcomes.

§484.110 Condition of participation: Clinical records

Consumer Voice recommends strengthening this section through the addition of a requirement that a copy of the discharge or transfer summary must also be sent to the patient, representative (if any) and the caregiver. This would help ensure that patients know their health care status and their needs, allowing them to be more actively engaged in their care post-discharge/transfer and to monitor that they receive the necessary care during the transition period. In addition, we support AARP's recommendation to make the 2 calendar day requirement a same day delivery requirement and to make the 7 day requirement a 2 calendar day requirement. This change would better achieve CMS's goal of assuring that providers assuming responsibility for the care of discharged patients have timely information about the patients' recent care, services, and medications.

In conclusion, we thank you, once again, for the opportunity to provide comments and for your work on this important issue.

Sincerely,



Robyn Grant

Director of Public Policy and Advocacy