



FIGHTING SENIOR POVERTY THROUGH LAW

September 16, 2019

Seema Verma Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-3347-P P.O. Box 8010 Baltimore, Maryland 21244

Re: Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities CMS-3347-P

Submitted electronically: http://www.regulations.gov

Dear Administrator Verma:

The National Consumer Voice for Quality Long-Term Care (Consumer Voice) and Justice in Aging appreciate the opportunity to comment on the proposed changes to the federal nursing facility regulations. Consumer Voice is a national non-profit organization that advocates with and on behalf of long-term care consumers across care settings. Justice in Aging is a national, nonprofit legal advocacy organization that fights senior poverty through law.

We object to several of the proposed changes and offer suggestions that would improve quality of care and quality of life for America's nursing facility residents.

We believe that an emphasis on reducing "provider burden" is counterproductive. Nursing facility operators already have significant flexibility in how they provide care. To the extent that current regulatory language is specific and detailed, that level of specificity generally is necessary to ensure quality of care and quality of life.

An undue focus on "provider burden" can harm nursing facility residents. Many of the proposed revisions to the current regulations would undermine resident health and safety, not improve or enhance it.

Finally, residents need the protections in the current regulations more than ever before. Over the years, residents have become frailer and more dependent, and the majority have dementia. Increased physical and cognitive impairments mean residents need additional care and are more vulnerable to abuse and neglect. Any revisions to the regulations should only be made if they strengthen resident protections, not reduce them.

Our detailed comments and recommendations are outlined below.

PHYSICIAN INFORMATION (Section 483.10(d))

The current regulation requires a facility to "ensure that each resident remains informed" of the name and contact information for the attending physician and other primary care professionals. The Centers for Medicare & Medicaid Services (CMS) now claims that "remains informed" is too strict of a standard, and proposes changes to reduce this obligation, and also to eliminate the requirement to provide information regarding "other" health care professionals.

Because many health care professionals refuse to see patients at a nursing facility, a resident may experience frequent changes of physician or other professionals. This regulation is important to ensure that residents always know their health care professionals and those professionals' contact information.

We suggest changes to protect a resident's ability to contact a provider, but consistent in part with CMS's proposal, we do not use the term "remains informed." We believe that "remains informed" is vague and unclear, and agree with the specificity provided by indicating exactly when information about the attending physician would be provided. The conjunction "and" should be used rather than "or" to make sure that the facility has an obligation in each specified situation — at admission, after a change, and upon request. We suggest that the term "attending" physician replace "primary care" physician in order to be consistent with the rest of the regulation.

The regulations should also retain a resident's right to have the same access to contact information for "other" professionals (psychiatrists, therapists, etc.), and that the times when such information is provided should be similar. This allows residents to contact these health care professionals on their own without having to ask and possibly wait for the information. Our proposed language uses the term "health care professional," rather than "primary care professional," because people may think that the term "primary care professional" is limited to the attending physician. "Health care professional" is a more common and inclusive term.

Recommended Revision to CMS's Proposed Language

The facility must provide <u>the resident</u> with the primary care physician's name and contact information <u>of the attending physician and other health care professionals responsible for the</u> <u>resident's care</u> upon admission, with any change of such information, <u>and</u>or upon the resident's request.

GRIEVANCES (Section 483.10(j))

Distinction between Grievances and "General Feedback" (Subsection 483.10(j)(1)-(4))

We are concerned about how CMS proposes to distinguish between a grievance and "general feedback."

We understand that not every complaint expressed by a resident should be subject to a full grievance process. For instance, if a resident said, "My food is cold and needs to be hotter," at a meal, we would expect staff to take care of that issue right then, rather than referring it to a grievance process.

However, CMS's approach is problematic. CMS does not define or clarify the distinction between a grievance and general feedback in the proposed regulation. Instead, it indicates in the preamble that each facility would decide for itself what it considers to be a grievance: "it would be the facility's responsibility to include how they made this determination as to whether a comment was a grievance or general feedback as part of their grievance policy." (84 Federal Register at page 34,741) There would be little to prevent a facility from setting an extremely high bar for how it defines a "grievance." As a result, many significant resident concerns could be improperly classified as general feedback. This would decrease the attention the facility pays to these complaints and increase the probability that such complaints would be discounted, dismissed and/or unresolved – as was frequently the case before the regulations were revised in 2016. Furthermore, permitting facilities to limit what they must investigate and document might not give surveyors an accurate picture of the resident experience or allow them to identify patterns. It would also reduce the facility's ability to take systemic action through QAPI or other means to address problems.

Even assuming that "general feedback" were properly distinguished from a grievance, the proposed regulation would not establish any protection from retaliation for the resident giving general feedback. Under the proposed regulation, the protections against discrimination or reprisal apply only to grievances and not to general feedback.

Thus, our proposed language protects against retaliation whether the resident has given general feedback or made a grievance. Furthermore, for distinguishing between feedback and a grievance, we propose using the comparable standards in CMS's hospital guidance. Under that guidance, a "complaint" is classified as a "grievance" if it "cannot be resolved at the time of the complaint by staff present, is postponed for later resolution, requires investigation, and/or requires further actions for resolution." (CMS State Operations Manual, Appendix A (Survey Protocol, Regulations and Interpretive Guidelines for Hospitals (Interpretive Guidance for 42 C.F.R. § 482.13(a)(2))) Notably, this standard is consistent with CMS's preamble statement accompanying the proposed regulations "that general feedback or complaints stem from general issues that can typically be resolved by staff present at the time a concern is voiced, while grievances are more serious and generally require investigation into allegations regarding the quality of care." (84 Federal Register at page 34,741)

We recommend additional changes to subsection (j)(4). A facility's obligation to consider grievances should include all aspects of quality of care and quality of life, and certainly should not be limited to "the resident's rights contained in this paragraph." Also, a grievance policy should be distributed to all residents, and not just those who specifically request it. The biggest benefit of such a notice is to those residents who, but for the notice, would not have known anything about grievances or the existence of a grievance policy.

Recommended Revision to CMS's Proposed Language

(1) The resident has the right to <u>communicate complaints and</u>voice grievances to the facility or other agency or entity that hears <u>complaints and</u> grievances without discrimination or reprisal and without fear of discrimination or reprisal. Such <u>complaints and</u> grievances include those with respect to care and treatment which has been furnished as well as that which has not been furnished, the behavior of staff and of other residents; and other <u>complaints and grievances</u> regarding their LTC facility staythat differ from general feedback from residents or their resident representative.

(2) The resident has the right to and the facility must make prompt efforts to resolve <u>complaints and grievances the resident may have, in accordance with this paragraph (j)</u>.

(3) The facility must make information on how to file a grievance or complaint available to the resident. A grievance is a written complaint, or an oral complaint that cannot be resolved at the time of the complaint by staff present, is postponed for later resolution, is referred to other staff for later resolution, requires investigation, and/or requires further actions for resolution.

(4) The facility must establish a grievance policy to ensure the prompt resolution of all grievancesregarding the residents' rights contained in this paragraph. Upon request, <u>T</u>the provider must give a copy of the grievance policy to <u>each</u> the resident. The grievance policy must include:

Contact information for Grievance Process (Subsection (j)(4)(i))

One of the most important components of a grievance process is that residents and their representatives know with whom a grievance can be filed. Complaints that are not filed with the correct individual may be lost, mishandled and/or never investigated. Residents should also know who in the facility is overseeing the entire grievance process so they know whom to go to with questions or concerns about the procedures.

The title of "Grievance Official" makes it clear whom residents should turn to with their grievances. If the title is eliminated, as CMS is proposing, it is essential that the facility still be required to identify and provide contact information for the person in charge of the process, as well as the person with whom a grievance should be filed (who may or may not be the individual with responsibility for the grievance procedure).

Recommended Revision to CMS's Proposed Language

(i) Notifying resident individually or through postings in prominent locations throughout the facility of the right to file grievances orally (meaning spoken) or in writing; the right to file grievances anonymously; <u>the contact information of the individual who is</u> <u>responsible for overseeing the grievance process and, if different, the person with</u> whom a grievance can be filed, that is, his or her name, business address (mailing and

<u>email) and business phone number;</u> a reasonable expected time frame for completing the review of the grievance; the right to obtain a written decision regarding his or her grievance; and the contact information of independent entities with whom grievances may be filed, that is, the pertinent State agency, Quality Improvement Organization, State Survey Agency and State Long-Term Care Ombudsman program or protection and advocacy system;

Deletion of Specified Duties for Handling Grievances (Subsection 483.10(j)(4)(ii))

We oppose CMS's proposal to eliminate the specified duties of the staff members handling grievances. Even if a facility does not have one specified Grievance Official, the duties remain necessary. The duties specified in the current regulation are basic, reasonable and necessary components of complaint investigation and resolution processes. They are also very broad – leaving a great deal of flexibility to facilities. Even more important, the consumer and advocate experience is that duties that aren't specified are very frequently not carried out. This could mean that complaints are discounted, ignored or not properly handled. Without specific duties, facilities will be very uneven in how they handle complaints. Residents in nursing homes where complaints are not properly addressed may suffer because unresolved complaints can impact quality of care and quality of life.

Recommended Revision to CMS's Proposed Language

Identifying an individual who is responsible for overseeing the grievance process. <u>This</u> <u>process must receive and track grievances through to their conclusion; maintain</u> <u>confidentiality of all information associated with grievances, for example, the identity of the resident for those grievances submitted anonymously; issue written grievance decisions to the resident; and coordinate with state and federal agencies as necessary in light of specific allegations;</u>

Written Decision (Subsection 483.10(j)(4)(v))

We support maintaining the requirement to provide residents with a written decision regarding their grievance. A written decision ensures that residents know that their grievance was investigated and what has been done about it.

We object, however, to removing most of the language detailing what must be included in the written decision. Only requiring that the decision provide "pertinent findings, including but not limited to a summary of the findings or conclusions and any corrective action taken or to be taken by the facility as a result of the grievance," is not sufficient.

The current contents of the written decision provide residents with important information. Without a summary statement of the grievance, residents will not be sure their complaint was properly identified and understood; and without information about the steps taken to investigate the grievance, residents will not have assurance that their complaint was properly reviewed. Removing the date the grievance was received and the date the decision was issued removes provider accountability for responding to complaints in a timely manner.

Additionally, as noted above, our experience has long been that, in general, if it's not required, it's not done. CMS's statement in the preamble that "We expect that information, such as the date the grievance was received and a summary statement of the resident's grievance, is included as a standard practice to ensure that the written decision is complete and informative" (84 Federal Register at page 34,741) does not correspond to what we observe. Unless the specific contents of the notice are mandated, most facilities will provide only the bare minimum called for in the proposed rule, leaving residents with questions and inadequate knowledge about the response to their grievance. The specificity in the current requirements also helps ensure that consistent and complete responses are provided to individuals who file a grievance.

That being said, in the current regulation the duty to provide "a summary of the pertinent findings or conclusions regarding the resident's concern(s)" seems to include the duty to provide "a statement as to whether the grievance was confirmed or not confirmed." We believe that language regarding confirmation is unnecessary.

Recommended Revision to CMS's Proposed Language

Ensuring that all written grievance decisions include any pertinent information including but not limited to <u>the date the grievance was received</u>, a <u>summary statement of the</u> <u>resident's grievance</u>, the <u>steps taken to investigate the grievance</u>, a <u>summary of the</u> findings or conclusions, and any corrective action taken or to be taken by the facility as a result of the grievance, and the date on which the written decision was issued;

Maintaining Evidence (Subsection 483.10(j)(4)(vii))

We disagree with CMS's position that maintaining evidence related to grievances for three years is burdensome. Any documents concerning grievances will almost certainly be electronic. If not, handwritten documents can be scanned and become electronic. CMS itself noted in the 2016 preamble to the final regulations that "such evidence may be maintained electronically, rather than utilizing physical storage space." (81 Federal Register at page 68,724) Preserving records online requires little to no effort or cost. If computer space becomes a problem, facilities can transfer the information to separate storage.

Contrary to burdening facilities, maintaining records can help them. As CMS pointed out in the preamble to the final regulations, the evidence provides a record of grievance investigations and can serve as a valuable information resource for facilities. The documentation can indicate the types of problems they have had in the past, what was done to address them and if those efforts were successful. This can help facilities avoid similar grievances in the future or consider different problem resolution strategies if previous ones were not successful. CMS also noted that grievances may provide valuable input to a facility's QAPI program and that grievances are one likely source of data and feedback from residents and resident representatives. (81 Federal Register at page 68,724) Grievance records can also assist facilities in proving that they did indeed respond to a resident complaint in cases where that is called into question.

Moreover, retaining evidence of grievances can assist surveyors to identify chronic, repeat deficiencies that are harming residents. When problems are not identified, they are not addressed.

The major result of eliminating or modifying this provision would be to lessen providers' accountability – not their cost or burden.

Recommended Revision to CMS's Proposed Language

Maintaining evidence demonstrating the results of all grievances for a period of no less than 18 months <u>3 years</u> from the issuance of the grievance decision.

Notice of Transfer/Discharge (Section 483.15)

We agree with what appears to be CMS's intent: requiring that transfer/discharge notices be sent to the Long-Term Care Ombudsman, but not in the case of hospitalizations where the facility has every intention of accepting the resident back following the hospitalization.

One possible way to achieve this intention would be to make the necessary changes through CMS's Guidance to Surveyors (guidance) rather than through regulatory revision, since the current situation is the result of guidance. We offer proposed revisions to the guidance below, along with proposed revisions to the regulations. Our recommended framework is consistent with the current statement in the guidance that a "facility-initiated discharge" has occurred when "the facility makes a determination to not allow the resident to return." (Tag F623)

We see significant problems with CMS's proposed regulatory language. Referring to "involuntary" transfer/discharge is too limiting, because use of the term suggests that transfer/discharge notice is not required unless a resident actively objects. Also, it would be confusing for the regulations to refer to "facility-initiated involuntary" transfer/discharge in one subsection, while simply referring to transfer/discharge in the remainder of the subsections.

Furthermore, referring to situations where return is "expected" is too vague about who is doing the expecting and when the determination is made. Use of the passive voice leaves confusion over which party (facility, resident, hospital, etc.) is doing the expecting. Also, the current language is not clear as to when the party is expecting that the resident will return. To address these issues and provide more clarity, we suggest that an expectation to return be based upon the facility's written documentation that the facility intends for the resident to return.

In addition, we are concerned about the preamble's definition of a "facility-initiated" transfer or discharge: one that "the resident objects to, did not originate through a resident's verbal or written request, and/or is not in alignment with the resident's stated goals for care and preferences." (84 Federal Register at page 34,741) We recognize that this definition is currently used in the guidance, and suggest that it be removed. To be clear, we do not object to use of the term "facility-initiated" in the guidance but, as previously discussed, object to the use of "facility-initiated" in the regulations, and also object to the guidance's current definition of "facility-initiated." The definition has the following problems. Even if a resident is intimidated and does not "object," a transfer or discharge may well be

initiated by a facility. Also, the resident's "stated goals" in the medical record are irrelevant: a resident has the right to decide when he or she wants to leave the facility (subject to the facility's right to force transfer or discharge under section 483.15(c)). Finally, the "and/or" formulation is confusing – a facility might well argue (wrongly) that it has no obligations if even one of these factors is not present.

Recommended Revision to Guidance (F623)

Emergency Transfers -- When a resident is temporarily transferred on an emergency basis to an acute care facility, this type of transfer is considered to be a facility-initiated transfer and a notice of transfer must be provided to the resident and resident representative as soon as practicable, according to 42 CFR §483.15(c)(4)(ii)(D). Copies of notices for emergency transfers must also still be sent to the ombudsman, when the facility does not intend to allow the resident to return. The notice must be sent to the ombudsman as soon as the facility makes the decision that it does not intend to allow the resident to returnbut they may be sent when practicable, such as in a list of residents on a monthly basis.

Recommended Revision to CMS's Proposed Language

Notify the resident and the resident's representative(s) of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. For facility-initiated involuntary transfers or discharges, other than emergency transfers to an acute care facility when return is expected, At the same time, the facility must send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman. Notice to the ombudsman program is not required when the resident is transferred to an acute care facility, and the facility has documented in the resident's medical record that it intends that the resident return to the facility following the stay in the acute care facility.

NURSING STAFFING DATA (Section 483.35)

Currently, nursing facilities must retain daily nurse staffing data for at least 18 months. CMS proposes to reduce this minimum time to 15 months.

We request that CMS retain the current 18-month minimum. Since surveys by law may be separated by as much as 15 months, 18 months provides leeway if a survey is late. Also, nursing facilities face no particular difficulty in retaining information for an additional three months, given that the information likely is retained in an electronic format. We note that CMS has estimated the cost savings of this proposal as "minimal." (84 Federal Register at page 34,759) Indeed, even if data were kept by filing a piece of paper for each day, the "extra" three months would require retaining less than 100 additional pages.

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Recommended Revision to CMS's Proposed Language

Facility data retention requirements. The facility must maintain the posted daily nurse staffing data for a minimum of $\underline{18}$ $\underline{15}$ months, or as required by state law, whichever is greater.

PSYCHOTROPIC DRUGS (Section 483.45(e))

Current regulations allow antipsychotic drugs to be prescribed on a PRN (as-needed) basis only for 14 days, unless the physician "evaluates the resident for the appropriateness of that medication." CMS now is saying that this requirement is too limiting on facilities, and proposes to allow antipsychotics to be prescribed for an indefinite time period, if the physician documents the rationale for a specified extended duration, and the extended time is consistent with facility policy and with new regulations that set standards for such facility policies.

We disagree with CMS's proposed changes: use of antipsychotic drugs should not be made easier. These drugs generally come with "black box" warnings stating that they increase the risk of death in older adults with dementia. In fact, for several years CMS has coordinated a nationwide initiative to reduce nursing facilities' use of antipsychotics (the National Partnership to Improve Dementia Care). Furthermore, in CMS's Nursing Home Compare website, excessive use of antipsychotic medications is a quality measure indicative of low quality.

We recognize that CMS proposes to mandate that facilities establish PRN procedures, but we do not believe that any such facility procedures would be impactful enough to compensate for the other proposed changes. Notably, under a facility's policy, a PRN order for psychotropic drugs (including antipsychotics) could be reviewed as infrequently as only once every two months. (Proposed Section 483.45(e)(5)(ii)(A))

What <u>could</u> be impactful would be a regulation requiring informed consent by a resident or resident representative prior to administration of any psychotropic medication. Tellingly, CMS's proposed regulation refers only to "disclosure" of an order for antipsychotics, even though state law across the country affirms that medication administration, like any other medical intervention, requires the patient's consent.

To ensure that nursing facility residents are afforded the same rights as all other Americans, we propose a simple affirmation of the principle that administration of psychotropic medication requires informed consent. Our proposed language follows immediately below.

Recommended Revision to Section 483.45(e)(1)

Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record. <u>Psychotropic drugs shall be administered only with the written informed consent of the resident or resident representative, consistent with the healthcare decision-making rights of section 483.10(c). For consent to be considered</u>

<u>"informed," the resident and representative must be given accurate, understandable</u> information regarding the medication's benefits and risks.

Recommended Revision to CMS's Proposed Language for Section 483.45(e)(4)-(5)

(e)(4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in § 483.45(e)(5), 4if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, the order can be extended in accordance with facility policy if he or she must documents their his or her rationale in the resident's medical record and indicates the duration for the PRN order.

(5) <u>PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed</u> <u>unless the attending physician or prescribing practitioner evaluates the resident for the</u> <u>appropriateness of that medication.</u> It develops and maintains policies, standards, and procedures regarding the use of PRN orders for psychotropics, using recognized standards of practice, including the circumstances in which PRN orders for psychotropic drugs can be extended beyond 14 days. The policy must:

(i) Take into consideration the facility's resident population, the individual residents' needs for psychotropic drugs, and their access to physicians and other health care practitioners; and

(ii) Include, at a minimum, the following elements:

(A) Standards regarding the frequency with which the attending physician or the prescribing practitioner must review the PRN order. The frequency of PRN review must be no less than the frequency of the required physician visits as set forth at § 483.30(c).

(B) Documentation requirements regarding the diagnosis, indications for use, including nursing documentation describing the circumstances that support the administration of the medication, and justification for prolonged use.

(C) Disclosure requirements that the facility must make to the resident and his or her representative for when a resident is prescribed an anti-psychotic.

FOOD AND NUTRITION (Section 483.60(a)(2))

We have significant concerns about the proposed reduction in qualifications for the director of food and nutrition services. As CMS states, effective management and oversight of the food and nutrition service are vital to residents' safety and well-being. CMS further notes that for that very reason, standards are important for this position. (84 Federal Register at page 34,744)

Yet CMS now plans to reduce standards sharply, citing the complaints of facility operators "regarding the need for existing dietary staff, who are experienced in the duties of a dietary manager and currently operate in the position, to now obtain new or additional training to become qualified under the requirements." (84 Federal Register at page 34,744). Such a lowering of standards would degrade residents' nutrition and well-being. Two years or more years of experience as a director of food and nutrition services does not mean a person is adequately equipped for the position. Simply because someone has been performing a job doesn't mean they are doing it well or the way it should be done — they may not even be aware of what they don't know. The proposed alternative qualification, a "course of study," is extremely vague (how many courses constitute a "course of study?" How many hours would it entail?), and the required contents of this course of study are not sufficiently detailed.

We believe that any concerns about current staff should be addressed by phase-ins and/or grandfathering. The current regulations could be revised to allow for grandfathering current personnel into compliance, and applying the qualifications mandated in the October 2016 final rule to anyone hired after the publication date of the new final rule.

Recommended Revision to CMS's Proposed Language

(2) If a qualified dietitian or other clinically qualified nutrition professional is not employed full-time, the facility must designate a person to serve as the director of food and nutrition services who ----

(i) <u>For designations prior to the date on which this regulation is first published in the Federal Register:</u><u>The director of food and nutrition services is one who at a minimum</u>.
(A) Has two or more years of experience in the position of director of food and nutrition services in a nursing facility setting or;

(B) Has completed a course of study in food safety and management that includes topics integral to managing dietary operations such as, but not limited to, foodborne illness, sanitation procedures, and food purchasing/receiving.

(ii) For designations on or after the date on which this regulation is first published in the Federal Register:

(A) Is a certified dietary manager; or

(B) Is a certified food service manager, or

(C) Has similar national certification for food service management and safety from a national certifying body; or

(D) Has an associate's or higher degree in food service management or in hospitality, if the course study includes food service or restaurant management, from an accredited institution of higher learning.

(iii) (iii) The director of food and nutrition services must receive frequently scheduled consultation from a qualified dietitian or other clinically qualified nutrition professional. (iv) In States that have established standards for food service managers or dietary managers, the director of food and nutrition services must meet State requirements for food service managers or dietary managers, in addition to the standards set forth here.

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FACILITY ASSESSMENTS (Section 483.70(e))

The facility assessment is critically important because it can help address the number one problem voiced by residents – lack of adequate numbers of well-trained and competent staff, particularly nursing staff. In an assessment, the facility follows a formal process to determine its staffing needs. The assessment requirement also helps prevent facilities from making staffing decisions based solely on fiscal considerations — a growing concern with the increasing number of corporate, for-profit nursing homes. Because a facility's resident population is not static and staff turnover is high, reviewing and updating the facility assessment at least annually is essential. Otherwise, too much time will elapse between reviews and the staffing levels may not reflect a change in the acuity level, types of diseases, conditions, and physical and cognitive disabilities of a facility's residents. This places residents at risk of not receiving the care they need when they need it.

Recommended Revision to CMS's Proposed Language

The facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must, in coordination with §§483.35, 483.40(a), 483.60(a), and 483.75, utilize information collected under the facility assessment to inform policies and procedures; review and update that assessment, as necessary, and at least <u>annuallybiennially</u>; and review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment.

INFECTION CONTROL §483.80(b)(3)

There is little distinction between the current regulation requiring the Infection Preventionist (IP) to work "at least part-time," and the proposed requirement mandating that the IP have "sufficient time at the facility to achieve the objectives set forth in the facility's IPCP." Both are vague, unclear, and ineffective. In addition, "sufficient time" is troubling because we know from the provision for "sufficient staffing" that it is subjective and difficult to measure. (Section 483.35)

In the preamble, CMS reports that infection is the leading cause of morbidity and mortality among the country's 1.7 million nursing home residents and cites disturbing statistics (1.6-3.8 million infections each year in nursing facilities and almost 388,000 resident deaths each year from infections). In light of the extent to which residents are at risk of developing or dying of an infection, we urge CMS to be more specific about the amount of time the IP should work.

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Consumer Voice and Justice in Aging thank CMS for its consideration of these comments.

Sincerely,

In Smetanka

Lori Smetanka Executive Director, Consumer Voice

Roy Groat

Robyn Grant Directory of Public Policy & Advocacy, Consumer Voice

Jennifer Goldberg Deputy Director, Justice in Aging

Eric Carlson Directing Attorney, Justice in Aging