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October 13, 2015

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3260-P
Baltimore, MD 21244

Re: File Code CMS-3260-P (submitted electronically)

Administrator Slavitt:

The American Health Care Association and National Center for Assisted Living (AHCA/NCAL) represent more than 12,000 non-profit and proprietary skilled nursing centers, assisted living communities, sub-acute centers and homes for individuals with intellectual and developmental disabilities. By delivering solutions for quality care, AHCA/NCAL aims to improve the lives of the millions of frail, elderly and individuals with disabilities who receive long term or post-acute care in our member facilities each day.

AHCA appreciates the opportunity to comment on the proposed rule *"Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities."* We concur with the Centers for Medicare & Medicaid Services (CMS) that updating the Requirements of Participation is necessary to reflect current standards of practice. While many of the updates/changes are positive, AHCA has concerns with some of the approaches that CMS has proposed. Following are fundamental concerns, general comments, responses to specific questions or solicitations for comments posed by CMS in the proposed rule, and comments to specific provisions of the proposed rule including, when appropriate, recommended modifications to the proposed rule.

The American Health Care Association and National Center for Assisted Living (AHCA/NCAL) represent more than 12,000 non-profit and proprietary skilled nursing centers, assisted living communities, sub-acute centers and homes for individuals with intellectual and developmental disabilities. By delivering solutions for quality care, AHCA/NCAL aims to improve the lives of the millions of frail, elderly and individuals with disabilities who receive long term or post-acute care in our member facilities each day.

Fundamental Concerns

1. AHCA believes that implementation of this proposed rule must occur on a staggered basis over a period of five years.
    a. Some provisions have already been incorporated into the current survey process through CMS Survey & Certification Memoranda. These provisions can be implemented one year following adoption of the final rule: §483.12 (b) (5) – reporting the suspicion of a crime, for those centers that receive at least $10,000 in Federal funds under the Social Security Act during the preceding year; §483.95(g)(2) – dementia management and resident abuse prevention training; §483.25(d)(8) – assisted nutrition and hydration; §483.25((a)(3) – cardiopulmonary resuscitation; §483.60(i)(1)(ii)(iii) and §483.60(i)(3) – under food safety requirements; and §483.25 (d)(13) – pain management.
    b. The new provisions/requirements in this proposed rule must be implemented more slowly and deliberately to permit providers and CMS to develop adequate systems and guidance for implementation and enforcement. State and federal surveyors must also be thoroughly trained and demonstrate competence in understanding and surveying to the new requirements. We will address these proposed provisions along with the recommended implementation time frame later in these comments.

2. AHCA strongly supports Quality Assurance and Performance Improvement (QAPI) and believe this is a key approach and process that when implemented and utilized by nursing centers will improve quality care to residents and patients of nursing centers.
    a. It is critical that QAPI documentation receives privilege protection. Without such protection, a candid and thorough review of identified concerns and efforts to improve is unlikely to occur. The proposal to show documentation to surveyors exceeds the statutory requirement on which this regulation is based. Further, we are concerned that as proposed the rule fails to protect quality assurance activities from disclosure pursuant to existing statutory protections for the quality assurance privilege (42 U.S.C. §§1395i-3(b)(1)(B) and1396r(b)(1)(B)). We will further discuss these concerns in the comments below related to proposed 42 C.F.R. §483.75.

3. CMS proposes to add a new subsection (n) to 42 C.F.R. § 483.70 that would, for the first time in the 50-year history of the Medicare and Medicaid programs, limit the exercise of federal arbitration rights belonging to nursing centers, as well as their residents. CMS also solicited comments on whether it should ban the use of such agreements altogether.

    AHCA strongly opposes CMS's arbitration-related proposals and is submitting a separate comment letter to underscore the importance of this issue to the entire long-term care profession. As outlined in AHCA's separate comment letter, CMS's arbitration-related proposal should be withdrawn for three independent

reasons: (1) the proposals exceed CMS's statutory authority; (2) the proposals are not necessary to protect resident health and safety; and (3) many of the stated factual and legal grounds for the proposals are incorrect.

4. The proposed rule reflects a change in the way the Requirements are currently written. Specifically, the design of the proposed rule is very similar to the approach taken in Conditions of Participation for other Medicare-certified providers. AHCA requests additional clarification about CMS's reason for this change. In addition, AHCA believes if CMS's intent is to change the Requirements approach to a Conditions approach that there must be a commitment to implement enforcement processes similar to the way Conditions are enforced. Following is an excerpt which further explains the approach we are recommending. This is taken from the State Operations Manual, Appendix A-Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, beginning on Page 19 of the on-line version. [emphasis added]

> **Determining the Severity of Deficiencies**
> The regulations at 42 CFR 488.26 state, "The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage, depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition." When noncompliance with a condition of participation is noted, the determination of whether a lack of compliance is at the **Standard or Condition level depends upon the nature (how severe, how dangerous, how critical, etc.) and extent (how prevalent, how many, how pervasive, how often, etc.) of the lack of compliance.** The cited level of the noncompliance is determined by the interrelationship between the nature and extent of the noncompliance. **A deficiency at the Condition level may be due to noncompliance with requirements in a single standard or several standards within the condition or with requirements of noncompliance with a single part (tag) representing a severe or critical health or safety breach.** Even a seemingly small breach in critical actions or at critical times can kill or severely injure a patient, and represents a critical or severe health or safety threat. **A deficiency is at the Standard level when there is noncompliance with any single requirement or several requirements within a particular standard that are not of such character as to substantially limit a facility's capacity to furnish adequate care, or which would not jeopardize or adversely affect the health or safety of patients if the deficient practice recurred.**
>
> When a deficient practice (noncompliance) is determined to have taken place prior to the survey and the hospital states that it has corrected the deficient practice/issue (noncompliance), issues for the survey team to consider would include: • Is the corrective action superficial or inadequate, or is the corrective action adequate and systemic? • Has the hospital

implemented the corrective intervention(s) or action(s)? • Has the hospital taken a QAPI approach to the corrective action to ensure monitoring, tracking and sustainability? The survey team uses their judgment to determine if any action(s) taken by the hospital prior to the survey is sufficient to correct the noncompliance and to prevent the deficient practice from continuing or recurring. If the deficient practice is corrected prior to the survey, do not cite noncompliance. However, if the noncompliance with any requirements is noted during the survey, even when the hospital corrects the noncompliance during the survey, cite noncompliance. All noted noncompliance must be cited even when corrected on site during the survey. Citing noncompliance at the appropriate level is important to the integrity of the survey process. **Citing too high a level is unfair to the hospital.** Citing noncompliance at a level below the noted degree and manner of the noncompliance does not ensure that the hospital will develop acceptable plans of correction and implement corrective actions, and does not depict accurately whether the care provided adversely affects the health and safety of patients; and continued deficient practices may lead to adverse patient outcomes such as injury or death. *(All emphases added.)*

Further, in order to achieve the goal of the IMPACT Act, which requires comparison of quality and other criteria across post-acute care settings, it is important that all post-acute care providers are judged similarly. This requires all post-acute care providers to be held to either "Conditions of Participation" or "Requirements of Participation." AHCA recommends CMS develop either "Conditions of Participation" or "Requirements of Participation" for all post-acute care providers and enforce them consistently across all post-acute care settings.

Our general and more detailed comments follow. Thank you in advance for your serious consideration of the issues we raise and our associated recommendations.

Sincerely,

David Gifford, MD, MPH

General Comments

- AHCA supports the concept of person-centered care that CMS has incorporated into this proposed rule. We do, however, make recommendations related to certain proposals that do not adequately address the balance of "person-centered care" with the safety and needs of all residents as well as staff, in the nursing center.

- We also appreciate that CMS acknowledges and incorporates the full scope of practice for non-physician practitioners related to actions that were formerly restricted to physicians only.

- The proposed rule has incorporated extensive language related to mental health services for patients. In addition, a new section has been added to the proposed rule related to "Behavioral Health Services." There are certain terms utilized that are not defined, and a search of various websites does not provide consistent definitions for these terms. Further, CMS references "behavioral health and mental illness." CMS must clearly define the terms "behavioral health", "behavioral health staff", and "qualified mental health professional". Without adequate definitions and description of such services, nursing centers and surveyors are left to their own subjective interpretations of these terms and CMS's expectations. **AHCA requests CMS to clearly define these terms including descriptions of services and activities expected.**

- The propose rule uses the term "cultural competency" in several places yet no definition is provided. Additionally, the phrase is not presented consistently: a hyphen is used between the words in some instances and not in others. **CMS must define this term in order for providers and surveyors to clearly understand the expectation of CMS and how the expectation will be met to achieve compliance with the requirement.**

- AHCA agrees that mental health care and services are integral to the goal of assuring the highest practicable well-being for these individuals. However, any discussion of existing mental health services for long-term care residents and proposals to enhance or improve these services must be considered with an understanding of the history, structure, and function of nursing centers.

  Preadmission screening and resident review (PASRR) as implemented under the OBRA '87 provisions was intended to **prevent** the inappropriate placement of individuals with mental illness and intellectual disabilities in nursing centers. Numerous provisions contained in this proposed rule regarding residents or potential residents with mental illness can be construed to contradict or confuse the intent of the PASRR provisions. In addition to the purposed new section "Behavioral Health Services," CMS makes numerous references to mental health

care and services related to resident assessment, and special rehabilitative services.

The statutory definitions of skilled nursing facility (SNF) and nursing facility (NF) (§1861(j); §1905(c) of the SSA) are clearly separate and distinct from the definitions of both Institutions for Mental Diseases (IMDs) and Institutions for Individuals with Intellectual Disabilities (IIDs). The primary focus of the regulatory design for SNFs/NFs was based on meeting the nursing and/or medical needs of residents. We have come a long way from the initial concepts to approaching nursing center care and services from a perspective far more holistic and person-centered, encompassing quality of life as well as quality of care. However, since it is also true that the need for clinical care and support continues to drive eligibility for admission to a nursing center, the extent to which mental health services can and should be provided within the context of that setting must be considered.

We recognize the intent of the proposed Behavioral Health requirements to enhance training and qualifications (specific comments on that section are below). These provisions notwithstanding, nursing homes, as defined in the SSA, will continue to generally lack capability in terms of specialized staffing, access to resources and specialized care, and the overall character of their populations, to manage many of the behaviors and manifestations that may accompany active, major, and/or severe mental illness, and/or to provide optimal or even adequate response to individuals who require long-term and intensive psychotherapy.

The provision of mental health services under the Medicaid Program is also directly impacted by federal policy that prohibits federal financial participation (FFP) to centers for services rendered in nursing homes that CMS finds qualify as Institutions for Mental Diseases (IMDs). CMS ['HCFA'] Guidelines for Making IMD Determinations (State Medicaid Manual; Chapter 4; Sect. 4390) sets out 10 criteria for whether the "overall character" of a facility is that it "is established or maintained primarily for the care and treatment of individuals with mental diseases." One criterion is particularly critical to the provision of mental health services in Medicaid-certified nursing homes. The '50%' rule categorizes the home as an IMD if more than half of its residents are determined to have mental diseases that require inpatient treatment. In the past, this rule served to inhibit the development and provision of services to residents since centers could never be sure what type of programs would be considered within the boundaries of inpatient care for mental illness. Similarly, while the guidelines specifically exempt persons "…with senility or organic brain syndrome…" from this classification system, a qualifier advises that these diagnoses will not be considered mental diseases "…if the facility is appropriately treating the patients by providing only general nursing care…" Finally, there is the criterion that categorizes an IMD by the fact that "…an unusually large portion of staff has specialized psychiatric or psychological training…"

We agree that mental health services must be considered a necessary component to meeting the total needs of nursing center residents, including those individuals with physical illnesses who may have had or who develop associated psychiatric, emotional, or behavioral conditions. However, these proposed changes seem to suggest that nursing centers are an appropriate setting in which to care for individuals with serious mental illness. One serious unintended consequence could be housing frail elderly individuals with dementia along with individuals with serious mental illness: a recipe for disaster.

AHCA Recommendation: Nursing centers are not the appropriate setting in which to meet the needs of those individuals for whom the diagnosis of mental illness is the primary and dominant focus of their need for care. As settings primarily designed and intended to serve the frail and elderly, or those recovering from an acute health/medical episode and requiring rehabilitation, nursing centers are largely unequipped to serve and meet the needs of persons who are acutely and/or chronically mentally ill. <u>Expectations regarding the degree of mental health intervention that can be offered must be balanced against facilities' ability to provide the services and the possible outcomes for the respective individuals /residents and the remaining population.</u>

Should CMS decide to maintain all the proposed language and expectations related to "mental health services" in this final rule, CMS must make changes to: IMD definitions and policies, reimbursement policies, and FFP policies. Consideration may also need to be given to the implications for the use of PASRR.

- AHCA is a strong proponent of Quality Assurance and Performance Improvement (QAPI) and has been encouraging our members to begin implementing QAPI, utilizing the tools and information on both the CMS website and AHCA's website.

  The proposed requirements, however, are very detailed and significantly exceed the QAPI Conditions of Participation for other health care providers. It is unclear why CMS is proposing a level of detail greater than for other providers.

  Additionally, the CMS QAPI pilot demonstrated that participating SNFs could not implement all the proposed components in the RoP during the one year pilot. As such, putting in this level of detail is likely to result in all SNFs/NFs being noncompliant and 100% of SNFs/NFs being found noncompliant potentially triggering a termination process. This will create the unintended consequence of either closing SNFs/NFs or accepting plans of corrections inconsistent with the original intent of QAPI so that SNFs/NFs do not get terminated. This will slow the adoption of QAPI or worse, result in QAPI programs that are inconsistent with the original intent and the value a robust QAPI plan and program can bring to the operations of a SNF.

Additionally, we are concerned that as proposed the rule fails to protect quality assurance activities from disclosure pursuant to existing statutory protections for the quality assurance privilege (42 U.S.C. § 1395i–3(b)(1)(B) and 42 U.S.C. § 1396r(b)(1)(B)). Below we provide additional comments and recommendations related to the QAPI provisions of the proposed rule.

- The preamble of the proposed rule proposes to clarify that when "*the resident who has been adjudged incompetent under the laws of a state retains the right to exercise those rights not addressed by a court order, that the resident representative can only exercise the rights that devolve to them as a result of the court order, that the resident's wishes and preferences should continue to be considered, and that the resident should continue to be involved in the care planning process to the extent practicable, as the resident is at the center of the care team. We believe that it is important for a resident who has been adjudicated incompetent to be treated with respect and dignity and to continue to make those decisions that are appropriate for him or her to make. Continuing to honor these residents' preferences and involving them in care planning will improve both quality of life and quality of care, resulting in better outcomes*." AHCA agrees that residents should retain as many rights as possible and their preferences be elicited and honored whenever possible. However, as written, this clarification will likely add confusion and is internally inconsistent.

  The court order for scope of decisions is not always clearly defined. In addition, the distinction between medical care decisions in the context of frail elderly in nursing homes and personal decisions regarding quality of life often is not clear. Therefore when is it appropriate for the court appointed individual to make decisions and when it is appropriate for the resident representative can be confusing. Also the court appointed guardian is to make decisions in the best interest of the resident, which includes seeking input from family members, friends, and other individuals who know the resident. We understand CMS to be stating that the court-appointed guardian is the resident representative.

- It is important to note that the median risk-adjusted stay for nursing homes in Quarter 3, 2014 was 26.1 days and the risk adjusted discharge to community rate for the same timeframe is 59.9%. This reflects the primary type of residents/patients that are in nursing centers in 2015: individuals with short-stay, rehabilitation needs who are then discharged to the community. Many of the proposed changes to the Requirements fail to take this into consideration.

- The proposed rule contains significant and substantive changes to the Requirements of Participation. **AHCA recommends that, prior to implementation of the new Requirements, CMS ensure all CMS federal and state surveyors are thoroughly trained about the substance of these new**

Requirements as well as current professional standards of care for all professionals working in nursing centers. Surveyors must also demonstrate competence in all these areas, as shown through testing and monitoring.

- We have serious concerns about the proposals related to "competencies" of staff. CMS provides no indication of how they will survey and determine that a center's staff is competent. Without adequate description and definition it will be entirely the subjective decision of each surveyor as to whether staff meet "competency." Additionally, nursing centers will have to invest significant resources (both labor and financial) to assess each staff person's competency. CMS must provide more clarity about its expectations.

- The proposed rule seems to be inconsistent with requirements of the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act. CMS must incorporate relevant sections of these two acts, particularly as it relates to those individuals who may review resident's/patient's records and how such information is shared.

- In February, 2015 the Administration for Community Living and the Administration on Aging released a final rule related to provisions for Long Term Care Ombudsman in the Older American's Act to be effective on July 1, 2016. This final rule limits the Ombudsman's access to certain administrative records of nursing facilities and also requires that a resident/patient must give permission for Ombudsman to review their clinical records. CMS must maintain consistency with these limitations and requirements in the Requirements of Participation. **AHCA recommends CMS carefully review the final rule for Long Term Care Ombudsman and provide consistency between that rule and the final rule reflecting changes to the Requirements of Participation.**

- The proposed rule references electronic health records (EHR) and the need for interoperability between health care providers. AHCA and its members recognize the importance of EHR and some providers are already using EHR within their nursing centers. We strongly encourage CMS to work with us to advocate funding from Congress to assist in the implementation of EHR in all nursing centers, consistent with the incentive funding that has been offered to many other health care providers.

- The proposed rule does not take into consideration the dramatic changes occurring in the provision of health care, specifically managed care for Medicare and Medicaid beneficiaries. Managed care plans often have requirements that will impact care of Medicare and Medicaid beneficiaries related to "care plans", "discharge plans", and other areas that are likely in conflict with expectations in this proposed rule. AHCA is already hearing from our members of conflicts between CMS SNF/NF regulatory requirements and managed care requirements

for SNFs/NFs caring for beneficiaries in managed care plans. It is essential that CMS work collaboratively among its various divisions to maintain consistency between the Requirements of Participation and requirements of payer sources.

Responses to Specific Questions Posed by CMS or Solicitation for Comments in the Preamble

- Page 42177, F.R. 80, No. 136 – *CMS solicits comments on how the requirements could acknowledge the special needs of short stay residents.*
    - Many nursing centers focus their care specifically for individuals who are rehabilitating from a hospital stay. The average length of stay for this group of individuals is 28 days. Two examples that fail to acknowledge the special needs of short stay residents are:
        - The likelihood of short stay patients and their families wanting a robust resident or family council is very low or non-existent. **AHCA recommends CMS acknowledge this in the Requirements by specifying that the need for and creation of a resident or family council is generated by the residents or families, based on their needs and desires.**
    - The ability for a center to address the right to select a roommate for short-stay residents is likely to be very difficult to accomplish. **AHCA recommends CMS acknowledge this in the Requirements by specifying that this resident right may not be possible for a center to accomplish for short stay patients.**
- Page 42177, F.R. 80, No. 136 – *CMS seeks comment on a number of issues related to the finalization and implementation of the proposed rule: Unintended consequences and unanticipated risks to SNF and NF residents, the involvement of stakeholders in developing sub-regulatory requirements and in implementing changes, and the timeline for proposed implementation following finalization of the rule.*
    - As mentioned previously, specific recommendations related to finalization and implementation of the proposed rule will be addressed within the comments to specific sections of the rule.
    - It is imperative that CMS develop sub-regulatory text with active and meaningful involvement of all stakeholders. AHCA has serious concerns about the approach CMS has been recently taking in which relatively brief conference calls with numerous callers (too numerous to allow effective discussion) to allegedly engage stakeholders in development of critical implementation issues. This is not sufficient stakeholder engagement. **AHCA recommends multiple in-person meetings convened by CMS with representatives of relevant stakeholders including consumers, providers, and regulators, to have serious discussions and obtain meaningful comments in order to develop sub-regulatory text for implementation of these updated Requirements of Participation.**

- Page 42189, F.R. 80, No. 136 – *CMS requests comment on proposed provisions and proposed implementation of section 1150B of the Act.[related to reporting the reasonable suspicion of a crime]*
    - **AHCA concurs with the approach CMS has taken to implement the provisions of section 1150B of the Social Security Act.** In fact, following issuance of the Survey and Certification Letter dated June 17, 2011, AHCA developed tools and materials for members' use to achieve compliance with the language of the Act.
- Page 42191, F.R. 80, No. 136 – *CMS solicits comment on both the information elements CMS is requiring and the time frame for transmission of the required information.*
    - **AHCA provides specific detailed comments about the transfer or discharge documentation later in this letter.**
- Page 42197, F.R. 80, No. 136 – *CMS solicits comments on the current requirements [for director of activities program] to determine if they remain appropriate and, if no, what the evidence is for changing the current requirements for this position and what stakeholders would recommend as minimum requirements for this position.*
    - **AHCA finds the current requirements for this position are adequate.** Additionally, the training requirements for all staff will provide additional education/development opportunities for the directors of activity programs.
- Page 42201, F.R. 80, No. 136 – *CMS welcomes comments on all of these options [establishing minimum nurse hours per resident day, establishing minimum nurse to resident ratios, requiring that an RN be present in every facility either 24 hours a day or 16 hours a day, and requiring that an RN be on-call whenever an RN was not present in the facility]. CMS specifically invites comments on the costs of mandating a 24 hour RN presence; the benefits of a mandatory 24 hour RN presence, including cost savings and improved resident outcomes, as well as any unintended consequences of implementing this requirement. CMS welcomes evidence of appropriate thresholds for minimum staffing requirements (for both nurses and direct care workers) and evidence of the actual cost of implementing recommended thresholds, including taking into account current staffing levels as well as projected savings from reduced hospitalizations and other adverse events.*

    - Costs of mandating a 24 hour RN presence should be estimated as at least triple cost increase in RN staffing because a 24 hour RN mandate would require a triple increase of the current requirement of 8 hours per day, which also offers waiver provision.

      Supporting literature from ANA Safe Staffing Literature Review, August 2014:

        - Nurse staffing is a complex issue with no easy quick solution. A literature review concluded that support, not regulation, is needed for safe nurse-patient ratios. There are many variables that affect

staffing decisions and the RN needs to be informed and take an active role in determining the best staffing ratio that promotes patient safety.
Hertel, R. (2012). Regulating patient staffing: A complex issue. *Med-Surg Matters*, 21(1), 3-7.

- A mandatory nurse-patient ratio takes away flexibility and negatively impacts the health care delivery system. The American Organization of Nurse Executives (AONE) made a formal statement that mandated staffing ratios will increase stress an overburdened health care system. AONE supports general standards when viewing the workload for nurses. Staffing ratios could be detrimental to nurses as organization may need to lay off ancillary staff in order to meet mandated ratios, leading to an increased workload for the RN.
  Rajecki, R. (2009) Mandatory staffing ratios: Boon or bane? *RN*, 72 (1), 22-25.

  There is insufficient data to project savings from 24 hour RN presence effect on reducing hospitalizations and other adverse events. Claims that project savings from mandating 24 hour RN presence assume that staffing levels are a sole or primary factor in reducing hospitalizations or other adverse events. Experience tells us the contrary. More or less staff does not necessarily equate to better quality outcomes.

  Supporting literature from ANA Safe Staffing Literature Review, August 2014:

  - A number of studies have not supported mandatory nurse-patient ratios. A report by the California Nursing Outcomes Coalition (2005) documented no statistically significant change in patient safety and quality outcomes such as decreased falls or the prevalence of pressure ulcers. Hertel, R. (2012). Regulating patient staffing: A complex issues. *Med-Surg Matters*, 21(1), 3-7.

  Nursing centers are complex environments with multiple dynamic factors that continuously interact and produce various results. The spirit of QAPI reflects the critical approach of comprehensive system and process changes. These changes may include staffing adjustments, but certainly not as a sole factor. CMS should be consistent in using QAPI principles as basis for regulatory interventions and move away from narrow, task-centered approaches that are reactionary.

In addition, there is a significant variety of nursing centers across the country with varied acuity, resident/patient populations, specialty services, and more. Some nursing centers primarily provide long term care services, while others primarily provide post-acute care services. These can be widely different bases of resident/patient need. Applying a "one size fits all" mandate of RN staffing level beyond the current requirements is neither appropriate nor reasonable to justify as a necessary or effective intervention.

AHCA opposes CMS imposing an increase in RN staffing requirements. Any requirements beyond current federal regulation must be left to the state regulatory agencies to define as states have done widely for years, based on the resident/patient characteristics and the specific circumstances unique to each state.

- Page 42201, F.R. 80, No. 136 – *"CMS invites comments on whether this proposed approach can reasonably be expected to enable facilities to determine and provide adequate levels of staffing to meet the needs of each resident".*
  - It is unclear what CMS envisions as a facility assessment or what evidence CMS used to support the validity of this proposed requirement. It is also unclear how CMS expects to see information from that assessment applied in center operations and further how surveyors would interpret the information in the facility assessment and use it to determine compliance.

    Nursing centers use multiple sources of data including the information CMS lists for the facility assessment (number of residents, resident acuity, diagnoses and care needs per care plan) in various ways to inform operational decisions. For example, the information CMS lists in the proposed facility assessment is currently used by nursing centers when developing care assignments for nurses and nurse aides which informs the number, type and skill of staff required.

    The needs of a nursing center can change on a day-to-day basis as patients/residents leave the center and new individuals move in. In addition, as patient/resident health status changes, the needs of the center will change. This approach, while acknowledging that the assessment must be updated as necessary, creates an incredibly burdensome task each time the patient/resident population changes.

    Each nursing center is a unique organization with certain organizational values, goals, experiences and other factors that drive how an organization operates. Organizational decisions and operational approaches should not be specifically directed or managed by CMS. This is contradictory to the spirit of QAPI where the life of an organization's operations is shaped by

the staff, residents, governing body, and other parties. Additional regulation only adds unnecessary complexity and burden which further detracts nursing centers from improving organizational performance to benefit the needs of the individuals who are served by the center.
AHCA opposes adoption of this proposed requirement. ACHA recommends CMS form a stakeholder workgroup to meet in person and explore the potential use of a "facility assessment" and discuss and consider alternate approaches. In addition, the stakeholder workgroup must discuss the potential unintended negative outcomes that may result from putting such a detailed assessment in the Requirements of Participation, and must determine a realistic implementation timeline. In order to begin this discussion, CMS must:

1) **Provide clarification about what CMS envisions for a facility assessment; and**
2) **Provide evidence for the value of proposing this facility assessment in the Requirements of Participation; and**
3) **Provide evidence-based models of facility assessment and process.**

- Page 42201, F.R. 80, No. 136 – *CMS solicits comments on whether CMS should consider adopting one of these or other approaches in determining adequate direct care staffing. We invite information regarding research on these approaches which indicate an association of a particular approach or approaches and the quality of care and/or quality of life outcomes experienced by residents, as well as any efficiency that might be realized through such approaches.*
    - Current regulations exist on both federal and state levels that address appropriate staffing levels to meet the needs of the residents. Further federal regulation would add additional and unnecessary regulatory burden, raise conflict between federal and state requirements and not contribute to improved quality of care.

      As stated above, there is significant variety of nursing centers across the country with varied acuity, resident/patient populations, specialty services, and more. Some nursing centers primarily provide long term care services, while others primarily provide post-acute care services. These can be widely different bases of resident/patient need. Applying a "one size fits all" mandate of staffing level beyond current the requirement is neither appropriate nor reasonable to justify as a necessary or effective intervention.
      AHCA supports retaining the current provisions related to staffing requirements. As mentioned previously, any requirements beyond current federal regulation must be left to the state regulatory agencies to define as states have done widely for years, based on the

resident/patient characteristics and the specific circumstances unique to each state.

- Page 42204, F.R. 80, No. 136 – *CMS specifically solicits comments on this definition [of psychotropic medications] and the types of drugs that should be included.* AND
- Page 42204, F.R. 80, No. 136 - *CMS appreciates comments on the use of PRN orders for these medications[psychotropics]and the proposal to limit PRN prescriptions for these drugs to 48 hours unless the resident's primary care provider provides a rationale for the continuation of the PRN order in the resident's clinical record.*

    - AHCA has concerns about the unintended impact and harm the proposed requirements related to the use of psychotropic drugs will have on individuals receiving care in the SNF and NF. The proposed changes (cited below), expands current regulations related to antipsychotics to any psychotropic and adds requirements about the PRN use of this class of medications.

      As written, the requirements appear to state CMS's position that the default practice for any psychotropic, regardless of diagnosis, is to not be used, and if used is subject to gradual dose reductions or to discontinue these medications and used for behavioral interventions and to not be prescribed for PRN use. This "default" practice may be applicable to antipsychotic use among individuals with dementia, but does not make sense for the proposed definition of psychotropic medications applying to all residents/patients. While the proposed requirements provide for documentation about the indication of these medications when prescribed for routine or PRN use, this requirement also supposes that any psychotropic started prior to admission to the SNF is appropriate and does not require the documentation but that all of them need a GRD along with behavioral intervention unless contraindicated. Thus, the default position is to not prescribe or withdraw patients off of these medications. However, this means anyone with depression who is stable, anyone with schizophrenia or bi-polar disorder must have GDR and behavior interventions, which in nearly all cases would be contra-indicated. It is unclear, why the default intention of this section would not apply in most situations. Thus this section of the RoP will dramatically increase the need for physician documentation in many circumstances of the drug use, since it will not apply. However, whenever such required documentation is lacking, even if unintentional, it will result in a SNF being out of compliance with the RoP as currently written. This noncompliance triggers a cascading sequence of penalties and time frames to correct. All

of which takes time and resources away from patient care. However, of greatest concern is the chilling effect these requirements will have on physician prescribing of these classes of medications, and therefore the unintended impact of patients needing these medications and not receiving them. This is of particular concern given for patients with chronic pain requiring opioids for management. As written, SNFs must attempt GDR and can't have PRN orders exceeding 48 hours to help address and provide appropriate intervention for patients with pain.

Even more concerning is the last category of psychotropic medication, defined as "*Any other drug that results in effects similar to the drugs listed in paragraphs (c) (3)(i)through (v) of this section affects brain activities associated with mental processes and behavior*" (that is, "*any drug that affects brain activities associated with mental processes and behavior*"). Nearly all medications including NSAIDs, beta-blockers, eye drops for glaucoma, anti -seizure medications, and anti-Parkinson medications meet this definition. As such, patients with pain needing PRN NSAIDs, patients with cardiac conditions and high blood pressure needing beta-blockers, glaucoma, seizure disorders, and Parkinson's disease all must now have extensive documentation added to justify the continued use or PRN use of medications for FDA- approved conditions. By taking the default position that these medications should not be used on a regular or PRN schedule or be subject to gradual dose reduction, will result in harm to patients either by providers not using these medications or unintentionally lacking documentation resulting in penalties to SNFs for noncompliance. Even missing documentation for one patient and one medication will result in the SNF potentially being on a termination track from Medicare and Medicaid, since these are being included in requirements of participation with strict language about their use.

Additionally, as written, there is absolutely no flexibility in enforcement or when drugs within a class do not meet the intended goal of this section. For example, as written, Compazine, a medication used exclusively for nausea and vomiting (frequently as a PRN order) would be captured by the current definition. As written, this means Compazine is included in the MDS definition of antipsychotics, which will inflate the quality measure definition, when Compazine is not used for individuals with schizophrenia (a use of this drug that would be excluded when calculating the quality measure).

AHCA recommends this section be rewritten to specify the goal and purpose for the use of such medications. Subsequently, define the classes of mediations, along with exceptions in interpretive guidance. Options to consider, include: 1) delete section "§483.45 (e) Psychotropic drugs" and specify in RoPs that a goal of caring for individuals with cognitive impairment is to limit the use of psychotropic medications; 2) specify in the RoPs that psychotropic medications should be used for FDA-approved conditions wihout limitations. Alternatively, change the language to either define "antipsychotic use in dementia" or "psychotropic in dementia to treat XX".

Related to antipsychotics, CMS must include language in the RoPs that does not capture all medications classified as antipsychotics regardless of their designed use and FDA approval. For example, Compazine, which is used to treat nausea and vomiting is classified as antipsychotic but is not used to treat dementia or behaviors.

- Page 42205, F.R. 80, No. 136 – *CMS welcomes comment on the need to specify the circumstances under which a facility is responsible for the loss or damage to a resident's dentures.*
    - **AHCA concurs with CMS: nursing centers already address responsibility for loss or damage to resident's property through policy and there is no need for CMS to identify specific circumstances.**
- Page 42209, F.R. 80, No. 136 – *CMS solicits comment on whether or not a HACCP program should be required in all SNFs and NFs.*
    - **AHCA concurs with CMS: a Hazard Analysis and Critical Control Points (HACCP) program is unnecessary and would result in a burdensome requirement on providers, particularly small nursing centers.**
- Page 42211, F.R. 80, No. 136 – *CMS solicits comments on whether binding arbitration agreements should be prohibited.*
    - **AHCA strongly opposes any reference to arbitration agreements in the Requirements of Participation and, as indicated earlier, is submitting a separate comment letter specific to this issue.**
- Page 42213, F.R. 80, No. 136 – *CMS welcomes comments on the proposed definition of adverse events.*
    - The definition CMS proposes to use for adverse events should specify adverse events may be preventable or non-preventable. In addition, the definition should specify that an adverse event must result in harm.
    - **AHCA recommends the definition for "adverse events" be amended to read:** *Adverse event. An adverse event is an untoward, undesirable, and usually unanticipated event that causes death or serious injury**~~, or the~~*

~~risk thereof~~. **An adverse event may be preventable or non-preventable."**

- Page 42213, F.R. 80, No. 136 – *CMS solicits comment on establishing mandatory PIPS [Performance Improvement Projects], specifically regarding the feasibility for and impact on facilities.*
    - **AHCA strongly opposes any mandate related to PIPSs. Such a mandate is in complete opposition to the concept of QAPI, which emphasizes a center's specific needs and opportunities for improvement. Further, CMS notes in the preamble that "***the number and frequency of improvement projects conducted by the facility would have to reflect the scope and complexity of the facility's services and available resources.***"**
- Page 42216, F.R. 80, No. 136 – *CMS solicits comment on the issue of IPCO [Infection Prevention and Control Officer]qualifications as well as the requirements for an effective IPCP [Infection Prevention and Control Program].*
    - **AHCA agrees that infection control is very important for the patients/residents in nursing centers.** We are very concerned about the qualifications for the IPCO, particularly in areas that already lack adequate numbers of RNs. Including in the Requirements of Participation the need for "a healthcare professional with specialized training in infection prevention and control beyond their initial professional degree" will be impossible to achieve for nursing centers in many locations that do not have access to such an individual. Further, limiting the responsibility to one person is unrealistic for some nursing centers. **AHCA recommends:**
        (1) Allow a <u>minimum</u> of two years and up to three years for nursing centers to meet the requirements for a healthcare professional with additional training to serve as an IPCO;
        (2) Allow two or more individuals to be responsible for the IPCP; and
        (3) Allow a <u>minimum</u> of two years and up to three years for a nursing center to fully develop and implement the IPCP.

- Page 42221, F.R. 80, No. 136 - CMS *solicits comments on requiring for periodic external audits specifically focusing on financial records and quality of care issues.* **AHCA does not believe that this is appropriate, as this would be duplicative and redundant to the operating organization's own efforts. Further, nursing centers would have to spend significant time and expense to educate the outside monitor and to comply with this requirement.**
- Page 42231, F.R. 80, No. 136 – CMS *solicits comment on each of these issues [list of four] for the following sections of this document that contain information collection requirements (ICRs).*
    - The estimates of cost related to Quality Assurance and Performance Improvement are grossly understated. CMS's use of time frames required by other Medicare providers to develop a QAPI plan is flawed, in that those other providers operate under Conditions of Participation rather than Requirements of Participation. The proposed regulation specifies an

extensive list of items which must be included in the plan and each specific item is a Requirement of Participation and noncompliance with any one of these items may result in the Secretary determining the facility must be decertified. The knowledge of this potential will result in a much more deliberate and painstaking process in development of the plan. CMS estimates a first year total cost of $118,419,977 and an annual cost year two and after of $47,402,511: $3,021 per facility (pp. 42238-42239 and 42241, FR 80, No. 136).

Appendix A is a QAPI Implementation Task List including costs associated with each task. This was prepared by an independently owned nursing center that cares for 133 residents/patients, most of whom are Medicaid beneficiaries. **Total cost for one nursing center to develop a QAPI plan is $30,120.00.** Implementation of the plan, and annual updates to the plan result in **an annual ongoing cost of $82,100**. This center has already begun implementation of QAPI and the costs and tasks are based on their experience.

- CMS estimates a total cost of $283,944,511 (pp. 42239 and 42241, FR 80, No. 136), or $18,096 per facility, for implementation and ongoing costs associated with the Infection Prevention and Control Program outlined in the proposed rule. This is grossly underestimated. It is important to note that the CMS cost estimate projects .15 FTE for the infection prevention and control officer, the preamble and the proposed rule requires this employee to have the infection prevention and control program as "a major responsibility." CMS is presenting an inconsistent approach by using a cost estimate of .15 FTE while also requiring the officer to have infection prevention and control as a "major responsibility."

  Appendix B includes an estimate (by the same center identified for the Appendix A information) of an Infection Prevention and Control Program, including an Antibiotic Stewardship Program for Asymptomatic Urinary Tract Infections. **The annual costs associated with a nursing center implementing this extensive infection prevention and control program as well an antibiotic stewardship program is $190,876**.

These are only three examples of the unrealistic costs estimates CMS uses for this proposed rule. AHCA believes **CMS must revise all cost estimates for implementation and ongoing maintenance of the new requirements of this proposed rule to more accurately reflect the actual costs that nursing centers will face to implement these new requirements of participation.**

Definitions (§ 483.5)

1) § 483.5(a) Abuse

AHCA agrees with including the word "willful" in the definition of abuse (that is, *abuse is the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish*). However, AHCA disagrees with CMS's further definition of "*willful*", specifying that "*…the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm*." This definition suggests that if the nurse "willfully" provides a medication to a patient and subsequently discovers that it was the wrong medication, the nurse is guilty of abuse. Certainly the nurse made an error and that is not good; however this is not a situation that should be considered abuse and there are other regulations that address such an error.

The sentence "*Abuse also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being" is misplaced*." The expansion of the definition of abuse in this instance sounds like a definition of neglect, which is already defined in current regulations:

> §483.5(m) "*Neglect is the failure of the facility its employees or service providers to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish or mental illness*."

2) **§** 483.5(g) Exploitation
The definition CMS proposes includes the term "selfish" which is unnecessary. The word is open to interpretation and not useful. The remainder of the definition is adequate for purposes of this rule.

AHCA Recommendation:

1) **Amend the last sentence of the definition to read: "Willful, as used in this definition of abuse, means the individual must have acted deliberately with the intent to inflict harm." Delete the sentence "~~Abuse also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being~~."**
2) **Amend the definition of §** 483.5(g) Exploitation **to read *Means the unfair treatment or use of a resident or the taking of ~~a selfish or~~ <u>an</u> unfair advantage of a resident for personal gain, through manipulation, intimidation, threats, or coercion.***

§483.5(p) Resident Representative

The proposed definition for "resident representative" does not incorporate an important phrase used several times in the preamble to the proposed rule and we believe it should be part of the definition, consistent with the expressed intent.
In the preamble to the proposed rule (pg. 42181), CMS states: "*For purposes of this regulation, we would define the term ''resident representative'' broadly to include both*

an individual of the resident's choice who has access to information and participates in healthcare discussions as well as personal representative ***with legal standing****, such as a power of attorney for healthcare, legal guardian, or health care surrogate or proxy appointed in accordance with state law to act in whole or in part on the resident's behalf. One individual may or may not fulfill both of these roles.*" (emphasis added)

While we agree that a resident has the right to designate an individual to have certain rights and/or responsibilities, such as the ability to make decisions about the resident's care, the ability to manage the resident's finances, or the ability to participate in discussions about the resident's care and the ability to access the resident's medical information, we believe this definition as written and subsequent use throughout the requirements of participation will creates problems and may supersede state laws, regulations or case laws about a patient's surrogate decision makers. Of particular concern are situations that may arise when these two individuals disagree about a decision that needs to be made. Who wins? The "legal" representative or the representative identified by the resident verbally and with no associated documentation, signed by the resident specifying the authority the representative has? The nursing center cannot be put into the position of making this choice.

ACHA Recommendation:
Amend the definition of "Resident representative" to read: "*For purposes of this subpart, the term resident representative means an individual of the resident's choice* **with legal standing, such as a power of attorney, legal guardian, or health care surrogate appointed or designated in accordance with state law who has access to information and participates in healthcare discussions**~~*, or a personal representative with legal standing, such as a power of attorney, legal guardian, or health care surrogate appointed or designated in accordance with state law*~~*. If selected as the resident representative, the same-sex spouse of a resident must be afforded treatment equal to that afforded to an opposite-sex spouse if the marriage was valid in the jurisdiction in which it was celebrated.*"

Resident rights (§ 483.10)

1) § 483.10(a)(3), proposes that residents have the "*right to designate a representative, the resident representative's limitation to those rights delegated by the resident, and the resident's retention of those rights not delegated, including the right to revoke a delegation*." The preamble notes "*that resident representatives fall into three categories: (1) court-ordered or otherwise designated under applicable law (e.g., state law), (2) supported by documentation (that is, an advance directive), and (3) informal/oral. The scope of resident representative authority may vary based on how they are designated*." [Emphasis added] We disagree that a resident has "the right to revoke delegation" of a court-appointed guardian when they have been deemed incompetent by a court. Similarly, if the practitioner in their professional opinion has determined the resident's medical condition impairs their decision- making capacity such that a resident's representative appointed by advanced directive or durable power

of attorney needs to make decisions, a resident cannot revoke that representative. We agree that should the representative not be making decisions in the best interest of the resident or consistent with the resident's specified wishes that the facility should try to resolve these discrepancies and if unresolvable seek to legally remove the assigned representative.

Having a resident representative in addition to one appointed by the court or by the resident's own authorization through advance directives or a durable power of attorney will slow notifications and increase the likelihood of disagreements which may delay health-care decisions and necessary care. We recommend the definition of resident representative be modified to apply only when the resident does not have either a court-appointed guardian or an already designated health care proxy such as a durable power of attorney for health care or person specified in a living will. This will avoid having multiple resident representatives that will delay decision-making while differences are reconciled and requiring multiple notifications of numerous parties.

2) §483.10(a)(4) "*In the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the rights of the resident devolve to and are exercised by the resident representative appointed under State law to act on the resident's behalf. (i) The resident may exercise his or her rights to the extent not prohibited by court order. (ii) The court-appointed resident representative exercises the resident's rights to the extent judged necessary by a court of competent jurisdiction, in accordance with State law. (iii) The resident's wishes and preferences must be considered in the exercise of rights by the representative. (iv) To the extent practicable, the resident must be provided with opportunities to participate in the care planning process.*"

AHCA agrees that residents should retain as many rights as possible and their preferences be elicited and honored whenever possible. However, this clarification will likely add confusion and is not internally consistent.

First, the court order for scope of decisions is not always clearly defined. In addition, the distinction between medical care decisions in the context of frail elderly in nursing homes and personal decisions regarding quality of life often is not clear. Therefore when it is appropriate for the court- appointed individual to make decisions and when it is appropriate for the resident representative can be confusing. Also the court-appointed guardian is to make decisions in the best interest of the resident, which includes seeking input from family members, friends, and other individuals who know the resident. Thus, the creation of a resident representative when there is a court appointed guardian does not make sense.

Second, the resident representative would only make decisions for a resident when he or she can no longer make decisions for themselves. Thus, the resident representative must be assigned prior to the resident developing incapacity to make decisions. Also, if the care team believes the resident can't make decisions and must turn to another person; this is the very situation for which a court appointed guardian has been named. It is unclear

why a second person who knows the resident enough to make personal decisions for the resident but was not named by the court or the resident in other documents must also be named. Thus, the creation of this new resident representative in the face of a court appointed or resident appointed decision maker when they can't make decisions seems to bypass the very intent and purpose of court appointed guardian or decision maker appointed by the resident and is duplicative and unnecessary. It only adds an additional person in the chain of notification and decision making that may conflict with other legally recognized individuals appointed by the resident or court. This increases the likelihood for conflict in decision making and delays in making decisions for a resident.

3) § 483.10 (b) (2) states "*The right to be informed, in advance, of the care to be furnished and the disciplines that will furnish care*." The meaning of the phrase "*and the disciplines that will furnish care*" is unclear.

4) §483.10(b)(3) "*The right to be informed in advance of the risks and benefits of proposed care, of treatment and treatment alternatives or treatment options and to choose the alternative or option he or she prefers*." Advising the resident of the risks and benefits of proposed care, treatment and treatment alternatives or options are the responsibilities of the practitioner, not the nursing center.

5) §483.10(b)(5)(i) "*The right to participate in the planning process, including the right to identify individuals or roles to be included in the planning process, the right to request meetings and the right to request revisions to the person centered plan of care.*" The use of the term "roles" is confusing and should be replaced with a word that is clearer as to the intent.

6) §483.10(c) "*Choice of attending physician. The resident has the right to choose his or her attending physician. (1) The physician must be licensed to practice, and (2) The physician must meet the professional credentialing requirements of the facility. (3) If the physician chosen by the resident refuses to or does not meet requirements specified in this part, the facility may seek alternate physician participation as specified in § 483.11(c) to assure provision of appropriate and adequate care and treatment."* AHCA urges CMS to confirm that this requirement applies to the attending physician only and not to a covering physician since that list can be extremely long and may change frequently. To the extent that CMS would apply this requirement to covering physicians, this would likely result in the unintended consequences of significant on-call coverage problems as well as potentially discouraging physicians from caring for SNF residents at a time when we need greater and more frequent physician involvement in SNF care.

AHCA also points out that verification of professional credentialing requirements can take time which may result in a resident's physician being unable to serve as the attending physician upon admission. Thus, the resident will have to have another "credentialed" physician until their physician completes the facility's credentialing process. This switching of physicians is not best practice and may result in resident's experiencing adverse events as the attending physician may not be familiar with the resident.

7) §483.10(e) "*Self-determination. The resident has the right to self-determination, including but not limited to the right to—*
(1) Choose activities, schedules (including sleeping and waking times), health care and providers of health care services consistent with his or her interests, assessments, and plan of care;"
As written, the nursing center could be required to contract with any and all hospice providers, therapists/therapy companies, etc. Additionally, this conflicts with the following provision in the proposed rule: §483.10(c) *Choice of attending physician. The resident has the right to choose his or her attending physician. (2) The physician must meet the professional credentialing requirements of the facility.*

8) §483.10(e)(2) "*Interact with members of the community and participate in community activities both inside and outside the facility"* Not all patients/residents are realistically able to participate in activities outside the nursing center.

9) §483.10(e)(3) "*Receive visitors of his or her choosing at the time of his or her choosing, subject to the resident's right to deny visitation, and in a manner that does not impose on the rights of another resident, including the individuals specified in § 483.11(d)*" Having unexpected visitors entering the nursing center at any time of day or night is unreasonable, disruptive, and potentially dangerous. In order for a nursing center to provide a safe and secure environment for all patients and residents there must be reasonable parameters applied to this visiting provision. It is reasonable, for example, for the relative of a resident to visit on their way home from their night-shift employment which may be at 1 a.m. This would be a pre-arranged visit. And it is reasonable for such off-hour visits to be occasionally unplanned, but advance notice via telephone that a visitor will be arriving outside of scheduled visiting hours would be appropriate.

10) §483.10(e)(5) "*Participate in family groups*" Not all nursing centers have family groups and in those centers that provide care for post-acute, short-stay patients, it is seldom that these individuals and their families have interest in participating in a family group.

11) §483.10 (f) (3)(ii) "*After receipt of his or her medical records for inspection, to purchase, a copy of the medical records or any portions thereof (including in an electronic form or format when such medical records are maintained electronically) upon request and 2 working days advance notice to the facility. The facility may impose a reasonable, cost-based fee on the provision of copies, provided that the fee includes only the cost of:*" 2 working days advance notice may not be adequate time depending upon the size of the records. In addition, there should be a definition of "working day."

12) §483.10(h)(2) "*The resident has the right to have reasonable access to and privacy in their use of electronic communications such as email and video communications and for internet research."* It is important that whatever internet research is being done is legal. For example, researching for sites that promote child pornography or other illegal activities must be limited. Further, providing absolute privacy for each resident wanting

to use email and video communication may require advance planning. For example, if a nursing center has one room with several computer terminals available for residents' use, privacy may require a resident to schedule private use in advance, during which time no other resident may use a terminal in that room.

AHCA Recommendations:

1) **The definition of "resident representative" must be modified to apply only when the resident has neither a court-appointed guardian nor a designated healthcare proxy through advance directives nor an identified durable power of attorney.**
2) **Amend language at §483.10(a)(4) (iii) to read: "(iii) The resident's wishes and preferences must be considered in the exercise of rights by the court-appointed representative."**
3) **Modify language at § 483.10 (b) (2) to read: "*The right to be informed, in advance, of the care to be furnished and the ~~disciplines~~* professions/practitioners/departments *that will furnish care.***
4) **Recommend amending the language at §483.10(b)(3) to read: "*The right to be informed ~~in advance~~* , by the physician or other relevant practitioner or professional*, of the risks and benefits of proposed care, of treatment and treatment alternatives or treatment options and to choose the alternative or option he or she prefers.*"**
5) **Recommend amending the language at §483.10(b)(5)(i) to read: "*The right to participate in the planning process, including the right to identify individuals or ~~roles~~* representatives of specific facility departments *to be included in the planning process, the right to request meetings and the right to request revisions to the person centered plan of care.*"**
6) **Recommend amending §483.10(c) to read: "*Choice of attending physician. The resident has the right to choose his or her attending physician. (1)* The facility must develop its own credentialing process that does not require primary source verification, which is typically conducted by state licensure entities or the process for conveying hospital admitting privileges or managed care certification. (2)*The physician must be licensed to practice, and* (3) *The physician must meet the professional credentialing requirements of the facility* within a timely manner following the resident's admission to the facility.**

   AHCA also requests CMS clarify that this provision only applies to the resident's attending physician and not all the attending physician's covering physicians.
7) **Amend §483.10(e)(1) to read: Choose activities, schedules (including sleeping and waking times), health care and providers of health care services, consistent with §483.10(c) and other relevant contracting requirements and consistent with his or her interests, assessments, and plan of care;**
8) **Amend §483.10(e)(2) to read: *Interact with members of the community and participate in community activities both inside and outside the facility*, as appropriate based on the resident's functional capability.**

9) **Amend §483.10(e)(3)to read:** ***Receive visitors of his or her choosing at the time of his or her choosing, and*** **consistent with facility policy regarding visits between the hours of 9 PM and 7 AM and** ***subject to the resident's right to deny visitation, and in a manner that does not impose on the rights of another resident, including the individuals specified in § 483.11(d).***
10) **Amend § 483.10(e)(5) to read: "*Participate in family groups,* if available."**
11) **Amend §483.10(f) (3)(ii) to read: "*After receipt of his or her medical records for inspection, to purchase, a copy of the medical records or any portions thereof (including in an electronic form or format when such medical records are maintained electronically) upon request and ~~2~~ 5 working days* (working days defined as between 8 a.m. and 6 p.m., Monday – Friday) *advance notice to the facility. The facility may impose a reasonable, cost-based fee on the provision of copies, provided that the fee includes only the cost of:*"**
12) **Amend §483.10(h)(2) to read "*The resident has the right to have reasonable access to and privacy in their use of electronic communications such as email and video communications and for internet research.* All such activities are limited to legal websites/activities as determined by state and federal laws. If absolute privacy is required, the facility may require advance scheduling of a computer to assure such privacy."**

Facility responsibilities (§ 483.11)

1) §483.11(a)(2) "*The facility must provide equal access to quality care regardless of diagnosis, severity of condition, or payment source."* As written, this suggests that every nursing center must provide care for every individual regardless of the center's care expertise or the ability to care for every condition any individual might have. For example, a person may require the use of a ventilator yet not every nursing center has the ability to provide care for such patients. Similarly, a center that provides care for frail elders is unlikely to have the expertise to care for a child who requires nursing center care.

2) §483.11(c) (2) "*The facility must inform the resident if the facility determines that the physician chosen by the resident is unable or unwilling to meet requirements specified in this part and the facility seeks alternate physician participation to assure provision of appropriate and adequate care and treatment. The facility must discuss the alternative physician participation with the resident and honor the resident's preferences, if any, among options.*" This is inconsistent with §483.10(c)(2)&(3) in the proposed rule.

3) §483.11(d)(2)(iv) "*Ensure that all visitors enjoy full and equal visitation privileges consistent with resident preferences.*" It is important that residents, visitors and staff understand that full visitation privileges does not include a visitor living in the nursing center. This occurs from time to time and is incredibly disruptive to other residents and center staff. Also, there are occasions when visitors come to the nursing center and are extremely boisterous, confrontational, under the influence of drugs or alcohol. A center must have the ability to protect staff and residents from this disrupting behavior.

4) §483.11(e)(2)(ii) (*The facility must:)* "*Allow the resident to purchase, after receipt of his or her medical records for inspection, a copy of the medical records or any portions thereof (including in an electronic form or format when such medical records are maintained electronically) upon request and 2 working days advance notice to the facility.*" A 2 working day time frame may be unrealistic in some instances, based on the size of a resident's medical record and staff limitations. In addition, "working day" should be further defined to identify times that staff who would typically prepare copies of these materials are working in the center.

5) §483.11(e)(3) "*The facility must make reports with respect to any surveys, certifications, and complaint investigations conducted by Federal or State surveyors during the 3 preceding years available for any individual to review upon request and any plan of correction in effect with respect to the facility available for examination in a place readily accessible to and in a form understandable by residents, and must post a notice of its availability.*" To require a nursing center to make every survey, certification and complaint investigation report available "in a form understandable by residents" is excessive and incomprehensibly burdensome.

6) §483.11(e)(7)(i) "*A facility must immediately inform the resident; consult with the resident's physician; and notify the resident representative(s) when there is—"* This must be consistent with resident representative state law, or the authority granted by the court in instances of a resident who has been adjudged incompetent, or the authority granted to the individual with the durable power of attorney.

7) §483.11(h) (3)(i)and (ii) (*The grievance policy must include:)* "*(i) Notifying resident individually or through postings in prominent locations throughout the facility of the right to file grievances verbally (meaning spoken) or in writing; the right to file grievances anonymously; the contact information of the grievance official with whom a grievance can be filed, that is, his or her name, business address (mailing and email) and business phone number; 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; (ii) Identifying a Grievance Official who is responsible for overseeing the grievance process, receiving and tracking grievances through their conclusion; leading any necessary investigations by the facility; maintaining the confidentiality of all information associated with grievances, for example, the identity of the resident for those grievances submitted anonymously; issuing written grievance decisions to the resident; and coordinating with State and Federal agencies as necessary in light of specific allegations*" AHCA completely

concurs with the importance of a grievance process within a nursing center. The process must be responsive and completed timely. Including specific grievance policy language in the Requirements of Participation is excessive. As well, identifying a "Grievance Official" with all of the specified requirements is excessive. The grievance process developed by a nursing center should be the responsibility of the Quality Assessment and Assurance Committee.

AHCA Recommendations:

1) **Amend §483.11(a)(2) to read: "*The facility must provide equal access to quality care regardless of ~~diagnosis~~, severity of condition, or payment source***
2) **Delete the last sentence of §483.11(c) (2): ~~The facility must discuss the alternative physician participation with the resident and honor the resident's preferences, if any, among options.~~**
3) **Amend §483.11(d)(2)(iv) to read:** "***Ensure that all visitors enjoy full and equal visitation privileges consistent with resident preferences*, to the extent that such visitors do not disrupt other residents and the care the facility is providing. Visitation privileges do not include "live-in" status of individuals who are not residents/patients of the nursing facility.**
4) **Amend §483.11(e)(2)(ii) to read:** (The facility must:) ***Allow the resident to purchase, after receipt of his or her medical records for inspection, a copy of the medical records or any portions thereof (including in an electronic form or format when such medical records are maintained electronically) upon request and ~~2~~ 5 working days* (working days defined as between 8 a.m. and 6 p.m., Monday – Friday) *advance notice to the facility.***
5) **Amend §483.11(e)(3) to read: *"The facility must make reports with respect to any surveys, certifications, and complaint investigations conducted by Federal or State surveyors during the 3 preceding years available for any individual to review upon request and any plan of correction in effect with respect to the facility available for examination in a place readily accessible to ~~and in a form understandable by~~ residents, and must post a notice of its availability."***
6) **Amend** §483.11(e)(7)(i) **to read:** A facility must immediately inform the resident; consult with the resident's physician; and ***consistent with any State law associated with resident representatives, or the authority granted by the court to a legal guardian when a resident has been adjudged incompetent, or the authority granted to the individual appointed by the resident to have his/her durable power of attorney*** notify the resident representative(s) when there is—
7) **Delete all language from this section starting at §483.11(h) (3) *"the grievance policy must include:"* Incorporate into quality assurance and performance improvement (§ 483.75) requirements related to developing a policy, having a process for receiving and tracking grievances, maintaining the confidentiality of all information, and taking appropriate corrective action in accordance with State law.**

Freedom from abuse, neglect, and exploitation (§ 483.12)

1) § 483.12(a)(1)(iii) (2) "*Not employ or otherwise engage individuals who— (iii) Have had a disciplinary action taken against a professional license by a state licensure body as a result of a finding of abuse, neglect, mistreatment of residents or misappropriation of resident property.*" Unless there is a centralized registry for such information, it is impossible for a center to check all 50 states to obtain the information.

2) § 483.12(c)(4) "*Report the results of all investigations to the administrator or his resident representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.*" This provision must clarify that information will be shared with the resident representative, consistent with state law.

AHCA Recommendations:

1) **Delete the language at § 483.12(a)(1)(iii) (2).**
2) **Amend the language at § 483.12(c)(4) to read: "*Report the results of all investigations to the administrator or ~~his~~* <u>the</u> *resident representative* <u>in accordance with state law</u> *and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.".***

Transitions of care (§ 483.15)

1) §483.15(2) (iii) states: *Not request or require residents or potential resident to waive potential facility liability for losses of personal property.* Residents should expect a nursing center to offer a secure place to store valuables. However, to expect a center to be responsible for all losses of patients' personal property is unreasonable. There are other requirements in place that address this, for example, reporting the suspicion of crime. A nursing center can offer secure storage and also, through their policies, identify those items the center would replace because they are essential for patient care or function.

2) §483.15(a)(4)(i)(E) relates to a person eligible for receiving Medicaid and specifies a nursing center may not discharge a resident for payment failure *"…unless the resident does not submit the necessary paperwork for third party payment or until the third party, including Medicare or Medicaid, denies the claim and the resident refuses to pay for his or her stay."* It is important the patient or patient representative show proof that they have applied for the Medicaid/third party payment within a specified period of time from the date the center notifies the patient that Medicare payment will expire on a date certain.

3) §483.15(a)(6) states: *A nursing facility must disclose and provide to a resident or potential resident, at or prior to time of admission, notice of special characteristics or service limitations of the facility.* AHCA agrees with the intent of this provision. However, it will be much more helpful to the potential resident to understand clearly those services a nursing center will provide.

4) §483.15(a)(7) states: *A nursing facility that is a composite distinct part as defined in*

§483.5(c) must disclose in its admission agreement its physical configuration, including the various locations that comprise the composite distinct part, and must specify the policies that apply to room changes between its different locations under paragraph (b)(10) of this section. This language should include the applicability of state law.

5) §483.15(b)(1)(ii)(C) states: *The facility must permit each resident to remain in the facility,, and not transfer or discharge the resident from the facility unless --The safety of individuals in the facility is endangered due to the clinical or behavioral status of the resident;* AHCA supports this clarification and recommends also including the safety of the resident.
6) §483.15(b)(1)(iii) states: "*The facility may not transfer or discharge the resident while the appeal is pending, pursuant to § 431.230 of this chapter, when a resident exercises his or her right to appeal a transfer or discharge notice from the facility pursuant to § 431.220(a)(3) of this chapter."* As we understand this language, a nursing center cannot discharge or transfer a resident while an appeal is pending. AHCA strongly opposes this prohibition on transferring or discharging a resident who is exercising their right to appeal. In some instances, the transfer or discharge may be related to the inability of the nursing center to adequately and safely care for a resident. If the intent of CMS is to prohibit transfer or discharge, at a minimum, Medicaid must be required to pay for the cost of the resident's care during the pending appeal.
7) §483.15(b)(2) *Documentation* seems to incorrectly reference *paragraphs (b)(1)(i)(A) through (F).* This reference paragraph (b)(1)(i) has only paragraphs (A) through (C). This reference must be corrected.
8) §483.15(b)(2)(iii) *Documentation. " (iii) Information provided to the receiving provider must include a minimum of the following:"*, which is followed by 18 distinct items that may or may not be relevant to each resident/patient who is discharged. A "receiving provider" as referenced in the proposed rule may be the family/spouse and while some of the information included in these 18 items may be relevant, certainly not all will be. Additionally, it significantly exceeds the hospitals' expectations at §482.43 Condition of participation: Discharge planning. There is no reason for requiring a nursing center to be held to a higher/different standard than a hospital.
9) §483.15(c)(3)(ii) states *"*(1) *Notice before transfer. Before a nursing facility transfers a resident to a hospital or the resident goes on therapeutic leave…"* The term "therapeutic leave" is used several times in the preamble to the proposed rule and within the proposed rule. There is no definition of the term "therapeutic leave."

AHCA Recommendations

1) **Amend** §483.15(2) (iii) **to read:** ~~*Not request or require residents or potential resident to waive potential facility liability for losses of personal property.*~~ **Include in its admissions policy information about how a resident can safely store personal items to prevent potential loss of personal property.**

2) **Amend** §483.15(a)(4)(i)(E) **to read:** *"…unless the resident does not submit the necessary paperwork for third party payment or until the third party, including Medicare or Medicaid, denies the claim and the resident refuses to pay for his or her stay.* **The resident must be able to show proof that such paperwork has been submitted timely.***"*
3) **Amend** §483.15(a)(6) **to read: "*A nursing facility must disclose and provide to a resident or potential resident, at or prior to time of admission, notice of ~~special characteristics or service limitations of the facility~~* those services a facility is able to provide.**"**
4) **Amend** §483.15(a)(7) **to read: "***A nursing facility that is a composite distinct part as defined in §483.5(c) must disclose in its admission agreement its physical configuration, including the various locations that comprise the composite distinct part, and must specify the policies that apply to room changes between its different locations under paragraph (b)(10) of this section.* **Any applicable state law requirements must also be included.**"
5) **Amend** §483.15(b)(1)(ii)(C) **to read: "***The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless --The safety of* **the resident, staff or other** *individuals in the facility is endangered due to the clinical or behavioral status of the resident;*"

   Delete §483.15(b)(1)(iii). **OR Amend §**483.15(b)(1)(iii) **to read:** "*~~The facility may not transfer or discharge the resident while the appeal is pending, pursuant to § 431.230 of this chapter, when a resident exercises his or her right to appeal a transfer or discharge notice from the facility pursuant to § 431.220(a)(3) of this chapter.~~* **When a resident exercises his or her right to appeal a transfer or discharge notice from the facility pursuant to this chapter, the facility may not transfer or discharge the resident while the appeal is pending and while, pursuant to § 431.230 of this chapter, the**
6) **CMS must correct the reference in this sentence:** §483.15(b)(2) "*Documentation. When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (b)(1)(i)(A) through (F) of this section…"*
7) **Amend** §483.15(b)(2)(iii) **to read:** *Documentation. " (iii) Information provided to the receiving provider must include* **necessary medical information to the resident and families and appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care.** *~~a minimum of the following: (A) Demographic information including but not limited to name, sex, date of birth, race, ethnicity, and preferred language. (B) Resident representative information including contact information. (C) Advance Directive information. (D) History of present illness/reason for transfer including primary care team contact information. (E) Past medical/surgical history, including procedures. (F) Active diagnoses/Current problem list and status. (G) Laboratory tests and the results of pertinent laboratory and other diagnostic testing. (H) Functional status. (I) Psychosocial assessment, including cognitive status. (J) Social Supports (K) Behavioral Health Issues (L) Medications. (M) Allergies, including medication allergies. (N) Immunizations. (O) Smoking status.~~*

~~*(P) Vital signs. (Q) Unique device identifier(s) for a patient's implantable device(s), if any. (R) Comprehensive Care plan goals, including health concerns, assessment and plan, resident preferences, interventions, including efforts to meet resident needs, and resident status.*~~

8) **Define the term "therapeutic leave" as it relates to its use in the preamble of the proposed rule as well as at** §483.15(c)(3)(ii).

Resident assessments (§ 483.20)

1) §483.20 (b)(1) requires "*a comprehensive assessment of a resident's needs, strengths, goals, life history and preferences…*" In some instances, it is not possible to obtain information from a resident about their strengths, goals, life history and preferences. In instances where family members or close friends are available, those individuals may be able to provide important information about these topics. The regulation must acknowledge that this information may not be possible to obtain.

2) In the proposed rule, CMS uses the acronym "PASARR" for the preadmission screening and resident review. This acronym is inconsistent with the acronym used on the Medicaid.gov website where this screening and review is explained.

AHCA Recommendation:

1) **Amend** §483.20 (b)(1) **to read:** "*Resident assessment instrument. A facility must make a comprehensive assessment of a resident's needs,* **and, to the extent possible,** *strengths, goals, life history and preferences, using the resident assessment instrument (RAI) specified by CMS.*
2) **Change the acronym in this proposed rule to "PASRR" to be consistent with the acronym used on the Medicaid.gov website http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Delivery-Systems/Institutional-Care/Preadmission-Screening-and-Resident-Review-PASRR.html.**

Comprehensive resident-centered care plans (§ 483.21)

1) §483.21 "*(b)(2) A comprehensive care plan must be—(ii) Prepared by an interdisciplinary team, that includes but is not limited to— (C) A nurse aide with responsibility for the resident. (D) A member of food and nutrition services staff. (E) A social worker.* " AHCA agrees with CMS: nurse aides are extremely valuable in the development of a care plan because frequently they have important knowledge and understanding of a patient/resident. Other staff, as identified in the proposed rule, are also valuable assets in the care planning process. However, there is a cost associated with having these additional individuals participate in each patient's/resident's care plan meeting and CMS has not adequately identified these costs. It is important this cost be considered, because when staff members

are in a meeting they are unable to provide care to other patients/residents and likely additional staff will be required.

Alternatively, participation by these additional employees can be accomplished through interview prior to the meeting or utilizing "Point of Care"- type documentation, or some other written means, obtaining this valuable information.

3) §483.21 "(b)(2)(ii)(F) *To the extent practicable, the participation of the resident and the resident's representative(s). An explanation must be included in a resident's medical record if the participation of the resident and their resident representative is determined not practicable for the development of the resident's care plan."* AHCA supports the resident's and his or her representative's involvement in the care plan development and review; specifying the level of detail that written explanation be included in the medical record is better defined in interpretative guidance rather than in Requirements of Participation. Since the Requirements must be modified and changed through rule making, which was last done over 20 years ago, the proposed changes may lock nursing centers and the CMS enforcement process into certain practices that no longer make sense. Thus, this level of detail should be removed from the RoP and specified in SOM. This would make the RoP more flexible to future changes and innovations as well as more adaptable to unforeseen circumstances.

4) §483.21(b)(3)(iii) requires the comprehensive care plan to *"Be culturally-competent and trauma-informed."* These terms require definition to ensure providers and surveyors clearly understand CMS's expectations.

AHCA Recommendations:

1) **CMS must specify alternative methods of additional employee participation in the care planning process. Alternatively, CMS must acknowledge and calculate the labor costs of additional employees participating in the interdisciplinary team meetings and include the logic and reasoning used for the calculation.**
2) **Delete the second sentence at §483.21 (b)(2)(ii)(F) ~~An explanation must be included in a resident's medical record if the participation of the resident and their resident representative is determined not practicable for the development of the resident's care~~ plan.**
3) **Amend to read: §483.21 "(b)(2)(ii)(F) *To the extent practicable, the participation of the resident and the resident's representative(s). ~~An explanation must be included in a resident's medical record if the participation of the resident and their resident representative is determined not practicable for the development of the resident's care plan."~~***
4)

<u>Quality of care and quality of life (§ 483.25)</u>

1) §483.25(d)(2)(i) requires an "*Attempt to use alternatives prior to installing a side or bed rail."* As written, this statement declares that the existence of a side or bed rail is deficient practice. Deficient practice is reflected by not implementing/attempting alternatives prior to the use or engagement of a side or bed rails.

2) §483.25(d) (15) "*Trauma-informed care. The facility must ensure that residents who are trauma survivors receive culturally competent, trauma-informed care in accordance with professional standards of practice and accounting for residents' experiences and preferences in order to eliminate or mitigate triggers that may cause re-traumatization of the resident.*"

- Providing "trauma-informed care" is prudent and extremely important for those individuals who have experience trauma in their lives and continue to live with residual effects from these experiences. CMS references the Substance Abuse and Mental Health Services Administration (SAMHSA) when discussing trauma-informed care and refers the reader to a SAMHSA publication for additional training and information (HHS Publication No. (SMA) 14–4884, available at *http:// store.samhsa.gov/shin/content/ SMA14=4884/SMA14-4884.pdf*).

- AHCA has several concerns regarding these proposed provisions. The first concern is using the link offered on page 42177 of the proposed rule results in reaching the following message: the webpage cannot be found.

- SAMHSA seems to have the most extensive information about trauma-induced care. It is important to keep in mind that the SAMHSA mission is to reduce the impact of substance abuse and mental illness on America's communities. Their focus is best shown by the SAMHSA

"**Six Key Principles of a Trauma-Informed Approach (http://www.samhsa.gov/nctic/trauma-interventions)**

A trauma-informed approach reflects adherence to six key principles rather than a prescribed set of practices or procedures. These principles may be generalizable across multiple types of settings, although terminology and application may be setting- or sector-specific:

1. Safety
2. Trustworthiness and Transparency
3. Peer support
4. Collaboration and mutuality
5. Empowerment, voice and choice
6. Cultural, Historical, and Gender Issues

From SAMHSA's perspective, it is critical to promote the linkage to recovery and resilience for those individuals and families impacted by trauma. Consistent with SAMHSA's definition of recovery, services and supports that are trauma-informed

build on the best evidence available and consumer and family engagement, empowerment, and collaboration." (Emphasis added)

- The reference to utilizing "professional standards of care" does not provide specific professional standards of care for individuals who are trauma survivors. Without specific identification of recognized and acceptable standards, determining compliance with this requirement will be varied and subjective.

- There is no clear definition provided for the term "culturally competent care."

- AHCA describes further concerns related to trauma-informed care in the earlier General Comments.

AHCA Recommendations:

1) **Amend** §483.25(d)(2)(i) **to read: "*Attempt to use alternatives prior to ~~installing~~* engaging *a side or bed rail.*"**
2) **Amend** §483.25(d) (15) **to read:** "*Trauma-informed care.* **When a facility is aware that a resident/patient is a trauma survivor, the** *~~The~~ facility must ensure ~~that residents who are trauma survivors~~* **these residents/patients** *receive* **care that takes into account the** *~~culturally competent, trauma-informed care in accordance with professional standards of practice and accounting for~~ residents' experiences and preferences in order to eliminate or mitigate triggers that may cause re-traumatization of the resident.*"
3) **CMS must define the terms "trauma-informed care" and "culturally competent care", including several examples of how to obtain educational materials to use when preparing staff in the nursing center to meet the expectations for providing such care.**
4) **AHCA recommends a five-year phase in for any requirements related to trauma-informed care.** This is necessary to allow adequate time for identifying appropriate training and implement the training in each nursing center.

J. Physician services (§ 483.30)

I. The proposal to require an in-person evaluation of a resident by a physician, a physician assistant, nurse practitioner, or clinical nurse specialist before an unscheduled transfer to a hospital unless the transfer is emergent and obtaining the in-person evaluation would endanger the health or safety of the individual or unreasonably delay the transfer. While this conceptually sounds reasonable, it is wholly dependent on both physician/clinician geographic availability to the SNF as well as to how "unscheduled transfer to a hospital" and a "non-emergent transfer" is defined. This proposed change will harm residents, since the determination of unscheduled non-emergent needs to be made by the nursing staff or will be determined by state survey & certification in hindsight and after the fact. Thus, residents may be kept at the SNF waiting for clinician to arrive at the SNF and see the resident prior to transfer. This will delay access to needed care. If unscheduled non-emergent care is defined broadly, this will delay access, if it is

defined narrowly, it is unclear how many if any residents it will fall under this requirement. As such it will only increase paperwork documentation that the transfer is emergent, again delaying transfer and access to needed care. In either case, this proposal does not make clinical sense and may harm residents.

AHCA supports the practice that SNFs should attempt to contact and discuss all transfers to the hospital prior to the transfer or document why such attempt was not made; rather than require physicians to see resident prior to transfer. In many circumstances a physician (or physician extender) can make an adequate assessment over the phone and does not need to perform an in-person assessment.

Also, this requirement may conflict with resident rights. What if the resident or family requests transfer to the emergency room or hospital but it is not considered an emergency? Must the facility comply or wait for a clinician to come and see the patient?

Finally, CMS has shown no reason to adopt this rule. Nursing centers and hospitals both have incentives to avoid unnecessary hospital transfer.

Recommendation:

- **This proposal should be removed from the Requirements of Participation and addressed through a Survey & Certification Memorandum that can better address the specifics and nuances of how and when clinicians should be involved in the assessment of residents prior to transfer to the hospital.**
- **AHCA supports the practice that nursing centers should attempt to contact and discuss all transfers to the hospital prior to the transfer or document why such attempt was not made. However, there should be no requirement that a physician (or physician extender) must see a resident prior to transfer.**

- Revisions to 483.30 will also allow a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist to provide orders for the resident's immediate care and needs upon admission. In our opinion, this will help assure more immediate access to care by allowing non-physicians to write admission orders.

  Recommendation:

  - **AHCA supports this change allowing non-physicians to write admission orders.**

- § 483.30(f)(2) & § 483.30(f)(3), proposes to delegate dietary and therapy orders to dieticians and therapists, to provide the physician with the flexibility to delegate to a qualified dietitian or other clinically qualified nutrition professional as well as therapists the task of writing dietary and therapy orders, to the extent

the dietitian or therapist is permitted to do so under state law. We support this as long as it is only the primary physician of record who is doing the delegation. The primary physician is the physician of record and has delegated that responsibility to his/her covering physicians. Asking all ordering physicians (e.g. covering physicians and consultants) would be an administrative burden without any benefit to the resident. If the attending physician of record is comfortable with this arrangement so should his/her covering physicians and consultants. We also seek clarification on whether the proposed definition of a therapist for this provision is limited to mean a qualified physical, occupational or speech-language professional to do so under state law. If CMS finalizes this proposed provision to permit the delegation of dietary and therapy orders, we anticipate that implementation will be facility-specific depending on many factors including state law and the preferences of the facility management, physicians, and dietary and therapy professionals involved. We strongly encourage CMS to collaborate with nursing centers and the professionals listed when developing surveyor guidance to ensure individual providers are afforded the appropriate flexibility in the implementation of this provision.

AHCA Recommendation:

- Amend § 483.30(f)(2) to read: "*A***n attending** *physician* **or that physician's covering physician,** *may delegate the task of writing dietary orders, consistent with § 483.60, to a qualified dietitian or other clinically qualified nutrition professional who*"
- Amend § 483.30(f)(3) to read: "*A**n attending** physician* **or that physician's covering physician** *may delegate the task of writing therapy orders, consistent with § 483.65, to a qualified* **physical therapist, occupational** *therapist* **or speech-language pathologist** *who"*

§483.30(g) "*Performance of physician tasks in NFs. At the option of the State, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility but who is working in collaboration with a physician.*" AHCA is concerned that this provision of the regulations is different for skilled nursing centers and nursing centers. There should be no prohibition for nursing facilities to employ and utilize these professionals to the full extent of their scope of practice.

AHCA Recommendation:

- Amend §483.30(g) to read: "*Performance of physician tasks in NFs. At the option of the State, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant ~~who is not an employee of the facility but~~ who is working in collaboration with a physician.*"

K. Nursing services (§ 483.35)

- *§483.35(g)(4) Facility data retention requirements. The facility must maintain the posted daily nurse staffing data for a minimum of 18 months, or as required by State law, whichever is greater.* It is important to recognize that electronically maintained data must be acceptable for compliance requirements.
- AHCA's further concerns are addressed earlier in this letter within the responses to specific questions posed by CMS.

AHCA Recommendations:

- **Amend** *§483.35(g)(4)* to read: ***Facility data retention requirements. The facility must maintain the posted daily nurse staffing data for a minimum of 18 months, or as required by State law, whichever is greater.*** **Data maintained electronically that reflects the data elements of (1) meets the maintenance requirements of this section.**

L. Behavioral health services (§ 483.40)

- As written, this section and the corresponding section of the preamble, create confusion regarding CMS's intent regarding "behavioral health services." Further concerns are raised by the multiple references to "rehabilitative services for mental illness." The preamble, in "*L. Behavioral Health Services (§ 483.40)* references mental illness and dementia, cognitive impairment and Alzheimer's disease. The proposed language goes far beyond providing care for individuals with cognitive impairment or dementia. As written, this section suggests that every nursing center must provide inpatient services for all mental health and substance abuse conditions.

  The result of the preamble (which suggests CMS's intent for the proposed regulations) and the proposed regulatory text is complete confusion.

- Refer to the serious concerns expressed in our earlier General Comments related to caring for individuals with mental illness and PASRR.

AHCA Recommendation:

- **CMS must provide clarity about its intent and expectations for providers related to care for individuals with mental illness and care for individuals with dementia.**
- **AHCA recommends CMS amend this section to specifically address care for individuals with dementia or cognitive impairment.**

M. Pharmacy services (§ 483.45)

- §483.45(c)(2) requires that the pharmacist "*review must include a review of the resident's medical chart at least every 6 months and: (i) When the resident is new, that is the individual has not previously been a resident in that facility; or (ii) When the resident returns or is transferred from a hospital or other facility; and (iii) During each monthly drug regimen review when the resident has been*

prescribed or is taking a psychotropic drug, an antibiotic, or any drug the QAA Committee has requested be included in the pharmacist's monthly drug review."

While we do not disagree with the value of pharmacist periodic review of a resident's medical regime, the level of detail and specificity is not appropriate for inclusion in the RoP. As experience is gained with increasing pharmacist review, CMS will likely need to modify the proposed language. Also, as new medications are developed or new knowledge is gained about medications, particularly in the frail elderly, the proposed language will need to be modified. We do not believe the current language affords CMS the appropriate flexibility to revise this language.

The preamble language is better for inclusion in the Requirements of Participation. The preamble for §483.45 states that "*there are specific circumstances under which the pharmacist must at least periodically review the resident's medical record concurrently with the drug regimen review. Those circumstances include transitions in care, specifically when the resident is new to the facility or is returning or being transferred from another facility. We also believe it is critical when a resident is on a psychotropic or antimicrobial medication."* Circumstances related to medication usage and prescribing will likely change over time. As e-prescribing is increasingly adopted, real-time reviews may become even more possible, making some of the requirements specified not applicable.

This requirement will increase the time pharmacists spend in a facility which will increase costs to facilities. The increase costs to pharmacies will likely also be incorporated into the medication costs that are frequently reimbursed by Medicaid or Medicare Part D. As such, we believe that this proposed change, represents an unfunded mandate to state Medicaid programs and Medicare Part D, which were not included in the CMS estimates of cost implications of the proposed rule.

AHCA Recommendation:

- While we agree with the intent and purpose of these proposed changes, we request deletion of the specificity in favor of more general and flexible language that can be specified and revised in a timelier manner through interpretative guidance.
- **Amend** §483.45(c)(2) **to read: <u>This review must occur on a regular basis including more frequetnt targeted reviews for medications that may be associated with an increase of adverse events or overutilization as well as when the resident experiences transitions in care or when requested by the facility.</u>** "~~**This review must include a review of the resident's medical chart at least every 6 months and: (i) When the resident is new, that is the individual has not previously been a resident in that facility; or (ii) When the resident returns or is transferred from a hospital or other facility; and (iii) During each monthly drug regimen review when the resident has been prescribed or is taking a psychotropic drug, an antibiotic, or any drug the QAA**~~

~~**Committee has requested be included in the pharmacist's monthly drug review.**~~"

- This requirement would require expansion of pharmacist responsibilities and retraining of pharmacists which would take time. **AHCA recommends an 18- month to 24-month phase in once this requirement is adopted**.
- **We request CMS estimate the costs relative to this proposed change as an unfunded mandate to state's Medicaid programs and Part D plans.**

- §483.45 proposes "*to require the pharmacist to document in a written report any irregularities noted during the drug regimen review that lists at a minimum, the resident's name, the relevant drug, and the irregularity identified, to be sent to the attending physician and the facility's medical director and director of nursing. We propose to require that the attending physician document in the resident's medical record that he or she has reviewed the identified irregularity and what, if any, action they have taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.*"

  As with previous comments, we agree with the intent but disagree with the level of specificity. Specifying that this be done in writing does not recognize and allow new and more effective methods of communication with physicians. Specifying each piece of information does not allow flexibility should new data elements be required or if currently proposed data elements are not helpful or redundant with how the communication may occur. For example, communications embedded within EMR would automatically have the resident's name but this requires restating the name. Also, specifying written communication be sent to multiple individuals increases the likelihood of miscommunication and errors. A principle of reducing adverse events in healthcare is to simplify systems. The level of specificity in the proposed rule would increase complexity. We recommend modifying the language to allow greater flexibility to accomplish the intent of §483.45 about notifying the attending physician of pharmacists' medication review. We also think the language should recognize, as elsewhere in the requirements, that there are other practitioners who can write medication orders. As such, the notification should be sent to the prescribing practitioner, not just the attending physician. Lastly, medications that may trigger an unnecessary medication determination by pharmacist review may have a legitimate and clinically acceptable rationale. Repeated notification of physicians and documenting, repeatedly, rationale related to pharmacist's findings is not a productive use of anyone's time and may lead to inadvertent changes in medication regime that could be harmful. As such, when a legitimate and clinically acceptable rationale is provided, physicians should not be required to repeatedly document the rationale in the medical record. Current language does not allow for this common situation.

Recommendation:

- **While AHCA agrees with the intent and purpose of these proposed changes, we believe CMS should delete the specificity and include more general and flexible language. The specifics can be included in interpretive guidance that can be revised more easily than making changes to regulations. We recommend change in language for section (4) under "c. drug regimen review" to "*pharmacist review of resident's medication regimen and recommendations must be communicated to the prescribing practitioner and the practitioner must document in the medical record their decision and rationale when those recommendations are not followed unless such documentation has been previously provided and acknowledged by the pharmacist.* The proposed components of the notification and documentation requirements can be specified in interpretative guidance.**
- **If CMS adopts this specific detailed language, accommodation for previous notifications to physicians and documentation of rationale needs to be taken into consideration.**
- **This requirement would require an increase in pharmacist hours and retraining of pharmacists which will take time. AHCA requests an 18-month to 24-month phase- in after this requirement is adopted.**
- **We request CMS to estimate the unfunded mandate costs associated with this requirement to state Medicaid programs and Part D plans of this proposed change since some states reimbursement are cost-based and increased medication costs that are likely to occur.**

N. Laboratory, radiology, and other diagnostic services (§ 483.50)

- § 483.50 proposes *to clarify that a physician assistant, nurse practitioner or clinical nurse specialist may order laboratory, radiology, and other diagnostic services for a resident in accordance with state law, including scope of practice laws*". This is in keeping with the literature supporting better quality with use of non-physician practitioners and consistent with state licensure laws.

  AHCA Recommendation:
  AHCA supports this change.

- § 483.50(a)(2)(ii) proposes "*to permit that the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist to be notified of laboratory results*" and that "*other practitioners have the ability to receive laboratory and radiology and other diagnostic results if these practitioners ordered the tests*." This will allow the ordering practitioner as well as any specialists and consultants to receive laboratory tests rather than funneling all results through the attending physician who may not have ordered the tests nor understand the context in which to interpret the results. This will help assure that

the results are interpreted in a timelier manner and improve the care of the resident.

AHCA Recommendation:
AHCA supports allowing other practitioners to receive laboratory results.

- § 483.50(a)(2)(ii) proposes to require that the SNF *"(ii) Promptly notify the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist of results that fall outside of clinical reference ranges in accordance with facility policies and procedures for notification of a practitioner or per the ordering physician's orders."* We disagree with CMS that this change will "ensure that the lab notifies the appropriate professional, we also want to reduce unnecessary notification of staff" and "this revision would improve the notification process, therefore saving time and reducing burden, while still ensuring resident safety." First, "promptly" is not defined and is used multiple times within the proposed rule, each with differing time frames implied or specified ranging from 3 days specified for denture replacement to multiple days or weeks implied for grievance resolution to hours for abuse notification to law enforcement. Second, many abnormal lab values are not associated with any medical problems nor require immediate intervention. Abnormal lab values are set at the 95% confidence interval on lab values for the general population. For some lab values, high or low values require an evaluation and interpretation (e.g., electrolytes such as potassium) since they can indicate a medical problem needing prompt evaluation and intervention. However, other lab values outside the 95% confidence interval, particularly if low, have no known medical implications. They are an artifact of how abnormal lab values are set. For example, liver enzymes that are low do not indicate any medical problem and should not require notification of a practitioner let alone "prompt" notification. Similarly, many of the values of a Complete Blood Count (CBC) are calculated values (e.g., MCHC) that help interpret measured values such as the hemoglobin and hematocrit. Having an abnormal calculated "lab value" for these interpretative values when the hematocrit and hemoglobin are normal does not indicate any urgent need for medical intervention. We believe this requirement will increase unnecessary notification of practitioners, often after hours, resulting in calls to covering physicians who don't know the patients, which will lead to unnecessary, repeat testing. This could both unnecessarily harm patients and increase medical costs. In addition, some lab values such as INR to measure blood clotting for individuals on anticoagulants should be abnormal. Thus, a normal value would indicate inadequate anticoagulation which may lead to harm of the patient if not addressed. It is unclear if this proposed language will also apply to EKG and CXR and other tests. If so, this will create significant problems since nearly all chest x-rays and EKGs in elderly will have some non-significant abnormality, most that do not require any further medical intervention.

We appreciate and support the concept that abnormal lab values need to be communicated to practitioners to assure they see the result in a timely manner to

determine if any further interventions are needed. However, as written "*promptly notifying*" practitioners for "*lab values that fall outside the normal range*" is too broad and will likely cause more harm than good. We believe the term "lab values that fall outside the normal range" should be deleted since it will lead to many inappropriate calls to physicians that do not help improve residents' care and outcomes. We do not believe that the proposed language of "in accordance with facility policies and procedures for notification of a practitioner or per ordering physician's orders" provides the flexibility needed to avoid the problems created by the language used in this proposed change. We would recommend revising language and specifying the details in interpretative guidance in the SOM.

AHCA Recommendation:

- **AHCA does not support this proposed change as written.**
- **We recommend changing the language to: <u>The facility must develop a policy and procedure for notifying the physician, physician assistant, nurse practitioner, or clinical nurse specialist of test results per the physician's orders or in a timely manner to assure that results requiring intervention or new orders are addressed by the practitioner in a timely manner.</u>**

O. Dental services (§ 483.55)

1) §483.55(a)(3) and §483.55(b)(4) "*May not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility;*" We understand this means the facility policy outlines those instances when the loss or damage of dentures is the facility's responsibility.
2) §483.55(a)(5) and §483.55(b)(3) "*Promptly, within three days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within three days, the facility must provide documentation of the extenuating circumstances that led to the delay.*" We understand this to mean the referral for services must occur within three days rather than the actual appointment and repair/replacement process must occur within three days. In some locations it will be impossible to obtain an appointment or services within three days.

AHCA Recommendations:

- **Amend** §483.55(a)(3) and §483.55(b)(4) "*May not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility;*" **to read: "<u>A facility must have a policy identifying those instances when the loss or damage of dentures is the facility's responsibility and</u>** *may not charge* **…."**
- §483.55(a)(5) and §483.55(b)(3) "*Promptly, within three days, refer residents with lost or damaged dentures for dental services.* **<u>For purposes of this provision, "refer" means to assist in making an appointment for repair or replacement of lost or damaged dentures rather than the appointment or repair/replacement must occur within three days…."</u>**

P. Food and nutrition services (§ 483.60)

1) §483.60(e)(2) should specify the attending physician, or that physician's covering physician may delegate the task of prescribing a resident's diet, etc. (Note: consistent with AHCA's recommended changes to §483.30(f)(2).

AHCA Recommendation:

- **Amend** §483.60(e)(2) **to read**: "*The* **attending** *physician* **or that physician's covering physician,** *may delegate to a registered or licensed dietitian the task of prescribing a resident's diet, including a therapeutic diet, to the extent allowed by State law.*"

Q. Specialized rehabilitative services (§ 483.65)

1) §483.65(a) "*Provision of services. If specialized rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, respiratory therapy, and rehabilitative services for mental illness and intellectual disability or services of a lesser intensity as set forth at § 483.120(c), are required in the resident's comprehensive plan of care, the facility must--*" AHCA is concerned that 'respiratory therapy' and the qualifications of individuals that would provide such services are not adequately defined in existing and proposed regulations. In this proposed rule §483.25((d)(11) on p. 42259 (and cross-reference chart on p. 42228) 'respiratory care' is mentioned in the discussion in the reorganization of the Quality of Care provisions. Other than tracheostomy care and tracheal suctioning, there is no definition of the scope of 'respiratory therapy' services under this rule other than a reference to the inclusion of respiratory therapy into the list of specialized rehabilitative services in §483.65, which is silent on the topic. With regards to qualifications, the only location in 42 CFR that defines the qualification of a respiratory therapist is within the Comprehensive Outpatient Rehabilitation Facility regulations under §485.70(j), which is not referenced in this proposed rule. However, the CMS RAI Version 3.0 Manual, Appendix A-19 includes a definition of respiratory therapy services that includes services furnished by "qualified professional" and includes the types of services that can be furnished by a 'respiratory therapist' and those that can be furnished by a 'respiratory nurse'. A clearer regulatory definition of the term and scope of 'respiratory therapy' services included under this rule and the qualifications necessary for individuals to furnish these services would help providers better understand how to meet these revised requirements.

AHCA is also concerned that very complex respiratory therapy services such as mechanical ventilation may be more challenging for smaller and more rural providers to provide or obtain under arrangement on a sporadic basis, particularly if they have conducted a facility-based and community-based risk assessment as proposed in §483.70 and could not identify adequate resources. In such cases, it would be reasonable to permit providers some flexibility in how the needs of these infrequent to rare beneficiary care needs in their locale are met. Additionally, in instances where providers agree to care for patients requiring

mechanical ventilation, it is often handled by special arrangements with the state and includes additional reimbursement.

2)§483.65(a)(2) "*Obtain the required services from an outside resource (in accordance with*
§483.70(g)) from a Medicare and/or Medicaid provider of specialized rehabilitative services."
The proposed insertion of the terms "Medicare and/or Medicaid" into §483.65(a)(2) implies these providers are separately certified to participate in Medicare and/or Medicaid programs. If implemented as proposed, this requirement would have a profound and deleterious impact on the ability of nursing center providers' ability to provide rehabilitation therapy services, particularly in rural and underserved areas. Rather, AHCA recommends that nursing centers continue to be permitted to obtain such necessary services from qualified therapy professionals that are appropriately licensed/certified to practice their profession within the respective state where the rehabilitation services are being furnished, and are not otherwise excluded from federally funded health care programs including Medicare and/or Medicaid.

Background

- Under consolidated billing regulations, all skilled nursing center rehabilitation services furnished under Medicare Part A or Medicare Part B to facility residents, including those obtained under arrangement, are subject to the skilled nursing center requirements of participation and applicable payment policies and are billed through the skilled nursing center.
- Those skilled nursing center rehabilitation therapy services that have been historically obtained under arrangement with:
    - Other Medicare Providers and Suppliers of therapy services (e.g., rehabilitation agencies and therapists in private practice,
    - Health care staffing agencies that are not enrolled as Medicare providers or suppliers but furnish temporary professional therapy staffing, and
    - Individual persons licensed/certified in their respective state to furnish therapy services (e.g., therapists providing temporary weekend, vacation coverage).
- Based upon data obtained from FY 2013 Medicare skilled nursing center cost reports, nearly one quarter of rehabilitation therapy services furnished in skilled nursing centers is obtained under arrangement (physical therapy – 23 percent of PT hours, occupational therapy – 25 percent of OT hours, and speech-language pathology – 26 percent of SLP hours).

AHCA Recommendations:

1) **AHCA recommends CMS clarify the definition and the scope of required respiratory therapy services and service providers in regulation.**

   AHCA also recommends CMS include provisions describing what complex respiratory services could be excluded from those services the center must furnish or provide under arrangement, and what steps the center must take, including potential avoidance of admission or transfer to another center, to

assure that the beneficiary care plan needs are met at a location with the appropriate capabilities.

2) **AHCA strongly opposes the insertion of the proposed language that appears to require that the outside resource obtained under arrangement must also be independently certified as a "Medicare and/or Medicaid" provider of specialized rehabilitative services, and recommends alternative language to §483.65 and §483.70 to provide necessary protections.**

Amend §483.65(a)(2) to read*: Obtain the required services from an outside resource (in accordance with §483.70(g)). ~~from a Medicare and/or Medicaid provider of specialized rehabilitative services~~*

Amend §483.70(g)(2) by adding a new "(ii)" and renumbering the current "(ii) to "(iii).

2*) Arrangements as described in section 1861(w) of the Act or agreements pertaining to services furnished by outside resources must specify in writing that the facility assumes responsibility for—*

(i) Obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility;

(ii) Assuring that the outside resource person or agency is not excluded from Federally funded health care programs pursuant to sections 1128 and 1156 of the Social Security Act; and

(iii) The timeliness of the services

R. Outpatient Rehabilitative Services (§ 483.67)

1) AHCA welcomes the efforts by CMS to add clarifying language in regulation to confirm that nursing centers may furnish outpatient therapy services to nonresidents and those services may be furnished at a location outside of the facility location or on-site at the facility on an outpatient basis. In addition, we appreciate the efforts to address the health and safety standards for those outpatient therapy locations not otherwise addressed in the resident-specific regulations. To date, there have been inconsistent interpretations by state agencies regarding how skilled nursing centers can furnish outpatient therapy services to non-residents, and this rule would be a step forward in standardization of such interpretations.

However, we note that outpatient therapy services furnished by skilled nursing centers much more closely resemble the delivery of those services furnished through outpatient rehabilitation providers described under 42 CFR Part 485, Subpart H, many of which are referred to as 'Rehabilitation Agencies", than how such services are furnished through outpatient hospital departments.

For example, outpatient hospital therapy departments are typically designed to be ambulatory care centers located either as part of a hospital or medical complex, or as a freestanding satellite ambulatory clinic some distance away from the main hospital. It is uncommon for hospitals to furnish outpatient therapy services in Medicare beneficiaries' home environments, including independent senior living or assisted living residences.

By contrast, while rehabilitation agencies may furnish outpatient therapy services through ambulatory care facilities, they also commonly furnish outpatient therapy services to residents of independent senior living and assisted living residents. Such services can be furnished to beneficiaries in their room/apartment, which is treated by Medicare as the beneficiary's home, or in a dedicated treatment area located (referred to as an extension location) in the independent living or assisted living complex. This is very similar to how skilled nursing centers' outpatient rehabilitation services are furnished to residents of independent living or assisted living residents that may reside on the same campus or within the same corporate umbrella as the skilled nursing center. If fact, many rehabilitation agencies furnishing outpatient therapy services to a residents in a freestanding assisted living residence may also be furnishing the same services billed through a skilled nursing center if they are otherwise providing therapy services under arrangement with the skilled nursing center.

The difference between treating an individual in the SNF versus in their home, which could be located in a senior residence, such as an assisted living center, may require a nuanced regulatory approach. For example, on April 3, 2015, CMS posted a memo on "Clarification of Requirements for Off-Premises Activities and Approval of Extension Locations for Providers of Outpatient Physical Therapy (OPT) and Speech-Language Pathology Services and Off-Premises Activities" at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-33.pdf. This clarification addressed off-premises treatment activities, and significant parts of these provisions could be extended appropriately to skilled nursing center-furnished outpatient therapy services to non-residents.

We believe that CMS can best meet the desired health and safety objectives of this rule by assuring appropriate flexibility for skilled nursing centers in how their outpatient therapy services are furnished to beneficiaries residing in residences other than the skilled nursing facility, that is consistent with that permitted in other Medicare outpatient therapy providers.

2) Medicare Part B outpatient therapy payment policy does not require treatment orders as it defers to state law (see Medicare Benefit Policy Manual, Chapter 15, §220.1.1). Medicare does require a plan of care to be certified by an applicable professional (currently a physician or certain non-physician practitioners). The minor modification we recommend would more clearly align with outpatient

therapy policy across all settings as well as meet the desired health and safety objectives of this rule.

AHCA Recommendations:

1) **AHCA recommends that the health and safety standards in the proposed outpatient rehabilitative services provisions assure appropriate flexibility for skilled nursing facilities to furnish off-premises outpatient therapy services to beneficiaries who live in a residence other than the licensed nursing facility, which is consistent with what is permitted for other Medicare outpatient therapy providers.**

2) **AHCA recommends that the proposed language in §483.67(c)(2) (p.42263) be revised as follows: "All rehabilitation services orders (when applicable), certification of the plan of care, and progress notes must be documented in the patient's clinical record in accordance with the requirements at § 483.70(i)."**

S. Administration (§ 483.70)
1) §483.70(e) requires a facility assessment. Earlier in these comments, (in the section Responses to Specific Questions Posed by CMS or Solicitation for Comments in the Preamble) we've included our concerns with this requirement. While some nursing centers may complete a similar assessment, the process is for how to best conduct their business, which includes providing quality care for the residents/patients they serve. This assessment is considered proprietary.

Additionally, putting this level of detail into the Requirements of Participation is unreasonable and will be extremely burdensome on providers. Because it must be updated as necessary, the potential is the facility will be updating it every time their patient-mix changes, they hire new staff, they hire a new Director of Nursing, conduct any remodeling, etc. CMS's reasoning for including this assessment as a Requirement of Participation is completely unclear.

AHCA Recommendation:

1) **Delete §483.70(e) in its entirety.**
2) **CMS must form a stakeholder workgroup to meet in person and explore the potential use of a "facility assessment" and discuss and consider alternate approaches. In addition, the stakeholder workgroup must discuss the potential unintended negative outcomes that may result from putting such a detailed assessment in the Requirements of Participation, and must determine a realistic implementation timeline. In order to begin this discussion, CMS must:**
    - **Provide clarification about what CMS envisions for a facility assessment; and**

- **Provide evidence for the value of proposing this facility assessment in the Requirements of Participation; and**
- **Provide evidence-based models of facility assessment and process.**

T. Quality assurance and performance improvement (§ 483.75)

As mentioned previously, AHCA is extremely supportive of the Quality Assurance and Performance Improvement (QAPI) legislation. For several years AHCA has been working to raise awareness and educate members on the principles and impending requirements, since the since the enactment of Affordable Care Act. In fact, AHCA has been encouraging members to adopt principles since before the release of QAPI, through its AHCA/NCAL National Quality Award program. This program, based on the criteria of the Baldrige Performance Excellence Program, has the same characteristics, principles and foundation as QAPI. The Baldrige criteria require applicants to describe their systematic processes in six key management areas (leadership, strategic planning, customer, measurement, analysis and knowledge management, workforce and operations). In explaining their processes, applicants are required to show an effective approach, deployment (to other work units or departments), learning (personal and organizational) and integration (with what the center identifies as important, i.e., mission, vision). The criteria also put a heavy emphasis on the outcomes applicants achieve in these key management areas. These requirements link solidly with the five elements of QAPI.

AHCA is very concerned about the language and approach CMS has taken in the proposed rule. The proposed rule[1] significantly modifies the current QAA-related provisions included in the Requirements for Participation for Long-Term Care Facilities.[2] CMS explains in the preamble discussion that proposed 42 C.F.R. § 483.75 would "establish [the] programmatic standards" "relating to facilities' QAPI program[s]" required by Section 6102 of the Affordable Care Act ("ACA").[3]

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1 80 Fed. Reg. 42,168 (July 16, 2015).

2 The current QAA regulations, found at 42 C.F.R. § 483.75(o) state:

Quality assessment and assurance.

(1) A facility must maintain a quality assessment and assurance committee consisting of—

(i) The director of nursing services;

(ii) A physician designated by the facility; and

(iii) At least 3 other members of the facility's staff.

(2) The quality assessment and assurance committee—

(i) Meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and

(ii) Develops and implements appropriate plans of action to correct identified quality deficiencies.

(3) A State or the Secretary may not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section.

(4) Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions. (Emphasis added.)

3 *Id*. at 42,212. In addition, Section 6102 of the ACA is codified at 42 U.S.C. § 1320a-7j(c).

In order to best understand the proposed rule's provisions, it is helpful to review the QAPI-related statutory provisions included in the ACA. Section 6102 of the ACA's QAPI-related provisions are codified at 42 U.S.C. § 1320a-7j(c). 42 U.S.C. § 1320a-7j(c) states:

> Quality Assurance And Performance Improvement Program.—
>
> > (1) In general.—Not later than December 31, 2011, the Secretary shall establish and implement a quality assurance and performance improvement program (in this subparagraph referred to as the "QAPI program") for facilities, including multi unit chains of facilities. Under the QAPI program, the Secretary shall establish standards relating to quality assurance and performance improvement with respect to facilities and provide technical assistance to facilities on the development of best practices in order to meet such standards. Not later than 1 year after the date on which the regulations are promulgated under paragraph (2), a facility must submit to the Secretary a plan for the facility to meet such standards and implement such best practices, including how to coordinate the implementation of such plan with quality assessment and assurance activities conducted under sections 1819(b)(1)(B) and 1919(b)(1)(B), as applicable.
> >
> > (2) Regulations.—The Secretary shall promulgate regulations to carry out this subsection. (Emphasis added.)

42 U.S.C. § 1320a-7j(c) requires the Secretary to "establish and implement a quality assurance and performance improvement program"; to "establish standards relating to quality assurance and performance improvement with respect to facilities and provide technical assistance to facilities on the development of best practices in order to meet such standards"; and to "promulgate regulations to carry out this subsection". In addition, the statute expressly requires facilities to "submit to the Secretary a plan for the facility to meet such standards and implement such best practices."

In the Proposed Rule, the Secretary significantly expands upon this statutory mandate by including a laundry list of requirements related to the QAPI program, including requiring the disclosure of or potentially requiring a facility provide access to a plethora of QAPI-related documentation and records by facilities. According to proposed 42 C.F.R. § 483.75(a), each facility must:

> (1) Maintain documentation and demonstrate evidence of its ongoing QAPI program that meets the requirements of this section;
>
> (2) Present its QAPI plan to the State Agency Surveyor at the first annual recertification survey that occurs after [the effective date of this regulation];

(3) Present its QAPI plan to a State Agency or Federal surveyor at each annual recertification survey and upon request during any other survey and to CMS upon request; and

(4) Present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with requirements to a State Agency, Federal surveyor or CMS upon request.

Notably, the proposed requirements in 42 C.F.R. § 483.75(a) exceed what a facility would be required to provide under the statute, 42 U.S.C. § 1320a-7j(c)(1), which requires only that a facility submit "a plan" to the Secretary to show how the facility will meet such standards and implement best practices, no later than one year after regulations are promulgated.

CMS further exceeds what documentation and reports a facility would be required to submit to the Secretary under the statute, 42 U.S.C. § 1320a-7j(c), by requiring, at the proposed 42 C.F.R. § 483.75(h):

Disclosure of information.

(1) A State or the Secretary may not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section.

(2) Demonstration of compliance with the requirements of this section may require State or Federal surveyor access to:

(i) Systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events;

(ii) Documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities; and

(iii) Other documentation considered necessary by a State or Federal surveyor in assessing compliance.

The proposed 42 C.F.R. § 483.75(h) is internally inconsistent. In particular, the proposed 42 C.F.R. § 483.75(h)(1) states, "[a] State or the Secretary may not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section," while the remainder of 42 C.F.R. § 483.75(h) seems to require the disclosure of QAA committee[4] records that would be unnecessary to demonstrate compliance with 42 C.F.R. § 483.75.

[4] AHCA refers to quality improvement/quality assurance committees as "QAA committees," while recognizing that some centers refer to such committees as quality improvement committees, or QIC.

Finally, the proposed 42 C.F.R. § 483.75(i) relates to sanctions, and states, "[g]ood faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions."

OVERVIEW OF FEDERAL QAA PRIVILEGE PROTECTION

A. The Statutory QAA Privilege Protection

42 U.S.C. § 1395i–3(b)(1)(B) and 42 U.S.C. § 1396r(b)(1)(B) state:

> Quality assessment and assurance.—A [skilled] nursing facility must maintain a quality assessment and assurance committee, consisting of the director of nursing services, a physician designated by the facility, and at least 3 other members of the facility's staff, which (i) meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary and (ii) develops and implements appropriate plans of action to correct identified quality deficiencies. A State or the Secretary may not require disclosure of the records of such committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this subparagraph. (Emphasis added.)

Congress enacted the Federal Nursing Home Reform Act, which included QAA provisions, as part of the Omnibus Budget Reconciliation Act of 1987 ("OBRA '87"). Section 4201 of OBRA '87 included some of the current QAA statutory language.[5] Congress amended the Federal Nursing Home Reform Act to include the QAA privilege protection in 1990.[6] The legislative history of the QAA privilege protection provision demonstrates Congressional intent with respect to the privilege protection. In particular, the House Committee on Budget stated, in its report:

> (3) Disclosure of Information of Quality Assessment and Assurance Committees. Under OBRA 1987, nursing facilities must establish and maintain a quality assessment and assurance committee designed to (1) identify quality assessment and assurance issues and (2) develop and implement appropriate plans of action to correct those quality deficiencies which have been identified. The Committee bill clarifies that the internal records of these committees are subject to disclosure **only** for the purpose of determining whether or not such a committee is meeting its statutory obligations, and, in turn, of determining whether a nursing facility is in compliance with this OBRA 1987 requirement.[7]

The statute provides that QAA privilege applies to the "records of" a QAA committee. Neither the statute, regulations[8] or guidance further define what constitutes the "records of" the QAA committee. Guidance to surveyors found in the *State Operations Manual* at

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5 Pub. L. 100-203.

6 Pub. L. 101-508, Sec. 4008.

7 *See* 101 H. Rpt. 881; part 1 (October 16, 1990) (emphasis added).

8 The current QAA regulations, 42 C.F.R. § 483.75(o)(3) state: "A State or the Secretary may not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section."

F520 states: "records of the committee meetings identifying quality deficiencies, by statute, may not be reviewed by surveyors unless the facility chooses to provide them. However, the documents the committee used to determine quality deficiencies are subject to review by the surveyors."[9] The *State Operations Manual* then states, "[a] State or the Secretary may not require disclosure of the records of the QAA committee except insofar as such disclosure is related to the compliance of the QAA committee with the regulations."[10]

Parallel State QAA or Quality Improvement Privilege Protections

Some states have enacted statutes that bolster the federal QAA privilege protections. Such statutes may provide privilege protection beyond the federal QAA privilege protection. For example, in Tennessee, Tenn. Code § 68-11-272 provides:

> (1) Records of a QIC and testimony or statements by a healthcare organization's officers, directors, trustees, healthcare providers, administrative staff, employees or other committee members or attendees relating to activities of the QIC shall be confidential and privileged and shall be protected from direct or indirect means of discovery, subpoena or admission into evidence in any judicial or administrative proceeding. Any person who supplies information, testifies or makes statements as part of a QIC may not be required to provide information as to the information, testimony or statements provided to or made before such a committee or opinions formed by such person as a result of committee participation.
>
> (2) Any information, documents or records, which are not produced for use by a QIC or which are not produced by persons acting on behalf of a QIC, and are otherwise available from original sources, shall not be construed as immune from discovery or use in any judicial or administrative proceeding merely because such information, documents or records were presented during proceedings of such committee. (Emphasis added.)

Further, the Tennessee statute defines "records" as, "records of interviews and all reports, incident reports, statements, minutes, memoranda, charts, statistics, evaluations, critiques, test results, corrective actions, disciplinary actions, and any and all other documentation generated by or in connection with activities of a QIC and any patient safety work product as defined at § 921 of the Patient Safety and Quality Improvement Act of 2005."[11] CMS's proposed QAPI provisions could diminish the privilege protection afforded by such state statutes.

PROPOSED QAPI PROGRAM REQUIREMENTS ARE INCONSISTENT WITH THE QAA PRIVILEGE PROTECTION FOUND AT 42 U.S.C. § 1395I–3(B)(1)(B) AND 42 U.S.C. § 1396R(B)(1)(B)

As explained above, 42 U.S.C. § 1395i–3(b)(1)(B) and 42 U.S.C. § 1396r(b)(1)(B) state:

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9 Centers for Medicare & Medicaid Services, *State Operations Manual*, Appendix PP, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf.

10 *Id*.

18 Tenn. Code § 68-11-272(b)(5).

> A State or the Secretary may not require disclosure of the records of [the quality assessment and assurance] committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this subparagraph.

The subparagraph referenced in this provision requires facilities to maintain a QAA committee, consisting of certain individuals, which meets at least quarterly and develops and implements appropriate plans of action to correct identified quality deficiencies. 42 U.S.C. § 1320a-7j(c) requires facilities to "submit to the Secretary a plan for the facility to meet [QAPI] standards and implement such best practices [developed by the Secretary]". Reading these two statutory provisions together, AHCA believes that "a State or the Secretary"—including state survey agencies—may not require disclosure of the records of the QAA committee with the exception of: (1) documents demonstrating compliance with the requirement to maintain a quality assessment and assurance committee; and (2) a plan for the facility to meet QAPI program standards and implement QAPI program best practices.

AHCA believes that the proposed regulations exceed the statutory authority granted to CMS. In particular, we believe that the proposed disclosure requirements found at 42 C.F.R. § 483.75(h)(2)(i)-(iii) conflict with the statutory framework. Proposed 42 C.F.R. § 483.75(h)(2) states that state or federal surveyors may require access to:

> (i) Systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events;
> (ii) Documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities; and
> (iii) Other documentation considered necessary by a State or Federal surveyor in assessing compliance.

Such documents and other materials could likely be the "records of" the QAA committee, and therefore, pursuant to 42 U.S.C. § 1395i–3(b)(1)(B) and 42 U.S.C. § 1396r(b)(1)(B), the Secretary may not require disclosure of such records. Notably, 42 U.S.C. § 1320a-7j(c) did not include an exception to the protections afforded at 42 U.S.C. § 1395i–3(b)(1)(B) and 42 U.S.C. § 1396r(b)(1)(B) and only expressly requires the disclosure of a plan to meet QAPI standards. The proposed 42 C.F.R. § 483.75(a), requiring facilities to "[p]resent documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with requirements to a State Agency, Federal surveyor or CMS upon request" also exceeds the permissibly required disclosures under the statute.

WAIVING PRIVILEGE PROTECTION

QAA committees frequently review and investigate incidents that may lead to litigation, and as such, certain documents and other materials produced by or at the request of QAA committees in furtherance of quality improvement could be valuable to plaintiffs' attorneys as they litigate liability claims against long-term care facilities. As a consequence, it is imperative for facilities to avoid inadvertently waiving the QAA privilege protection, found in either federal law or state law, in order to protect the potential disclosure of such materials during the discovery process of a liability litigation.

Both state and federal QAA privilege protection can be waived by a facility's own conduct. For example, voluntary disclosure of documents or other materials potentially protected by QAA privilege in one context (*e.g.*, to state surveyors or CMS) may be deemed to waive the privilege in other contexts, thereby potentially requiring disclosure of such documents or other materials during the litigation discovery process. Under the proposed 42 C.F.R. § 483.75, federal or state surveyors could require the disclosure of a wide variety of QAPI documents or other materials. The disclosure of such QAPI documents or other materials to federal or state surveyors would likely waive any federal QAA privilege protection that would otherwise attach to the materials, a result that seems contrary to Congressional intent with respect to QAA privilege protection.

We also note that some AHCA members have been threatened with decertification if they refuse to provide state surveyors with certain QAA privileged material. This leaves providers between a rock and a hard place: lose privilege protection or decertification.

LEGAL BASIS TO PREVENT CMS AND STATE SURVEY AGENCIES FROM USING QAPI MATERIALS FOR THE BASIS FOR SANCTIONS

The proposed 42 C.F.R. § 483.75(i) relates to potential sanctions that would stem from QAPI materials furnished to CMS and state survey agencies, and states, "[g]ood faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions." This language mirrors the language found at the current 42 C.F.R. § 483.75(o)(3). CMS provides the following guidance with respect the current 42 C.F.R. § 483.75(o)(3) in the *State Operations Manual*:

> The regulation states that good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions. The facility is not required to release the records of the QAA committee to the surveyors to review, and the facility is not required to disclose records of the QAA committee beyond those that demonstrate compliance with the regulation (F520). However the facility may choose such disclosure if it is the facility's only means of showing the composition and functioning of the QAA committee. <u>If the facility has provided the records for surveyor review, this information may not be used to cite deficiencies unrelated to the QAA committee requirement</u>. It is recommended that surveyors not review QAA records (if provided) until after they complete their investigations of other tags.
>
> If the survey team's review of the QAA committee records reveals that the committee is making good faith efforts to identify quality deficiencies and to develop action plans to correct quality deficiencies, this requirement (F520) should not be cited. However, if the survey team had already independently (not through use of the records) identified noncompliance in the same areas as those

that have been selected by the QAA committee, the team is expected to cite the noncompliance for the other requirements.[12]

Importantly, the current and proposed regulation, and CMS' current *State Operations Manual* guidance, limits how CMS may utilize the QAA/QAPI materials furnished to a CMS or a state survey agency. However, of course, the regulation qualifies such limitation, stating that the QAPI materials at issue must be "[g]ood faith attempts by the committee to identify and correct quality deficiencies". In addition, of course, this limitation seems difficult, if not impossible, to monitor. For example, it may be unrealistic for a facility to identify that a surveyor became aware of a potential deficiency through QAA/QAPI materials as opposed to other findings resulting from investigations related to other F-tags.

There are strong policy arguments regarding why utilizing QAA/QAPI materials to cite deficiencies unrelated to the QAA/QAPI requirement is inimical to the purpose of furnishing confidentiality and privilege to such materials. The purpose of the confidentiality and privilege that attaches to QAA/QAPI documents and other materials is to encourage a thorough and candid review of facilities' practices and operations in an effort to improve the quality of care furnished to residents. CMS' proposal to require submission of various QAPI documents to state and federal surveyors could substantially undermine the purpose of QAA committees/QAPI programs. Moreover, CMS does not address the fact that, once disclosed, the materials could be publicly available through Freedom of Information Act ("FOIA") or other state open records processes, available to plaintiffs' lawyers and others who could misuse or misinterpret this information for their own, unrelated purposes. As a consequence, we recommend that AHCA strongly urges CMS to delete the QAPI disclosure requirements as written and reinforce the existing QAA privilege. AHCA also requests that CMS strengthen the provision disallowing attempts by the committee to identify and correct quality deficiencies as the basis for sanctions.

AHCA Recommendation:

- Delete the proposed regulations for QAPI and replace with the statutory language: Not later than 1 year after the date on which the regulations are promulgated under paragraph (2), a facility must submit to the Secretary a plan for the facility to meet such standards and implement such best practices, including how to coordinate the implementation of such plan with quality assessment and assurance activities conducted under sections 1819(b)(1)(B) and 1919(b)(1)(B), as applicable.

- Provide a staggered implementation timeline for the QAPI program over a 5-year period, during which time each nursing center would show progress in its implementation process during the annual standard survey.

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[19] Centers for Medicare & Medicaid Services, *State Operations Manual*, Appendix PP, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf (emphasis added).

Infection control (§ 483.80)

The infection control proposed language addresses an important issue facing individuals in SNFs and NFs. The proposed language specifies in detail the scope and components of an infection control program. The detail goes well beyond what is specified in hospital Conditions of Participation, a setting with much greater risk of infections and individuals at higher risk of adverse events from infections. We recommend adopting more general language similar to that used in the hospital Conditions about infection control in place of the proposed detailed language and specify details in interpretive guidance development done in partnership with stakeholders. The hospital Condition language is provided below for comparison:

> ***Hospital 482.42 Condition of participation: Infection control.***
> *The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.*
> *(a) Standard: Organization and policies. A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.*
> *(1) The infection control officer or officers must develop a system for identifying reporting, investigating, and controlling infections and communicable diseases of patients and personnel.*
> *(2) The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.*
> *(b) Standard: Responsibilities of chief executive officer, medical staff, and director of nursing services. The chief executive officer, the medical staff, and the director of nursing services must—*
> *(1) Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and*
> *(2) Be responsible for the implementation of successful corrective action plans in affected problem areas.*

We think referring to the goal and purpose of infection control program along with following national standards allows the goal and intent to be accomplished. Affording providers greater flexibility and creativity in how to achieve the goals also provides CMS flexibility to provide additional suggested approaches in interpretative guidance. Further, modifying and updating the guidance as new and better practices are identified over time is preferable to the long and arduous formal rulemaking process to update the Requirements.

In addition, the detail about the Infection Prevention and Control Officer (IPCO) requirements is unnecessary, increases costs and is inconsistent with Hospital Conditions. For example, a person with a public health background who is not a clinician can serve as IPCO in a hospital but would not be allowed to serve as such in a SNF/NF given the proposed language. Also, Hospital Conditions do not require the IPCP as a major

responsibility of the IPCO or require the IPCO to have specialized training in infection prevention and control.

We recommend allowing a person to serve as IPCO who has received training in infection control and specify such acceptable training in interpretive guidance. In the end, it is the practice of infection control and resulting outcomes that are important to the residents rather than having a person with specific credentials, which does not necessarily ensure effective infection control practices. The proposed specifications also make it harder to hire an IPCO, particularly in rural areas. If CMS persists with the requirements of an IPCO, then CMS must allow 2-3 years for SNFs to find, hire and train such a person and provide some waiver process when due diligence has been followed but such a person is not available.

The meaning of "major responsibility" is unclear in the proposed requirement that the IPCP is "*a major responsibility for the individual assigned as the facility's IPCO*." "Major responsibility" could easily be interpreted as 0.50 FTE or more, however the CMS cost estimate of an average facility designated the IPCO as 0.15 FTE to responsibilities under IPCP, which is not consistent with simple interpretation of "major responsibility" language. This lack of clarity will lead to confusion and inconsistencies for providers and surveyors, resulting in technical misunderstandings that will undermine the intent of this requirement. We appreciate CMS's recognition that the percentage of IPCO FTE required will vary greatly among facilities, therefore we recommend language change to remove the word "major".

AHCA supports the efforts to address antibiotic stewardship. However, this is not a problem isolated to the long term care community. For example, efforts to follow SHEA criteria for urinary tract infections in the SNF setting have been undermined by two common situations that cause a disconnect. First, the hospital emergency rooms obtaining a urine analysis on nearly all SNF or NF transfers, which the literature would indicate that over 50% will have asymptomatic bacteria which would not meet SHEA criteria for antibiotic treatment. Regardless, the ER frequently starts antibiotics and returns the residents to the SNF/NF. Thus, the hospital Conditions need the same language. Second common example of disconnect is how State Survey Agency's enforce adverse events, UTIs and/or urosepsis that do develop in some patients with bacteria on urine analysis but do not meet SHEA criteria for antibiotic treatment. If Centers follow national standards for antibiotic use yet an infection develops, the State Survey Agency should not cite providers for the adverse event; otherwise all efforts to improve antibiotic stewardship will be undermined. This scenario has occurred across the country over the past several years as providers have attempted to follow the SHEA criteria.

AHCA Recommendation:

- **Amend** § 483.80(a) and (b) **to read:**

The facility must establish and maintain an infection prevention and control program designed to provide a safe~~,~~ **and** *sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections.*

(a)Infection prevention and control program. The facility must establish an infection prevention and control program (IPCP)~~that must include, at a minimum, the following elements:~~

~~(1)A system~~ for preventing, identifying, reporting, investigating, and controlling infections and

communicable diseases **in the facility** *~~for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement based upon the facility assessment conducted according to § 483.75(e) and~~* **that follows** *~~following~~ accepted national standards~~;~~.*

The IPCP should also include but not be limited to the following:

~~(2) Written standards, policies, and procedures for the program, which must include, but are not limited to:~~

~~(i) A system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;~~

~~(ii) When and to whom possible incidents of communicable disease or infections should be reported;~~

~~(iii) Standard and transmission-based precautions to be followed to prevent spread of infections;~~

~~(iv) When isolation should be used for a resident;~~

~~(v) The circumstances under which the facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct~~

~~contact will transmit the disease; and~~

~~(vi) The hand hygiene procedures to be followed by staff involved in direct resident contact,~~

~~(3)~~ **(1)An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.**

(2) A system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility.

(b) Infection prevention and control officer **or officers***. The facility must designate one* **or more** *individual***s** *as the infection prevention and control officer***s** *(IPCO) ~~for whom the IPCP at that facility is a majorresponsibility~~. The IPCO must* **have training in infection prevention and control to effectively carry out he IPCP.**~~:~~

~~(1) Be a clinician who works at least part-time at the facility, and~~

~~(2) Have specialized training in infection prevention and control beyond their initial professional degree.~~

~~(c) IPCO participation on quality assessment and assurance committee. The person designated as the IPCO must be a member of the facility's quality assessment and assurance committee~~

~~and report to the committee on the IPCP on a regular basis.~~

- **Should CMS move forward with specifying the details of the IPCP in the Requirements, we recommend using the word "should" instead of "must" to allow flexibility for both providers and CMS when legitimate exceptions are identified or new and better practices are identified.**

- **Should CMS move forward with specifying the requirements of an IPCO, then CMS must allow 2-3 years for SNFs to find, hire and train such a person and provide some waiver process when due diligence has been followed but such a person is not available.**
- **Should CMS move forward with the Requirements as proposed, CMS must clarify the meaning of "major responsibility" and "specialized training" for IPCO.**
- **Should CMS move forward with the Requirements as proposed, add language to the antibiotic stewardship that indicates providers will not be cited if an infection develops when the provider has followed nationally accepted guidelines for antibiotic use (e.g. SHEA).**
- **We recommend CMS update Conditions of Participation for hospitals, physicians and other providers to include antibiotic stewardship program because physicians ultimately are the prescriber of antibiotics and many of the antibiotics in the SNF population were started in the hospital or emergency rooms.**

§ 483.80(d) Influenza and pneumococcal immunizations
The specificity and process outlined is detailed, and much greater than is specified in CMS Conditions of Participation for other providers (such as hospitals and physicians). No justification is provided as to why individuals in SNF or NF settings require a different process. It is also unclear why these particular vaccines require detailed specifications when for Conditions of Participation for hospitals, physicians and other providers medications and lab tests that have a much higher risk to individuals, no such requirement is made here or for other providers. Similarly, other vaccines that may have higher risks of side-effects are not specified. There are already standards in place about physicians and health care providers obtaining informed consent prior to medication, lab tests or vaccine administration. The reason for influenza and pneumococcal vaccines requiring additional emphasis is unclear and unjustified. If anything, the long term care population is at higher risk from influenza and pneumococcal pneumonia, particularly for individuals living in settings such as SNFs/NFs where outbreaks can occur. Therefore, it seems illogical to put in place more detailed and restrictive requirements that may lower vaccination rates in SNFs and NFs compared to hospitals and physician offices.

In addition, the process may have the unintended result of lowering vaccination rates due to the detailed nature of the language. Informed consent does NOT require written or signed consent. The requirement of adding documentation in the medical record is moving in the wrong direction and does not recognize the movement of EMRs. The language should be modified to indicate "**standard documentation or as required by the State**" rather than as proposed.

The proposed rule is unclear as to what happens when the resident and the resident representative disagree.

Specifying the date ranges for administering the vaccine also is not consistent with good public health practices and allows for influenza outbreaks that may occur early or late in

the season. Some medical literature suggests that early vaccination in September may be beneficial to the elderly. By providing this level of detail in the Requirements, CMS is making it more difficult to modify and update the standards as CDC and others make newer recommendations. For example, it has taken several years for CMS to propose to modify the current requirement to offer a second pneumococcal pneumonia vaccine (PPV) despite guidance that this practice is no longer appropriate. Providing the same level of detail in the new language runs the risk of CMS continuing to require practices that are no longer appropriate. The details should be removed from the Requirements and placed in interpretative guidance that can be modified and changed in timelier manner.

AHCA Recommendations:

Amend § 483.80(d) to read:
(d) *Influenza and pneumococcal immunizations*—~~(1) *Influenza*~~. The facility must develop policies and procedures to ensure that **all residents and employees with direct patient care contact are offered and receive the influenza vaccine, unless they decline, per CDC guidance. All residents are offered and receive the pneumococcal vaccine, unless they decline, per CDC guidance.**
~~(i) Before offering the influenza immunization, each resident or the resident's representative receives education regarding the benefits and potential side effects of the immunization;~~
~~(ii) Each resident is offered an influenza immunization October 1 through March 31 annually, unless the immunization is medically contraindicated or the resident has already been immunized during this time period;~~
~~(iii) The resident or the resident's representative has the opportunity to refuse immunization; and~~
~~(iv) The resident's medical record includes documentation that indicates, at a minimum, the following:~~
~~(A) That the resident or resident's representative was provided education regarding the benefits and potential side effects of influenza immunization; and~~
~~(B) That the resident either received the influenza immunization or did not receive the influenza immunization due to medical contraindications or refusal.~~
~~(2) *Pneumococcal disease*. The facility must develop policies and procedures to ensure that—~~
~~(i) Before offering the pneumococcal immunization, each resident or the resident's representative receives education regarding the benefits and potential side effects of the immunization;~~
~~(ii) Each resident is offered a pneumococcal immunization, unless the immunization is medically~~
~~contraindicated or the resident has already been immunized;~~
~~(iii) The resident or the resident's representative has the opportunity to refuse immunization; and (iv) The resident's medical record includes documentation that indicates, at a minimum, the following:~~
~~(A) That the resident or resident's representative was provided education regarding the benefits and potential side effects of pneumococcal immunization; and~~

~~(B) That the resident either received the pneumococcal immunization or did not receive the pneumococcal immunization due to medical contraindication or refusal.~~

V. Compliance and ethics program (§ 483.85)

For many years, AHCA/NCAL has worked closely with the US Department of Health and Human Services (HHS), Office of Inspector General (OIG) to provide background information, submit informal and formal comments and educate our membership regarding the *OIG Compliance Program Guidance for Nursing Facilities* (65 *Fed. Reg.* 14,289 (Mar. 16, 2000) and the *OIG Supplemental Compliance Program Guidance for Nursing Facilities* (73 *Fed. Reg.* 56,832, Sept. 30, 2008**).** AHCA supports the seven basic elements of an effective compliance program outlined in those guidance documents. We also understand and have educated our membership about the obligations under the Affordable Care Act (ACA), requiring skilled nursing facilities and nursing facilities to have an effective compliance and ethics program in place. Since as early as 1998, AHCA/NCAL has consistently evaluated and updated compliance program educational tools for our membership, and currently, the most relevant compliance and ethics program information is posted to our website.

CMS' proposed rule indicates that every nursing center must have a compliance and ethics program in place one year after adoption of the final rule. In addition, pursuant to the proposed rule, the program must have certain specified components. In operating organizations that have five or more centers, there must be a designated compliance officer for whom the program is a "major responsibility," as well as a compliance liaison at each individual nursing center within the organization. That liaison must report directly to the operating organization's governing body.

AHCA appreciates CMS' recognition of the different levels of resources available to larger and smaller organizations to develop and implement compliance and ethics programs. AHCA also appreciates CMS' application of a reasonableness standard to several components of the proposed rule. At the same time, we continue to believe that certain elements of the proposed rule are unduly prescriptive and costly and could impose an unnecessarily onerous burden on some of our members.

Cost Estimates:

AHCA is concerned that CMS' economic impact statement for the cost to develop and implement a compliance program is unrealistically low and in fact may be only about half of the actual cost to develop and implement a compliance and ethics program. CMS estimates that provider's compliance with the program requirements (not including compliance and ethics training) would cost nursing facilities $139,356,716 for the first year, and $120,327,296 for the second year. (*See* page 42,173). In fact, CMS projects the compliance and ethics program to be the second most costly regulatory requirement for facilities seeking to comply with the proposed rule. Using simple calculations, the CMS estimate means that each of the nation's 16,000 nursing centers would spend approximately $8,710 in the first year and $7,520 in the second year to meet CMS'

proposed requirements. These estimates are too low. Some of the large operating organizations budget over a million dollars annually to implement a compliance and ethics program. Even CMS' estimates for the small and independent nursing centers is too low. Compliance and ethics program development and implementation could easily require hiring additional staff or consultants to provide process and oversight guidance. Significant funding also would be required to draft new policies/procedures, implement internal or external monitoring/auditing and other systems support for learning management, hotlines, personnel, etc. For example, although not required, learning management systems make it easier to track monitoring/auditing, and yet can easily cost several thousand dollars per month. Lastly, the proposed requirement for an annual reassessment is very costly. Some of the larger operating organizations pay up to $75,000/per year for a reassessment of their compliance program, so it is not hard to imagine that a small nursing center would easily spend $5,000-$8,000/per year on this task alone.

AHCA Recommendation:

Large nursing centers already have robust compliance and ethics programs in place. Some small and medium-sized nursing centers may have to invest significant monies into their current compliance and ethics programs. **CMS must allow all providers at least two years to implement the compliance and ethics requirements included in the final rule to allow operating organizations to budget these costs into their current financial plans.** A year for full implementation, as suggested by the proposed rule, simply is not long enough to ensure full compliance without imposing an undue financial burden on operating organizations.

Definitions:

Proposed § 483.85(a) includes definitions for "compliance and ethics program," "high level personnel," and "operating organization." (*See* pages 42218-9) AHCA is concerned, however, that there is no definition for "reasonable" or "reasonably." CMS acknowledges that it uses ''reasonable'' or ''reasonably'' in the definition of a compliance and ethics program and in three of the proposed required components of the program in proposed § 483.85(c)(1), (6) and (8); and specifically asks for comments on how to evaluate "reasonableness." (*See* pages 42,211)

AHCA Recommendation:

We applaud CMS' recognition that "reasonableness" may depend on the applicable facts and circumstances. We also agree that CMS must define the word "reasonable," as it is unclear what the term means not only in the compliance and ethics proposed sections, but throughout the entire proposed rule. **AHCA recommends that CMS use Black's Law Dictionary for the "reasonable person" standard that is often used in other areas of the law (*e.g.*, an ordinary person who exercises care while avoiding extremes of boldness and carefulness).**

Compliance Date:

Proposed § 483.85(b) requires the operating organization for each facility to have in operation a compliance and ethics program that meets the requirements of this section beginning on the date that is one year after the rule's effective date. (*See* page 42,219)

AHCA Recommendation:

Under the ACA, Section 6102, *Accountability Requirements for Skilled Nursing Facilities and Nursing Facilities*, which was signed into law on March 23, 2010, it states "Not later than the date that is 2 years after such date of the enactment, the Secretary, working jointly with the Inspector General of the Department of Health and Human Services, shall promulgate regulations for an effective compliance and ethics program for operating organizations, which may include a model compliance program." Nursing centers have been asking and waiting for the long overdue compliance and ethics program regulations for over three years past the statutory deadline. In the meantime, nursing center providers have been doing their best to develop and implement effective compliance and ethics programs, using past OIG guidance to do so. **CMS must allow providers at least 2 years to implement the new requirements of the proposed rule into their current compliance and ethics programs, allowing adequate time to change and adjust current processes and procedures and to reconfigure nursing center budgets.**

Compliance Program Components:

Proposed § 483.85(c) requires the operating organization for each facility to develop, implement, and maintain an effective compliance and ethics program that contains, at a minimum, certain components. Specifically, § 483.85(c)(1), (5) and (6) state that nursing centers must establish "disciplinary standards," communicate "the standards, policies, and procedures…includ[ing]…mandatory participation in training or orientation programs and and/or dissemination of information," and "ensure that reasonable steps were being taken to achieve compliance" by any of the nursing center staff, and "individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles." AHCA is concerned that CMS' expectation to train and orient all contractual staff and volunteers, just as if they were the center's staff, is not a good use of limited resources and is inconsistent with best practices currently in place.

AHCA Recommendation:

Currently, the best practice to educate contractors or volunteers is for center staff to inform those individuals about the center's compliance program, seven core elements of an effective compliance program, code of conduct, reporting processes (hot line numbers and other alternative reporting mechanisms) and correction processes. Nursing centers sometimes accomplish educating contractors and volunteers by furnishing written materials for the contractor or volunteer to review and attest to reviewing. Mandating that those individuals participate in regularly scheduled staff training, is not only inappropriate at times; but would require significantly more resources than the centers currently have available. Contractor

agencies in particular should discuss compliance matters with their own staff, provide background checks and disseminate important information about compliance and ethics programs. In fact, many contractual arrangements between nursing centers and contractor agencies require contractor agencies to perform such compliance and ethics-related duties. It is understood that the nursing center would be responsible to orient contractual staff to the individual nuances of the compliance program in their own center. **AHCA recommends requiring nursing centers to orient volunteers and contractor agency personnel with an overview of their specific program. Nursing centers must not be required to provide full training and education to volunteers and contractor agency personnel. Contractor agencies must educate and train their employees regarding general compliance and ethics program requirements.**

Requirements for Five or More Nursing Centers:

Proposed § 483.85(d) requires operating organizations that operate five or more facilities to have mandatory annual training, and designate a compliance officer that reports directly to the governing body for the operating organization and who is not subordinate to the general counsel (GC), chief financial officer (CFO)or the chief operating officer (COO). It also requires a compliance and ethics liaison at each of the operating organization's facilities. AHCA is concerned that the proposed rule would impose additional requirements on an operating organization with an arbitrary number of facilities (*i.e.*, operating five or more facilities), limits who could serve as a compliance officer, and creates an unrealistic expectation to have a compliance liaison at each of the operating organization's facilities.

AHCA Recommendation:

AHCA does not understand CMS' basis for imposing additional requirements on operating organizations with five or more facilities. We understand that CMS is attempting to consider resources available to the small operating organizations; but this number does not consider the medium-sized operating organizations that also have limited resources. **AHCA recommends changing this section from "five or more facilities" to "fifteen or more facilities."**

CMS' proposed rule does not specifically restrict the GC, CFO or COO from being the compliance officer. We support this position. In many large operating organizations, for example, the GC is the compliance officer. These organizations have purposefully structured their organizations in this way because this individual acts not only as the compliance officer, but has other legal roles and responsibilities within the organization. As a result, this person is well-qualified to lead the organization's compliance efforts and promptly address any potential legal violations and other areas of concern. When difficult compliance-related problems are identified that must be addressed, the GC typically hires outside counsel to ensure that there are no problems with retribution or conflict of interest. In mid-size organizations too, the GC, CFO or COO in many instances is the compliance officer because the organization cannot always financially support a full-time compliance officer. Ensuring that the GC, CFO or COO can serve as the compliance

officer in these organizations avoids the designation of compliance officers who may be less qualified with less potential influence on the organization and with the Board.

We appreciate that CMS is considering not who is the "higher level" compliance officer; but instead focusing on ensuring that there is an independent review and investigation within the organization whenever such independent review and investigation is appropriate and necessary. We also appreciate that CMS does not automatically assume that the GC, CFO or COO cannot be "independent." As CMS has indicated previously, the compliance officer must be comfortable in addressing difficult matters with the Board and the CEO. We have heard different interpretations from other organizations on this point. Prohibiting operating organizations' GC, CFO or COO from serving as the compliance officer would strain resources and dilute the valuable expertise and experience these individuals can bring to the compliance officer role.
AHCA recommends amending §483.85 (d)(1) by adding a sentence to follow the current last sentence. "The GC, CFO, or COO may serve as the compliance officer."

AHCA recommends eliminating the concept of a compliance liaison for each facility in an operating organization. It is not good policy to appoint an individual at the facility level that does not have the critical experience, education or knowledge of the compliance officer, which skills are important to make good compliance and ethics decisions. Further, the expectation that each nursing center, regardless of size, could hire an individual with background or expertise in compliance would not be fiscally feasible for many organizations. Corporate compliance officers know their staff in the various nursing centers well and should continue reaching out to the administrator and other key staff in the facility if/and when there is a significant problem.

W. Physical environment (§ 483.90)
1) § 483.90 (h) (5) "*Establish policies, in accordance with applicable Federal, State, and local laws and regulations, regarding smoking, including tobacco cessation, smoking areas and safety, including but not limited to non-smoking residents*." While smoking cessation is a noble cause, this should not be required in every nursing center's policies, particularly if a nursing center has adopted a policy for non-smoking. Smoking cessation programs may be appropriate for some nursing centers but certainly not all.

Further, as written, this sentence is confusing. It is not clear how these policies will include but not be limited to non-smoking residents.

AHCA Recommendation:

1) **Delete this sentence at** § 483.90 (h) (5) **as written. Insert: Establish policies, in accordance with applicable Federal, State, and local laws and regulations, regarding smoking, including smoking areas and safe smoking that also takes into account residents who do not smoke. These policies must also address electronic cigarettes (also known as e-cigarettes).**

X. Training requirements (§ 483.95)

1) The proposed rule states: "*A facility must develop, implement, and maintain an effective training program for all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles.*" It is unclear if the development, implementation and maintenance of this training program must be done solely by employees of the nursing center. Currently, many centers use consultants or contractors to complete such training. The expectation CMS has for the type of training volunteers should receive is unclear. Additionally, the expectation that a nursing center be responsible for training all individuals under a contractual arrangement is unreasonable

2) §483.95(a) requires "*…effective communications as mandatory training for direct care/direct access personnel*." There is no definition of "direct access personnel."

3) §483.95(f)(2) requires "*Annual* [compliance and ethics] *training if the operating organization operates five or more facilities."* As mentioned in earlier comments, we believe this should include medium-sized organizations that also have limited resources.

4) §483.95(i) requires "*A facility must provide behavioral health training consistent with the requirements at §483.40…."* As stated in General Comments earlier in this letter, AHCA has serious concerns about transforming nursing centers into mental health centers.

AHCA Recommendations:

1) **Amend** *§483.95 Training Requirements* **to read:** "*A facility must ~~develop,~~ implement, and maintain an effective training program for all new and existing staff; ~~individuals providing services under a contractual arrangement;~~ and volunteers, consistent with their expected roles*. **In the case of volunteers, training should include only material that is relevant to the work the volunteer will be performing. Individuals providing services under a contractual arrangement will receive training from the facility that is facility-specific and not already provided by the contractor. Training may be provided by consultants, and, if relevant, include facility-specific information/material.**"
2) **Amend** *§483.95(a)***to read:** "*…effective communications as mandatory training for direct care~~/direct access~~ personnel*."
3) **Amend** *§483.95(f)(2)* **to read:** *Annual* [compliance and ethics] *training if the operating organization operates ~~five~~* **fifteen** *or more facilities."*
4) **Amend** *§483.95(i)* requires "*A facility must provide ~~behavioral health~~ training ~~consistent with the requirements at §483.40~~* **related to care for individuals with dementia**…."

The American Health Care Association and National Center for Assisted Living (AHCA/NCAL) represent more than 12,000 non-profit and proprietary skilled nursing centers, assisted living communities, sub-acute centers and homes for individuals with intellectual and developmental disabilities. By delivering solutions for quality care, AHCA/NCAL aims to improve the lives of the millions of frail, elderly and individuals with disabilities who receive long term or post-acute care in our member facilities each day.