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October 14, 2015

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities; Proposed Rule [CMS-3260-P]

Dear Acting Administrator Slavitt:

AMDA – The Society for Post-Acute and Long-Term Care Medicine represents over 4,800 physicians, nurse practitioners and physician assistants as well as other professional team members that serve residents in nursing homes. Our members provide medical direction and serve as attending physicians for patients across the post-acute continuum, including short-stay post-acute patients and long-stay nursing home residents.

AMDA offers education, advocacy, information and professional development to promote the delivery of quality post-acute and long-term care (PA/LTC) practice. We offer comprehensive training on quality assurance and performance improvement (QAPI), interprofessional care approaches, compassionate patient-centered care, the vital physician and medical director role in supporting and improving diagnostic quality and overall care, and advanced training and certification for long term care physicians and medical directors.

Our collective knowledge, experience, and advocacy encompasses most of the key areas covered in these regulations, including diagnosis and management of residents/patients, quality assurance and performance improvement (QAPI), interprofessional care coordination, facility performance and management, infection control, antibiotic utilization and stewardship, behavior and psychiatric issues, and appropriate prescribing and use of medications.

Based on our central role in post-acute and long-term care, and on our knowledge of relevant aspects of care, service, and management, AMDA is responding to the proposed revisions to the OBRA regulations, "Medicare and Medicaid Programs: Reform of Requirements for Long-Term Care Facilities."

Summary of AMDA's comments

Overall, AMDA supports the intention of these proposed regulatory updates. We agree with many of the recommended approaches and have reservations about others.

Our general comments summarize areas of agreement and concern, and our comments at specific regulations offer a detailed rationale, relevant references, and suggested wording changes. We can provide copies of cited references on request. Our introductory comments take the following format:

1. Considering the Rationale for These Proposed Regulations
2. Quality Care that is Focused on the Resident/Patient
    - We agree with the intent to improve care quality
3. Alignment With Current Standards of Practice
    - We have significant concerns about the notion of "current clinical practice"
    - All risks, symptoms, and illnesses must be viewed in context
    - We are concerned about inadvertent reinforcement of the "silo" approach to care
4. Education, knowledge, and training
    - We support additional training for staff and practitioners
    - We urge CMS to establish expectations for medical director and physician training and competencies
    - We advocate much more attention to some highly relevant sources
5. Considering Individuals with Impaired Mood, Cognition, and Behavior Issues
    - The proposed regulations focus substantially on behavior and psychiatric conditions
    - We agree that knowledge and skills in these areas need improvement
    - We differ on which knowledge and skills need improving, and how to improve them
    - We advocate a more balanced dialogue and approach to improve these aspects of care
6. Medications
    - The regulatory proposals are intended to influence prescribing of certain medications
    - AMDA strongly supports the appropriate prescribing and use of medications
    - CMS should take a broader perspective in understanding and correcting the causes of medication issues
    - We question the value of proposed changes in terminology related to medications
7. Care Transitions Requirements
    - The proposals try to improve care transitions and focus on discharge
    - We urge a broader consideration of causes and solutions related to hospitalization
    - Competent clinical practice is a key foundation for reducing hospitalization
8. Quality assurance and performance improvement (QAPI)
    - The proposals require more structured approaches to oversight and quality improvement
    - We advocate a better balance regarding proposed approaches to QAPI
    - We agree that the expectations for defining and refining facility scope of services are reasonable
9. Additional general approaches to improving care
    - Input was sought about what to augment or change in this proposed plan
    - We ask that CMS take a fresh and broader look at causes and solutions
    - There are no viable substitutes for technically competent practice
    - We urge caution, and realistic expectations, about health information technology
    - The value of information depends on its correct interpretation and application

- We urge CMS to reconsider the attributes and drawbacks of existing requirements

Considering the Rationale for These Proposed Regulations

AMDA has reviewed the preamble to the regulations, which included CMS' discussion of intent and rationale. As an organization committed to the care of nursing home residents/patients, AMDA generally supports the efforts to revise and update the regulations, as well as the basic themes that they embody.

In the preamble, CMS states: "Many of the revisions are aimed at aligning requirements with current clinical practice standards to improve resident safety along with the quality and effectiveness of care and services delivered to residents. Additionally, we believe that these proposed revisions may eliminate or significantly reduce those instances where the requirements are duplicative, unnecessary, and/or burdensome."

AMDA recognizes that there are current national goals for improving health care. We also note CMS' requests for input about concerns and suggestions for modifying or adding approaches.

Therefore, we based our review substantially on CMS' explanations, comments, and requests for input. We compared the proposed changes with our understanding of current clinical standards of practice. Based on our knowledge and experience in caring for residents/patients and in improving systems and approaches to care, we considered whether these proposals are likely to improve resident/patient safety and the quality and effectiveness of care while eliminating or reducing duplicative, unnecessary, or burdensome requirements.

While we believe that many of the proposals are consistent with current clinical standards, we identified some significant discrepancies. Our comments at specific regulations indicate areas of agreement and areas of concern. We identify where we believe there may be a better alternative to achieve the goals to support quality care and quality of life outcomes.

Although we are concerned about operational issues as they impact these goals, our comments focus primarily on specific aspects affecting care provision for residents/patients. We believe that all proposed changes should be made in the context of our overall health care system goals and universal principles.

Quality Care that is focused on the Resident/Patient

We agree with the intent to improve care quality

We agree that the U.S. health care system and the roles of nursing homes have changed significantly. We believe that the care of nursing home residents/patients has improved over the past two decades in many ways, and that there are areas where additional improvement is warranted.

We support the proposal to combine quality of care and quality of life requirements, based on the rationale that these are intertwined and are relevant to all residents/patients regardless of the length of their stay or reasons for their admission.

As our comments emphasize repeatedly, we strongly agree with the principles of high-quality, individualized care. As evidence of that support, AMDA has collaborated with the Institute for Healthcare Improvement (IHI) to identify principles for quality patient-centered care for nursing

home residents. Among other things, these principles include (1) tailoring personal care to fit the needs and preferences of each individual, and appropriate for their medical conditions, based on detailed and adequate assessment, clinical reasoning, and current evidence and clinical standards of practice; (2) encouraging residents/patients or their representatives to collaborate with their care partners and clinicians to create and update their plans of care; (3) advocating for care providers to facilitate this partnership by using diverse methods to communicate appropriately and understandably with residents/patients about their conditions; (4) providing care to residents/patients that is in their best interest and consistent with their expressed goals and preferences; (5) providing guidance to residents/patients, their care partners and/or representatives on treatment options for end-of-life care; and (6) providing care that considers key quality of life domains (physical, mental, psychological, social and spiritual), and reflects resident/patient life choices and safety issues.

Alignment with Current Standards of Practice

The concept of "current clinical practice" is a significant concern

Regarding CMS' assertion that these regulations attempt to align with "current clinical standards," we are unsure how the term is being understood and used. For example, does this mean current common approaches, or does it mean "current clinical standards of practice," referring to authoritative sources with a clear evidence basis, or something else?

As our comments at specific regulations discuss in more detail, we are concerned that some of the proposed regulations may reflect or reinforce common and persistent misconceptions about how to make clinical decisions and provide care. There is evidence that many common approaches to care (for example, pain, falls, swallowing, and behavior) are questionable and may need reconsideration rather than reinforcement. [*Reference: Levenson SA, Morley JE. Evidence rocks in long-term care, but does it roll? J Am Med Dir Assoc 2007, 8:493-501.*]

All risks, symptoms, and illnesses must be viewed and managed in context

We are concerned that some of the proposed requirements contradict basic principles about how to correctly diagnose and manage individuals with complex medical and psychiatric conditions, and may inhibit the flexibility needed to provide appropriate care to our patients. [*Reference: Balogh EP, Miller BT, and Ball JR (eds) and the Committee on Diagnostic Error in Health Care; Board on Health Care Services. Improving Diagnosis in Health Care. Institute of Medicine; The National Academies of Sciences, Engineering, and Medicine, 2015.*]

We are especially concerned that by singling out a few specific diseases and conditions while ignoring others, or by specifying additional training and skills only for selected conditions or diagnoses, CMS may be unwittingly supporting and expanding the "silo" approach to care that may lead to less holistic, patient-centered care.

We are concerned about inadvertent reinforcement of the "silo" approach to care

We are concerned that parts of these regulations may have the unintended consequence of undermining rather than promoting integrated, comprehensive care. For example, these

regulations appear to us to repeatedly reflect the notion that different aspects of care are the domain of specific health professionals; for example, nutrition is the purview of dieticians, psychiatric illnesses should involve mental health specialists, and medications are the domain of consultant pharmacists.

Over many years, significant problems related to such thinking have been identified. Although it is common practice to authorize or imply that different health professions have dominion over specific topics, it is inconsistent with good practice and with human biological function. While accountability for care is shared, proper care requires that all aspects of care be closely linked and coordinated by the primary provider with input from various health professionals.

Instead, our experience suggests that the proposed requirements are likely to facilitate letting certain health professionals (e.g., dieticians and therapists) write orders without adequately consulting with a medical practitioner. Our experience is that doing so may lead to inappropriate interventions based either on inadequate clinical reasoning (e.g., unnecessary tests and consults, misinterpretation of symptoms and test results, incorrect treatment selection), or on decisions unrelated to the care needs of the resident/patient [*Reference: The Medicare Payment System for Skilled Nursing Facilities Needs to be Re-evaluated. Office of the Inspector General (OEI-02-13-00610) September 2015.*]

Education, knowledge, and training

More comprehensive training for staff and practitioners will benefit patient care

AMDA agrees that facilities should have knowledgeable and skilled staff and practitioners who collaborate to care for the facility's residents/patients. [*Reference: American Association of Colleges of Nursing, American Association of Colleges of Osteopathic Medicine, American Association of Colleges of Pharmacy, American Dental Education Association, Association of American Medical Colleges, and Association of Schools of Public Health. Core Competencies for Interprofessional Collaborative Practice: Report of an Expert Panel, 2011*.]

Elsewhere, AMDA has noted its concerns about inadequate staff and practitioner training and skills specific to the nursing home population. Some health care professionals providing care in nursing homes have limited knowledge of general or geriatric medicine and relevant regulatory requirements. We agree that merely being a licensed health care practitioner does not ensure competence to provide high-quality nursing home care.

However, we note that the proposed requirements related to competencies appear to focus extensively on a relative handful of topics (for example, behavior, pain, depression, dementia, trauma, cultural competence) with little or no mention of many equally important issues that affect the correct approaches to these complex and challenging post-acute and long-term care residents/patients. We disagree with the presumption that additional selective topic-based training will have a meaningful impact on care quality.

We are concerned that the proposed approach undermines "person-centered" care by focusing too much on a few topics without adequate context. The likely result is an excessive

focus on those few things for compliance reasons while inadequate attention is paid to other equally important things.

For example, the proposed regulations overlook vital universally relevant topics such as how to do proper clinical cause identification, how to make sure that all health professionals contribute to diagnostic quality and avoid diagnostic error, or how to apply the syndromal rather than symptom-based approach to care, where a single symptom may be due to multiple causes or multiple symptoms may have a common cause. [*Reference: Inouye SK, Studenski S, Tinetti ME, Kuchen GA. Geriatric syndromes: Clinical, research, and policy implications of a core geriatric concept. J Am Geriatr Soc. 2007;55:780(791)*]. Our experience is that these skills are essential to correctly managing all conditions and problems, including such things as behavior and pain.

We believe that this limited approach also undermines the clinical principle of approaching all situations with an open mind and a broad perspective (that is, with minimal predispositions and assumptions). Limited perspectives may inhibit adequate preparation and training to care for the diverse and complex individuals who receive care in nursing homes; i.e., those with multiple simultaneous active conditions causing their symptoms and impairments, or who have symptoms or problems (such as behavior challenges) that may result from something other than an obvious diagnosis such as dementia.

Therefore, AMDA recommends that CMS focus much more on how we can all strengthen the basic skills and knowledge that can help improve the management of a broad spectrum of residents/patients with their diverse conditions and risks—not just on facts and techniques related to a few specific conditions.

Expectations for medical director and physician training and competencies are needed

In addition, AMDA strongly recommends that nursing facilities have a means to evaluate the competencies of their medical directors, attending physicians and other medical practitioners. Considering that CMS is proposing regulations that dieticians carry a national certification, AMDA recommends that these regulations acknowledge the need for adequate medical director knowledge and training, and acknowledge the need for and availability of core competencies for attending physicians.

We advocate greater attention to highly relevant information sources

We note that the preamble to these proposed regulations cited several references from geriatrics journals. The benefits of the discipline of geriatrics have been known for several decades. The 1986 Institute of Medicine (IOM) report Improving the Quality of Care in Nursing Homes, on which the original OBRA '87 regulations were based, repeatedly emphasized incorporating geriatrics principles and training broadly into the nursing home, as does the IOM 2008 report Retooling for an Aging America: Building the Health Care Workforce. Three decades after the 1986 IOM report, we believe that geriatrics and relevant medical resources remain largely untapped in most facilities as a reliable source of information about competent care and excellent clinical practice.

AMDA notes that clinical geriatrics focuses heavily on the tenets of person-centered care, including giving all treatment (not just medical treatment) in the proper context. Broad-based,

consistent adherence by those of all health professions in all settings to geriatrics approaches would greatly reduce the need for geriatricians to correct the many problems resulting from failure to adhere to those precepts [*Reference: Boult C, Boult L, Kane RL. How effective is geriatrics: a review of the evidence. In: Katz PR, Kane RL, Mezey MD, eds. Quality care in geriatric settings: focus on ethical issues. New York: Springer, 1995*].

In addition, there is strong evidence that effective clinical reasoning is not just a function of physicians but of all staff and practitioners who comprise the care team. We note that there are many readily available resources and references covering these topics. [*References: Trowbridge R, Rencic J, Durning S. Teaching clinical reasoning. American College of Physicians, 2015. Symptom to Diagnosis: An Evidence-Based Guide, 3rd ed (electronic), 2014. LeBlond RF, Brown DD, DeGowin RL. DeGowin's Diagnostic Examination. (9th ed.), New York:McGraw-Hill, 2008. McGee S. Evidence-Based Physical Diagnosis, 2012*]. These resources provide a consistent and reliable clinical standard of practice for all staff and facilities and a primary route to improving care and outcomes.

AMDA strongly recommends that these regulations make meaningful reference to applying the complete care delivery process (not just assessment and care planning), clinical reasoning and problem solving to address specific issues such as behavior and psychiatric conditions. In addition, AMDA recommends identifying these vital topics in the regulations as content areas to improve the knowledge and skills of staff and practitioners. For instance, a simple requirement that every nursing home should have and use at least one of the many available geriatrics or medical references could help improve care quality far more than many of the other proposed requirements.

Considering Individuals with Impaired Mood, Cognition, and Behavior Issues

The proposed regulations focus substantially on behavior and psychiatric conditions

We note that these regulatory proposals focus extensively on individuals who have mood, cognition, and behavior issues or risks. Our responses to this section of the proposed regulations cover both our agreement and our concerns.

We agree that knowledge and skills in these areas need improvement

As noted, AMDA supports competent care for all conditions and risks in all individuals. We agree that it is desirable to try to improve the management of individuals with cognitive, mood, and behavior issues, that the knowledge and skills of both staff and practitioners could be better, and that medications have often been used inappropriately and sometimes excessively.

We differ on which knowledge and skills need improving, and how to improve them

Nevertheless, while we support the intentions of these and related regulations, we are concerned about some of the proposed approaches. We believe that only some of the diverse causes of the issues regarding management of behavior and psychiatric symptoms have been adequately considered, and that this aspect of care is much less "black-and-white" than is

commonly portrayed. A more balanced and thoughtful approach is needed to improve care for people with behavior and psychiatric impairments, including dementia.

We note that all psychiatric and behavior disturbances have a significant medical and biological component. Again, many reliable and reputable references and resources in medicine, neurology, psychiatry, and other disciplines explain how health professionals other than psychiatrists should properly assess, diagnose, and manage behavior and psychiatric issues [e.g., *Lyketsos, C., Lipsey, J., Rabins, P., and Slavney, P. Psychiatric Aspects of Neurological Diseases. New York: Oxford University Press, 2008*]. In our experience, health professionals who are not psychiatrists can be guided to understand and apply this information to help inform care decisions.

We also note our experience that many of our residents/patients come to post-acute and long-term care with inadequate and incorrect diagnosis and management of their psychiatric and behavior issues prior to transfer. This strongly suggests that the problem is widespread and is about much more than just medications.

A more balanced dialogue and approach is needed to improve these aspects of care

AMDA strongly recommends that the proposed regulations and any discussions related to specific topics take a broader and more balanced approach, and include much more about the value of these medical and technical aspects of behavior and psychiatric care. As noted in our regulation-specific comments, we are concerned that some of the proposed requirements on this aspect of care are inconsistent with a proper, objective assessment. Instead of emphasizing sound clinical reasoning and problem solving, they are likely to encourage inflexible "cookbook" approaches that impede adequate considerations of causes and treatment options.

Our concern is that the view of dementia and other disorders in these proposed regulations is primarily psychosocial and focuses on psychosocial interventions while largely ignoring or underemphasizing the reality of dementia as a neurological disorder and the benefits of competent medical assessment and diagnosis [e.g., *Reston JT, Schoelles KM. In-facility delirium prevention programs as a patient safety strategy: A systematic review. Ann Intern Med 2013;158:375e380*].

We question the construct and definition of "behavioral health," and we are confused by the diffuse and shifting use of terms in various places such as behavioral health, dementia care, behavioral health staff, mental health, mental disorders, and mental health conditions. In addition, "substance abuse disorders," "trauma-informed care" and "PTSD" are added elsewhere to considerations of behavior and mental illness.

We also are concerned about imposing additional reporting and documentation requirements as well as some statements about who should be involved in managing behavior and psychiatric issues. For example, the preamble to the regulations states that "… a qualified mental health professional should be involved when residents are diagnosed with mental health conditions or prescribed psychotropic drugs." We disagree with that declaration and we are again concerned that such an approach will tend to perpetuate "silos" of care (i.e., each body part or symptom gets its own discipline or consultant) that undermine managing all symptoms and conditions within the context of each person's "big picture."

Our experience suggests that a mental health professional is often not needed and may sometimes be unhelpful. Many conditions and situations, including medications, can be handled appropriately by properly trained staff and non-psychiatric practitioners. Passing the problem to consultants is unlikely to improve vital staff and practitioner understanding and performance.

Medications

There are regulatory proposals intended to influence prescribing of certain medications

We have offered comments about proposed regulations related to medications. We identified CMS' intention to (1) modify and expand the consultant pharmacist requirement related to drug regimen reviews, including identification of drug irregularities, and to require additional physician documentation related to certain categories of medications; (2) specify structural requirements related to certain categories of medications; and (3) expand requirements related to antipsychotic medications to other categories of psychopharmacological medications (including medications that may affect brain function that are given primarily for reasons unrelated to behavior) and to change the name to "psychotropic" medications; and (4) move medication-related requirements to pharmacy services.

AMDA strongly supports the appropriate prescribing and use of medications

AMDA as an organization and individual AMDA members have been intimately involved since the early days of OBRA in developing and refining the surveyor guidance and training related to medications. This includes the 2006 major overhaul of F329 and a subsequent refinement several years ago in conjunction with issuing the dementia care guidance.

Understanding and correcting the causes of medication issues needs a broader perspective

AMDA agrees with the need to tailor medication prescribing and use for all medications in all categories for all conditions and situations (i.e., indications, dose, duration, monitoring, and minimizing adverse consequences), as per the F329 guidance.

We believe that—if used properly—surveyor guidance related to existing regulations already offers substantial support for accountability, as it provides guiding principles covering all categories of medications used for all conditions and circumstances [*Reference: CMS State Operations Manual, F329 Unnecessary Drugs*]. In addition, ample reliable and readily available references and resources about medications already exist.

AMDA also believes that current consultant pharmacist requirements are substantial and sufficient. It is imperative to identify, understand, and address the diverse underlying reasons for ongoing issues of medication prescribing and use, rather than impose additional auditing and documentation requirements.

As we note in our comments, we believe that most medication management and related issues emanate from shortcomings of the care delivery process and clinical reasoning and diagnosis. We believe that it is undesirable to create yet another "silo" by moving this section under Pharmacy

Services. Our members and our consultant pharmacist colleagues agree that this issue is about clinical practice and care process, and is clearly not primarily about one specific health profession.

As elsewhere, implementation is the primary challenge here. Any regulations (new or existing) on this topic must be applied adequately and consistently in reviewing care. We believe that everyone's time and effort would be better spent in enforcing and reinforcing existing requirements, combined with an intensified focus on some of the key underlying reasons for problematic prescribing and use of medications (including medication-related problems during care transitions and acute changes of condition), regardless of the medication category or underlying medical condition. For example, care would improve substantially by more clearly recognizing the major limits of the Minimum Data Set (MDS) relative to cause identification, by promoting assessment that goes beyond the RAI, and by requiring QAPI that is based on case reviews instead of on data analysis alone, and that considers the quality of the facility's reasoning and problem-solving activities.

Proposed changes in terminology related to medications are of questionable value

We have concerns about changing the wording from psychopharmacological medications to psychotropic medications and about expanding the definition. We believe that current definitions are adequate to meet concerns about use of medications, including their inappropriate or excessive use in relation to behavior and psychiatric issues.

We are concerned about the potential impact of expanding this definition to include any drug that affects brain function. As we have noted in our comments, many medications (e.g., opioids, antihistamines and anticholinergics) can affect mood, behavior, and cognition by directly or indirectly influencing brain activity. [*Reference: Drugs That May Cause Psychiatric Symptoms. The Medical Letter on Drugs and Therapeutics, December 15, 2008 (Issue 1301)*] However, unlike psychopharmacological medications, those other medications are not prescribed with the primary intention of affecting brain activity but may have side effects that do so.

Care Transitions Requirements

There are proposals to try to improve care transitions and focus on discharge

In the preamble, CMS states that these regulations propose ". . . to revise the title to reflect current terminology that applies to all instances where care of a resident is transferred, and to implement additional discharge planning requirements, including more detailed discharge planning from the time of admission."

AMDA agrees that it is desirable, for various reasons and whenever possible, to minimize hospitalization and rehospitalization of residents/patients. We also support efforts to improve accountability for better transitions to community-based care.

AMDA agrees that improving communication at the time of care transitions is critical to avoid adverse events that can cause harm and unnecessary cost. However, any regulatory changes need to be done in concert with regulatory requirements for other care settings (for example, hospital and community) so that everyone is held to the same communication and documentation standards. Our members and our facilities struggle with many issues created by inadequate performance by referral sources across the care continuum.

A broader consideration of causes and potential solutions related to hospitalization is needed

Our comments also express our concerns about the rationale and virtues of some of the other regulatory proposals in this section. We believe that there are more diverse reasons for rehospitalization than were identified in this regulatory proposal document. It does not appear that some of the cited articles on this topic adequately considered other salient issues such as diagnostic error, unsafe or poor care, and inconsistent patient monitoring.

Competent clinical practice is a key foundation for reducing hospitalization

Elsewhere, the preamble states that these proposed regulations will reduce hospitalization by "[e]nsuring ongoing evaluation of care process through implementation of a robust QAPI plan." However, our comments note that the QAPI section appears to focus almost exclusively on data, outcomes measures, and PIPs. It appears to us that there was little meaningful focus on requiring QAPI programs to review and strengthen clinical decision-making processes, improve diagnostic quality, or enhance individual accountability for related activities.

While we agree that discharge information should have certain components, we suggest that so-called "transfer forms" have limited utility and we recommend much more emphasis on such approaches as an organized, adequately detailed chronological story of the resident/patient's illness or course in the facility and an adequate rationale for current treatments.

Based on our knowledge and experience, we believe that hospitalization is minimized when (among other things) residents/patients receive high-quality care that defines issues correctly, accurately diagnoses their causes (including the adverse effects of existing treatments), tailors interventions to the "big picture" of each resident/patient, monitors progress effectively, and identifies and addresses risks and complications appropriately and in a timely fashion.

Again, we believe that there is as much or more to gain by strengthening the care delivery process and clinical reasoning and problem solving, than by general requirements such as a "robust interdisciplinary team, comprehensive person-centered care planning process and . . . training requirements."

Quality assurance and performance improvement (QAPI)

There are proposals to require more structured approaches to oversight and quality improvement

CMS proposes to change current requirements related to quality assurance and specify a requirement for a quality assurance and performance improvement program, including some specific requirements for content and methods.

AMDA acknowledges the need to intensify and expand quality assurance and performance improvement activities in facilities. We agree with promoting more consistent and standardized methodologies.

A better balance is needed regarding proposed approaches to QAPI

AMDA's comments express our concerns about some of the definitions, the prescriptive nature of some of the proposed methods and techniques, and the imbalances between data-driven QAPI and other equally or more important methods. While we support the use of data to help facilities analyze their improvement activities, our comments note why both information and data are equally vital, and explain the difference between them.

We suggest that a better balance is needed between qualitative and quantitative approaches to improving quality. There should be much more emphasis on QAPI as simple real-time problem solving and prevention, relative to the proposed emphasis on data and on large-scale PIP projects. While we agree with the need to identify and address high volume, high risk, and problem-prone aspects, we also explain in our comments why QAPI must go beyond these to focus attention on promoting everyday quality in doing "the right thing in the right way."

Our experience is that effective problem solving—including correctly defining issues and identifying and addressing underlying causes—is essential to any human endeavor. We believe that QAPI needs to acknowledge the relevance of methods that emphasize a careful and detailed empirical approach to gathering and analyzing evidence (clinical reasoning and problem solving) as a viable model for QAPI activities. We were concerned that these proposed regulations barely acknowledge some relevant concepts and resources.

We believe that these regulations should focus on expected systems and application of QAPI and be more flexible about techniques. While we acknowledge the relevance of performance improvement projects (PIPs), we believe that they are overemphasized and that specific techniques such as PIPs should not be mandated.

Expectations for defining and refining facility scope of services are reasonable

We agree with the notion that facilities should review and define their scope of services annually and when they create new services, and match this with to their needs for staff as well as staff education, training, and competencies. We believe this analysis should also include a review of the need for medical staff and for other healthcare professionals that care for the residents/patients.

Additional general approaches to improving care

Input was sought about what to augment or change in this proposed plan

In its preamble, CMS asks for suggestions about additional or modified approaches.

A fresh and broader look at causes and solutions is needed

We believe that there are a number of reasons why care might still not be as good as desired overall. We recommend taking a broader look at causation, including seeking other specific causes of multiple issues and key issues that have multiple causes. [*References: Levenson SA. The basis for improving and reforming long-term care. J Am Med Dir Assoc 2009; 10: 459-465. 2009; 10: 520-529. 2009; 10: 597-606. 2010; 11: 84-91. 2010; 11: 161-170*]. We believe there also needs to be a greater acknowledgement of the increasing numbers of patients who inherently may have an

extremely poor prognosis, such as those with serious and multiple co-morbidities, complex wounds, organ failure and dependence on assistive technologies.

There are no viable substitutes for technically competent practice

As noted throughout, AMDA supports a balanced approach to care in all dimensions to support and promote good quality of life. To accomplish this, we strongly encourage much more emphasis on applying basic principles of clinical reasoning and problem solving to all situations, as a key foundation for attaining all of the desired attributes of quality as defined by the IOM (safe, patient-centered, effective, efficient, timely, and equitable).

We are concerned that many of the approaches in these proposed regulatory changes constitute "workarounds," that is, additional and more time consuming structural approaches to try to fix inadequate process and practice. We doubt that the results of such workarounds will be as good as addressing the underlying root causes that we have discussed in our comments.

We suggest that it is extremely important to pay much more attention to applying the evidence base derived from the disciplines of geriatrics and general medicine as a key foundation to optimize individual resident/patient outcomes including function and quality of life. We do not believe it is necessary to keep "reinventing the wheel."

We urge caution, and having realistic expectations, about health information technology

We also note statements in the preamble to these proposed regulations about the potential benefits of health information technology for providing quality care and reviewing care quality. We agree that more complete, accurate, and readily available information, shared effectively across care settings, would help improve care and its oversight.

The value of information depends on its correct interpretation and application

However, we emphasize again that most nursing home records (short- and long-stay) already have huge amounts of information, which must be (but often is not) interpreted and used effectively. As for measuring quality, knowing how to interpret data correctly to provide and improve care is just as important as having it.

Thus, regarding both care and its oversight, it is not necessarily better to have more data. Instead, more emphasis is needed on how to interpret and apply existing data properly. We advise caution about extolling the virtues of electronic health records. They are only a tool that can facilitate the performance and practice of those who already know how to interpret information on paper, but they cannot instill clinical competence in those who do not.

We are also concerned about the challenges of sharing information meaningfully from the current multiple information "silos," for example, the separate EHRs for facilities, pharmacies, and physicians.

There is a need to reconsider the attributes and drawbacks of existing requirements

More documentation and structural requirements tend to consume a lot of time and resources. Before adding requirements, it would be prudent and fruitful to take a fresh look at whether existing requirements (such as the RAI and other examples mentioned in our comments) facilitate or inhibit key aspects of performance and practice that affect outcomes. As with the care of individual residents/patients, revising existing approaches is often more beneficial than adding new ones.

Through the years, many AMDA members have been involved in various advisory and consultative capacities; for example, in revising F314 Pressure Ulcers and F329 Unnecessary Medications. In our prior experience, adequate time was routinely allotted for open debate and discussion of subject matter, with multiple parties present simultaneously.

AMDA is very concerned about the very different approach taken with this massive overhaul of all of the regulations. Considering that it has been several decades since the original regulations were written, it seems unnecessarily rushed. We are concerned that making written comments without any opportunity for open and joint discussion about the issues, including adequate give-and-take, is inadequate to consider the many issues raised by these proposals.

Therefore, AMDA is asking CMS to postpone final decisions about these regulations and implementation at least until these many issues can be discussed fairly and openly.

Our detailed comments follow, regarding specific aspects of the proposed regulatory updates. To facilitate CMS' review, we have inserted our comments in boxes next to the proposed text and we have used the "track changes" feature in the software to indicate our recommended changes and additions in the exact location. We have highlighted all areas in the proposed regulations where we have offered suggested changes, to make them easier to locate. Where our recommended revisions are minor, they may not have an accompanying comment in a box.

We appreciate the opportunity to offer our perspective on these proposed regulations. This letter represents our consensus and our desire to provide meaningful and constructive feedback, and our commitment to provide high-quality care and to improve our own performance as health care practitioners and medical directors.

AMDA looks forward to continuing to work with CMS on improving care in the nursing home. If you have any questions or wish to discuss this issue further, please contact Alex Bardakh, Director of Public Policy and Advocacy, at abardakh@amda.com or 410-992-3132.

Sincerely,

Naushira Pandya, MD, FACP, CMD
President

Christopher E. Laxton, CAE
Executive Director

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority citation for part 405 continues to read as follows:

Authority : Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

§405.926 [Amended]

2. In §405.926, amend paragraph (f) by removing the reference "§483.12" and add in its place, the reference "§§483.5(n) and 483.15".

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

3. The authority citation for part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302).

§431.206 [Amended]

4. In §431.206, amend paragraph (c)(3) by removing the reference "§483.12" and adding in its place the reference "§483.15".

§431.213 [Amended]

5. In §431.213, amend paragraph (h) by removing reference "§483.12 (a)(5)(ii)" and adding in its place the reference "§483.15(b)(4)(ii) and (b)(8)" and by removing the reference "§483.12 (a)(5)(i)" and adding in its place the reference "§483.15(b)(4)(i) of this chapter".

PART 447—PAYMENTS FOR SERVICES

6. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§447.253 [Amended]

7. In §447.253, amend paragraph (b)(1)(iii)(B) by removing the reference "§483.30(c)" and adding in its place the reference "§483.35(e)".

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

8. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

9. In §482.58, paragraphs (b) (1) through (8) are revised and paragraph (b)(9) is added to read as follows:

§482.58 Special requirements for hospital providers of long-term care services ("swing-beds").

* * * * *

(b) * * *

(1) Resident rights (§483.10(a)(4)(iv), (b), (c), (d)(1), (d)(3), (e)(8), (g), and (h)(3)).

(2) Facility responsibilities (§483.11(d)(1)(i), (d)(1)(iii), (d)(4), (e)(11), (e)(12), (e)(14)(iii), and (f)(1)(i)).

(3) Transitions of care (§483.5(n), §483.15(b)(1), (b)(2), (b)(3)(i) through(iii), (b)(4), (b)(5)(i) through (vii), and (b)(7)).

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

(5) Patient activities (§483.25(c)).

(6) Social services (§483.40(d) and §483.75(p)).

(7) Discharge planning (§483.20(e)).

(8) Specialized rehabilitative services (§483.65).

(9) Dental services (§483.55).

PART 483 – REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

10. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102, 1128I and 1871 of the Social Security Act (42 U.S.C. 1302, 1320a-7j, and 1395hh.

11. Section 483.1 is amended by revising paragraphs (a)(1) introductory text, (a)(3), and (b) and adding paragraphs (a)(4) and (a)(5) to read as follows:

§483.1 Basis and scope.

(a) * * *

(1) Sections 1819(a), (b), (c), (d), and (f) of the Act provide that—

* * * * *

(3) Sections 1919(a), (b), (c), (d), and (f) of the Act provide that nursing facilities participating in Medicaid must meet certain specific requirements.

(4) Sections 1128I(b) and (c) require that--

(i) Skilled nursing facilities or nursing facility have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations.

(ii) The Secretary establish and implement a quality assurance and performance improvement program for facilities, including multi-unit chains of facilities.

(5) Section 1150B establishes requirements for reporting to law enforcement crimes occurring in federally funded LTC facilities.

(b) Scope. The provisions of this part contain the requirements that an institution must meet in order to qualify to participate as a Skilled Nursing Facility in the Medicare program, and

as a nursing facility in the Medicaid program. They serve as the basis for survey activities for the purpose of determining whether a facility meets the requirements for participation in Medicare and Medicaid.

12. Section 483.5 is amended by—

a. Removing the paragraph designations for paragraphs (a), (b), (c), (d), (e), and (f) and placing the definitions in alphabetical order.

b. Adding introductory text.

c. Revising the definition of "common area".

d. Amending the definition of "composite distinct part" by adding paragraph (2)(v).

e. Amending the definition of "Facility" by removing the italicized word "defined".

f. Adding the new definitions of "abuse", "adverse event", "exploitation", "licensed health professional", "misappropriation of resident property", "neglect", "nurse aide", "person-centered care", "resident representative", "sexual abuse", and "transfer and discharge" in alphabetical order.

The revisions and additions read as follows:

§483.5 Definitions.

As used in this subpart, the following definitions apply:

Abuse. Abuse is the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. ~~Abuse also includes the w i l l f u l deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. This presumes that instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm,~~

~~pain or mental anguish~~. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology. Willful, as used in this definition of abuse, means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm.

AMDA COMMENTS:
AMDA agrees that it is important to prevent abuse. However, the proposed definition potentially creates major and unreasonable legal complications for facilities and practitioners, who often must make difficult decisions in unclear circumstances.

AMDA recommends deleting the clause about "deprivation of goods and services. . ." We believe that this is potentially very problematic, especially in light of the definition of "willful."

As it is written, differences of opinion about clinical decisions could result in accusations of abuse; for example, regarding the withholding or withdrawing life-sustaining treatment or a decision not to order an optional treatment.

In any event, the definition of "neglect" (below) addresses the situation of depriving a person of necessary services.

In addition, we believe that the intention and meaning of the sentence "This presumes (etc.)" should be removed. Our perspective is that definitions should not include "presumptions." When evaluating a situation, either the criteria are met or they are not. If they are not met, then the situation does not fit the definition. In addition, we are unclear about the meaning of the phrase "instances of abuse of all residents."

Definitions are the foundation for case review, which applies specific, detailed criteria to determine compliance. Any additional interpretation of the definition belongs elsewhere, after the various implications and complications are carefully considered, in order to avoid serious unintended consequences.

Adverse event. An adverse event is an untoward, undesirable ~~, and usually unanticipated~~ event that causes, or has the potential to cause, injury or death ~~or serious injury, or the risk thereof~~.

AMDA COMMENT:
AMDA suggests that an adverse event is adverse whether or not it is anticipated. Actually, many adverse events (for example, adverse consequences caused by medications) can be anticipated. Therefore, the concept of anticipation is not essential to the definition, and it may actually be misleading. Also, an event that causes injury is adverse, regardless of the seriousness of the injury.

AMDA also proposes additional wording changes, as noted, to improve clarity.

Common area. Common areas are areas in the facility where residents may gather together with other residents, visitors, and staff or engage in individual pursuits, apart from their residential rooms. This includes but is not limited to living rooms, dining rooms, activity rooms, outdoor areas, and meeting rooms where residents are located on a regular basis.

Composite distinct part. * * *

(2) * * *

(v) Use of composite distinct parts to segregate residents by payment source or on a basis other than care needs is prohibited.

* * * * *

Exploitation. Means the unfair treatment or ~~use of a resident or the~~ taking ~~of a selfish or~~ unfair advantage of a resident by using intimidation, threats, coercion, or deception for unfair personal advantage.~~for personal gain, through manipulation, intimidation, threats, or coercion.~~

AMDA Comment: AMDA agrees that intimidation, threats, and coercion are unacceptable. However, "manipulation" is much more difficult to identify and pinpoint. Again, given that it is proposed in regulation, and regulation is the equivalent of law, the definition of "exploitation" must be viable and not create serious unanticipated consequences. AMDA believes that it would be nearly impossible to objectively identify "manipulation." Since all human beings use some manipulation at some time to try to get their way, it is a normal human action. Instead, AMDA recommends substituting the word "deception" for the term "manipulation," as a more readily evaluated criterion. AMDA also proposes additional wording changes, as noted, to improve clarity.

* * * * *

Licensed health professional. A licensed health professional is a physician; physician assistant; nurse practitioner; physical, speech, or occupational therapist; physical or occupational therapy assistant; registered professional nurse; licensed practical nurse; consultant pharmacist, psychologist, podiatrists, dentists, respiratory therapists, or licensed or certified social worker.

AMDA COMMENT: Psychologists, respiratory therapists, and consultant pharmacists are licensed health professionals and should be included in the definition.

* * * * *

Misappropriation of resident property means the ~~deliberate~~ willful misplacement, exploitation, or wrongful~~,~~ temporary or permanent use of a resident's belongings or money without the resident's consent.

AMDA COMMENT:
It appears that "deliberate" is the same as "willful." If so, then AMDA recommends using the same terminology ("willful") here as elsewhere, for consistency.

Neglect is the substantial or ongoing deliberate 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, or extreme emotional distress ~~or mental illness~~.

AMDA COMMENT:
AMDA agrees that neglect is highly problematic.

However, we are concerned about the wording of the proposed definition.

Given the serious implications of allegations of neglect, the definition must allow for workable criteria and objective review and interpretation of findings.

Mental illness is a specific term commonly used to refer to conditions such as schizophrenia and bipolar disorder. It is highly implausible that those conditions could be attributed to neglect.
If the concept here is that neglect could lead to increased psychiatric or behavioral symptoms, then the proposed definition should say that explicitly, but it does not.

Nursing assistant~~e aide~~. A ~~nurse aide~~ nursing assistant is any unlicensed individual providing nursing care-related ~~nursing or nursing-related~~ support services to residents in a facility. This term may also include an individual who provides these services through an agency or under a contract with the facility, but is not a licensed health professional, a registered dietitian, or someone who volunteers to provide such services without pay. ~~Nurse aides~~ The term does not refer to ~~include those~~ individuals who furnish services to residents only as paid feeding assistants as defined in §488.301 of this chapter.

AMDA COMMENT:
AMDA recommends changing the wording to more clearly differentiate the role from that of a nurse.

AMDA's understanding from our nursing colleagues is that the contemporary term is "nursing assistant." Therefore, we recommend changing the terminology to reflect that.

Person-centered care. For purposes of this subpart, person-centered care means individualized and appropriate care and services of any kind that directly and indirectly

accommodate and support resident quality of life, input, and choice, to the extent practicable. ~~to focus on the resident as the locus of control and support the resident in making their own choices and having control over their daily lives~~.

AMDA COMMENT:
AMDA agrees that it is desirable to promote individual choices and to promote and provide highly individualized care.

However, AMDA is concerned that the proposed definition of "person-centered care" is too narrow. It does not appear to acknowledge anything other than the "resident as locus of control" and resident choice.

This is especially important because the regulations propose to require elsewhere that the facility have a "person-centered" care plan. If "person-centered" is defined so narrowly here, then most of what facilities and practitioners do will not count towards the requirement for a "person-centered" plan.

Furthermore, there is ample information to support many other things as being relevant to person-centered care.

For example, competent clinical reasoning and problem solving that facilitate the individualized care of medical, functional, and psychosocial conditions are an essential route to person-centered care. The book Teaching Clinical Reasoning (American College of Physicians, 2015) discusses in detail how competent diagnostic reasoning supports individualized patient care.

It defines clinical reasoning as "the . . . process by which a health care professional . . . interacts with the patient and environment to . . . weigh the benefits and risks of actions, and understand patient preferences to determine a working diagnostic and therapeutic management plan whose purpose is to improve a patient's well-being. . . *It entails establishing both a diagnosis and a treatment plan that is specific to a patient's circumstances and preferences"* [emphasis added]. (2015-07-23). Teaching Clinical Reasoning (Teaching Medicine Series) (Kindle Locations 198-203). American College of Physicians. Kindle Edition.

In fact, it is essential to consider the many specific things that help individualize care and not just focus on something as general as a "locus of control" concept.

In addition, it is difficult for us to understand how a surveyor or anyone else would objectively determine whether some aspect of care meets the "locus of control" concept.

We suggest providing a pertinent and sufficiently inclusive definition that would accommodate more than one particular philosophical viewpoint.

A more appropriate definition is something like this: "individualized care and services of any kind that directly and indirectly accommodate and support resident quality of life, input, and choice, to the extent practicable."

Resident representative. For purposes of this subpart, the term resident representative means an individual of the resident's choice 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~~.

AMDA COMMENT: If an individual state law covers this, then it will apply. Therefore, it is superfluous to specify one particular group or individual in a regulatory document, while omitting others.

Sexual abuse is intentional non-consensual sexual contact of any type with a resident.

AMDA COMMENT: AMDA recommends modifying this definition, as indicated, so that accidental touching, such as might occur while moving or cleaning a person, will not be misconstrued as abuse.

Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.

13. Section 483.10 is revised to read as follows:

§483.10 Resident rights.

The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility, including those specified in this section.

(a) Exercise of rights. (1) The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.

(2) The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights and to be supported by the facility in the exercise of his or her rights as required under this subpart.

(3) A resident has the right to designate a representative, in accordance with State law.

(i) The resident representative has the right to exercise the resident's rights to the extent

those rights are delegated to the resident representative.

(ii) The resident retains the right to exercise those rights not delegated to a resident representative, including the right to revoke a delegation of rights, except as limited by State law.

(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 of his or her decision-making capacity and unless otherwise adjudicated to be incompetent~~not prohibited by court order~~.

AMDA COMMENT:
AMDA agrees that individuals should be able to exercise their rights to the extent that their decision making capacity permits.

However, it is not clear what the proposed statement means, as written. AMDA recommends rewording for clarification, as noted above.

If it refers to judicial determination of incompetence or declaration under state laws that someone lacks decision-making capacity, then it should be stated as such.

Judicial proceedings are only sometimes needed to determine competency. Typically, states have procedures to support non-judicial determination of decision-making capacity.

A court sometimes determines incompetence but does not generally issue “court orders” that limit people’s rights in the sense implied here.

(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.

(5) In the case of a resident who has not been adjudged incompetent by the state court, any legal surrogate designated in accordance with state law may exercise the resident’s rights to the extent provided by state law. ~~The same-sex spouse of a resident must be~~ allowed ~~to exercise such rights afforded treatment equal to that afforded to an opposite-sex spouse if the marriage~~

~~was valid in the jurisdiction in which it was celebrated.~~

AMDA COMMENT:
AMDA supports the right of individuals who have been determined to be incompetent to have someone else exercise their rights on their behalf.

The first sentence in this section covers everyone who is covered under state law. Therefore, it is superfluous to single out a specific group later on in the paragraph.

(b) Planning and implementing care. The resident has the right to be informed of, and participate in, his or her treatment, including:

(1) The right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition.

(2) The right to be informed, in advance, of the care to be furnished and the disciplines that will furnish care.

(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.

(4) The right to request, refuse, and/or discontinue treatment, to participate in or refuse to participate in experimental research, and to formulate an advance directive as specified in §483.11(e)(6).

(2) The right to participate in the development and implementation of his or her individualized ~~person-centered~~ plan of care, including but not limited to:

AMDA COMMENT:
AMDA supports the notion of individualized care that reflects each person's wishes and goals.

However, a good care plan has many other desirable attributes. Since the notion of "person-centered" has already been stated elsewhere in requirements, and it is just one of several aspects of care plan quality, we believe that it is redundant and unnecessary to repeatedly single out just one attribute while omitting the others.

(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.

AMDA COMMENT: As noted above.

(ii) The right to participate in establishing the expected goals and outcomes of care, the type, amount, frequency, and duration of care, and any other factors related to the effectiveness of the plan of care.

(iii) The right to be informed, in advance, of changes to the plan of care.

(iv) The right to receive the services and/or items included in the plan of care.

(v) The right to see the care plan, including the right to sign after changes to the plan of care.

(6) The right to self-administer medications if the interdisciplinary team has determined that this practice is clinically appropriate in accordance with §483.11(b)(2).

(7) Nothing in this paragraph should be construed as the right of the resident to receive ~~the provision of~~ {NOTE: This is redundant} medical treatment or medical services deemed medically unnecessary or inappropriate.

(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, practice, and performance requirements of the facility.

AMDA COMMENT: AMDA recommends additional wording in order to support the role of the medical director (as identified in F501) in attaining practitioner accountability for improved performance. Credentialing refers only to background, education, training, licensing, etc. Just requiring credentialing is not enough to ensure adequate physician performance such as timely visits and competent care. Addressing the challenges of medical care requires support for holding people accountable for their performance and practice, not just their credentials.

~~(3)~~(2) 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.

(d) Respect and dignity. The resident has a right to be treated with respect and dignity, including:

(1) The right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.

(2) The right to retain and use personal possessions, including furnishings, and clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

(3) The right to reside and receive services in the facility with reasonable accommodation of resident needs and preferences except when to do so would endanger the health or safety of the resident or other residents.

(4) The right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

(5) The right to share a room with his or her roommate of choice when practicable, when both residents live in the same facility and both residents consent to the arrangement.

(6) The right to receive notice before the resident’s room or roommate in the facility is changed.

(7) The right to refuse to transfer to another room in the facility, if the purpose of the transfer is to relocate:

(i) A resident of a SNF from the distinct part of the institution that is a SNF to a part of the institution that is not a SNF, or

(ii) A resident of a NF from the distinct part of the institution that is a NF to a

distinct part of the institution that is a SNF.

(8) A resident's exercise of the right to refuse transfer does not affect the resident's eligibility or entitlement to Medicare or Medicaid benefits.

(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;

(2) Interact with members of the community and participate in community activities both inside and outside the facility;

(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~~visiting, and in a manner that does not impose on the rights of another resident, including the individuals specified in §483.11(d);

AMDA COMMENT: It appears that the word "visitation" is defined elsewhere as "an official or formal visit, a disaster or difficulty regarded as a divine punishment. . ." [https://encrypted.google.com/webhp?hl=en&lr=all#hl=en&tbs=lr:all&q=define:visitation] Therefore, AMDA recommends changing here and elsewhere to "visit" or "visiting," which is not the same thing as "visitation."

(1) Organize and participate in resident groups in the facility;

(2) Participate in family groups;

(3) Have family member(s) or other resident representative(s) meet in the facility with the families or resident representative(s) of other residents in the facility;

(4) Participate in other activities, including social, religious, and community activities that do not interfere with the rights of other residents in the facility;

(5) Choose to or refuse to perform services for the facility subject to the facility requirements in §483.11(d)(4);

(6) Manage his or her financial affairs. This includes the right to know, in advance, what charges a facility may impose against a resident's personal funds as specified in §483.11(d)(6)(ii);

(7) Make choices about aspects of his or her life in the facility that are significant to the resident.

(f) Access to information. (1) The resident has the right to be informed of his or her rights and of all rules and regulations governing resident conduct and responsibilities during his or her stay in the facility.

(2) The resident has the right to receive notices verbally (meaning spoken) and in writing (including Braille) in a format and a language he or she understands, including

(i) Required notices as specified in §483.11(e);

(ii) Information and contact information for State and local advocacy organizations, including but not limited to the State Long-Term Care Ombudsman program (established under section 712 of the Older Americans Act of 1965, as amended 2006 (42 U.S.C. 3001 et seq) and the protection and advocacy system (as designated by the state, and as established under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15001 et seq.);

(iii) Information regarding Medicare and Medicaid eligibility and coverage;

(iv) Contact information for the Aging and Disability Resource Center (established under Section 202(a)(20)(B)(iii) of the Older Americans Act); or other No Wrong Door Program

(v) Contact information for the Medicaid fraud control unit; and

(vi) Information and contact information for filing grievances or complaints about abuse, neglect, misappropriation of resident property in the facility, and non-compliance with §489.102 of this chapter.

(3) The resident has the right to access medical records pertaining to him or herself,—

(i) Upon an oral or written request, in the form and format requested by the individual, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, including current

medical records, within 24 hours (excluding weekends and holidays); and

(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:

(A) Labor for copying the medical records requested by the individual, whether in paper or electronic form;

(B) Supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media; and

(C) Postage, when the individual has requested the copy be mailed.

(4) The resident has the right to—

(i) Examine the results of the most recent survey of the facility conducted by Federal or State surveyors and any plan of correction in effect with respect to the facility; and

(ii) Receive information from agencies acting as client advocates, and be afforded the opportunity to contact these agencies.

(g) Privacy and confidentiality. The resident has a right to personal privacy and confidentiality of his or her personal and medical records.

(1) This includes the right to privacy in his or her verbal (that is, spoken), written, and electronic communications, including the right to send and promptly receive unopened mail and other letters, packages and other materials delivered to the facility for the resident, including those delivered through a means other than a postal service.

(2) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident;

(3) The resident has a right to a secure and confidential medical record.

(4) The resident has the right to refuse the release of personal and medical records except as provided at §483.70(i)(2) or other applicable federal or state laws.

(h) Communication. (1) The resident has the right to have reasonable access to the use of a telephone, including TTY and TDD services, and a place in the facility where calls can be made without being overheard. This includes the right to retain and use a cellular phone at the resident's own expense.

(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.

(i) If the access is available to the facility

(ii) At the resident's expense, if any additional expense is incurred by the facility to provide such access to the resident.

(3) The resident has the right to send and receive mail, and to receive letters, packages and other materials delivered to the facility for the resident through a means other than a postal service, including the right to:

(i) Privacy of such communications consistent with paragraph (g)(1) of this section; and

(ii) Access to stationery, postage, and writing implements at the resident's own expense.

(i) Safe environment. The resident has a right to a safe, clean, comfortable and homelike environment in accordance with §483.11(g), including but not limited to receiving treatment and supports for daily living safely.

(j) Grievances. (1) The resident has the right to voice grievances to the facility or other agency or entity that hears grievances without discrimination or reprisal and without fear of discrimination or reprisal. Such grievances include those with respect to care and treatment ~~which~~ that has been furnished as well as that which has not been furnished.

(2) The resident has the right to prompt efforts by the facility to resolve grievances in accordance with §483.11(h).

14. Section 483.11 is added to subpart B to read as follows:

§483.11 Facility responsibilities

A facility must treat each resident with respect and dignity and care for each resident in a manner and in an environment that promotes maintenance or enhancement of his or her quality of life~~, recognizing each resident's individuality~~. The facility must protect and promote the rights of the resident as specified in §483.10, including, but not limited to the following obligations:

AMDA COMMENT: As noted previously.

(a) Exercise of rights. (1) The facility must ensure that the resident can exercise his or her rights without interference, coercion, discrimination, or reprisal from the facility.

(2) The facility must provide ~~equal access to~~ quality care regardless of diagnosis, severity of condition, or payment source. A facility must establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services under the State plan for all residents regardless of payment source.

AMDA COMMENT:

AMDA supports the expectation to provide quality care (i.e., safe, effective, person-centered, equitable, efficient, and timely) to everyone.

However, terms such as "equal access" can easily be misconstrued as requiring the same amount of care or comparable treatments regardless of need or condition.

Therefore, AMDA recommends deleting this phrase as it is unnecessary and potentially problematic.

(3) The facility must treat the decisions of a resident representative as the decisions of the resident to the extent required by the court or delegated by the resident, in accordance with applicable law.

(4) The facility shall not extend the resident representative the right to make decisions on behalf of the resident beyond the extent required by the court or delegated by the resident, in accordance with applicable law.

(5) If the facility has reason to believe that a resident representative is making decisions or taking actions that are not in the best interests of a resident, the facility may report such concerns as permitted and shall report such concerns when and in the manner required under State law.

(b) Planning and implementing care. (1) The facility shall inform the resident of the right to participate in his or her treatment and shall support the resident in this right, consistent with §483.10(b). The planning process must:

(i) Facilitate the inclusion of the resident or resident representative.

(ii) Include an assessment of the resident's strengths and needs.

(iii) Incorporate the resident's personal and cultural preferences in developing goals of care.

(2) The interdisciplinary team, as defined by §483.21(b)(2)(ii), is responsible for determining if resident self-administration of medications is clinically appropriate.

(c) Attending physician. (1) The facility must ensure that each resident remains informed of the name, specialty, and way of contacting the physician and other primary care professionals

responsible for his or her care.

(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 relevant options.

AMDA COMMENT:
AMDA again notes that adequate performance and practice go beyond just "credentialing."

Adequate oversight of physician performance and practice are essential to attaining quality care (i.e., safe, effective, efficient, patient-centered, timely, and equitable). This requires effective collaboration between the medical director and the facility.

Therefore, the requirement to honor a resident's preference regarding physicians must be related to the physician's responsibility to practice appropriately and provide quality care. The failure to hold physicians to this standard has major adverse consequences for long-term and post-acute care residents/patients. We suggest adding the word "relevant" to emphasize that the choice needs to consider the physician's performance and practice as well as other factors.

(2) If the resident subsequently selects another attending physician who meets the requirements specified in this part, the facility must honor that choice.

(d) Self-determination. The facility must promote and facilitate resident self-determination through support of resident choice as specified in §483.10(e) and as follows:

(1) The facility must:

(i) Provide immediate access to any resident by:

(A) Any representative of the Secretary,

(B) Any representative of the State,

(C) Any representative of the Office of the State long term care ombudsman, (established under section 712 of the Older Americans Act of 1965, as amended 2006 (42 U.S.C. 3001 et seq);

(D) The resident's individual physician,

(E) Any representative of the protection and advocacy systems, as designated by the

state, and as established under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15001 et seq.),

(F) Any representative of the agency responsible for the protection and advocacy system for individuals with mental illness (established under the Protection and Advocacy for Mentally Ill Individuals Act of 2000 (42 U.S.C. 10802); and

(G) The resident representative.

(ii) Provide immediate access to a resident by immediate family and other relatives of the resident, subject to the resident's right to deny or withdraw consent at any time;

(iii) Provide immediate access to a resident by others who are visiting with the consent of the resident, subject to reasonable clinical and safety restrictions and the resident's right to deny or withdraw consent at any time;

(iv) Provide reasonable access to a resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident's right to deny or withdraw consent at any time; and

(2) The facility must have written policies and procedures regarding the ~~visitation~~visiting {NOTE: Again, "v~~V~~isitation" is not the same as "visiting" in this context. The most appropriate word is "visiting."} rights of residents, including those setting forth any clinically necessary or reasonable restriction or limitation or safety restriction or limitation that the facility may need to place on such rights and the reasons for the clinical or safety restriction or limitation. A facility must meet the following requirements:

(i) Inform each resident (or resident representative, where appropriate) of his or her ~~visitation~~visiting rights, including any clinical or safety restriction or limitation on such rights, when he or she is informed of his or her other rights under this section.

(ii) Inform each resident of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse (including a same-sex spouse), a domestic partner (including a same-sex domestic partner), another family member, or

a friend, and his or her right to withdraw or deny such consent at any time.

(iii) Not restrict, limit, or otherwise deny ~~visitation~~visiting privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(iv) Ensure that all visitors enjoy full and equal ~~visitation~~visiting privileges consistent with facility rules regarding visitors and with resident preferences.

(3) The facility must provide a resident or family group, if one exists, with private space; and

(i) Staff or visitors may attend meetings between the resident and the visitors only at the group's invitation;

(ii) The facility must provide a designated staff person who is approved by the resident or family group and the facility and who is responsible for providing assistance and responding to written requests that result from group meetings;

(iii) The facility must consider the views of a resident or family group and act upon the grievances and recommendations of such groups concerning issues of resident care and life in the facility.

(A) This should not be construed to mean that the facility must implement as recommended every request of the resident or family group.

(B) The facility must be able to demonstrate their response and the rationale for such response.

(4) The facility must not require a resident to perform services for the facility. The resident may perform services for the facility, if he or she chooses, when—

(i) The facility has documented the resident's need or desire for work in the plan of care;

(ii) The plan specifies the nature of the services performed and whether the services are voluntary or paid;

(iii) Compensation for paid services is at or above prevailing rates; and

(iv) The resident agrees to the work arrangement described in the plan of care.

(5) The facility must not require residents to deposit their personal funds with the facility. If a resident chooses to deposit personal funds with the facility, the facility must adhere to the following requirements.

(i) Management of personal funds. Upon written authorization of a resident, the facility must hold, safeguard, manage, and account for the personal funds of the resident deposited with the facility, as specified in this section.

(ii) Deposit of funds.

(A) In general:

(1) Except as set out in paragraph (d)(5)(ii)(B)(1) of this section, the facility must deposit any residents' personal funds in excess of $100 in an interest bearing account (or accounts) that is separate from any of the facility's operating accounts, and that credits all interest earned on resident's funds to that account. (In pooled accounts, there must be a separate accounting for each resident's share.)

(2) The facility must maintain a resident's personal funds that do not exceed $100 in a non-interest bearing account, interest-bearing account, or petty cash fund.

(B) Residents whose care is funded by Medicaid:

(1) The facility must deposit the residents' personal funds in excess of $50 in an interest bearing account (or accounts) that is separate from any of the facility's operating accounts, and that credits all interest earned on resident's funds to that account. (In pooled accounts, there must be a separate accounting for each resident's share.)

(2) The facility must maintain personal funds that do not exceed $50 in a non-interest bearing account, interest-bearing account, or petty cash fund.

(iii) Accounting and records. (A) The facility must establish and maintain a system that assures a full and complete and separate accounting, according to generally accepted accounting principles, of each resident's personal funds entrusted to the facility on the resident's behalf.

(B) The system must not combine~~preclude any commingling of~~ resident funds with

facility funds or with the funds of any persons other than another resident.

(C) The individual financial record must be available to the resident through quarterly statements and upon request.

(iv) Notice of certain balances. The facility must notify each resident that receives Medicaid benefits—

(A)) When the amount in the resident's account reaches $200 less than the SSI resource limit for one person, specified in section 1611(a)(3)(B) of the Act; and

(B) That, if the amount in the account, in addition to the value of the resident's other nonexempt resources, reaches the SSI resource limit for one person, the resident may lose eligibility for Medicaid or SSI.

(v) Conveyance upon discharge, eviction, or death. Upon the discharge, eviction, or death of a resident with a personal fund deposited with the facility, the facility must convey within 30 days the resident's funds, and a final accounting of those funds, to the resident, or in the case of death, the individual or probate jurisdiction administering the resident's estate, in accordance with State law.

(vi) Assurance of financial security. The facility must purchase a surety bond, or otherwise provide assurance satisfactory to the Secretary, to assure the security of all personal funds of residents deposited with the facility.

(6) The facility must not impose a charge against the personal funds of a resident for any item or service for which payment is made under Medicaid or Medicare (except for applicable deductible and coinsurance amounts). The facility may charge the resident for requested services that are more expensive than or in excess of covered services in accordance with §489.32 of this chapter. (This does not affect the prohibition on facility charges for items and services for which Medicaid has paid. See §447.15 of this chapter, which limits participation in the Medicaid program to providers who accept, as payment in full, Medicaid payment plus any deductible, coinsurance, or copayment required by the plan to be paid by the individual.)

(i) Services included in Medicare or Medicaid payment. During the course of a covered Medicare or Medicaid stay, facilities may not charge a resident for the following categories of items and services:

(A) Nursing services as required at §483.35.

(B) Food and Nutrition services as required at §483.60.

(C) An activities program as required at §483.25(c).

(D)) Room/bed maintenance services.

(E)) Routine personal hygiene items and services as required to meet the needs of residents, including, but not limited to, hair hygiene supplies, comb, brush, bath soap, disinfecting soaps or specialized cleansing agents when indicated to treat special skin problems or to fight infection, razor, shaving cream, toothbrush, toothpaste, denture adhesive, denture cleaner, dental floss, moisturizing lotion, tissues, cotton balls, cotton swabs, deodorant, incontinence care and supplies, sanitary napkins and related supplies, towels, washcloths, hospital gowns, over-the-counter drugs, hair and nail hygiene services, bathing assistance, and basic personal laundry.

(F) Medically-related social services as required at §483.40(d).

(G) Hospice services elected by the resident and paid for under the Medicare Hospice Benefit or paid for by Medicaid under a state plan.

(ii) Items and services that may be charged to residents' funds. Listed below in paragraphs (d)(6)(ii)(A) through (L) of this section are general categories and examples of items and services that the facility may charge to residents' funds if they are requested by a resident, if they are not required to achieve the goals stated in the resident’s care plan, if the facility informs the resident that there will be a charge, and if payment is not made by Medicare or Medicaid:

(A) Telephone, including a cellular phone.

(B) Television/radio, personal computer or other electronic device for personal use.

(C) Personal comfort items, including smoking materials, notions and novelties, and

confections.

(D)) Cosmetic and grooming items and services in excess of those for which payment is made under Medicaid or Medicare.

(E)) Personal clothing.

(F)) Personal reading matter.

(G) Gifts purchased on behalf of a resident.

(H) Flowers and plants.

(I) Cost to participate in social events and entertainment outside the scope of the activities program, provided under §483.25(c).

(J) Noncovered special care services such as privately hired nurses or aides.

(K)) Private room, except when therapeutically required (for example, isolation for infection control).

(L) Except as provided below, specially prepared or alternative food requested instead of the food and meals generally prepared by the facility, as required by §483.60.

(1) The facility may not charge for special foods and meals, including medically prescribed dietary supplements, ordered by the resident's health care provider, as these are included per §483.60.

(2) In accordance with §483.60(c) through (f), when preparing foods and meals, a facility must take into consideration residents' needs and preferences and the overall cultural and religious make-up of the facility's population.

(iii) Requests for items and services. (A) The facility can only charge a resident for any noncovered item or service if such item or service is specifically requested by the resident.

(B) The facility must not require a resident to request any item or service as a condition of admission or continued stay.

(C) The facility must inform, orally and in writing, the resident requesting an item or service for which a charge will be made that there will be a charge for the item or service and

what the charge will be.

(e) Information and communication. (1) With the exception of information described in paragraph (e)(2) of this section, the facility must ensure that information is provided to each resident in a form and manner that the resident can access and understand, including in an alternative format or in a language that the resident can understand. Summaries that translate information described in paragraph (e)(2) of this section may be made available to the patient at their request and expense in accordance with applicable law.

(2) The facility must:

(i) Provide the resident with access to medical records pertaining to him or herself, upon an oral or written request, in the form and format requested by the individual, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, within 24 hours (excluding weekends and holidays); and

(ii) 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.

(iii) The facility may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:

(A) Labor for copying the medical records requested by the individual, whether in paper or electronic form;

(B)) Supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media; and

(C) Postage, when the individual has requested the copy be mailed.

(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.

(4) The facility must post, in a form and manner accessible and understandable to residents, resident representatives and support person:

(i) A list of names, addresses (mailing and email), and telephone numbers of all pertinent State agencies and advocacy groups, such as the State survey and certification agency, the State licensure office, adult protective services where state law provides for jurisdiction in long-term care facilities, the Office of the State Long-Term Care Ombudsman program, the protection and advocacy network, home and community based service programs, and the Medicaid fraud control unit; and

(ii) A statement that the resident may file a complaint with the State survey and certification agency concerning resident abuse, neglect, misappropriation of resident property in the facility, and non-compliance with the requirements specified in 42 CFR part 489 subpart I (Advance Directives).

(5) The facility must comply with the requirements specified in 42 CFR part 489, subpart I (Advance Directives).

(i) These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the resident's option, formulate an advance directive.

(ii) This includes a written description of the facility's policies to implement advance directives and applicable State law.

(iii) Facilities are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met.

(iv) If an adult individual is incapacitated at the time of admission and is unable to

receive information or articulate whether or not he or she has executed an advance directive, the facility may give advance directive information to the individual's resident representative in accordance with State law.

(v) The facility is not relieved of its obligation to provide this information to the individual once he or she is able to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

(6) The facility must display in the facility written information, and provide to residents and applicants for admission, oral and written information about how to apply for and use Medicare and Medicaid benefits, and how to receive refunds for previous payments covered by such benefits.

(7) Notification of changes. (i) A facility must immediately inform the resident; consult with the resident's physician; and notify the resident representative(s) when there is—

(A) An accident involving the resident which results in injury ~~and~~ that ~~has the potential for requiring~~ requires physician review or intervention;

AMDA COMMENT: AMDA agrees that physicians should be involved in managing significant injures. However, we believe that it is reasonable to allow facilities to triage situations and to notify physicians based on evidence that the injury is significant enough to require a medical assessment and/or intervention. It is reasonable to expect that each facility have and use a protocol for physician notification and that the staff make a preliminary assessment and then monitor for delayed complications.

(B) A significant change in the resident's physical, mental, or psychosocial status (that is, a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);

(C) A need to alter treatment significantly (that is, a need to discontinue or change an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or

(D)) A decision to transfer or discharge the resident from the facility as specified in §483.15(b)(1)(ii).

(ii) When making notification under paragraph (e)(7)(i) of this section, the facility must ensure that all pertinent information specified in §483.15(b)(2) is available and provided upon request to the physician.

(iii) The facility must also promptly notify the resident and the resident representative, if any, when there is—

(A)) A change in room or roommate assignment as specified in §483.10(d)(6); or

(B) A change in resident rights under Federal or State law or regulations as specified in paragraph (e)(10) of this section.

(iv) The facility must record and periodically update the address (mailing and email) and phone number of the resident representative(s).

(8) Admission to a composite distinct part. A facility that is a composite distinct part (as defined in §483.5 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 §483.15(b)(9).

(9) The facility must provide a notice of rights and services to the resident prior to or upon admission and during the resident's stay.

(i) The facility must inform the resident both orally and in writing in a language that the resident understands of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility.

(ii) The facility must also provide the resident with the State-developed notice of Medicaid rights and obligations, if any.

(iii) Receipt of such information, and any amendments to it, must be acknowledged in writing;

(10) The facility must:

(i) Inform each Medicaid-eligible resident, in writing, at the time of admission to the nursing facility and when the resident becomes eligible for Medicaid of—

(A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;

(B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and

(ii) Inform each Medicaid-eligible resident when changes are made to the items and services specified in paragraphs (e)(10)(i)(A) and (B) of this section.

(11) The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare/Medicaid or by the facility's per diem rate.

(i) Where changes in coverage are made to items and services covered by Medicare and/or by the Medicaid State plan, the facility must provide notice to residents of the change as soon as is reasonably possible;

(ii) Where changes are made to charges for other items and services that the facility offers, the facility must inform the resident in writing at least 60 days prior to implementation of the change.

(iii) If a resident dies or is hospitalized or is transferred and does not return to the facility, the facility must refund to the resident, resident representative, or estate, as applicable, any deposit or charges already paid, less the facility’s per diem rate, for the days the resident actually resided or reserved or retained a bed in the facility, regardless of any minimum stay or discharge notice requirements.

(iv) The facility must refund to the resident or resident representative any and all refunds due the resident within thirty days from the resident's date of discharge from the facility.

(v) Where the facility requires the execution of an admission contract by or on behalf of an individual seeking admission to the facility, the terms of the contract must not conflict with the requirements of these regulations.

(12) The facility must furnish to each resident a written description of legal rights ~~which~~ that includes—

(i) A description of the manner of protecting personal funds, under paragraph (d)(5) of this section;

(ii) A description of the requirements and procedures for establishing eligibility for Medicaid, including the right to request an assessment of resources under section 1924(c) of the Social Security Act.

(iii) A list of names, addresses (mailing and email), and telephone numbers of all pertinent State regulatory and informational agencies, resident advocacy groups such as the State survey and certification agency, the State licensure office, the State Long-Term Care Ombudsman program, the protection and advocacy agency, adult protective services where state law provides for jurisdiction in long-term care facilities, the local contact agency for information about returning to the community and the Medicaid fraud control unit; and

(iv) A statement that the resident may file a complaint with the State survey and certification agency concerning any suspected violation of state or federal nursing facility regulations, including but not limited to resident abuse, neglect, misappropriation of resident property in the facility, non-compliance with the advance directives requirements and requests for information regarding returning to the community.

(13) The facility must protect and facilitate that resident's right to communicate with individuals and entities within and external to the facility, consistent with §483.10(h), including reasonable access to:

(i) A telephone, including TTY and TDD services;

(ii) The internet, to the extent available to the facility; and

(iii) Stationery, postage, writing implements and the ability to send mail.

(f) Privacy and confidentiality. (1) The facility must respect the resident's right to personal privacy, including privacy in his or her verbal (meaning spoken), written and electronic

communications.

(i) This includes ensuring that a resident can send and promptly receive mail that is unopened; as well as receive, unopened, letters, packages and other materials delivered to the facility for the resident through a means other than a postal service.

(ii) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident;

(2) The facility must comply with the residents' rights in §483.10(g)(3) regarding his or her medical records.

(3) The facility must allow representatives of the Office of the State Long-Term Care Ombudsman to examine a resident's medical, social, and administrative records in accordance with State law.

(g) Safe environment. The facility must provide:

(1) A safe, clean, comfortable, and homelike environment, allowing the resident to use his or her personal belongings to the extent possible. This includes ensuring:

(i) That the resident can receive care and services safely.

(ii) That the physical layout of the facility maximizes independence and does not pose a safety risk.

(2) Housekeeping and maintenance services necessary to maintain a sanitary, orderly, and comfortable interior;

(3) Clean bed and bath linens that are in good condition;

(4) Private closet space in each resident room, as specified in §483.90(d)(2)(iv);

(5) Adequate and comfortable lighting levels in all areas;

(6) Comfortable and safe temperature levels. Facilities initially certified after October 1, 1990 must maintain an average overall temperature range of 71–81°F; and

AMDA COMMENT: AMDA agrees that facility temperatures should not be extreme. However, there is great variability in what people identify as comfortable. Furthermore, there is scientific evidence regarding desirable temperatures in various situations. For example, optimal sleeping temperature has been identified as being somewhere between 68 and 72 degrees, and varies with the individual. Excessive heat can affect sleep in some individuals and may contribute to medical issues. Different areas of a facility may have different temperature ranges. Therefore, some qualifier is needed here.

(7) For the maintenance of comfortable sound levels.

(h) Grievances. (1) The facility must make information on how to file a grievance or complaint available to the resident, including the information required under paragraph (f)(2) of this section.

(2) The facility must make prompt efforts to resolve grievances the resident may have, including those with respect to the behavior of other residents.

(3) The facility must establish a grievance policy to ensure the prompt resolution of all grievances regarding the residents' rights contained in §483.10. Upon request, the provider must give a copy of the grievance policy to the resident. 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;

(iii) As necessary, taking immediate action to prevent further potential violations of any resident right while the alleged violation is being investigated;

(iv) Immediately reporting all alleged violations involving neglect, abuse, including injuries of unknown source, and/or misappropriation of resident property, by anyone furnishing services on behalf of the provider, to the administrator of the provider; and as required by State law;

(v) Ensuring that all written grievance decisions include the date the grievance was received, a summary statement of the resident's grievance, the steps taken to investigate the grievance, a summary of the pertinent findings or conclusions regarding the resident's concern(s), a statement as to whether the grievance was confirmed or not confirmed, any corrective action taken or to be taken by the facility as a result of the grievance, and the date the written decision was issued;

(vi) Taking appropriate corrective action in accordance with State law if the alleged violation of the residents' rights is confirmed by the facility or if an outside entity having jurisdiction, such as the State survey and certification agency, Quality Improvement Organization, or local law enforcement agency confirms a violation of any of these residents' rights within its area of responsibility; and

(vii) Maintaining evidence demonstrating the results of all grievances for a period of no less than three years from the issuance of the grievance decision.

(i) Contact with external entities. A facility must not prohibit or in any way discourage a resident from communicating with Federal, State, or local officials, including, but not limited to, Federal and State surveyors, other Federal or State health department employees, including representatives of the Office of the State Long-Term Care Ombudsman and of the protection and

advocacy system, regarding any matter, whether or not subject to arbitration or any other type of judicial or regulatory action.

15. Section 483.12 is revised to read as follows:

§483.12 Freedom from abuse, neglect, and exploitation.

The resident has the right to be free from abuse, neglect, misappropriation of resident property, and exploitation as defined in this subpart. This includes but is not limited to freedom from corporal punishment, involuntary seclusion and any physical or chemical restraint not required to treat the resident's medical symptoms.

(a) The facility must—

(1) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;

(2) Not employ or otherwise engage individuals who—

(i) Have been found guilty of felony abuse, neglect, misappropriation of property, or mistreatment by a court of law, in relation to care or service for an ~~nursing home resident~~elderly individual;

AMDA COMMENT: AMDA strongly supports efforts to address abuse, neglect, and mistreatment. However, we are concerned that the proposed language could disqualify for life anyone—including practitioners—for reasons that are unrelated to their care of nursing home patients. We believe that it is appropriate to look at the circumstances and details of each situation, and not just apply the blanket exclusion in the proposed language. Therefore, we recommend modifying the wording, as above.

(ii) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; or

(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.

(3) Report to the State nurse aide registry or licensing authorities any knowledge it has of

actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff.

(b) The facility must develop and implement written policies and procedures that:

(1) Prohibit and prevent abuse, neglect, and exploitation of residents and misappropriation of resident property,

(2) Establish policies and procedures to investigate any such allegations, and

(3) Include training as required at paragraph §483.95.

(4) ~~Establish coordination~~Coordinate with the QAPI program required under §483.75.

(5) Ensure reporting of crimes occurring in federally-funded long-term care facilities in accordance with section 1150B of the Social Security Act. The policies and procedures must include but are not limited to the following elements.

(i) Annually notifying covered individuals, as defined at section 1150B(a)(3) of the Act, of that individual's obligation to comply with the following reporting requirements.

(A) Each covered individual shall report to the State Agency and one or more law enforcement entities for the political subdivision in which the facility is located any reasonable suspicion of a crime against any individual who is a resident of, or is receiving care from, the facility.

(B) Each covered individual shall report not later than 2 hours after forming the suspicion, if the events that cause the suspicion result in serious bodily injury, or not later than 24 hours if the events that cause the suspicion do not result in serious bodily injury.

(ii) Posting a conspicuous notice of employee rights, as defined at section 1150B(d)(3) of the Act.

(iii) Prohibiting and preventing retaliation, as defined at section 1150B(d)(1) and (2) of the Act.

(c) In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must:

(1) Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, are reported immediately to the administrator of the facility and to other officials (including to the State survey and certification agency and adult protective services where state law provides for jurisdiction in long-term care facilities) in accordance with State law through established procedures.

(2) Have evidence that all alleged violations are thoroughly investigated.

(3) Prevent further potential abuse, neglect, exploitation, or mistreatment while the investigation is in progress.

(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.

§483.13 [Removed]

16. Remove §483.13.

17. Section 483.15 is revised to read as follows:

§483.15 Transitions of care.

Transitions of care include admissions to and discharges or transfers to or from a SNF or NF. This section also addresses bed-hold policies and therapeutic leave.

(a) Admissions policy. (1) The facility must establish and implement an admissions policy.

(2) The facility must—

(i) Not request or require residents or potential residents to waive their rights as set forth in this subpart and in applicable State, Federal or local licensing or certification laws, including but not limited to their rights to Medicare or Medicaid; and

(ii) Not request or require oral or written assurance that residents or potential residents

are not eligible for, or will not apply for, Medicare or Medicaid benefits.

(iii) Not request or require residents or potential residents to waive potential facility liability for losses of personal property

(3) The facility must not request or require a third party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in the facility. However, the facility may request and require a resident representative who has legal access to a resident's income or resources available to pay for facility care to sign a contract, without incurring personal financial liability, to provide facility payment from the resident's income or resources.

(4) In the case of a person eligible for Medicaid, a nursing facility must not charge, solicit, accept, or receive, in addition to any amount otherwise required to be paid under the State plan, any gift, money, donation, or other consideration as a precondition of admission, expedited admission or continued stay in the facility. However,—

(i) A nursing facility may charge a resident who is eligible for Medicaid for items and services the resident has requested and received, and that are not specified in the State plan as included in the term “nursing facility services” so long as the facility gives proper notice of the availability and cost of these services to residents and does not condition the resident's admission or continued stay on the request for and receipt of such additional services; and

(ii) A nursing facility may solicit, accept, or receive a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to a Medicaid eligible resident or potential resident, but only to the extent that the contribution is not a condition of admission, expedited admission, or continued stay in the facility for a Medicaid eligible resident.

(5) States or political subdivisions may apply stricter admissions standards under State or local laws than are specified in this section, to prohibit discrimination against individuals entitled to Medicaid.

(6) 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.

(7) 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.

(b) Transfer and discharge—(1) Facility requirements—(i) Equal access to quality care. (A)) A facility must establish, maintain and implement identical policies and practices regarding transfer, discharge, and the provision of services for all individuals regardless of source of payment;

(B) The facility may charge any amount for services furnished to non-Medicaid residents unless otherwise limited by state law and consistent with the notice requirement in §483.11(e)(11)(i) and (e)(12) describing the charges; and

(C) The State is not required to offer additional services on behalf of a resident other than services provided in the State plan.

(ii) The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless—

(A) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;

(B) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;

(C) The safety of individuals in the facility is endangered due to the clinical or behavioral status of the resident;

(D) The health of individuals in the facility would otherwise be endangered;

(E) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. Non-payment ~~does not apply unless~~ only applies if the resident ~~does not~~ has submitted the necessary paperwork for third party payment or

~~until~~ after the third party, including Medicare or Medicaid, denies the claim and the resident refuses to pay for his or her stay. {NOTE: Double negatives are harder to follow.} For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or

(F) The facility ceases to operate.

(iii) 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.

(2) Documentation. When the facility transfers or discharges a resident under any of the non-emergency circumstances specified in paragraphs (b)(1)(i)(A) through (F) of this section, the facility must ensure that the transfer or discharge is documented in the resident's clinical record and appropriate information is communicated to the receiving health care institution or provider.

(i) Documentation in the resident's clinical record must include:

(A) The basis for the transfer per paragraph (b)(1)(ii).

(B) In the case of paragraph (b)(1)(ii)(A) of this section, the specific resident need(s) that cannot be met, facility attempts to meet the resident needs, and the services available at the receiving facility to meet the need(s).

(ii) The documentation must be made by, or based on information provided by~~—~~

The resident's physician when transfer or discharge is necessary under paragraph (b)(1)(i)(A) or (B) of this section; and

AMDA COMMENT:
AMDA agrees that there is room to improve facility transfers and the provision of information related to those transfers. AMDA supports substantive efforts to reduce hospitalization, such as improved staff assessment, dialogue between staff and practitioners, and holding timely conversations about life-sustaining treatment options.

However, we are concerned about the feasibility of this proposed requirement for the physician to document directly. For example, during an urgent transfer to a hospital, sending the physician's previously documented history and physical, pertinent progress notes, consultations, and laboratory tests, supplemented by nursing documentation of the events and rationale leading to the transfer, should suffice.

This proposed requirement also appears to ignore the growing presence of telemedicine, which is often highly effective at managing condition changes appropriately and preventing hospitalization. (Grabowski DC, O'Malley AJ. Use of telemedicine can reduce hospitalizations of nursing home residents and generate savings for Medicare. Health Aff [Millwood]. 2014 Feb;33[2]:244-50.)

Again, we wish to emphasize that structural requirements are very unlikely to correct process problems. Therefore, we recommend modifying the wording, as is indicated above.

(A) A physician when transfer or discharge is necessary under paragraph (b)(1)(i)(C) or (D)) of this section.

(iii) Information provided to the receiving provider must include ~~a minimum of~~ at least 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) Behavior ~~al Health~~ Issues

AMDA COMMENT:
Sharing information electronically or on paper forms is not the same as communication regarding the patient. The elements listed are important, but in urgent or emergent situations only information pertinent to the acute condition change should be required. Too much information can overload and confuse the accepting emergency facility. Additional information could be provided the next working day if the resident is actually admitted to the hospital. Ongoing dialogue and oral reporting when patients are transitioned is more important, and cannot be replaced by forms and electronic information exchange.

Again, while AMDA strongly supports improved approaches to managing behavior, we disagree with the attempt to create a topic called "behavioral health" that is not, and cannot be, adequately defined, as we have explained elsewhere. Behavior issues can be covered under other sections; for example, psychosocial assessment and functional status, and underlying causes can be covered under active diagnoses, history of present illness, and current problem list.

Ultimately, regardless of the name, the issue to be conveyed is whether behavior is personally and socially appropriate, or at least not excessively disruptive or destructive to the individual and to others.

(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.

(iv) This requirement may be satisfied by the discharge summary providing it meets the requirements of §483.21(c) and includes at a minimum the information specified in paragraph (b)(2)(iii) of this section.

(3)Notice before transfer. Before a facility transfers or discharges a resident, the facility must—

(i) Notify the resident and the resident's representative(s) of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. ~~Subject to the resident's agreement, the facility must send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman.~~

AMDA COMMENT: AMDA is unclear about why the ombudsman's office needs notification of every routine discharge or transfer. We feel that such notification should be reserved for situations where the transfer or discharge is contested. We doubt that ombudsman offices would have the capacity to receive and act upon even a small portion of this information.

(ii) Record the reasons for the transfer or discharge in the resident's clinical record in accordance with paragraph (b)(2) of this section; and

(iii) Include in the notice the items described in paragraph (b)(5) of this section.

(4) Timing of the notice. (i) Except as specified in paragraphs (b)(4)(ii) and (b)(8) of this section, the notice of transfer or discharge required under this section must be made by the facility at least 30 days before the resident is transferred or discharged.

(ii) Notice must be made as soon as practicable before transfer or discharge when—

(A) The safety of individuals in the facility would be endangered under paragraph (b)(1)(ii)(C) of this section;

(B) The health of individuals in the facility would be endangered, under paragraph (b)(1)(ii)(D) of this section;

(C) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (b)(1)(ii)(B) of this section;

(D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (b)(1)(ii)(A) of this section; or

(E)) A resident has not resided in the facility for 30 days.

(5) Contents of the notice. The written notice specified in paragraph (b)(3) of this section must include the following:

(i) The reason for transfer or discharge;

(ii) The effective date of transfer or discharge;

(iii) The location to which the resident is expected to be transferred or discharged;

(iv) A statement that the resident has the right to appeal the action to the State, the name, address (mailing and email), and telephone number of the State entity which receives such requests; and information on how to obtain an appeal form and assistance in completing the form and submitting the appeal hearing request;

(v) The name, address (mailing and email) and telephone number of the Office of

the State Long-Term Care Ombudsman;

(vi) For nursing facility residents with intellectual and developmental disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with developmental disabilities established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 10802); and

(vii) For nursing facility residents with mental illness, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with mental illness established under the Protection and Advocacy for Mentally Ill Individuals Act.

(6) Changes to the notice. If the information in the notice changes prior to effecting the transfer or discharge, the facility must update the recipients of the notice as soon as practicable once the updated information becomes available.

(7) Orientation for transfer or discharge. A facility must provide and document sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility. This orientation must be provided in a form and manner that the resident can understand.

(8) Notice in advance of facility closure. In the case of facility closure, the individual who is the administrator of the facility must provide written notification prior to the impending closure to the State Survey Agency, the Office of the State Long-Term Care Ombudsman, residents of the facility, and the resident representatives of the residents or other responsible parties, as well as the plan for the transfer and adequate relocation of the residents, as required at §483.70(l).

(9) Room changes in a composite distinct part. Room changes in a facility that is a composite distinct part (as defined in §483.5) are subject to the requirements of §483.10(d)(7) and must be limited to moves within the particular building in which the resident resides, unless the resident voluntarily agrees to move to another of the composite distinct part's locations.

(c) Notice of bed-hold policy and readmission —(1) Notice before transfer. Before a

nursing facility transfers a resident to a hospital or the resident goes on therapeutic leave, the nursing facility must provide written information to the resident or resident representative that specifies—

(i) The duration of the state bed-hold policy, if any, during which the resident is permitted to return and resume residence in the nursing facility;

(ii) The reserve bed payment policy in the state plan, under §447.40 of this chapter, if any;

(iii) The nursing facility's policies regarding bed-hold periods, which must be consistent with paragraph (c)(3) of this section, permitting a resident to return; and

(iv) The information specified in paragraph (c)(3) of this section.

(2) Bed-hold notice upon transfer. At the time of transfer of a resident for hospitalization or therapeutic leave, a nursing facility must provide to the resident and the resident representative written notice which specifies the duration of the bed-hold policy described in paragraph (c)(1) of this section.

(3) Permitting resident to return to facility. A nursing facility must establish and follow a written policy on permitting residents to return to the facility after they are hospitalized or placed on therapeutic leave. The policy must provide for the following.

(i) A resident, whose hospitalization or therapeutic leave exceeds the bed-hold period under the State plan, is readmitted to the facility to their previous room if available or immediately upon the first availability of a bed in a semi-private room if the resident—

(A)) Requires the services provided by the facility; and

(B) Is eligible for Medicaid nursing facility services.

(ii) A resident who is hospitalized or placed on therapeutic leave with an expectation of returning to the facility must be notified in writing by the facility when the facility determines that the resident cannot be readmitted to the facility, the reason the resident cannot be readmitted to the facility, and the information specified in paragraphs (b)(5)(iv) through (vii) of this section.

(4) Readmission to a composite distinct part. When the nursing facility to which a resident is readmitted is a composite distinct part (as defined in §483.5), the resident must be permitted to return to an available bed in the particular location of the composite distinct part in which he or she resided previously. If a bed is not available in that location at the time of readmission, the resident must be given the option to return to that location upon the first availability of a bed there.

§483.20 [Amended]

18. In §483.20—

a. Revise paragraph (b)(1) introductory text.

b. Revise paragraphs (b)(1)(xvi) and (xviii).

c. Revise paragraph (e).

d. Remove paragraphs (k) and (l).

. e. Redesignate paragraph (m) as paragraph (k).

f. Revise newly designated paragraph (k).

The revisions read as follows:

§483.20 Resident assessment.

* * * * *

(b) * * *

(1) Resident assessment instrument. A facility must make a comprehensive assessment of a resident's medical conditions, needs, strengths, goals, life history and preferences, using the resident assessment instrument (RAI) specified by CMS. The assessment must include at least the following:

* * * * *

(xvi) Discharge planning.

* * * * *

(xviii) Documentation of participation in assessment. The assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care/direct access staff members on all shifts.

* * * * *

(e) Coordination. A facility must coordinate assessments with the preadmission screening and resident review (PASARR) program under Medicaid in subpart C of this part to the maximum extent practicable to avoid duplicative testing and effort. Coordination includes—

(1) Incorporating the recommendations from the PASARR level II determination and the PASARR evaluation report into a resident's assessment, care planning, and transitions of care.

~~(2) Referring all level II residents and all residents with newly evident or possible serious mental illness, intellectual disability, or a related condition for level II resident review upon a significant change in status assessment.~~

* * * * *

(k) Preadmission screening for individuals with mental illness and individuals with intellectual disability.

AMDA COMMENT:
AMDA supports the appropriate assessment and management of individuals with mental illness.

We note that these regulations not only propose to continue the PASARR requirement but to expand it on discharge. We also note that no substantive evidence is provided to confirm the efficacy of PASARR or support the value of the additional requirement for notifying the state mental health authority on discharge.

In fact, our review of the literature identified few meaningful studies of the subject. A study published in 2006 assessed the implementation of state Preadmission Screening and Resident Review (PASARR) programs with respect to identification of serious mental illness among nursing facility applicants and residents and access to mental health services. The authors concluded that ". . . many nursing facility residents have some type of psychiatric illness, and PASRR legislation does not appear to have enhanced their ability to gain access to mental health services beyond standard psychiatric consultation and medication therapy." *[Reference: Linkins KW, Lucca AM, Housman M, Smith SA. Use of PASRR programs to assess serious mental illness and service access in nursing homes. Psychiatr Serv. 2006 Mar;57(3):325-32*]

Given that nursing homes today must handle diverse behavior and psychiatric issues, we

question the assumption that PASRR continues to serve a purpose and that there is anything meaningful to be gained by expanding the requirement to discharge.

In fact, as we have noted elsewhere, everyone's time and effort would be better served to improve skills of nursing home staff and practitioners in assessment, diagnosis, and resident/patient management related to behavior and psychiatric conditions by rethinking the approach to mental illness and behavior management everywhere, by strengthening the care delivery process and improving clinical reasoning and problem solving across the board, in all settings—not just long-term and post-acute care.

(1) A nursing facility must not admit, on or after January 1, 1989, any new resident with—

(i) Mental illness as defined in paragraph (k)(3)(i) of this section, unless the State mental health authority has determined, based on an independent physical and mental evaluation performed by a person or entity other than the State mental health authority, prior to admission,

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

(B) If the individual requires such level of services, whether the individual requires specialized services; or

(ii) Intellectual disability, as defined in paragraph (k)(3)(ii) of this section, unless the State intellectual disability or developmental disability authority has determined prior to admission—

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

(B) If the individual requires such level of services, whether the individual requires specialized services for intellectual disability.

(2) Exceptions. For purposes of this section—

(i) The preadmission screening program under paragraph (k)(1) of this section need not provide for determinations in the case of the readmission to a nursing facility of an individual who, after being admitted to the nursing facility, was transferred for care in a hospital.

(ii) The State may choose not to apply the preadmission screening program under

paragraph (k)(1) of this section to the admission to a nursing facility of an individual—

(A)) Who is admitted to the facility directly from a hospital after receiving acute inpatient care at the hospital,

(B)) Who requires nursing facility services for the condition for which the individual received care in the hospital, and

(C) Whose attending physician has certified, before admission to the facility that the individual is likely to require less than 30 days of nursing facility services.

(3) Definition. For purposes of this section—

(i) An individual is considered to have mental illness if the individual has a serious mental illness as defined in §483.102(b)(1).

(ii) An individual is considered to have an intellectual disability if the individual has an intellectual disability as defined in §483.102(b)(3) or is a person with a related condition as described in §435.1010 of this chapter.

(4) A nursing facility must notify the state mental health authority or state intellectual disability authority, as applicable, promptly after a significant change in the mental or physical condition of a resident who has mental illness or intellectual disability for resident review.

19. Section 483.21 is added to read as follows:

§483.21 Comprehensive ~~person-centered~~ care planning.

AMDA COMMENT: As noted throughout, the Institute of Medicine (IOM) has identified six major quality attributes (safe, effective, efficient, timely, patient-centered, and equitable). AMDA believes that all of these are desirable elements of the care as well as the care plan. We believe that it may not send the right message to single out just one of those attributes repeatedly, and we have noted that it has been defined too narrowly herein. We note that CMS has indicated that it is trying to reconcile the diverse populations that nursing homes serve. Doing so requires recognizing that all of the elements of quality—not just selected ones—apply to all residents/patients, albeit to different degrees. The essence of individualized care is to find the right balance for each resident/patient, depending on the situation and on the individual's values, goals, and wishes, and not just focus on one aspect or another.

(a) Baseline care plans. (1) The facility must develop a baseline care plan for each resident that includes the instructions needed to provide effective, individualized ~~and person-centered~~ care of the resident that meet professional standards of quality care. The baseline care plan must--

(i) Be developed within 48 hours of a resident's admission.

(ii) Include the minimum healthcare information necessary to properly care for a resident including, but not limited to—

(A) Initial goals based on current condition, diagnoses, and admission orders.

AMDA COMMENT: AMDA agrees that a baseline care plan is desirable, pending a more comprehensive assessment. However, we strongly recommend that this should include something about their recent and current health condition and diagnoses, not just the orders. Often, the reason for orders that originate in another setting is unclear, and it is necessary to determine the individual's current condition and symptoms to decide whether the orders that are received are still relevant in the current setting or need to be modified. In addition, stabilizing the acute and chronic medical conditions is often a priority at admission.

(B)) Physician orders.

(C) Dietary orders.

(D) Therapy services.

(E)) Social services.

(F)) PASARR recommendation, if applicable.

(2) The facility may develop a comprehensive care plan in place of the baseline care plan if the comprehensive care plan--

(i) Is developed within 48 hours of the resident's admission.

(ii) Meets the requirements set forth in paragraph (b) of this section (excepting paragraph (b)(2)(i) of this section).

~~(b)~~ Comprehensive care plans. (1) The facility must develop a comprehensive ~~person-~~

(b) ~~centered~~ care plan for each resident, consistent with §483.10(b)(1) and §483.11(b)(1), that includes measurable objectives and time frames ~~tables~~ to meet a resident's medical, nursing, ~~and~~ mental, and psychosocial needs that are identified in the

comprehensive assessment. The comprehensive care plan must describe the following —

AMDA COMMENT: As noted above, there are several equally desirable attributes of care plans, no one of which should be emphasized to the exclusion of others. In addition, we recommend a wording change because a timetable (such as airlines might issue) is not the same as a time frame. The time frame for attaining care-related goals is not nearly that rigid or predictable.

(i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under §483.25 or §483.40; and

(ii) Any services that would otherwise be required under §483.25 or §483.40 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(b)(4).

(iii) Any specialized services ~~or specialized rehabilitative services~~ {NOTE: Rehabilitative services are services just like other services} that the nursing facility will provide as a result of PASARR recommendations. If a facility disagrees with the findings of the PASARR, it must indicate its rationale in the resident's medical record.

(iv) In consultation with the resident and the resident's representative (s)—

(A) The resident's goals for admission and desired outcomes.

(B) The resident's preference and potential for future discharge. Facilities must document whether the resident's desire to return to the community was assessed and any referrals to local contact agencies and/or other appropriate entities, for this purpose.

(C) Discharge plans in the comprehensive care plan, as appropriate, in accordance with the requirements set forth in paragraph (c) of this section.

(2) A comprehensive care plan must be—

(i) Developed within 7 days after completion of the comprehensive assessment.

(ii) Prepared by an interdisciplinary team, that includes but is not limited to--

(A) The attending physician.

(B) A registered nurse with responsibility for the resident.

(C) A nurse aide with responsibility for the resident.

(D)) A member of food and nutrition services staff.

(E)) A social worker.

(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.

(G) Other appropriate staff or professionals in disciplines as determined by the resident's needs or as requested by the resident.

(iii) Reviewed and revised by the interdisciplinary team after each assessment, including both the comprehensive and quarterly review assessments.

(3) The services provided or arranged by the facility, as outlined by the comprehensive care plan, must—

(i) Meet professional standards of quality.

(ii) Be provided by qualified persons in accordance with each resident's written plan of care.

(iii) Be mindful of, and tailored to cultural differences and preferences ~~Be culturally-competent and trauma-informed~~

AMDA COMMENT:
AMDA agrees that it is reasonable to tailor interventions to cultural preferences and differences.

However, that is different from requiring adherence to ill-defined concepts such as "culturally competent" or "trauma-informed." We are concerned as to how surveyors (or, for that matter, anyone) could consistently and fairly identify whether a facility's efforts are sufficiently "culturally competent" or "trauma informed," but they could potentially evaluate whether the facility considered and tried to tailor services to cultural differences and preferences as well as personal history and major issues.

This sort of topic requires explicit and pertinent criteria. Therefore, we recommend changing the wording, as noted above.

(c) Discharge planning—(1) Discharge planning process. The facility must develop and

implement an effective discharge planning process that focuses on the resident's discharge goals and preparing residents to be active partners in post-discharge care, where discharge is appropriate, as well as effective transition of the resident from SNF to post-SNF care, and the reduction of factors leading to preventable readmissions. The facility's discharge planning process must—

(i) Ensure that the discharge needs of each resident are identified and ~~result~~ contribute to ~~in~~ the development of a discharge plan for each resident.

(ii) Include regular re-evaluation of residents to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.

(iii) Involve the interdisciplinary team, as defined by §483.20(b)(2)(ii), in the ongoing process of developing the discharge plan.

(iv) Consider caregiver/support person availability and the resident's or caregiver's/support person(s) capacity and capability to perform required care, as part of the identification of discharge needs.

(v) Involve the resident and resident representative in the development of the discharge plan and inform the resident and resident representative of the final plan.

(vi) Address the resident's goals of care and treatment preferences.

(vii) Document that a resident has been asked about their interest in receiving information regarding returning to the community, where appropriate.

(A) If the resident indicates an interest in returning to the community, the facility must document any referrals to local contact agencies or other appropriate entities made for this purpose.

(B) Facilities must update a resident's comprehensive care plan and discharge plan, as appropriate, in response to information received from referrals to local contact agencies or other appropriate entities.

(C) If discharge to the community is determined to not be feasible, the facility must document who made the determination and why.

(viii) For residents who are transferred to another SNF or who are discharged to a HHA, IRF, or LTCH, inform ~~assist~~ residents and their resident representatives ~~in selecting a~~ about post-acute care provider options by using pertinent ~~data~~ information~~;~~ for example, ~~that includes, but is not limited to~~ SNF, HHA, IRF, or LTCH case reviews based on experience, standardized patient assessment data, data on quality measures, and data on resource use to the extent the ~~data~~ information is available and is ~~. The facility must ensure that the post-acute care standardized patient assessment data, data on quality measures, and data on resource use is~~ relevant and applicable to the resident's goals of care and treatment preferences.

AMDA COMMENT: AMDA agrees with the notion of trying to inform patients and families about other organizations and facilities to which they are being transferred. However, we are unclear as to how it would be practical or pertinent to use the data that are mandated in this section. While these items could be listed as examples, they appear to be proposed as mandates. Furthermore, the most pertinent information—actual experience with the care provided, including case reviews of individuals sent to the facility from elsewhere over time—is not mentioned. We believe that any requirements should include consideration of actual care of patients and residents that were referred previously. We are also concerned about the potential challenge—including conflict of interest—of requiring facilities to recommend others. We are also concerned about how facilities would be expected to use the data to advise patients and families and how surveyors would judge whether facilities had done so adequately. For all of these reasons, we recommend deleting those problematic and unenforceable portions of this section, as noted above.

(ix) Document, complete on a timely basis based on the resident's needs, and include in the clinical record, the ~~evaluation of the~~ resident's discharge needs and discharge plan. The results of the evaluation must be discussed with the resident or resident's representative. All relevant resident information must be incorporated into the discharge plan to facilitate its implementation and to avoid unnecessary delays in the resident's discharge or transfer.

(2) Discharge summary. When the facility anticipates discharge a resident must have a discharge summary that includes, but is not limited to, the following:

(i) A recapitulation of the resident's stay that includes, but is not limited to, diagnoses, course of illness/treatment or therapy, rationale for interventions, and pertinent lab, radiology, and consultation results.

AMDA COMMENT:
AMDA agrees that discharge summaries should contain enough information to be meaningful to the receiving provider, regardless of setting.

We are concerned about a key missing element from the examples; i.e., the rationale for interventions. "Rationale" refers to the specific information or evidence that explains the conclusion (for example, the basis for a new diagnosis or a change in management of an existing problem), not just the conclusion. If the discharge summary does not explain the rationale (not just the diagnosis) for the intervention, then the receiving facility and even the best clinicians are left guessing.

AMDA also recommends that including "rationale" should be a key expectation for all care settings, not just long-term and post-acute care. Our members find that key explanations often are missing or incorrect in discharge summaries from diverse settings.

(ii) A final summary of the resident's status to include items in paragraph (b)(1) of §483.20, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or resident's representative.

(iii) Reconciliation of all pre-discharge medications with the resident's post-discharge medications (both prescribed and over-the-counter) and rationale for all medications.

AMDA COMMENT: "Reconciliation" only means matching them up. However, often the pre-discharge medications are unnecessary, irrelevant, or potentially hazardous for the patient. Often, hospitals do not reconsider the need for continuing medications after discharge or even advise the next facility that certain medications could potentially be stopped, reduced, or changed.

For example, the patient may no longer need the high potency analgesics or the sedative that they were receiving earlier in their stay. Without a clinically pertinent explanation of the rationale for changes, the receiving facility and practitioner are left to guess.

(iv) A post-discharge plan of care that is developed with the participation of the resident and, with the resident's consent, his or her family, which will ~~assist~~ help the resident ~~to~~ adjust to his or her new living environment, where applicable. The post-discharge plan of care must

indicate where the individual plans to reside, any arrangements that have been made for the resident's follow up care and any post-discharge medical and non-medical services.

20. Section 483.25 is revised to read as follows:

§483.25 Quality of care and quality of life.

Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, consistent with the resident's comprehensive assessment and plan of care.

(a) Based on the comprehensive assessment of a resident and consistent with the resident's needs and choices, the facility must provide the necessary care and services to ensure that a resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that such diminution was unavoidable. This includes the facility ensuring that:

(1) A resident is given the appropriate treatment and services to maintain or improve his or her ability to carry out the activities of daily living, including those specified in paragraph (b) of this section,

(2) A resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene, and

(3) Personnel provide basic life support, including CPR, to a resident requiring such emergency care prior to the arrival of emergency medical personnel and subject to the resident's advance directives, orders related to life-sustaining treatments (such as POLST Paradigm forms or pre-hospital Do Not Resuscitate forms.) or other legally relevant documents.

AMDA COMMENT: AMDA notes that there are other documents besides advance directives that may guide orders and actions related to life-sustaining treatments. Therefore, we recommend modifying the wording of this section, as noted above.

(b) Activities of daily living. (1) Hygiene –bathing, dressing, grooming, and oral care,

(2) Mobility—transfer and ambulation,

(3) Elimination-toileting,

(4) Dining-eating, including meals and snacks,

(5) Communication, including

(i) Speech,

(ii) Language,

(iii) Other functional communication systems.

(c) Activities. (1) The facility must provide, based on the comprehensive assessment and care plan and the preferences of each resident, an ongoing program to support residents in their choice of activities, both facility-sponsored group and individual activities and independent activities, designed to meet the interests of and support the physical, mental, and psychosocial well-being of each resident, encouraging both independence and interaction in the community.

(2) The activities program must be directed by a qualified professional who is a qualified therapeutic recreation specialist or an activities professional who—

(i) Is licensed or registered, if applicable, by the State in which practicing; and

(ii) Is:

(A) Eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or

(B) Has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a therapeutic activities program; or

(C) Is a qualified occupational therapist or occupational therapy assistant; or

(D) Has completed a training course approved by the State.

(d) Special care issues. Based on the comprehensive assessment of a resident, the facility must ensure that residents receive treatment and care, in accordance with professional standards of practice and the residents choices, related to the following special concerns—

(1) Restraints. The facility must ensure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the

resident's medical symptoms. When the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints.

(2) Bed rails. The facility must ensure correct installation, use and maintenance of bed rails, including but not limited to the following elements.

(i) Attempt to use alternatives, as appropriate, prior to installing a side or bed rail.

AMDA COMMENT:
AMDA agrees with limiting the use of bed side rails.

However, we are concerned about this and other proposed regulations that mandate specific approaches and lack adequate qualifiers to allow for various real-life situations. If a situation arises where there is not a viable alternative, the facility is automatically in violation because of the wording.

Although alternatives to side rails usually exist, there are exceptions. Sometimes, they benefit the individual; for example, in case of poor safety awareness or to enable the individual to turn and sit up.

AMDA believes that compliance determinations must focus on a fair and consistent surveyor review of these situations based on the facts of each case, instead of on a priori designations of inappropriateness prior to any case review.

(ii) Assess resident for risk of entrapment from bed rails prior to installation.

(iii) Review the risks and benefits of bed rails with the resident or resident representative and obtain informed consent prior to installation

(iv) Ensure that the bed is appropriate for the resident's size and weight ~~are appropriate for the bed's dimensions~~. {NOTE: This is backwards, as worded`.}

(v) Follow the manufacturers' recommendations and specifications for installing and maintaining bed rails.

(3) Vision and hearing. To ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities, the facility must, if necessary, assist the resident—

(i) In making appointments, and

(ii) By arranging for transportation to and from the office of a practitioner specializing in

the treatment of vision or hearing impairment or the office of a professional specializing in the provision of vision or hearing assistive devices.

(4) Skin integrity— (i) Pressure ulcers. Based on the comprehensive assessment of a resident, the facility must ensure that—

(A)) A resident receives care, consistent with ~~professional~~ current clinical standards of practice, to prevent pressure ulcers and does not develop pressure ulcers unless the individual's clinical condition demonstrates that they were unavoidable; and

(B) A resident with pressure ulcers receives necessary treatment and services, consistent with professional standards of practice, to promote healing, prevent infection and prevent new ulcers from developing.

(ii) Foot care. To ensure that residents receive proper treatment and care to maintain mobility and good foot health, the facility must:

(A)) Provide foot care and treatment, in accordance with professional standards of practice, including to prevent complications from the resident's medical condition(s) and

(B) If necessary, assist the resident in making appointments with a qualified person, and arranging for transportation to and from such appointments.

(5) Mobility. (i) The facility must ensure that a resident who enters the facility without limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable; and

(ii) A resident with limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion.

(iii) A resident with limited mobility receives appropriate services, equipment, and assistance to maintain or improve mobility with the maximum practicable independence unless a reduction in mobility is demonstrably unavoidable.

(6) Incontinence. (i) The facility must ensure that resident who is continent of bladder

and bowel on admission receives services and assistance to maintain continence unless his or her clinical condition is or becomes such that continence is not possible to maintain.

(ii) For a resident with urinary incontinence, based on the resident's comprehensive assessment, the facility must ensure that—

(A) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary;

(B) A resident who enters the facility with an indwelling catheter or subsequently receives one is assessed for removal of the catheter as soon as possible unless the resident's clinical condition demonstrates that catheterization is necessary and

(C) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore ~~as much normal bladder function~~continence ~~as~~ to the extent possible.

AMDA COMMENT:
The urinary tract includes more than just the bladder (i.e., kidneys, ureters, urethra, prostate).

Various conditions and factors (e.g., delirium, metabolic disorders, functional impairments, diuretic use) may affect continence.

We propose a wording change that more accurately reflects that the goal is to try to improve continence.

(iii) For a resident with fecal incontinence, based on the resident's comprehensive assessment, the facility must ensure that a resident who is incontinent of bowel receives appropriate treatment and services to restore as much normal bowel function as possible.

(7) Colostomy, ureterostomy, or ileostomy care.

(8) Assisted nutrition and hydration. (Includes naso-gastric and gastrostomy tubes, both percutaneous endoscopic gastrostomy and percutaneous endoscopic jejunostomy, total parenteral nutrition, and enteral fluids). Based on a resident's comprehensive assessment, the facility must ensure that a resident—

(i) Maintains acceptable parameters of nutritional status, such as usual body weight or desirable body weight range ~~and protein levels~~, unless the resident's clinical condition demonstrates that this is not possible or resident preferences indicate otherwise;

AMDA COMMENT:
AMDA recognizes that nutritional status has many components and considerations.

There are actually tens of thousands of different proteins (e.g., insulin and hemobglobin) in the human body. Serum protein sometimes is helpful, but often does not accurately reflect the quality and utility of the body's proteins (i.e., whether proteins such as insulin and hemoglobin function adequately). In addition, it has been identified in recent years that low serum albumin is typically a marker of inflammation and not of nutritional status. In conditions such as nephrotic syndrome, no amount of external protein is likely to improve the serum protein level, since it is leaking through the kidneys and into the urine faster than it can be replenished.

Therefore, AMDA recommends that, in the process of updating these regulations, that it is timely to modernize thinking and modify long-held beliefs that have been challenged over time.

(ii) Is offered sufficient fluid intake and other support to maintain proper hydration and electrolyte balance and health, unless the resident's clinical condition demonstrates that this is not possible or resident preferences indicate otherwise; and

AMDA COMMENT:
Again, AMDA recommends updating long held but erroneous beliefs and practices about various topics; in this case, hydration and fluids.

In the human body, fluid and electrolyte issues are inseparable. There are many situations when just giving fluids not only does not correct underlying disorders but can make them worse.

Because it is important to look at all topics and conditions in the proper context, we recommend modifying the wording, as noted above, to more accurately reflect actual biological function.

We recommend the additional language in (ii) above about unavoidable dehydration, such as when a person is receiving palliative measures on hospice and is not eating and drinking.

(iii) Is offered a therapeutic diet when there is a nutritional problem and the health care provider orders a therapeutic diet.

(iv) A resident who has been able to eat enough alone or with assistance is not fed by enteral methods unless the resident's clinical condition demonstrates that enteral feeding was

clinically indicated and consented to by the resident; and

(v) A resident who is fed by enteral means receives the appropriate treatment and services to restore, if possible, oral eating skills and to prevent complications of enteral feeding including but not limited to aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers.

(9) Parenteral fluids.

(10) Accidents. The facility must ensure that—

(i) The resident environment remains as free of accident hazards as is possible; and

(ii) Each resident receives adequate supervision and assistance devices to prevent accidents.

(11) Respiratory care, including tracheostomy care and tracheal suctioning. See §483.65 re: specialized rehabilitative services.

(12) Prostheses.

(13) Pain management.

(14) Dialysis.

~~(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~~.

AMDA COMMENT:
AMDA agrees that facilities and practitioners should get a good history and try to tailor their interventions to each individual's history and background, among other things.

As noted earlier, it is reasonable to expect that a plan of care is tailored to a person's cultural preferences and personal history. However, it is one thing to advocate for a concept or approach and quite another to specify just a few condition-specific expectations in regulations.

We also question how it is possible for surveyors to try to objectively and consistently evaluate whether care is "culturally competent" and "trauma informed."

In addition, many other issues and concerns that are equally or more important to other individuals with other conditions and history are not specified in regulations or even

mentioned in guidance or survey.

Therefore, we recommend to delete this section from regulation—which is not to say that we oppose trying to give good care to trauma survivors, along with everyone else. Competent care is the aggregate result of many factors that are already covered adequately in various parts of the existing regulations.

21. In the table below, each section and paragraph indicated in the first column is redesignated as the section and paragraph indicated in the second column:

Existing CFR SECTION	**New CFR Section**
§483.30	§483.35
§483.35	§483.60
§483.40	§483.30
§483.45	§483.65
§483.60	§483.45
§483.65	§483.80
§483.70	§483.90
§483.75	§483.70

22. In newly redesignated §483.30—

a. Revise the introductory text.

b. Revise paragraph (b)(3).

c. Redesignate paragraphs (e) and (f) as paragraphs (f) and (g), respectively.

d. Amend newly designated paragraph (f)(1) introductory text by removing the reference "paragraph (e)(2)" and adding in its place the reference "paragraph (f)(4)".

e. Add a new paragraph (e).

f. Amend newly redesignated paragraph (f) by further redesignating paragraph (f)(2) as paragraph (f)(4).

g. Add new paragraphs (f)(2) and (f)(3). The

revisions and additions read as follows:

§483.30 Physician services.

A physician must personally approve in writing a recommendation that an individual be

admitted to a facility. Each resident must remain under the care of a physician. A physician, physician assistant, nurse practitioner, or clinical nurse specialist must provide orders for the resident's immediate care and needs.

* * * * *

(b) * * *

(3) Sign and date all orders with the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved facility policy after an assessment for contraindications.

* * * * *

~~(d)~~ ~~Availability of a physician, physician assistant, nurse practitioner, or clinical nurse specialist to evaluate resident for non-emergent transfer to a hospital. The facility must provide or arrange for an in-person evaluation of a resident by a physician, a physician assistant, nurse practitioner, or clinical nurse specialist prior to transferring the resident to a hospital. The evaluation must occur expeditiously once the potential need for a transfer is identified.~~

~~(6)~~(1) ~~This requirement does not apply in emergency situations where the health or safety of the individual would be endangered.~~

AMDA COMMENT:
As mentioned previously, AMDA agrees that it is desirable to try to reduce unplanned hospitalization or rehospitalization.

However, we do not believe that this proposed regulation is the preferred approach, or even viable. While they can be available by phone to discuss a situation, a physician or NPP often cannot be available on site to evaluate an ill resident who has suffered a change of condition. AMDA is concerned that as a potentially serious adverse consequence of this regulation, facilities may delay timely transfer of seriously ill individuals in order to wait for an in-person evaluation to try to comply.

This proposed requirement also appears to ignore the growing presence of telemedicine, which is often highly effective at managing condition changes appropriately and preventing hospitalization. (Grabowski DC, O'Malley AJ. Use of telemedicine can reduce hospitalizations of nursing home residents and generate savings for Medicare. Health Aff [Millwood]. 2014 Feb;33[2]:244-50.)

AMDA supports other, more fruitful and appropriate approaches to reducing hospitalization, including improved staff assessment and frequent reassessment after interventions are made, early recognition of changes in condition, good dialogue between

staff and practitioners, obtaining and interpreting advance directive and other discussions about life-sustaining treatments, discussion of patient progress and complications, good diagnostic efforts, and more prudent prescribing of medications and treatments.

We again emphasize that structural requirements are very unlikely to correct process problems. Therefore, we strongly recommend deleting the proposed wording, as is noted above.

(f) * * *

~~(1) A physician may delegate the task of writing dietary orders, consistent with §483.60, to a qualified dietitian or other clinically qualified nutrition professional who –~~

~~(ii) Is acting within the scope of practice as defined by State law; and~~

~~(iv)(i) Is under the supervision of the physician~~.

AMDA COMMENT:
AMDA agrees with the statement elsewhere in these regulations that therapeutic diets should be prescribed by the attending physician.

Therefore, as we comment elsewhere, AMDA is concerned about a regulatory proposal that would authorize those of another discipline to write (i.e., prescribe) a resident's diet. It is one thing to recommend an intervention, and quite another to prescribe it.

As noted elsewhere, there are other key considerations that need to be taken into account, such as the impact of various medical conditions, the need to identify causes of anorexia and weight loss, and ethical issues. An example a reference that shows the true scope of nutritional issues is Morley JE and Thomas DR (eds.) book Geriatric Nutrition, CRC Press, 2007.

The clinical nuances of hydration and "dehydration" often require skilled medical analysis of fluid and electrolyte balance, not just administration of fluids [*Reference: Thomas DR, Cote TR, Lawhorne L, Levenson SA, Rubenstein LZ, Smith DA, Stefanacci RG, Tangelos EG, Morley JE, and the Dehydration Council. Understanding clinical dehydration and its treatment. J Am Med Dir Assoc 2008; 9: 292–301.*]

We acknowledge that there has been a real challenge through the years of getting physicians to fulfill their responsibilities in this aspect of care. However, there are solutions to this problem such as more optimal use of the medical director, more detailed assessment of resident/patient appetite and weight issues, better communication of expectations to attending physicians, facility use of reliable and comprehensive references on nutrition, and facility adoption of protocols based on reputable references and resources.

Nothing presently prevents facilities from developing protocols to allocate responsibility to those of other disciplines. However, that should be done on a facility level based on knowledge of staff capabilities and close oversight of who is allowed to write orders in consultation with a medical practitioner. It is not in the interest of the residents/patients to put a blanket authorization in regulation, with its potential for misuse to the detriment of the residents/patients.

~~(1) A physician may delegate the task of writing therapy orders, consistent with §483.65, to a qualified therapist who –~~

~~( ) Is acting within the scope of practice as defined by State law; and~~

(ii) ~~Is under the supervision of the physician.~~

AMDA COMMENT:
AMDA agrees that services should be ordered in a timely fashion.

AMDA also recognizes the challenges that facilities have faced through the years of getting physicians to fulfill their responsibilities in relation to this aspect of care. However, there are solutions to this problem such as more optimal use and empowerment of the medical director, better communication of expectations to attending physicians, facility use of reliable and comprehensive references on the link between function and medical causes, and facility adoption of protocols based on reputable resources, including practice guidelines. We believe that these and other potential solutions have only sometimes been deployed effectively.

The problem is that function involves much more than just therapies; for example, medical stability. Many aspects of function, movement, pain, falls, swallowing, etc. require clinical reasoning and problem solving by a medical practitioner including a search for underlying causes, not just the writing of "therapy" orders.

A classic article about rehabilitation clearly states that "appropriate use of rehabilitation necessitates a clear understanding of the causes of disability . . . . Diseases and impairments often interact to cause disability in older persons. . . . **The rehabilitation plan should be guided by the nature of the disability and by the pathological conditions underlying the disability** [emphasis added] . . . ." It adds that the four basic steps to disability assessment are: "(1)characterize the disabilities; (2)identify the causal impairments; (3)determine the specific diseases underlying the identified causal impairments; (4)discover any contributing factors." [*Reference: Hoenig H, Nusbaum N, Brummel-Smith K. Geriatric rehabilitation: State of the Art. J Am Geriatr Soc 45:1371-1381, 1997.*].

Our members have identified adverse resident/patient outcomes related to orders written out of context and without adequate consideration of the whole picture, including underlying causes and ethical issues; for example, orders to restrict food intake and texture or disallow all oral intake (nothing by mouth) without adequate efforts to seek or identify causes of impaired function and swallowing or accommodate resident wishes.

Again, facilities can already develop protocols, but these should be based on knowledge of staff capabilities and close oversight to avoid harm to residents/patients.

We believe that a blanket regulatory authorization is inadvisable. Therefore, we strongly recommend deleting this proposed section, as noted above.

* * * * *

23. In newly redesignated §483.35—

a. Revise the introductory text.

b. Amend paragraph (a)(1)(i) by removing the reference "paragraph (c)" and adding in its place the reference "paragraph (e)".

c. Revise paragraph (a)(1)(ii).

d. Add paragraphs (a)(3) and (4).

e. Amend paragraphs (b)(1) and (b)(2) by removing the reference "paragraph (c) or (d)" and adding in its place the reference "paragraph (e) or (f)".

f. Redesignate paragraphs (c), (d) and (e) as paragraphs (e), (f), and (g), respectively.

g. Add new paragraphs (c) and (d).

h. Revise redesignated paragraphs (e)(6) and (7).

i. Revise redesignated paragraphs (f)(1)(iv) and (v).

The revisions and additions read as follows:

§483.35 Nursing services.

The facility must have sufficient nursing staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at §483.70(e).

(a) * * *

(1) * * *

(ii) Other nursing personnel, including but not limited to nurse aides.

* * * * *

(3) The facility must ensure that its licensed nurses collectively have the specific

competencies and skill sets necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

AMDA COMMENT: AMDA recognizes that nurses need many diverse skills. However, the meaning of this proposed requirement is unclear. Does this mean all of nursing in the aggregate, or every nurse individually? Would it mean that each nurse has to have competencies for all the residents/patients under their care each day, or on the unit on which they work? We are unclear about how surveyors would evaluate this requirement fairly and consistently, in order to judge a facility's compliance with this provision. Therefore, we recommend wording changes, as noted above and below.

(4) Providing care includes but is not limited to assessing, evaluating, planning and implementing resident care plans and responding to resident's needs.

* * * * *

~~(c)~~ Proficiency of nurse aides. The facility must ensure that nurse aides ~~are able to~~ ~~demonstrate competency in~~ have the basic skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

~~(d)~~(c) Requirements for facility hiring and use of nursing aides —(1) General rule. A facility must not use any individual working in the facility as a nurse aide for more than 4 months, on a full-time basis, unless:

(i) That individual is competent to provide nursing and nursing related services; and

(ii)(A) That individual has completed a training and competency evaluation program, or a competency evaluation program approved by the State as meeting the requirements of §§483.151 through 483.154; or

(B) That individual has been deemed or determined competent as provided in §483.150(a) and (b).

(2) Non-permanent employees. A facility must not use on a temporary, per diem, leased, or any basis other than a permanent employee any individual who does not meet the

requirements in paragraphs (d)(1) (i) and (ii) of this section.

AMDA COMMENT:
We are unsure what this sentence means and whether it actually says what it is supposed to mean. It appears to state that a facility cannot have a temporary worker that does not meet the requirements but can have a permanent employee who does not meet the requirements.

(3) Minimum competency. A facility must not use any individual who has worked less than 4 months as a nurse aide in that facility unless the individual—

(i) Is a full-time employee in a State-approved training and competency evaluation program;

(ii) Has demonstrated competence through satisfactory participation in a State-approved nurse aide training and competency evaluation program or competency evaluation program; or

(iii) Has been deemed or determined competent as provided in §483.150(a) and (b).

(4) Registry verification. Before allowing an individual to serve as a nurse aide, a facility must receive registry verification that the individual has met competency evaluation requirements unless—

(i) The individual is a full-time employee in a training and competency evaluation program approved by the State; or

(ii) The individual can prove that he or she has recently successfully completed a training and competency evaluation program or competency evaluation program approved by the State and has not yet been included in the registry. Facilities must follow up to ensure that such an individual actually becomes registered.

(5) Multi-State registry verification. Before allowing an individual to serve as a nurse aide, a facility must seek information from every State registry established under sections 1819(e)(2)(A) or 1919(e)(2)(A) of the Act that the facility believes will include information on the individual.

(6) Required retraining. If, since an individual's most recent completion of a training and

competency evaluation program, there has been a continuous period of 24 consecutive months during none of which the individual provided nursing or nursing-related services for monetary compensation, the individual must complete a new training and competency evaluation program or a new competency evaluation program.

(7) Regular ~~in-service~~ education. The facility must complete a performance review of every nurse aide at least once every 12 months, and must provide regular ~~in-service~~ education and training based on the outcome of these reviews. ~~In-service~~Education and training must comply with the requirements of §483.95(g).

AMDA COMMENT:
Traditional inservice education has been largely supplanted by other approaches and may have marginal value in imparting skills and attitudes and in improving performance. Self-education, computer-based training, real-time coaching, mentoring, and other forms of education and training and coaching are often more productive. Furthermore, "inservice education" is not defined and lacks pertinent standards.

Therefore, we recommend changing the wording, as noted above, to reflect more flexible, efficient, effective, and modern approaches to the issue. Otherwise, regulatory compliance is limited by the inflexible specific requirement for "inservice education."

(e) * * *

(6) The State agency granting a waiver of such requirements provides notice of the waiver to the Office of the State Long-Term Care Ombudsman (established under section 712 of the Older Americans Act of 1965) and the protection and advocacy system in the State for individuals with developmental disabilities or mental illnesses; and

(7) The nursing facility that is granted such a waiver by a State notifies residents of the facility and their resident representatives of the waiver.

(f) * * *

(1) * * *

(iv) The Secretary provides notice of the waiver to the Office of the State Long-Term Care Ombudsman (established under section 712 of the Older Americans Act of 1965) and the protection and advocacy system in the State for individuals with developmental disabilities or

mental illnesses; and

(v) The facility that is granted such a waiver notifies residents of the facility and their resident representatives of the waiver.

* * * * *

24. Section 483.40 is added to read as follows:

§483.40 Management of b~~B~~ehavior~~al~~ and P~~p~~sychiatric C~~c~~onditions ~~health-related services~~.

Each resident must receive and the facility must provide the necessary ~~behavioral health~~ care and services related to behavior and mental health concerns to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

AMDA COMMENT:
AMDA agrees that facility staff and practitioners should be able to manage behavior and psychiatric issues. Facilities and practitioners can potentially do many things to try to stabilize and manage individuals with cognitive, mood, and behavioral risks and disorders.

However, we are concerned about the proposed regulatory mandates. We believe that the intent of the original regulations was to get consistent and adequate management of individuals with behavior, mood, and cognitive, and other mental and psychiatric disorders and impairments. Instead of maintaining that focus, we are concerned about an apparent shift to mandating nebulous concepts such as "behavioral health," "behavioral health care," and "behavioral health services."

In addition, the proposed language appears to imply that facilities are somehow responsible for assuring that people with disorders maintain stable emotions and behavior, while increasingly mandating techniques and restrictions about various approaches (for example, emphasizing nonpharmacological interventions over the judicious and appropriate use of medications). AMDA believes that such an approach is not well grounded in sound clinical practice.

In 2001, the World Health Organization published " Mental Health: New Understanding, New Hope," with the aim of raising "public and professional awareness of the real burden of mental disorders and their costs in human, social and economic terms." [*Reference: WHO. Mental Health: New Understanding, New Hope. WHO, Geneva. 2001*.] One of their ten recommendations for action is that "[e]ssential psychotropic drugs should be provided and made constantly available at all levels of health care. These medicines should be included in every country's essential drugs list, and the best drugs to treat conditions should be made available whenever possible. In some countries, this may require enabling legislation changes. These drugs can ameliorate symptoms, reduce disability, shorten the course of many disorders, and prevent relapse. "

AMDA has actively supported efforts to reduce unnecessary antipsychotic use, and we believe in the judicious use of medications for appropriate indications with adequate monitoring of efficacy and side effects. However, we also believe that an anti-medication orientation is excessive and counterproductive, as it also inhibits the appropriate use of necessary medications that can effectively and safely relieve symptoms such as distressing delusions, hallucinations, and self-harming behavior.

We are concerned that these proposed regulations appear to be increasingly taking sides and promoting specific approaches while inhibiting others, despite substantial literature and experience that show the need for flexibility, pragmatism, and case-specific clinical reasoning to manage these complex and demanding residents/patients and conditions.

We recommend changes to the wording, as noted above, to focus on objective support for all potentially useful interventions done in the proper context, as identified by a clinically competent assessment.

(a) The facility must have sufficient direct care/direct access staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with §483.70(e). These competencies and skills ~~sets~~ include, but are not limited to, knowledge of and appropriate training and supervision for:

Caring for the conditions and symptoms of their residents ~~with~~ , including mental illnesses, psychiatric conditions, and psychosocial disorders, ~~as well as residents with a history of trauma and/or post-traumatic stress disorder~~, as ~~that have been~~ identified in the facility assessment conducted pursuant to §483.70(e), and

(1) Implementing appropriate interventions and treatments, including both pharmacological and non-pharmacological interventions.

AMDA COMMENT:
AMDA supports the expectation for competent management of behavior and psychiatric disorders.

However, for several reasons, we disagree with mentioning or mandating knowledge about these other specific conditions or disorders.

Based on CMS' stated objective to have these regulations help improve care while focusing on valid current clinical standards, we believe that the listed conditions are neither more nor less relevant than the countless other significant psychiatric and behavior disorders (see

American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders 5th edition, 2013) that require adequate understanding and capable management.

We are concerned that making that a regulatory mandate about a few select conditions but not others will artificially direct attention towards a few conditions while resulting in inadequate attention to other equally or more important things.

Again, as noted previously, we are concerned about the unbalanced focus on nonpharmacological interventions. There is minimal credible evidence about the efficacy of most of these interventions in many situations and conditions. Competent and reputable sources such as the WHO (cited previously) emphasize the judicious use of medications in appropriate situations to produce remarkable improvement in function and quality of life.

We believe that a priori exclusions or predispositions that attempt to steer clinical decision making in this manner is unlikely to promote good practice.

For these reasons, we recommend changing the wording as noted above.

(b) Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who displays or is diagnosed with mental or psychosocial adjustment difficulty, or who has a history of trauma and/or post-traumatic stress disorder, receives appropriate treatment and services to address ~~correct~~ the assessed problem to the extent possible, ~~or~~ to attain the highest practicable mental and psychosocial well-being, and

(2) ~~A resident whose assessment did not reveal or who does not have a diagnosis of a mental or psychosocial adjustment difficulty or a documented history of trauma and/or post-traumatic stress disorder does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that development of such a pattern was unavoidable~~.

AMDA COMMENT:
AMDA agrees that facilities and practitioners should address behavioral and psychiatric symptoms in a clinically appropriate manner. However, we are concerned about the implications of the wording in this section.

Mood disturbances and related behavior are not discrete objects or conditions like pressure ulcers or indwelling urinary catheters, where you either have them or you do not.

Many of the individuals who enter long-term and post-acute care facilities have longstanding personality traits and other disorders that have resulted in intermittent or frequent behavioral and mood disturbances. Sometimes, their behavior and psychiatric issues have been misdiagnosed or inappropriately or inadequately managed prior to their admission to long-term and post-acute care.

Many of them wind up in a nursing home because their behavior has been too difficult to manage or control elsewhere.

We are concerned that the proposed wording appears to imply that the facility would be held responsible (i.e., determined to be in violation of these regulations) if these individuals cannot adjust or behave adequately in a social setting, or if they withdraw, get angry, or don't interact well with others.

In addition, we are unclear about the meaning of a "mental adjustment difficulty" and how surveyors would be able to fairly and objectively determine whether someone's responses, mood, and behavior were attributable to something a facility does or does not do, or does incorrectly.

Therefore, we recommend the changes and deletions as noted above.

~~(c) If rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, and rehabilitative services for mental illness and intellectual disability, are required in the resident's comprehensive plan of care, the facility must—~~

~~(1) Provide the required services, including specialized rehabilitation services as required in §483.45; or~~

AMDA COMMENT:
Again, AMDA agrees that facilities should provide necessary services for conditions and problems identified through the comprehensive assessment.

However, we are concerned about singling out a few specific interventions (rehabilitative services) for a handful of conditions or situations. In addition, we are concerned by the lack of clarity regarding "specialized rehabilitative services" and are confused as to the meaning of "rehabilitative services such as . . . rehabilitative services for mental illness and intellectual disability. . ."

Therefore, we recommend the wording changes and deletions as noted above and otherwise clarifying the intent of this section.

~~(2)~~(3) Obtain the required services from an outside resource (in accordance with § 483.75(g) of this part) from a Medicare and/or Medicaid provider of specialized rehabilitative services.

~~(d)~~(c) The facility must provide medically-related social services to attain or maintain the highest practicable mental and psychosocial well-being of each resident.

25. In newly redesignated §483.45—

a. Amend the introductory text by removing the reference "§483.75(h) of this part" and

add in its place the reference "§483.70(g)".

b. Redesignate paragraph (c)(2) as paragraph (c)(4).

c. Add new paragraphs (c)(2) and (3).

d. Revise newly designated paragraph (c)(4).

e. Redesignate paragraphs (d) and (e) as paragraphs (g) and (h), respectively.

f. Add new paragraphs (d), (e), and (f).

The additions and revisions read as follows:

§483.45 Pharmacy services.

* * * * *

(c) * * *

(2) ~~This review must include a review of the resident's medical chart at least every 6 months and~~:

AMDA COMMENT:
AMDA supports the safe and appropriate use of medications for all conditions and situations.

However, we are concerned about the proposed approach.

Requirements for a monthly drug regimen review have existed for several decades. We are concerned that the proposed 6-month chart review requirement is unlikely to add anything meaningful to the existing requirements, and may actually lessen them.

We recognize that many factors contribute to the challenges of safe and effective medication prescribing and use in nursing homes. Many of those factors concern the effectiveness of timely and detailed patient assessment combined with clinical reasoning and problem solving. These can only be addressed adequately by focusing on improving the clinical decision making process, including diagnosis, and having medical practitioners and others apply existing knowledge about medications to the care of specific patients. They cannot be addressed adequately by simply adding to requirements for more review and documentation.

Ultimately, having general knowledge about medications is not the same as applying that knowledge to the facts about an individual patient to make a clinical decision about the appropriate interventions in a specific situation.

Therefore, we recommend the changes as noted above. It would be preferable to focus much more on defining and addressing the underlying multiple reasons for continuing issues with medications despite existing requirements, instead of mandating even more structural requirements with questionable additional value.

~~(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~~

~~(iv)~~(i) ~~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~~.

AMDA COMMENT:
AMDA believes that each resident/patient should receive appropriate and competent care, regardless of their disorders and conditions.

Therefore, as noted previously, we are concerned that these proposed requirements appear to single out specific topics rather than a broad "patient-centered" approach that CMS has identified as a desired target.

Also, we question whether these additional structural requirements are likely to correct what are essentially process problems. The current substantial requirements for consultant pharmacist involvement have existed for decades.

AMDA believes that good medical practice requires that all issues and conditions be viewed and managed in the proper context, and not as isolated conditions or risks. Singling out several topics actually limits and reverses the current requirement, because it distracts attention from other equally or more important issues. Specifically, facilities learn only to address those medications that are on the radar screen, resulting in problematic use of many medications that are not under intense scrutiny.

We believe that the most effective approach would be to focus all providers and practitioners on thorough evaluation of each individual patient to establish a clinically valid rationale for all current treatments, and to effectively use existing requirements and F329 surveyor guidance to help surveyors look for evidence of appropriate clinical care, documentation, and implementation.

Therefore, we recommend the wording changes and deletions as noted above.

(3) A ~~psychotropic drug~~psychopharmacological medication is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories:

(i) Anti-psychotic;

(ii) Anti-depressant;

(iii) Anti-anxiety;

(iv) Hypnotic;

(v) ~~Opioid analgesic~~Sedative;
(vi) Cholinesterase inhibitor
(vii) Anticonvulsant
~~(v) and~~

~~(vii)~~(viii) ~~Any other drug that results in effects similar to the drugs listed in paragraphs (c)(3)(i) through (v) of this section.~~

AMDA COMMENT:
AMDA agrees that it is good practice to consider the effects and side effects of all medications that may influence mood, cognition, and behavior.

However, AMDA is concerned about the proposed revisions in this section.

Psychopharmacological medications are those medication that are given with the specific purpose of affecting mood, cognition, or behavior because of known direct effects on brain activity.

However, the fact that a medication affects the brain does not make it a psychopharmacological medication. For example, opioid analgesics can directly or indirectly affect mood, cognition, and behavior, either adversely or positively, but they are not primarily psychopharmacological medications. Insulin can affect brain function by causing hypoglycemia and digoxin can do so as a side effect while being used to treat heart failure.

We believe that the existing F329 has adequately defined a psychopharmacological medications and also identifies that many medications can affect the brain and thereby influence behavior.
Reputable publications have identified many medications that can have significant direct or indirect effects on brain function and therefore influence mood, cognition, and behavior. [*Reference: Drugs That May Cause Psychiatric Symptoms. The Medical Letter on Drugs and Therapeutics, December 15, 2008 (Issue 1301)*]. In addition, many other factors from thyroid gland function to fluid and electrolyte balance can influence or be influenced by medications.

We do not see any advantage to changing the name of this category to psychotropic medications. Wording and definitions changes are unlikely to improve or correct process problems.

Therefore, we recommend keeping the term “psychopharmacological medications,” and keeping F329 in its original location.

(4) The pharmacist must report any irregularities to the attending physician and facility’s medical director and director of nursing, and these reports must be acted upon.

###

(i) Irregularities include, but are not limited to, any drug that meets the criteria set forth

in paragraph (d) of this section for an unnecessary drug.

(ii) Any irregularities noted by the pharmacist during this review must be documented ~~on a separate, written~~and reported {NOTE: Separate from what?} in writing ~~that is sent~~ to the attending physician and the facility's medical director and director of nursing and lists, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified.

(iii) The attending physician must document in the resident's medical record that the identified irregularity has been reviewed and what, if any, action has been taken to address it.

(iv) Unnecessary drugs — General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

(1) In excessive dose (including duplicate drug therapy); or

(2) For excessive duration; or

(3) Without adequate monitoring; or

(4) Without adequate indications for its use; or

(5) In the presence of adverse consequences ~~which~~ that indicate the dose should be reduced or discontinued; or

(6) Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section.

AMDA COMMENT:
AMDA continues to strongly support efforts to improve medication prescribing and reduce medication-related adverse consequences. We recognize the challenges that are still faced in getting safe and clinically appropriate medication prescribing.

However, we feel that the proposal to move this section on Unnecessary Drugs (F329) to Pharmacy Services sends the wrong message and may well lessen the opportunity to achieve our mutual goal of improving medication prescribing. Therefore, we strongly advocate for leaving this Section in its current location at F329.

Medications affect, and are strongly influenced by, both quality of care and quality of life considerations. The existing F329 guidance clearly and correctly identifies the care delivery process and clinical decision making as the basis for all prescribing.

Therefore, while the consultant pharmacist and other IDT members certainly provide input to the prescriber, the prescriber—not the consultant pharmacist—ultimately determines which medications are appropriate, based on clinical condition, goals of care, and risks, benefits and

alternatives to specific medications.

We are concerned that moving the regulation to Pharmacy Services and focusing too much attention on medication regimen reviews as a proposed "solution" sends the wrong messages and downplays the key role of improved quality of care (care process, including diagnosis and clinical decision making) as the primary route to improving medication prescribing and use in order to enhance quality of life.

While we support efforts to address shortcomings of clinical reasoning and problem solving processes as they relate to improving medication prescribing and utilization, we do not believe these proposed changes are likely to do so, and we recommend leaving the Unnecessary Drugs regulation and guidance in its current location.

(e) ~~Psychotropic drugs~~ Psychopharmacological medications. Based on a comprehensive assessment of a resident, the facility must ensure that—

(1) Residents who have not used ~~psychotropic drugs~~ psychopharmacological medications are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;

(2) Residents who use ~~psychotropic drugs~~ psychopharmacological medications receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;

~~(3) Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and~~

~~(4)~~(3) If PRN orders for ~~psychotropic drugs~~ psychopharmacological medications are ~~limited to 48 hours and cannot be~~ continued beyond 7 days, ~~that time unless~~ the resident's physician or primary care provider shall document~~s~~ the rationale for this continuation in the resident's clinical record.

AMDA COMMENT:
AMDA strongly supports the appropriate and judicious use of all medications, including orders for PRN medications.

AMDA agrees that PRN medications are at times ordered and used incorrectly in nursing facilities, and we agree that PRN medications should be reviewed for effectiveness, indications, and side effects. However, we are concerned that the proposed parameters are an unreasonable approach to a clinical decision making issue.

While the use of PRN psychopharmacological medications has been under assault in recent years, there are unquestionably times when such use is appropriate and beneficial. Those times do not necessarily relate to a "diagnosed specific condition."

For example, there are legitimate uses of PRN medications as a therapeutic trial (i.e., a time-limited trial to try to confirm a diagnosis or to evaluate a medication's effectiveness), as well as to address intermittent symptoms that do not require standing orders.

Often, it requires much more than 48 hours of treatment and observation to ascertain the relevance and effectiveness of a therapeutic trial. This is especially true for behavior and psychiatric symptoms.

Current surveyor guidance defines an acute psychiatric situation and allows use of psychopharmacological medications for up to a week before additional documentation is needed. We believe that this current guidance, if used correctly to review care, is adequate to identify prescribing and use concerns.

Therefore, we recommend against the proposed wording and requirements, especially in regulation that would make the requirement much more inflexible than in current surveyor guidance. As noted, there are other more clinically appropriate ways to address this issue. Structural requirements are unlikely to correct process issues.

(f) Medication errors. The facility must ensure that its--

(1) Medication error rates are not five percent or greater; and

(2) Residents are free of any significant medication errors.

* * * * *

26. A new §483.50 is added and is amended as follows:

a. Section heading is added.

b. New paragraphs (a) and (b) are redesignated from paragraphs (j) and (k) of newly redesignated §483.70.

c. Newly designated paragraphs (a)(2)(i), (a)(2)(ii), (b)(2)(i) and (b)(2)(ii) are revised.

The additions and revisions read as follows:

§483.50 Laboratory, radiology, and other diagnostic services.

(a) * * *

(2) * * *

(i) Provide or obtain laboratory services only when ordered by a physician,; physician

assistant,; nurse practitioner or clinical nurse specialist in accordance with State law, including scope of practice laws.

(ii) Promptly nNotify the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist, in a timely manner, of laboratory 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.

AMDA COMMENT:
AMDA agrees that facilities and practitioners should address diagnostic test results in a timely fashion.

However, it is reasonable to allow facilities, medical directors, and medical practitioners to establish parameters and use protocols to allow test results to be triaged and addressed in the proper context. For example, depending on the resident/patient's condition or situation, abnormal results could be handled routinely and so-called "normal" results may need urgent attention. Often, individuals with chronic medical conditions (e.g., chronic kidney disease or anemia of chronic disease) will have persistently abnormal diagnostic test results, which do not necessitate further intervention or immediate notification.

In contrast, the word "promptly" means immediately. This has led countless facilities to promote unnecessary and excessive immediate notification of all test results due to regulatory concerns.

A fair and consistent surveyor review of actual practice related to the management of residents/patients and related test results is needed to identify whether the facility and practitioners have reported and responded to diagnostic test results in a timely fashion.

We disagree with CMS' assertion that this revision "would improve the notification process, therefore saving time and reducing burden, while still ensuring resident safety." We believe that rigid time frames do not correct the problems of those who do not report or respond to test results appropriately, but instead are an unnecessary and excessive burden on those who do.

Therefore, we recommend wording changes as noted above.

* * *

(b) * * *

(2) * * *

(i) Provide or obtain radiology and other diagnostic services only when ordered by a physician; physician assistant; nurse practitioner or clinical nurse specialist in accordance with State law, including scope of practice laws.

AMDA COMMENT:
AMDA agrees with the wording here, that diagnostic services should only be provided or obtained when ordered by a licensed health care practitioner.

We wish to point out that this provision helps clarify our subsequent comments about the inadvisability of proposed regulations that authorize dieticians and therapists to write orders without the direct and current authorization of the attending physician or another responsible supervising practitioner. Lab tests should be ordered for appropriate reasons and interpreted judiciously and should always be related to a clinical analysis of the patient.

As stated previously, it is up to facilities, guided by their medical director, to decide whether and to what extent those of other disciplines can write orders. There is substantial reason to be concerned about those of any other disciplines recommending or ordering tests (labs, X-Ray studies), treatments, and consults. This should only be done by medical practitioners.

(ii) ~~Promptly n~~Notify the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist in a timely fashion 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.

AMDA COMMENT:
Again, AMDA agrees that test results should be handled in a timely fashion. However, they can and should be triaged and addressed in context.

Therefore, as above, we strongly recommend a wording change to allow the necessary flexibility.

* * * * *

27. Section 483.55 is amended by—

a. Amending paragraph (a)(1) by removing the reference "§483.75(h) of this part" and adding in its place the reference "§483.70(g)".

b. Redesignating paragraph (a)(3) and (4) as paragraphs (a)(4) and (5), respectively.

c. Adding a new paragraph (a)(3).

d. Revising newly redesignated paragraph (a)(4) introductory text and (a)(4)(ii).

e. Revising newly redesignated paragraph (a)(5).

f. Amending paragraph (b)(1) introductory text by removing the reference "§483.75(h) of this part" and adding in its place the reference "§483.70(g)".

g. Revising paragraph (b)(2) introductory text, (b)(2)(ii), and (b)(3).

h. Adding paragraphs (b)(4) and (5).

The revisions and additions read as follows:

§483.55 Dental services.

* * * * *

(a). * * *

(3) May not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility;

(4) Must if necessary or if requested, assist the resident—

* * *

(ii) By arranging for transportation to and from the dental services location; and

(5) 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.

(b) * * *

(2) Must, if necessary or if requested, assist the resident—

* * *

(ii) By arranging for transportation to and from the dental services locations;

(3) Must promptly~~, within three days,~~ refer residents with lost or damaged dentures for dental services or identify a viable alternative. If a referral does not occur within three days, the facility must provide documentation ~~of the extenuating circumstances that led to the delay~~about what they did to correct the problem and to ensure that the resident could still eat and drink adequately while awaiting service for the dentures;

AMDA COMMENT: AMDA recognizes the importance of dental care. Our experience is that it may be difficult to arrange a dental consultation in the short term. In the event of a problem with dentures or natural dentition, we believe that what matters most is that the resident/patient gets enough food and fluids while waiting for the consultation.

Therefore, we recommend changing the focus from requiring discussion of the extenuating circumstances to ensuring that the resident is able to eat and drink adequately while awaiting the dental services.

(4) May not charge a resident for dentures when the facility determines that it is responsible for the loss or damage of dentures ~~determined in accordance with facility policy to be the facility's responsibility~~; and

(5) Must assist residents who are eligible and wish to participate to apply for reimbursement of dental services as an incurred medical expense under the State plan.

28. Newly redesignated §483.60 is revised to read as follows:

§483.60 Food and nutrition services.

The facility must provide each resident with a nourishing, palatable, ~~well-~~balanced diet that meets his or her daily nutritional and special dietary needs, taking into consideration the preferences of each resident.

(a) Staffing. The facility must employ sufficient staff with the appropriate competencies and skills ~~sets~~ {NOTE: "skill sets" really just means "skills."} to carry out the functions of the food and nutrition service, taking into consideration resident assessments, individual plans of care and the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at §483.70(e). This includes:

(1) A qualified dietitian or other clinically qualified nutrition professional either full-time, part-time, or on a consultant basis. A qualified dietitian or other clinically qualified nutrition professional is one who is qualified based on:

(i) Meeting State requirements to practice dietetics, including licensure or certification, or

(ii) If the state does not have requirements, registration by the Commission on Dietetic Registration of the Academy of Nutrition and Dietetics, or

(iii) For dietitians hired or contracted with prior to [effective date of final rule], meets these requirements no later than 5 years after [effective date of final rule] or as required by state

law.

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

(i) For designations prior to [effective date of final rule], meets the following requirements no later than 5 years after [effective date of final rule], is:

(A)) A certified dietary manager; or

(B) A certified food service manager, or

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

(D) Has an associate's or higher degree in food service management or hospitality from an accredited institution of higher learning; or

(ii) In States that have established standards for food service managers or dietary managers, meets State requirements for food service managers or dietary managers, and

(iii) Receives frequently scheduled consultations from a qualified dietitian or other clinically qualified nutrition professional.

(3) Support staff. The facility must provide sufficient support personnel to safely and effectively carry out the functions of the food and nutrition service.

(b) A member of the Food and Nutrition Services staff must participate on the interdisciplinary team as required in §483.21(b)(2)(ii).

(c) Menus and nutritional adequacy. Menus must—

(1) Meet the nutritional needs of residents in accordance with established national guidelines or industry standards.;

(2) Be prepared in advance;

(3) Be followed;

(4) Reflect the religious, cultural and ethnic needs of the residents, as well as input

received from residents and resident groups;

(5) Be updated periodically;

(6) Be reviewed by the facility's dietitian or other clinically qualified nutrition professional for nutritional adequacy; and

(7) Nothing in this paragraph should be construed to limit the resident's right to make personal dietary choices.

(d) Food and drink. Each resident receives and the facility provides—

(1) Food prepared by methods that conserve nutritive value, flavor, and appearance;

(2) Food and drink that is palatable, attractive, and at a safe and appetizing temperature;

(3) Food prepared in a form designed to meet individual needs;

(4) Food that accommodates resident allergies, intolerances, and preferences;

(5) Appealing substitutes of similar nutritive value to residents who choose not to eat food that is initially served or who request an alternative meal; and

(6) Drinks, including water and other liquids consistent with resident needs and preferences and sufficient to maintain resident hydration.

(e) Therapeutic diets. (1) Therapeutic diets must be prescribed by the attending physician.

(6) (2) ~~The attending 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.~~

AMDA COMMENT:
AMDA agrees that therapeutic diets should be prescribed by the attending physician.

However, AMDA is concerned about a regulatory proposal that would authorize those of another discipline to "prescribe" a resident's diet. It is one thing to recommend an intervention, and quite another to prescribe it.

The notion of a "therapeutic" diet is that it affects and is affected by other aspects of the patient; for example, the absorption and effectiveness of nutrients and medications. There are also other key considerations such as the impact of various medical conditions, the need to identify causes of anorexia and weight loss, and ethical issues. [*Reference: Morley J and Thomas D (eds.). Geriatric Nutrition. CRC Press, 2007*]

We acknowledge that there has been a real challenge through the years of getting physicians to fulfill their responsibilities in this aspect of care. However, there are solutions to this

problem such as more optimal use of the medical director, more detailed assessment of resident/patient appetite and weight issues, better communication of expectations to attending physicians, facility use of reliable and comprehensive references on nutrition, and facility adoption of protocols based on reputable protocols. In reality, those solutions have only sometimes been deployed effectively.

In summary, we believe that it is vital to modernize and improve on the widespread "silo" habit of simply turning over issues related to diet and nutrition to one discipline.

There is nothing to stop facilities at present from working with the medical director and medical practitioners to develop protocols to allocate responsibilities to those of other disciplines. However, that should be done on a facility level based on knowledge of staff capabilities and close oversight of any medical order writing. It is not in the interests of the residents/patients to put a blanket authorization in regulation, with its potential for misuse to the detriment of the residents/patients.

Frequency of meals. (1) Each resident must receive and the facility must provide at least three meals daily, at regular times comparable to normal mealtimes in the community or in accordance with resident needs, preferences, requests, and plan of care.

(2) Suitable, nourishing alternative meals and snacks must be available for residents who want to eat at non-traditional times or outside of scheduled meal service times and in accordance with the resident plan of care.

(f) Assistive devices. The facility must provide special eating equipment and utensils for residents who need them and appropriate assistance to ensure that the resident can use the assistive devices when consuming meals and snacks.

(g) Paid feeding assistants —(1) State-approved training course. A facility may use a paid feeding assistant, as defined in §488.301 of this chapter, if—

(h)The feeding assistant has successfully completed a State-approved training course that meets the requirements of §483.160 before feeding residents; and

(ii) The use of feeding assistants is consistent with State law.

(2) Supervision. (i) A feeding assistant must work under the supervision of a registered nurse (RN) or licensed practical nurse (LPN).

(ii) In an emergency, a feeding assistant must call a supervisory nurse for help.

(3) Resident selection criteria. (i) A facility must ensure that a feeding assistant provides dining assistance only for residents who have no complicated feeding problems.

(ii) Complicated feeding problems include, but are not limited to, difficulty swallowing, recurrent lung aspirations, and tube or parenteral/IV feedings.

(iii) The facility must base resident selection on the interdisciplinary team's assessment and the resident's latest assessment and plan of care. Appropriateness for this program should be reflected in the comprehensive care plan.

(i) Food safety requirements. The facility must—

(1) Procure food from sources approved or considered satisfactory by Federal, State, or local authorities;

(i) This may include food items obtained directly from local producers, subject to applicable State and local laws or regulations.

(ii) This provision does not prohibit or prevent facilities from using produce grown in facility gardens, subject to compliance with applicable safe growing and food-handling practices.

(iii) This provision does not preclude residents from consuming foods not procured by the facility.

(2) Store, prepare, distribute, and serve food in accordance with professional standards for food service safety.

(3) Have a policy regarding use and storage of foods brought to residents by family and other visitors to ensure safe and sanitary storage, handling, and consumption, and

(4) Dispose of garbage and refuse properly.

29. In newly redesignated 483.65, revise paragraphs (a) introductory text and (a)(2) to read as follows:

§483.65 Specialized rehabilitative services.

(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—

* * * * *

(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.

* * * * *

30. Section 483.67 is added to read as follows:

§483.67 Outpatient rehabilitation services.

If the facility provides outpatient rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must meet the needs of the patients in accordance with acceptable standards of practice and the facility must meet the following requirements.

(a) Organization and staffing. (1) The organization of the service must be appropriate to the scope of the services offered.

(2) The facility must ensure the services are organized and staffed to ensure the health and safety of residents.

(b) Personnel. (1) The facility must assign one or more individuals to be responsible for outpatient rehabilitative services. The individual responsible for the outpatient rehabilitative services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(2) The facility must have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.

(3) Physical therapy, occupational therapy, speech-language pathology or audiology services, if provided, must be provided by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, speech-language pathologists,

or audiologists as defined in part 484 of this chapter.

(c) Delivery of services. (1) Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under state law.

All rehabilitation services orders and progress notes must be documented in the patient's clinical record in accordance with the requirements at §483.70(i).

(2) The provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice.

31. In newly redesignated §483.70—

a. Revise paragraph (c).

b. Revise paragraph (d)(2).

c. Add paragraph (d)(3).

d. Revise paragraph (e).

e. Remove paragraphs (f), (j), (k), (m), (o), and (q).

f. Redesignate paragraphs (g), (h), (i), (l), (n), (p), (r), (s), and (t) as paragraphs (f), (g), (h), (i), (j), (k), (l), (m), and (o), respectively.

g. Revise newly redesignated paragraphs (i)(1) introductory text, and (i)(2), (3), (4), and (5).

h. Revise newly redesignated paragraphs (j)(1)(i) and (ii).

i. Revise newly redesignated paragraph (m).

j. Add new paragraph (n).

k. Add new paragraph (p).

l. In the table below, for each newly redesignated paragraph indicated in the first and second columns, remove the reference indicated in the third column and add the reference indicated in the fourth column.

Paragraphs	Remove	Add

(g)(1)	(h)(2)	(g)(2)

(k)(3)	(p)(2)	(k)(2)
(m)	(r)	(l)
(o)(2) introductory text	(t)(1)(i)	(o)(1)(i)

The revisions and additions read as follows:

§483.70 Administration.

* * * * *

(c) Relationship to other HHS regulations. In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR part 80); nondiscrimination on the basis of disability (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455) and protection of individually identifiable health information (45 CFR parts 160 and 164). Violations of such other provisions may result in a finding of non-compliance with this paragraph. .

(d) * * *

(2) The governing body appoints the administrator who is—

(i) Licensed by the State;

(ii) Responsible for management of the facility; and

(iii) Reports to and is accountable to the governing body.

(3) The governing body is responsible and accountable for the QAPI program, in accordance with §483.75(f).

(e) Facility assessment. The LTC facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update that

assessment, as necessary, and at least annually. The facility must also review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment. The facility assessment must address or include:

(1) The facility's resident population, including, but not limited to,

(i) Both the number of residents and the facility's resident capacity;

(ii) The care and technical support required by the resident population considering the types of diseases, conditions, required treatments, physical and ~~cognitive~~ mental disabilities, overall acuity, and other pertinent facts that are present within that population;

AMDA COMMENT: Dialysis, ventilator support, specialized wound care treatments, implantable pain management devices, and insulin pumps are some examples of treatments that would be relevant to such a review.

(iii) The staff competencies that are necessary to provide the level and types of care needed for the resident population;

(iv) The physical environment, equipment, services, and other physical plant considerations that are necessary to care for this population; and

(v) Any ethnic, cultural, or religious factors that may potentially affect the care provided by the facility, including, but not limited to, activities and food and nutrition services.

(2) The facility's resources, including but not limited to,

(i) All buildings and/or other physical structures and vehicles;

(ii) Equipment (medical and non-medical);

(iii) Services provided, such as physical therapy, pharmacy, and specific rehabilitation therapies;

(iv) All personnel, including managers, staff (both employees and those who provide services under contract), and volunteers, as well as their education and/or training and any competencies related to resident care;

(v) Contracts, memorandums of understanding, or other agreements with third parties to provide services or equipment to the facility during both normal operations and emergencies; and

(vi) Health information technology resources, such as systems for electronically managing patient records and electronically sharing information with other organizations.

(3) A facility-based and community-based risk assessment, utilizing an all-hazards approach.

* * * * *

(i) Medical records. (1) In accordance with accepted professional standards and practices, the facility must maintain medical records on each resident that are—

* * *

(2) The facility must keep confidential all information contained in the resident's records, regardless of the form or storage method of the records, except when release is—

(i) To the individual, or their resident representative where permitted by applicable law;

(ii) Required by Law;

(iii) For treatment, payment, or health care operations, as permitted by and in compliance with 45 CFR 164.506;

(iv) For public health activities, reporting of abuse, neglect, or domestic violence, health oversight activities, judicial and administrative proceedings, law enforcement purposes, organ donation purposes, research purposes, or to coroners, medical examiners, funeral directors, and to avert a serious threat to health or safety as permitted by and in compliance with 45 CFR 164.512.

(3) The facility must safeguard medical record information against loss, destruction, or unauthorized use;

(4) Medical records must be retained for—

(i) The period of time required by State law; or

(ii) Five years from the date of discharge when there is no requirement in State law; or

(iii) For a minor, three years after a resident reaches legal age under State law.

(5) The medical record must contain—

(i) Sufficient information to identify the resident;

(ii) A record of the resident's assessments;

(iii) The comprehensive plan of care and services provided;

(iv) The results of any preadmission screening and resident review evaluations and determinations conducted by the State;

(v) Physician's, nurse's, and other licensed professional's progress notes; and

(vi) Laboratory, radiology and other diagnostic services reports as required under §483.50.

(j) * * *

(1) * * *

(i) Residents will be transferred from the facility to the hospital, and ensured of timely admission to the hospital when transfer is medically appropriate as determined by the attending physician or, in an emergency situation, by another practitioner in accordance with facility policy and consistent with state law; and

AMDA Comment: AMDA believes that this is a fair and adequate statement of a requirement for facilities to be judicious about hospitalizing and rehospitalizing people. As noted previously, we do not believe that the additional structural requirements proposed elsewhere throughout these regulations related to hospital transfers are warranted or that they will somehow correct what are essentially process problems due to diverse causes.

(ii) Medical and other information needed for care and treatment of residents and, when the transferring facility deems it appropriate, for determining whether such residents can receive appropriate services or receive services in a less restrictive setting than either the facility or the hospital, or reintegrated into the community, will be exchanged between the providers, including but not limited to the information required under §483.15(b)(2)(iii).

* * * * *

(m) Facility closure. The facility must have in place policies and procedures to ensure that the administrator's duties and responsibilities involve providing the appropriate notices in the event of a facility closure, as required at paragraph (l) of this section.

(n) Binding arbitration agreements. If the facility enters into an agreement for binding arbitration with its residents:

(1) The facility must ensure that:

(i) The agreement is explained to the resident in a form and manner that he or she understands, including in a language the resident understands, and

(ii) The resident acknowledges that he or she understands the agreement.

(2) The agreement must:

(i) Be entered into by the resident voluntarily;

(ii) Provide for the selection of a neutral arbiter;

(iii) Provide for selection of a venue convenient to both parties.

(3) Admission to the facility must not be contingent upon the resident or the resident representative signing a binding arbitration agreement.

(4) The agreement must not contain any language that prohibits or discourages the resident or anyone else from communicating with Federal, State, or local officials, including but not limited to, Federal and State surveyors, other federal or state health department employees, and representatives of the Office of the State Long-Term Care Ombudsman, in accordance with §483.11(i).

(5) The agreement may be signed by another individual if:

(i) Allowed by state law;

(ii) All of the requirements in this section are met; and

(iii) That individual has no interest in the facility.

* * * * *

(p) Social worker. Any facility with more than 120 beds must employ a qualified social worker on a full-time basis. A qualified social worker is:

(1) An individual with a minimum of a bachelor's degree in social work or a bachelor's degree in a human services field including, but not limited to, sociology, gerontology, special education, rehabilitation counseling, and psychology; and

(2) One year of supervised social work experience in a health care setting working directly with individuals.

32. A new §483.75 is added to read as follows:

§483.75 Quality assurance and performance improvement.

(a) Quality assurance and performance improvement (QAPI) program. Each LTC facility, including a facility that is part of a multiunit chain, must develop, implement, and maintain an effective, comprehensive , ~~data-driven~~ QAPI program that focuses on processes, practices, and outcomes related to both ~~indicators of the outcomes~~ quality of care and quality of life. The facility must:

AMDA COMMENT:
AMDA strongly supports the concept of an effective quality assurance and performance improvement program.

However, AMDA is concerned about the proposed wording and its implications.

We believe that any requirements about QAPI programs should focus attention on improving processes and practices, including those related to both clinical and nonclinical decision making, reasoning, and problem solving.

We note that there is a substantial and relevant literature about the importance of these components in influencing outcomes; for example, based on improving diagnostic quality and avoiding diagnostic error. [Reference: Teaching clinical reasoning. American College of Physicians, 2015]

Excessive emphasis on data and results distracts attention from improving the basis for those results. In many cases, results fluctuate over time, and available quality measures and data represent only a small part of the many aspects of quality care. In addition, aggregate results may not faithfully reflect the quality of the overall care of individual residents/patients.

Outcomes are a rough screen for quality, but ultimately processes and practices—including critical clinical reasoning and problem solving activities—are the route to meaningful improvement. Even facilities and practitioners that have better quality numbers have room to improve their performance in the care of residents/patients.

We are concerned that the QAPI requirements focus excessively on data and outcomes and do not adequately acknowledge the qualitative processes such as clinical reasoning, correct diagnoses, and the nuances of selecting individualized treatments that are the ultimate foundation of high-quality results.

Therefore, we recommend modifying the wording of the QAPI requirement, to strike a better balance between looking at data and focusing attention on processes and practices that need to be optimized regardless of data.

(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 survey? 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 survey Agency, Federal surveyor or CMS upon request.

(b) Program design and scope. A facility must design its QAPI program to be ongoing, comprehensive, and to address the full range of care and services provided by the facility. It must:

(1) Address all systems of care and management practices;

(2) Include clinical care, quality of life, and resident choice;

(7) Utilize the best available evidence to set goals and define, implement, and refine ~~-~~ processes of care and facility operations that are relevant to attaining desired outcomes for SNF and NF residents~~and measure indicators of quality and facility goals that reflect processes of care and facility operations that have been shown to be predictive of desired outcomes for residents of a SNF or NF~~.

AMDA COMMENT:
AMDA believes that the "best available evidence" makes it clear that reasoning and problem solving skills are critical to diverse outcomes, ranging from improving management of behavior to reducing rehospitalization. [*References: Trowbridge R, Rencic J, Durning S. Teaching clinical reasoning. American College of Physicians, 2015. Symptom to Diagnosis: An Evidence-Based Guide, 3rd ed (electronic), 2014. LeBlond RF, Brown DD, DeGowin RL. DeGowin's Diagnostic Examination. (9th ed.), New York:McGraw-Hill, 2008. McGee S. Evidence-Based Physical Diagnosis, 2012*]

We note that the 2014 OIG report on Patient Safety identifies the case review as the "gold standard" for reviewing quality practice. We also note that the report identifies diagnostic error as a key issue in patient safety.

We believe that a better balance is needed between outcomes and data and the knowledge, skills, processes and practices that are needed to achieve diverse outcomes. Measuring indicators of quality is the end result, not the means to the end.

Therefore, we strongly recommend that these proposed QAPI requirements include a vital method (case review) and pay more attention to promoting case reviews as a vital means to improve performance, and that they emphasize qualitative—not just quantitative—analysis of thinking, reasoning, and problem solving that will influence quality of care.

(3) Reflect the complexities, unique care, and services that the facility provides.

(c) Program feedback, data systems and monitoring. A facility must establish and implement written policies and procedures for feedback, clinical and operational reasoning and problem solving, data collections ~~systems~~, and monitoring, including preventing and managing adverse events ~~monitoring~~. The policies and procedures must include, at a minimum, the following:

(2) Facility ~~maintenance of effective systems~~ approaches to obtain and use ~~of~~ feedback and input from direct care/direct access workers, medical directors and practitioners, other staff, residents, and resident representatives, including input into identifying and addressing ~~how such information will be used to identify problems that are~~ high risk, high volume, or problem-prone areas, and opportunities for improvement.

AMDA COMMENT:
AMDA agrees with the intent of this section, that each facility should seek and use input from its staff, residents, and others to help identify and address its issues.

However, we are concerned that the proposed QAPI requirement says very little about the key role of medical practitioners (including the medical director) and the importance of facilities in getting their input—especially when F501 (Medical Direction) already indicates the vital

medical director role in overseeing facility practices and practitioner performance.

Therefore, we recommend rewording this section for greater clarity and to include the vital role of the practitioners and medical director.

(3) Facility maintenance of effective systems to identify, collect, and use information ~~data~~ from all departments, including but not limited to the facility assessment required at §483.75(e) and including how such information will be used to help develop and monitor performance indicators.

AMDA COMMENT:
Again, AMDA notes that these proposed requirements repeatedly focus on data rather than information generally.

"Information" is that which informs, i.e. an answer to a question, as well as that from which knowledge and data can be derived (as data represents values attributed to parameters, and knowledge signifies understanding of real things or abstract concepts).[http://www.merriam-webster.com/dictionary/information]

"Data" is defined as "facts or information used usually to calculate, analyze, or plan something" [http://www.merriam-webster.com/dictionary/data]

Thus, data and information are not synonymous. Data is a subset of information, but not all information is necessarily data.

We are concerned that the proposed QAPI requirements overemphasize data and hardly mention knowledge and reasoning.

We strongly recommend rewording this section, as noted above, to include a more balanced approach, including a focus on qualitative—not just quantitative—activities such as clinical reasoning and problem solving, not just on data such as quality measures and statistical analyses.

(1) Facility development, monitoring, and evaluation of performance indicators, including the methodology and frequency for such development, monitoring, and evaluation.

(8) Facility adverse event monitoring, including the methods by which the facility will systematically identify, report, track, investigate, analyze and use data and information relating to adverse events in the facility, including how the facility will use the ~~data~~ information ~~to develop activities~~ to help it prevent and manage adverse events.

AMDA COMMENT:
AMDA agrees that it is important to monitor, evaluate, and address performance and practice, as well as adverse events.

Collecting data is only valuable if people know how to analyze data to draw appropriate conclusions. The overwhelming evidence is that reasoning and problems solving skills are paramount in providing care. Outcomes improvement results from using reasoning to apply knowledge to interpret data.

Effective analysis of a facility's care involves reasoning and drawing conclusions. More emphasis is needed on reasoning and problem solving, review of cases in which a poor outcome was unexpected, and modification of subsequent care processes.

The QAPI requirement should identify a better balance between analyzing data and improving the knowledge and skills to interpret data correctly, including its application to making care decisions about specific aspects of care in individual residents/patients.

(d) Program systematic analysis and systemic action. (1) The facility must take actions aimed at performance improvement and, after implementing those actions, measure its success, and track performance to ensure that improvements are realized and sustained.

(2) The facility will develop and implement policies addressing:

(i) How they will use a systematic approach (such as basic induction and deduction, root cause analysis, or reverse tracer methodology~~, or health care failure and effects analysis~~) to ~~determine~~ identify and address underlying causes of problems impacting larger systems;

(ii) Development of corrective actions and performance and process improvements that ~~will be~~ are designed to effect change at the systems level to prevent quality of care, quality of life, or safety problems ; and

(iii) How the facility will monitor the effectiveness of its performance improvement activities to ensure that improvements are sustained.

(e) Program activities. (1) The facility must set priorities for its performance improvement activities that focus on everyday practices and processes as well as high-risk, high-volume, or problem-prone areas; consider the incidence, prevalence, and severity of problems in those areas; and affect health outcomes, resident safety, resident autonomy, resident choice, and quality of care.

AMDA COMMENT:
AMDA supports improvement in basic problem solving and prevention, as well as in clinical reasoning that helps improve the care of residents/patients.

We are concerned about the imbalance in these proposed regulations between statistical and mathematical methods and qualitative reasoning, thinking, and problem solving.

Qualitative reasoning is vital both for patient care and in general problem solving. Regulations should acknowledge and promote the huge benefits in establishing systematic, sound routine practices and processes. An excessive focus on problems and exceptions misses the key idea of doing the "right thing in the right way" every day as the basis for preventing problems and exceptions. While perhaps not apparent to outsiders, it is the hallmark of successful high-quality long-term and post-acute care programs and facilities.

(2) Performance improvement activities must track medical errors and adverse resident events, analyze their causes, and improve everyday systems and processes by various means, including but not limited to implementing preventive actions and mechanisms that include feedback and learning throughout the facility.

(9) The facility must conduct activities that improve performance, including but not limited to distinct performance improvement projects as needed. ~~The number and frequency of~~ Performance improvement activities ~~projects~~ conducted by the facility must ~~reflect the scope and complexity~~ relate to of the facility's services and available resources, as reflected in the facility assessment required at §483.70(e). Improvement projects must include at least annually ~~a project that focuses~~ activities that address ~~on~~ high risk or problem-prone areas identified through reviews of care as well as the data collection and analysis described in paragraphs (c) and (d) of this section.

AMDA COMMENT:
AMDA supports meaningful and relevant quality assurance and performance improvement-related activities.

However, we believe that the PIP mandate, as written, is too prescriptive.

There are many ways to improve performance and problem solve that do not involve formal PIPs. A well-run QAPI program is built in to everyday activities. Often, basic real time sensible problem solving is much more useful and relevant than elaborate and extensive PIPs. PIPs can be unnecessarily time consuming and cumbersome.

We are concerned that overemphasizing PIPs will simply promote projects for the sake of compliance while missing countless opportunities to improve care and practice by much

simpler and more effective actions including real-time problem solving.

We believe that regulations should be much more flexible on this subject and should not mandate specific performance improvement activities in this fashion. Instead, these proposed QAPI requirements should focus much more on the benefits of competent qualitative reasoning and cause identification using induction and deduction.

Therefore, we recommend modifying the wording, as noted above.

(f) Governance and leadership. The governing body and/or executive leadership (or organized group or individual who assumes full legal authority and responsibility for operation of the facility) is responsible and accountable for ensuring that:

(1) An ongoing QAPI program is defined, implemented, and maintained and addresses ongoing facility activities and identified priorities.

(2) The QAPI program is sustained during transitions in leadership and staffing;

(3) The QAPI program is adequately resourced, including ensuring staff time, equipment, and technical training as needed;

(4) The QAPI program identifies and prioritizes problems and opportunities based on various factors, including key process of care and service and others such as performance indicator data, and resident and staff input that reflects organizational processes, functions, and services provided to residents.

(5) Corrective actions address inadequate or inappropriate performance and processes such as gaps in systems, and are evaluated for effectiveness; and

(6) Clear expectations are set around safety, quality, rights, choice, technically appropriate care and practice, and respect.

(g) Quality assessment and assurance. (1) A facility must maintain a quality assessment and assurance committee consisting of at ~~a minimum of~~least:

(i) The director of nursing services;

(ii) The Medical Director or his/her designee;

(iii) At least 3 other members of the facility's staff, at least one of who must be the administrator, owner, a board member or other individual in a leadership role; and

(iv) The infection control and prevention officer.

(2) The quality assessment and assurance committee reports to the facility's governing body, or designated person(s) functioning as a governing body regarding its activities, including implementation of the QAPI program required under paragraphs (a) through (e) of this section. The committee must:

(10) Meet at least quarterly and as needed to coordinate and evaluate activities under the QAPI program, such as identifying issues with respect to which quality assessment and assurance activities, including appropriate problem solving and performance improvement activities ~~performance improvement projects~~ required under the QAPI program, are necessary; and

AMDA COMMENT: As noted above, AMDA believes that the PIP requirement is problematic and that these regulations need a better balance of diverse methods including qualitative reasoning and real-time problem solving.

(i) Develop and implement appropriate plans of action to sustain appropriate performance and correct identified quality deficiencies; and

(ii) Regularly review and analyze information and data, including ~~data~~ that which is collected under the QAPI program and data resulting from drug regimen reviews, and act on available data to make improvements.

(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.

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

33. Newly redesignated §483.80 is revised to read as follows:

§483.80 Infection control.

The facility must establish and maintain an infection prevention and control program designed to provide a safe, 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 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 following accepted national standards;

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

(4)) 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. The facility must designate one individual as the infection prevention and control ~~officer~~ coordinator (IPCC~~O~~) who is responsible for ~~whom the~~ coordinating the facility's IPCP ~~at that facility is a major responsibility~~. The IPCO must:

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

AMDA COMMENT: AMDA supports effective and efficient infection control programs, coordinated by adequately trained individuals and overseen by the facility's QAPI program. However, we are concerned about the viability of the proposed mandate for an infection control "officer." The notion of an "officer" is ill-defined and its rationale is unclear. We doubt that the mandates in this section are viable as proposed. Again, as throughout this document, we are concerned that structure is being mandated instead of focusing on process expectations. This leaves little or no opportunity to accomplish the objective through means other than those prescribed by the structure-related regulation.

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

(c) IPCC~~O~~ participation on quality assessment and assurance committee. The person designated as the IPCC~~O~~ 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.

(d) Influenza and pneumococcal immunizations — (1) Influenza. The facility must develop policies and procedures to ensure that—

(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 informed about ~~provided education regarding~~ the benefits and potential side effects of influenza immunization; and

COMMENT: AMDA agrees with informing residents and/or their representatives about influenza and pneumococcal immunization. However, since it is impossible to identify or judge whether they were sufficiently "educated," we recommend that the wording be changed accordingly. AMDA is concerned that for influenza immunizations, it is possible that the recommended dates for immunization may change or vary in different regions. We do not see a valid reason to be so prescriptive about the exact date range, and doing so may make the regulations obsolete in the future.

(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~~ informed about 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.

(e) Linens. Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.

(f) Annual review. The facility will conduct an annual review of its IPCP and update their program, as necessary.

34. Section 483.85 is added to read as follows:

§483.85 Compliance and ethics program.

(a) Definitions. For purposes of this section, the following definitions apply:

Compliance and ethics program means, with respect to a facility, a program of the operating organization that--

(i) Has been reasonably designed, implemented, and enforced so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care; and

(ii) Includes, at a minimum, the required components specified in paragraph (c) of this section.

High-level personnel means individual(s) who have substantial control over the operating organization or who have a substantial role in ~~the~~ making ~~of~~ policy within the operating organization.

Operating organization means the individual(s) or entity that operates a facility.

(b) General rule. Beginning on **[1 year after the effective date of the final rule]**, the operating organization for each facility must have in operation a compliance and ethics program (as defined in paragraph (a) of this section) that meets the requirements of this section.

(c) Required components for all facilities. The operating organization for each facility must develop, implement, and maintain an effective compliance and ethics program that contains, at a minimum, the following components:

(1) Established written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act and promote quality of care, which include, but are not limited to, the designation of an appropriate compliance and ethics program contact to which individuals may report suspected violations, as well as an alternate method of reporting suspected violations anonymously without fear of retribution; and disciplinary standards that set out the consequences for committing violations for the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles.

(2) Assignment of specific individuals within the high-level personnel of the operating organization with the overall responsibility to oversee compliance with the operating organization's compliance and ethics program's standards, policies, and procedures, such as, but not limited to, the chief executive officer (CEO), members of the board of directors, or directors of major divisions in the operating organization.

(3) Sufficient resources and authority to the specific individuals designated in paragraph (c)(2) of this section to reasonably assure compliance with such standards, policies, and procedures.

(4) Due care not to delegate substantial discretionary authority to individuals who the operating organization knew, or should have known through the exercise of due diligence, had a

propensity to engage in criminal, civil, and administrative violations under the Social Security Act.

(5) The facility takes steps to effectively communicate the standards, policies, and procedures in the operating organization’s compliance and ethics program to the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles. Requirements include, but are not limited to, mandatory participation in training as set forth at §483.95(f) or orientation programs, or disseminating information that explains in a practical manner what is required under the program.

(6) The facility takes reasonable steps to achieve compliance with the program's standards, policies, and procedures. Such steps include, but are not limited to, utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under the Social Security Act by any of the operating organization's staff, individuals providing services under a contractual arrangement, or volunteers, having in place and publicizing a reporting system whereby any of these individuals could report violations by others anonymously within the operating organization without fear of retribution, and having a process for ensuring the integrity of any reported data.

(7) Consistent enforcement of the operating organization's standards, policies, and procedures through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect and report a violation to the compliance and ethics program contact identified in the operating organization's compliance and ethics program.

(8) After a violation is detected, the operating organization must ensure that all reasonable steps identified in its program are taken to respond appropriately to the violation and to prevent further similar violations, including any necessary modification to the operating organization's program to prevent and detect criminal, civil, and administrative violations under the Act.

(d) Additional required components for operating organizations with five or more facilities. In addition to all of the other requirements in paragraphs (a), (b), (c), and (e) of this section, operating organizations that operate five or more facilities must also include, at a minimum, the following components in their compliance and ethics program:

(1) A mandatory annual training program on the operating organization's compliance and ethics program that meets the requirements set forth in §483.95(f).

(2) A designated compliance officer for whom the operating organization's compliance and ethics program is a major responsibility. This individual must report directly to the operating organization's governing body and not be subordinate to the general counsel, chief financial officer or chief operating officer.

(3) Designated compliance liaisons located at each of the operating organization's facilities.

(e) Annual review. The operating organization for each facility must review its compliance and ethics program annually and revise its program as needed to reflect changes in all applicable laws or regulations and within the operating organization and its facilities to improve its performance in deterring, reducing, and detecting violations under Act and in promoting quality of care. The information from the compliance program should be integrated into the facility's QAPI program.

AMDA COMMENT:
AMDA believes that compliance must be coordinated into ongoing activities so that the primary focus remains on doing the right thing in the right way routinely, and on proper clinical reasoning and problem solving, with regulatory and legal compliance always kept in mind but not as a separate or predominant activity. An excessive or separate focus on compliance can potentially result in clinically questionable activities in the name of "compliance" that are inconsistent with desirable care approaches.

35. In newly redesignated §483.90—

a. Revise paragraph (c).

b. Revise paragraphs (d)(1)(i) and (d)(2)(i).

c. Revise paragraph (e).

d. Revise paragraphs (f) introductory text and (f)(1).

e. Revise paragraph (g)(2).

f. Add paragraph (h)(5).

The revisions and additions read as follows:

§483.90 Physical environment.

* * * * *

(c) Space and equipment. The facility must—

(1) Provide sufficient space and equipment in dining, health services, recreation, living, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's assessment and plan of care; and

(2) Maintain all mechanical, electrical, and patient care equipment in safe operating condition.

(3) Conduct regular inspection of all bed frames, mattresses, and bed rails, if any, as part of a regular maintenance program to identify areas of possible entrapment. When bed rails and mattresses are used and purchased separately from the bed frame, the facility must ensure that the bed rails, mattress, and bed frame are compatible.

(d). * * *

(1) * * *

(i) Accommodate no more than four residents. For facilities that receive approval of construction or reconstruction plans by State and local authorities or are newly certified after **[effective date of final rule]**, bedrooms must accommodate no more than two residents.

* * * * *

(2) * * *

(i) A separate bed of proper size and height for the safety and convenience of the resident;

* * * * *

(e) Toilet facilities. Each resident room must be equipped with or located near toilet and bathing facilities. For facilities that receive approval of construction or reconstruction plans from State and local authorities or are newly certified after **[effective date of the final rule],** each resident room must have its own bathroom equipped with at least a toilet, sink and shower.

(f) Resident call system. The facility must be adequately equipped to allow residents to call for staff assistance through a communication system which relays the call directly to a staff member or to a centralized staff work area from—

(1) Each resident's bedside; and

* * * * *

(g) * * *

(2) Be well ventilated;

* * * * *

(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.

36. Section 483.95 is added to subpart B to read as follows:

§483.95 Training requirements.

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. A facility must determine the amount and types of training necessary based on a facility assessment as specified at §483.70(e). Training topics must include but are not limited to--

(a) Communication. A facility must include effective communications as mandatory training for direct care/direct access personnel.

(b) Resident's rights and facility responsibilities. A facility must ensure that staff members are educated on the rights of the resident and the responsibilities of a facility to properly care for its residents as set forth at §483.10 and §483.11, respectively.

(c) Abuse, neglect, and exploitation. In addition to the freedom from abuse, neglect, and exploitation requirements in §483.12, facilities must also provide training to their staff that at a minimum educates staff on—

(1) Activities that constitute abuse, neglect, exploitation, and misappropriation of resident property as set forth at §483.12.

(2) Procedures for reporting incidents of abuse, neglect, exploitation, or the misappropriation of resident property.

(d) Quality assurance and performance improvement. A facility must include as part of its QAPI program mandatory training that outlines and informs staff of the elements and goals of the facility's QAPI program as set forth at §483.75.

(e) Infection control. A facility must include as part of its infection prevention and control program mandatory training that includes the written standards, policies, and procedures for the program as described at §483.80(a)(2).

(f) Compliance and ethics. The operating organization for each facility must include as part of its compliance and ethics program, as set forth at §483.85--

(1) An effective way to communicate that program's standards, policies, and procedures through a training program or in another practical manner which explains the requirements under the program.

(2) Annual training if the operating organization operates five or more facilities.

(11) Required ~~in-service~~ education and training for nurse aides. ~~In-service~~ Education and training must—

AMDA COMMENT:
As noted previously, there are more modern and diverse ways to educate and train, including real time oversight and coaching.

We are concerned that the prescribed structure is too narrow and specific. We believe that it is preferable to focus on the expected objectives of the education and training, not on mandating methods.

(3) Be sufficient to ensure the continuing competence of nurse aides, but must be no less than 12 hours per year.

(4) Include dementia management training and resident abuse prevention training.

(5) Address areas of weakness as determined in nurse aides' performance reviews and facility assessment at §483.70(e) and may address the special needs of residents as determined by the facility staff.

(6) For nurse aides providing services to individuals with cognitive impairments, also address the care of the cognitively impaired.

(g) Required training of feeding assistants. A facility must not use any individual working in the facility as a paid feeding assistant unless that individual has successfully completed a State-approved training program for feeding assistants, as specified in §483.160.

(h) Behavior~~al health~~. A facility must provide ~~behavioral health~~ training in dealing with behavior that is consistent with the requirements at §483.40 and as determined by the facility assessment at §483.70(e).

AMDA COMMENT:
AMDA repeats its concerns regarding a proposed "behavioral health" requirement, and strongly recommends that the wording change to reflect the reality that we are dealing with behavior, not a nebulous concept such as "behavioral health." "Behavioral health" is a nebulous concept that lacks meaningful clinical correlation. The focus should be on managing behavior appropriately by effectively addressing its various medical and other underlying causes.

§483.118 [Amended]

37. In §483.118, amend paragraphs (b)(1) and (c)(2)(i) by removing the reference "§483.12(a)" and adding in its place the reference "§483.15(b)".

§483.130 [Amended]

38. In §483.130, amend paragraphs (m)(5) and (m)(6) by removing the reference

"§483.12(a)" and adding in its place the reference §483.15(b)".

§483.138 [Amended]

39. In §483.138, amend paragraphs (a) introductory text and (b)(1) by removing the reference "§483.12(a)" and adding in its place the reference "§483.15(b)".

§483.151 [Amended]

40. In §483.151, amend paragraph (a)(3) by removing the reference "§483.75(e)" and adding in its place the reference "§483.35(c) and (d) and §483.95(g)".

§483.204 [Amended]

41. In §483.204, amend paragraph (b) by removing the reference "§483.12 of this part" and adding in its place the reference "§483.15(h)".

§483.206 [Amended]

42. In §483.206, amend paragraph (a) by removing the reference "(See §§483.5 and 483.12(a)(1))" and adding in its place the reference "(See §483.5)".

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

43. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

§485.635 [Amended]

44. In §485.635, amend paragraph (a)(3)(vii) by removing the reference "§483.25(i)" and adding in its place the reference "§483.25(d)(8)".

45. In §485.645, paragraphs (d)(1) through (9) are revised and paragraph (d)(10) is added to read as follows:

§485.645 Special requirements for CAH providers of long-term care services ("swing-beds")

* * * *

(d) * * *

(1) Resident rights (§483.10(a)(4)(iv), (b), (c), (d)(1), (d)(3), (e)(8), (g), and (h)(3)).

(2) Facility responsibilities (§483.11(d)(1)(i), (d)(1)(iii), (d)(4), (e)(11), (e)(12), (e)(14)(iii), and (f)(1)(i)).

(3) Transitions of care (§483.5(n), §483.15(b)(1), (b)(2), (b)(3)(i) through (iii), (b)(4), (b)(5)(i) through (vii), and (b)(7)).

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

(5) ~~Patient~~ Resident activities (§483.25(c)), except that the services may be directed either by a qualified professional meeting the requirements of §485.25(c)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

(6) Social services (§483.40(d) and §483.75(p)).

(7) Comprehensive assessment, comprehensive care plan, and discharge planning (§483.20(b), and §483.21(b) and (c)), except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under §483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in §413.343(b) of this chapter).

(8) Specialized rehabilitative services (§483.65).

(9) Dental services (§483.55).

(10) Nutrition (§483.25(d)(8) of this chapter).

(11) Desirable approaches to diagnose and manage elderly and acutely and chronically ill patients, including diagnostic quality and avoidance of diagnostic error

AMDA COMMENT:
Again, AMDA recommends that these regulations pay more attention to other less publicized but equally important issues that have been identified as related to improving care quality, such as the correct way to do cause identification for symptoms and condition changes.

Several recent publications and initiatives have focused on diagnostic quality and error as major concerns in health care today. [*References: Balogh EP, Miller BT, Ball JR (eds.) and*

the Committee on Diagnostic Error in Health Care. Improving Diagnosis in Health Care, National Academies Press, 2015; McDonald KM, Matesic B, Contopoulos-Ioannidis DG et al. Patient safety strategies targeted at diagnostic errors: a systematic review. Ann Intern Med 2013;158:381-389.] This is very relevant to any efforts to improve long-term and post-acute care.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

46. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102, 1128I and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302, 1320a-7j, and 1395hh); Pub. L. 110-149, 121 Stat. 1819. Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§488.56 [Amended]

47. In §488.56, paragraph (a) introductory text is amended by removing the reference "§483.30" and adding in its place the reference "§483.35".

48. Section 488.301 is amended by revising the definitions of "nurse aide", "paid feeding assistant", and "substandard quality of care" to read as follows:

§488.301 Definitions.

* * * * *

Nurse aide means an individual, as defined in §483.5(n) of this chapter.

* * * * *

Paid feeding assistant means an individual who meets the requirements specified in §483.60(h)(1) of this chapter and who is paid to feed residents by a facility, or who is used under an arrangement with another agency or organization.

* * * * *

Substandard quality of care means one or more deficiencies related to participation requirements under §483.10 "Resident rights", paragraphs (d) and (e); §483.11 "Facility Responsibilities", paragraphs (d) and (g); §483.12 "Freedom from abuse, neglect, and exploitation"; §483.25 "Quality of care, and quality of life"; §483.40 "Behavioral health services", paragraphs (b) and (d); §483.45 "Pharmacy services", paragraphs (d), (e), and (f); and

§483.80 “Infection control”, paragraph (d) of this chapter, which constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm.

* * * * *

§488.426 [Amended]

49. In §488.426, paragraph (b) is amended by removing the reference “§483.75(r)” and adding in its place the reference “§483.70(l)” and paragraph (c) is amended by removing the reference “§483.75(r)(1)(ii)” and adding in its place the reference “§483.70(l)”.

§488.446 [Amended]

50. In §488.446, the introductory text is amended by removing the reference “§483.75(r)” and adding in its place the reference “§483.70(l)”.

CMS-3260-P

Dated: May 12, 2015

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Approved: July 8, 2015

Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

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