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CMS Issues Proposed Rule Significantly Modifying the Requirements for Long-Term Care Facilities Participating in the Medicare and Medicaid Programs; Extends Comment Period

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Introduction On July 16, 2015, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule comprehensively updating and extensively revising the requirements for participation for long term care ("LTC") facilities participating in the Medicare and Medicaid programs (the "Proposed Rule").[1] Signifying the considerable potential impact of the Proposed Rule, CMS estimates that the total projected cost of implementing the proposed requirements would be $729 million in the first year (or an estimated $46,491 per facility) and would cost approximately $638 million in the second and subsequent years (or $40,685 per facility). CMS explains in the preamble discussion that while the LTC facility requirements for participation have been periodically reviewed and updated due to legislative mandates or specific issues, the agency has not thoroughly reviewed and updated the LTC facility requirements for participation since 1991.

Comments to the Proposed Rule were originally due to CMS by September 14, 2015. In response to inquiries from hospital associations and other industry stakeholders regarding the 60-day comment period, CMS revisited the length of the comment period. Specifically, given the scope and complexity of the Proposed Rule, on September 9, 2015, CMS determined to extend the comment period an additional 30 days.[2] Comments are now due to CMS by ***October 14, 2015***.

Overview of the Proposed Rule Explaining the need for the significant revisions included in the Proposed Rule, CMS states in the preamble discussion that the population in nursing facilities ("NFs") and skilled nursing facilities ("SNFs") has become more diverse and clinically complex since 1991. Further,

evidence-based research has improved knowledge regarding resident safety, health outcomes, individual choice, and quality assurance and performance improvement. In CMS' view, the proposed revisions would streamline the requirements by eliminating duplicative, unnecessary, and burdensome provisions.

Additionally, a number of the proposed revisions support broader quality initiatives promoted by the Department of Health and Human Services ("HHS"), including reducing avoidable hospitalizations and fostering the use of health information technology ("IT"). Similarly, the Proposed Rule would address certain "cross-cutting" health policy issues, including decreasing the inappropriate use of antipsychotic medications and reducing healthcare-associated infections. Finally, the Proposed Rule codifies certain provisions included in the Patient Protection and Affordable Care Act ("ACA"), including the requirement that SNFs and NFs have in operation a compliance and ethics program. In addition, the Proposed Rule would implement an Improving Medicare Post-Acute Care Transformation Act of 2014 ("IMPACT Act") requirement regarding the discharge planning process.

In addition to the substantial costs estimated by CMS in the Proposed Rule, the agency's request for comments regarding the appropriate implementation period for the final rule indicates the significance and scope of the proposed changes. In particular, CMS seeks comments regarding the appropriate timeframe for implementation of the proposed rule, noting that the agency anticipates that a longer period of time than is customary (12 months) may be required to implement the changes outlined in the final rule.

The Proposed Rule includes the following key provisions:

- Implementing a "competency based" staffing approach to ensure that LTC facilities are appropriately staffed;
- Restructuring the residents' rights section of the requirements for participation regulations;
- Specifying that a resident's attending physician must be licensed in the state where the facility is located and satisfy the credentialing requirements of the facility;
- Requiring LTC facilities to adopt certain written policies and procedures, including policies and procedures prohibiting and preventing abuse, neglect, and mistreatment of residents or misappropriation of their property, and policies and procedures regarding visitation rights of residents;
- Mandating "open visitation" in LTC facilities, similar to the hospital conditions of participation ("CoPs");
- Requiring a facility-wide assessment to determine the resources necessary to care for the LTC facility's residents;

- Mandating that LTC facilities provide certain specified clinical information to a provider or facility receiving a patient discharged from the LTC facility;
- Requiring LTC facilities to develop, adopt, and maintain certain training programs for all new and existing staff;
- Requiring all LTC facilities to develop, implement, and maintain an effective, comprehensive, and data-driven quality assistance and performance improvement ("QAPI") program (which would include certain disclosure requirements to state surveyors or CMS);
- Mandating a pharmacist review of a resident's medical chart every six months (or at a greater frequency) and in instances where the resident is new to the facility, a prior resident returns to the facility, or is transferred from a hospital or other facility;
- Requiring that an LTC facility's operating organization develop, implement, and maintain a compliance and ethics program satisfying certain specific requirements; and
- Limiting an LTC facility's use of binding arbitration agreements.

Why Revise the LTC Facility Requirements and What is CMS Seeking to Achieve? Throughout the Proposed Rule, CMS seeks to modernize LTC facility requirements, synchronize them with other laws, and implement certain provisions of the ACA. Since 1991, as noted above, CMS has only issued piecemeal, issue-specific updates to LTC facility requirements. Further, since 1991, there have been many changes to the composition of the population seeking LTC facility services and CMS seeks to respond to this more diverse population requiring different, more intensive services.

CMS categorizes the changes to the population seeking LTC facility services in three primary ways. First, there has simply been an increase in the number of Medicare beneficiaries accessing care in a SNF. The number has increased from 636,000 (19 per 1,000 enrollees) in 1989 to 1,839,000 (52 per 1,000 enrollees) in 2010, not including managed care enrollees.[3] Second, residents in LTC facilities have more clinically complex conditions or are higher acuity as a result of two changes: (1) the 1983 shift to a prospective payment system ("PPS") for hospitals, which in turn encouraged shorter hospital stays along with increased funding for post-acute care stays – all resulting in a drastic increase in the number of residents recuperating from an acute episode of care in an LTC facility when such patients previously would have been discharged to their homes; and (2) an increase in assisted living facilities and other alternatives to NFs in the marketplace. Third, CMS notes that there has been an increase in the SNF resident population requiring behavioral health services for illnesses like dementia and depression.

In light of these developments, one of CMS' goals with respect to the Proposed Rule is to align its minimum health and safety requirements for LTC facilities with

current clinical practices actually applied in the SNF and NF care settings. The agency also seeks to "allow flexibility to accommodate multiple care delivery models to meet the needs of diverse populations that are provided services in these facilities."[4] Therefore, CMS has proposed a "competency-based" approach to staffing that allows for innovative care models, but also mandates that LTC facilities meet the statutory requirement that each resident is provided care "that allows the resident to maintain or attain their highest practicable physical, mental, and psychosocial well-being."[5]

The second goal for the Proposed Rule is to encourage and support HHS' current quality initiatives and CMS' own efforts to provide high-quality and affordable care to LTC facility residents. Specifically:

- *Unnecessary Hospitalization* – In response to the high rate of "avoidable hospitalizations" among Medicare and Medicaid beneficiaries receiving either SNF or NF services (which, according to CMS research, is approximately 45 percent of hospitalizations for patients receiving either Medicare SNF services or Medicaid NF services), the HHS Partnership for Patients Initiative seeks to reduce the number of individuals who experience these preventable complications often resulting in hospitalization. CMS asserts that regulatory changes can assist in reducing such avoidable hospitalizations. For example, the Proposed Rule includes certain minimum health and safety standards for LTC facility residents to accomplish the goal of reducing avoidable hospitalizations (*e.g.*, requiring a practitioner assessment prior to transfer to a hospital, except in emergencies).

- *Healthcare-Associated Infections ("HAIs")* – CMS also proposes revisions to the LTC facility requirements to support HHS' initiatives dedicated to reducing the incidence of HAIs across providers thereby assisting in reducing overall healthcare costs (e.g., integrating the infection prevention and control program ("IPCP") with the facility's QAPI processes).

- *Behavioral Health* – CMS proposes regulatory changes to support its initiative aimed at improving behavioral healthcare and reducing the use of unnecessary antipsychotic medications in LTC facilities.

- *Health Information Technology* – To support HHS' health IT initiatives and the exchange of health information to improve healthcare, CMS proposes regulations governing the exchange of important information across the care team, spectrum of care, and the adoption of Office of the National Coordinator for Health Information Technology ("ONC") certified health IT and interoperability standards.

- *Trauma-Informed Care* – CMS also intends to assist HHS' activities designed to support and raise awareness for trauma survivors (*e.g.*, a lack of privacy or confinement in a crowded or small space).

- *Long-Stay Nursing Facility Residents* – Finally, CMS acknowledged that it is internally reviewing issues regarding long-stay NF residents and acknowledges

> that the current LTC facility requirements do not reflect the distinction between residents covered by LTC insurance or paying privately (i.e., the distinction between residents receiving care indefinitely versus those who are receiving rehabilitation followed by discharge to the community). The agency states that it will not propose specific changes to the regulations applicable to long-stay residents in this Proposed Rule due to lack of verifiable information. As such, CMS seeks comments regarding this issue.[6]

The third goal of the Proposed Rule is to implement certain ACA provisions, including requirements to: (1) implement a compliance and ethics program for SNFs and NFs (section 6102 of the ACA, codified at 42 U.S.C. § 1320a-7j(b)); (2) establish and implement QAPI program requirements for facilities (codified at 42 U.S.C. § 1320a-7j(c)); and (3) train nursing aides on dementia management and abuse prevention (section 6121 of the ACA amending 42 U.S.C. § 1395i–3(f)(2)(A)(i)(I) and 42 U.S.C. § 1396r(f)(2)(A)(i)(I)).[7]

Finally, CMS hopes to eliminate unnecessary, outdated, confusing, and/or duplicative regulations in accordance with President Obama's request of agencies in Executive Order 13563, "Improving Regulation and Regulatory Review."[8] Below we discuss the Proposed Rule's key proposals.

Residents' Rights and Facility Responsibilities The current requirements for participation regulations address a number of resident rights and facility requirements, including those establishing a resident's ability to exercise his or her rights associated with a dignified existence, self-determination, planning and implementing care, access to information, privacy, and confidentiality. CMS proposes to retain all existing residents' rights, but update the language and organization of the resident rights and facility responsibilities provisions to: (1) improve logical order and readability; (2) clarify certain aspects of the regulation; and (3) update provisions to include technological advances such as electronic communications.

CMS proposes to clarify the resident's right to designate a representative, the resident representative's limitation to those rights delegated by the resident, and the resident's retention of those rights not delegated, including the right to revoke a delegation. CMS' proposed clarification is intended to ensure that facilities do not afford more decision-making authority to a resident representative than is intended by the resident or permitted under applicable law. Specifically, CMS proposes to clarify that a resident who has been adjudged incompetent under the laws of a state: (1) retains the right to exercise those rights not addressed by a court order; (2) the resident representative can only exercise the rights that devolve to them as a result of the court order; (3) the resident's wishes and preferences should continue to be considered; and (4) the resident should continue to be involved in the care planning process to the extent practicable.

Notably, CMS proposes a number of new resident rights related to planning and implementing care, including the right to participate in the care planning process, 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. While existing facility responsibilities include treating residents with respect and dignity and providing care and services for residents in a manner and in an environment that promotes maintenance or enhancement of the resident's quality of life, CMS proposes to require the facility to recognize each resident's individuality and provide services in a personalized manner. Specifically, CMS proposes to specify the resident's right to participate in the development of his or her comprehensive care plan and to include the resident's right to self-administer medication if the interdisciplinary team has determined that doing so would be clinically appropriate.

With regard to issues related to respect, dignity, and self-determination, CMS includes in the Proposed Rule the resident's right to share a room with his or her roommate of choice in instances where both residents live in the same facility, both residents consent to the arrangement, and the facility can reasonably accommodate the arrangement. CMS' proposal is intentionally broad to include married couples, whether opposite or same sex, siblings, other relatives, long term friends, or any other combination as long as the aforementioned requirements are met. We believe that such a requirement may burden facilities and that the implementation of such a requirement may not be practicable in many facilities.

CMS also includes revisions ensuring that the resident can receive his or her visitors of choice at the time of his or her choosing, among other visitation rights of residents. While CMS compares such an "open visitation" requirement to the hospital CoP visitation requirement, hospitals and LTC facilities operate in different manners and under dissimilar financial margins. For example, full-time security, which actively monitor and screen visitors in some, if not most, hospitals, may not be practicable in many LTC facilities.

The Proposed Rules also endeavors to update provisions related to the resident's right to access facility-specific information, medical records, information about advocacy and fraud control organizations, Medicare and Medicaid coverage, surveys of the facility conducted by federal or state surveyors, any plan of correction in effect with respect to the facility for the preceding three years, and other notices and information that the facility is required to provide the resident. Significantly, CMS' revisions take into account electronic medical records that are compliant with HIPAA and privacy requirements as well as other electronic communications, such as reasonable access and personal privacy related to the internet and email or internet-based interpersonal video communications. CMS also specifies that the facility is responsible for ensuring that information provided to the resident is provided in a form and manner that the resident can access and understand, including addressing any language barriers that may exist.

Further, the Proposed Rule would require that the facility establish a grievance policy to ensure the prompt resolution of grievances and to identify a Grievance Officer. The facility would be required to provide a copy of this policy upon request, as well as make information about filing grievances available to residents.

In addition, the facility would be required to take a number of specified actions in response to a grievance.

With regard to issues related to resident funds and charges, CMS proposes new requirements focusing on the facility's responsibility related to the protection of resident funds. Specifically, CMS proposes to include provisions related to security deposits and the return of funds to residents upon discharge or eviction. A facility would be prohibited from charging the resident for hospice services elected by the resident and paid for under Medicare or Medicaid, whether provided directly by the LTC facility or by a hospice provider under agreement with the LTC facility. The Proposed Rule further clarifies that a facility could not charge for special food and meals ordered for a resident by a physician, physician assistant, nurse practitioner, clinical nurse specialist, dietitian, or other clinically qualified nutrition professional. Additionally, the facility would be required to provide notice to residents when changes are made to the items and services covered by Medicare and/or Medicaid or to the amount that the facility charges for items and services.

Finally, CMS proposes to require the facility to ensure that the attending physician is appropriately licensed and credentialed to provide care and meet the requirements of applicable regulations. CMS specifies that the physician chosen by the resident must be licensed to practice medicine and must meet professional credentialing requirements of the facility. However, the Proposed Rule would not specify what the professional credentialing requirements of the facility must include. If the physician is not appropriately credentialed or is unwilling or unable to meet the delineated requirements, the facility could seek an alternate physician after informing and discussing this matter with the resident. Further, in order to ensure that the resident could seek out a suitable alternative, CMS specifies that if the resident subsequently finds a new physician who meets the necessary requirements, the facility would be required to honor that selection.

Freedom from Exploitation, Neglect and Abuse CMS proposes to redesignate the current 42 C.F.R. § 483.13, "Resident Behavior and Facility Practices" as proposed § 483.13, "Freedom from Abuse, Neglect and Exploitation." In the preamble, the agency indicates that the proposed changes to this regulation reflect that exploitation, neglect and abuse in LTC facilities remain a concern and also the agency's goal to bolster progress to improve conditions in NFs and SNFs. In the Proposed Rule, CMS would modify a current prohibition on the employment of individuals who: (1) have been found guilty of abuse, neglect, or mistreatment of residents by a court of law; or (2) had a finding of abuse, neglect, mistreatment of resident or misappropriation of property reported into a state nurse aide registry, to include a prohibition on "otherwise engag[ing]" such individuals and also to include a prohibition on employing or otherwise engaging individuals who have (3) had a disciplinary action taken against a professional license by a state licensure body as a result of a finding of abuse, neglect, or mistreatment of residents or a finding of misappropriation of property.

The Proposed Rule would also require the development and implementation of a variety of written policies and procedures related to abuse, neglect, and exploitation of residents in addition to the misappropriation of residents' property. Such policy and procedure requirements include: policies and procedures related to the prohibition and prevention of abuse, neglect and exploitation; the investigation of allegations of abuse, neglect, exploitation or misappropriation of property; and training related to abuse, neglect and exploitation. Finally, the Proposed Rule would require the development and adoption of written policies and procedures—satisfying certain elements—that would ensure reporting of crimes occurring in accordance with 42 U.S.C. § 1320b–25.

Transitions of Care, Assessments, and Care Plans Pursuant to the Proposed Rule, the former section addressing admissions, transfers, and discharge rights would be redesignated as "transitions of care." First, LTC facilities would be prohibited from requesting or requiring that current residents or potential residents waive any potential facility liability for the loss or loss of use of their personal property. With this provision, CMS seeks to encourage facilities to develop policies and procedures to safeguard residents' personal property without effectively prohibiting a resident's use of their personal possessions. However, we would note that this proposal may not adequately account for residents' personal responsibility with respect to safeguarding their own personal property.

Second, facilities would be required to disclose and provide current residents or potential residents with notice of any special characteristics or service limitations at the facility. CMS' goal with this proposal would be to allow residents to make informed decisions about initial admission or continued admission. For example, any religious affiliations impacting resident care would have to be disclosed. Similarly, notice would be required regarding any limitations in the types of care offered at the facility (e.g., inability to provide psychiatric care).

With respect to discharges, the Proposed Rule would allow a resident to be discharged when the safety of other individuals is endangered due to the clinical or behavioral status of the resident. Importantly, in a significant change from the current regulations, LTC facilities would be prohibited from transferring or discharging a resident when a resident exercises their appeal rights to challenge a transfer or discharge. In the preamble, CMS notes that such discharges/evictions historically have been the first or second most frequent category of facility complaint reported by the LTC Ombudsman. However, we would note that we read this proposal to effectively mean that an LTC facility could never discharge a resident if an appeal is pending (which could take months, and possibly even years, in certain instances).

Noting the importance of effective communication between providers during transitions of care, CMS makes several proposals. Transfers and discharges would need to be documented in the resident's clinical record and appropriate information communicated to the receiving care setting. In an effort to discourage inappropriate transfers or discharges, where such transitions are based upon the

resident's safety and welfare, facilities would be required to include in the clinical record the resident needs that cannot be met and the services available at the receiving care setting that sufficiently satisfy those needs.

Regardless of the care setting to which the LTC facility resident is transferring, the transferring LTC facility would be required to provide certain information to the receiving entity. While CMS is not proposing a certain form, format, or methodology for this communication, the agency is proposing specific data elements and information that must be provided. Further, in the Proposed Rule, CMS would not mandate a specific time frame for this communication, but expects that the communication would occur shortly before or close to the actual transfer time and that the facility would document that the communication has occurred. Importantly, CMS is soliciting comments regarding both the proposed data elements and the time frame for such communications. We would note that, currently, hospitals are not required to provide the same amount of information to an LTC facility prior to transferring a hospital patient to an LTC facility. Therefore, while the transmission of the clinical information and data elements CMS proposes to require an LTC facility to transmit to the setting to which the LTC resident is transferring could improve communication between providers as well as the continuity of care, there is no comparable requirement designed to achieve the same enhanced communication with respect to the transfers from an acute-care hospital (or other setting) to an LTC facility.

With respect to resident assessments and encouraging resident-centered care plans, CMS seeks to clarify that the resident assessment instrument is not merely for the purpose of understanding a resident's needs, but also to understand their strengths, goals, life history, and preferences. In other words, CMS asserts that the resident's actual preferences and expectations should guide facility decision-making rather than the facility's judgments.

Lastly, through the care planning process, CMS seeks to encourage facilities to establish and document the services that will assist residents in attaining or maintaining their highest quality of life. In the preamble discussion, CMS acknowledges that the diversity of the LTC facility population can create challenges for facilities in meeting care planning requirements. Nonetheless, CMS cites two OIG reports highlighting perceived gaps in the care planning process as at least partial justification for its proposed changes.

Specifically, CMS proposes the following: (1) a baseline interim care plan (or a comprehensive care plan) must be completed for each resident within 48 hours of admission to the facility in an effort to increase resident safety and mitigate against adverse events that are most likely to occur immediately following admission; (2) discharge assessment and planning must be a part of developing the comprehensive care plan; and (3) members of a resident's interdisciplinary team must include a nurse aide, a member of the food and nutrition services staff, a social worker, and to the extent practicable the resident and resident representative.

Given CMS' desire to ensure safe transitions of care across all providers, the Proposed Rule would seek to strengthen LTC facility requirements for discharge planning. The proposed changes also would support the agency's initiative to safely reduce hospital readmissions and unnecessary hospitalizations by improving communications. Several requirements of the IMPACT Act also would be implemented or bolstered with the proposal.

Specifically, the Proposed Rule would add a requirement that LTC facilities develop and implement an effective discharge planning process. Such a process must ensure that the discharge goals and needs of each resident are identified. Further, the discharge plan must be re-evaluated on a regular basis to identify and implement changes to the plan.

Physician Services, Nursing Services, Behavioral Health Services Under the Proposed Rule, CMS reorganizes and amends current regulations regarding physician services and nursing services and proposes a new section for behavioral health services.

CMS proposes to move current section 42 C.F.R. § 483.40 for physician services to § 483.30 and add to the current requirements for physicians. These new requirements are intended to support CMS' goal of reducing unnecessary hospitalizations. First, CMS proposes to revise the introduction to proposed §š483.30 to specify the requirement of both: (1) a physician's recommendation that an individual be admitted to a facility; and (2) orders by a physician, physician assistant, a nurse practitioner or a clinical nurse specialist for the resident's immediate care and needs. In addition, CMS proposes to add a new section, § 483.30(e), which would require that prior to an unscheduled transfer of a resident to a hospital, the facility "provide or arrange for an in-person evaluation of a resident, to be conducted expeditiously, by a physician, a physician assistant, nurse practitioner, or clinical nurse specialist […]". According to the agency, this evaluation should be performed prior to transferring the resident to the hospital except in an emergency or if it would otherwise endanger the health or safety of the individual or unreasonably delay the transfer. CMS explains that the evaluation requirement is intended to pinpoint opportunities where the resident could be treated outside of the hospital setting and provide important assessment information for the receiving facility. However, we would note that this requirement may not be practicable in certain instances (e.g., a facility in a rural setting) and may compromise resident care.

In addition, CMS proposes to provide the physician with further flexibility to delegate certain tasks. Under proposed § 483.30(f)(2), to the extent it is permissible under state law, a physician will have the ability to delegate to a qualified dietitian or other appropriate nutrition professional the task of writing dietary orders. Similarly, under proposed § 483.30(f)(3), to optimize a physician's time and necessary adjustments to a resident's therapy program, a physician can delegate to a qualified therapist the task of writing therapy orders, to the extent it is permitted under state law.[9]

Pursuant the Proposed Rule, CMS also seeks to revise the requirements for nursing services starting with a change to the location of the regulatory text from § 483.30 to proposed § 483.35. CMS acknowledges that the current regulations do not contemplate certain areas like the competencies of licensed nurses and the need to consider resident acuity. Therefore, CMS engages in an extensive discussion of nursing hours and staffing levels and also proposes certain other changes to the regulations.[10]

CMS proposes to revise the nursing services section to include language requiring that nursing service personnel have the competencies and skills necessary to provide nursing and related services to assure resident safety and assist residents "to attain or maintain the highest practicable physical, mental, and psychosocial well-being." Along similar lines, CMS proposes to add language to proposed § 483.35 and §483.35(a)(3) and (4) that requires the facility to ensure that staff, including licensed nurses, have appropriate competencies and skill sets to assure resident safety and to care for resident needs, as identified through resident assessments and as described in the resident's plan of care. Caring for the resident's needs includes, but is not limited to, assessing, evaluating, planning, and implementing resident care plans and responding to their needs. Staffing considerations should account for the number, acuity, and diagnoses of the resident population. In addition, CMS proposes to revise various areas of the law to reflect that nurse aides provide much of the direct care in nursing facilities and are, subsequently, important for inclusion under proposed § 483.35. One of these changes would be to specifically include nurse aides in the term "other nursing personnel" under §483.35(a)(1)(ii).[11]

CMS also recognizes the "long-standing interest in increasing the required hours of nurse staffing per day," possibly either through an increase in the number of hours per resident day or a mandate for the presence of a registered nurse in a nursing facility for more hours than currently required. Current regulations at § 483.30 require that a registered nurse provide services in a facility eight consecutive hours a day, seven days a week; licensed practical nurses twenty-four hours a day, and sufficient staff to meet resident needs. However, considering relevant, and sometimes non-conclusory or contradictory, research in the field on nurse staffing levels at LTC facilities, CMS concludes that it does not have sufficient information at this time to require a specific number of staff or hours of nursing care per resident. The agency states that "the focus should be on the skill sets and specific competencies of assigned staff to provide the nursing care a resident needs rather than a static number of staff or hours of nursing care that does not consider resident characteristics such as stability, intensity and acuity and staffing abilities […]".[12] CMS requests comments on certain options including, among other things, establishing minimum nurse hours per resident day, establishing minimum nurse-to-resident ratios, and/or requiring that a registered nurse be on call when a registered nurse is not present at the facility.

CMS also requests comments or information on various other areas including: (1) costs, benefits, and unintended consequences of a 24-hour registered nurse

presence mandate; (2) evidence of appropriate thresholds for minimum staffing requirements and the cost of these thresholds; (3) CMS' proposal to have a facility assessment process where facilities are required to determine adequate staffing based on the assessment that evaluates the number of residents, resident acuity, range of diagnoses, and content of care plans; and (4) other approaches in determining adequate direct care staffing similar to mentioned state models (e.g., Maine's requirement for at least one direct care provider for every five residents during the day shift, one per ten in the evening, and one per fifteen in the night).[13]

Third, CMS proposes to add a new section, proposed § 483.40, regarding requirements for behavioral health services and for social workers. CMS states that this proposed regulatory section would respond to the prevalence of mental health disorders and other cognitive impairments found in LTC facilities and also would emphasize the importance of providing necessary behavioral health services in order for an LTC facility to meet its requirement to provide services to attain or maintain the highest practicable physical, mental and psychosocial well-being. The proposed requirements for LTC facilities under this new section include: (1) employing sufficient direct care staff with the appropriate competencies and skills to provide nursing and related services; (2) based on the comprehensive assessment of a resident, ensuring "that a resident who displays or is diagnosed with mental or psychosocial adjustment difficulty receives appropriate treatment to correct the assessed problem or to attain the highest practicable mental health and psychosocial well-being"; and (3) if required in the resident's plan of care, providing or otherwise coordinating the provision of required rehabilitative services (e.g., physical therapy, occupational therapy, speech-language therapy) or special rehabilitative services dedicated to mental illness and intellectual disability or those required under proposed § 483.45. CMS also provides certain clarifying information with respect to these requirements. The necessary competencies and skills include, among other things, knowledge of, training in, and supervision for caring for residents with mental illness, psychosocial problems, or trauma-related issues and training in implementing non-pharmacological interventions. Further, CMS clarifies "that a resident whose assessment does not reveal or who does not have a diagnosis of a mental illness or psychosocial adjustment difficulty will not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors," unless this resident's specific clinical condition demonstrates that the pattern is unavoidable.[14]

Pharmacy Services The current requirements for participation related to pharmacy services require that each resident's drug regimen be reviewed by a pharmacist at least once a month. The Proposed Rule would require that a pharmacist review the resident's medical record coincident with the drug regimen review when: (1) the resident is newly admitted to the facility; (2) a prior resident returns or is transferred from a hospital or other facility; and (3) during each monthly drug regimen review when the resident has been prescribed or is taking a psychotropic drug, an antibiotic, or any drug the quality assessment

and assurance ("QAA") committee has requested be included in the pharmacist's monthly drug review. CMS encourages the QAA Committee to collaborate with the pharmacist to enhance the committee's understanding and oversight of the facility's pharmaceutical practices, especially concerning the use of psychotropic drugs and its antibiotic stewardship, as well as their QAPI activities.

The current LTC requirements also specifically identify antipsychotic drugs and provide specific safeguards for their use. The safeguards in the current rule include, for example, residents who have not previously been prescribed antipsychotics not be given them unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record, and residents taking antipsychotics should receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue use of these drugs. In the Proposed Rule, CMS expands the drugs to which these safeguards (and others) would apply to include all psychotropic medications. Under the Proposed Rule, CMS broadly would define psychotropic medications to include, but not be limited to, drugs in the following categories: (1) antipsychotic; (2) anti-depressant; (3) anti-anxiety; (4) hypnotic; (5) opioid analgesic; and (6) any other drug that results in effects similar to the drugs listed in (1) – (5). CMS is soliciting comments on this definition and the types of drugs that should be considered psychotropic medications. CMS is also soliciting comments on the use of PRN orders for these medications and on the proposal to limit PRN prescriptions for these drugs to 48 hours unless the resident's primary care provider provides a rationale for the continuation of the PRN order in the resident's clinical record. Notably, limiting PRN orders to 48 hours could potentially result in adverse clinical outcomes for LTC facility residents.

Lastly, CMS proposes clarifications surrounding the existing requirement that the pharmacist conducting the monthly drug regimen must report any irregularities to the attending physician and the director of nursing. These clarifications include greater specification regarding the documentation of irregularities, provide additional individuals to whom the irregularities must be reported, and set forth a clear definition as to what "irregularities" are included pursuant to the requirement.

Food and Nutrition Services In the Proposed Rule, CMS seeks to establish minimum health and safety standards that support the nutritional well-being of all LTC facility residents while respecting each resident's right to make informed choices about his or her care, including decisions about diet. CMS states that the proposed revisions to this section also take into account flexibility for the facility to avoid impractical or financially unreasonable requirements.

Specifically, CMS proposes to require that the facility employ sufficient staff, including a qualified dietitian and/or director of food and nutrition services—both with new credential requirements under the Proposed Rule—with the appropriate competencies and skill sets 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. The

Proposed Rule would also modify the current strict meal frequency requirements by adding language to clarify that meals should be served at times in accordance with resident needs, preferences, requests and the plan of care. Additionally, CMS clarifies that facilities may procure food directly from local producers (i.e., farmers and growers) in accordance with state and local laws, as well as utilize produce grown in facility gardens, subject to compliance with applicable safe growing and handling practices. Lastly, the Proposed Rule would add a new requirement that the facility have a policy in place regarding use and storage of foods brought to residents by visitors to ensure safe and sanitary handling.

Infection Control Noting the increased incidence and costs associated with HAIs, CMS proposes to update and strengthen the current requirements for infection control. Specifically, CMS proposes to revise the regulatory description of an infection control program to: (1) include infection prevention, identification, surveillance, and antibiotic stewardship; (2) require each LTC facility to periodically review and update its program; (3) require performance of an analysis of their resident population and facility; (4) designate an infection prevention and control officer; (5) integrate the officer with the facility's quality assurance and performance improvement program; and (6) establish written policies and procedures and provide training for the infection prevention and control program.

Importantly, CMS does not propose specific requirements for the precautions to be utilized to prevent the spread of HAIs. Noting the importance of properly addressing this issue, CMS proposes that the infection prevention and control officer be a health care professional with specialized training in the infection control area and beyond their initial professional degree. CMS solicits comments on both the officer's specific qualifications and the requirements of an effective infection prevention and control program.

Quality Assurance and Performance Improvement Requirements The Proposed Rule would significantly modify the QAA-related provisions included in the current requirements for participation for LTC facilities.[15] CMS explains in the preamble discussion that proposed 42 C.F.R. § 483.75 would "establish [the] programmatic standards" "relating to facilities' QAPI program[s]" required by Section 6102 of the ACA.

The statutory language CMS intends to implement through the proposed QAPI regulations, Section 6102 of the ACA, is codified at 42 U.S.C. § 1320a-7j(c). 42 U.S.C. § 1320a-7j(c) requires the Secretary to: "establish and implement a quality assurance and performance improvement program"; "establish standards relating to quality assurance and performance improvement with respect to facilities and provide technical assistance to facilities on the development of best practices in order to meet such standards"; and "promulgate regulations to carry out this subsection." In addition, the statute expressly requires facilities to "submit to the Secretary a plan for the facility to meet such standards and implement such best practices."

In the Proposed Rule, the Secretary significantly expands upon the statutory mandate found at 42 U.S.C. § 1320a-7j(c) by including a laundry list of requirements related to the QAPI program, including requiring the disclosure of or potentially requiring a facility to provide access to a plethora of QAPI-related documentation and records by facilities. According to proposed 42 C.F.R. § 483.75(a), each facility must:

(1) Maintain documentation and demonstrate evidence of its ongoing QAPI program that meets the requirements of this section;

(2) Present its QAPI plan to the State Agency Surveyor at the first annual recertification survey that occurs after [the effective date of this regulation];

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

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

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

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

> 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.

While proposed 42 C.F.R. § 483.75(h)(1) provides that "[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," the remainder of 42 C.F.R. § 483.75(h) seems to require the disclosure of QAA committee[17] records that would be unnecessary to demonstrate compliance with 42 C.F.R. § 483.75. Significantly, the Proposed

Rule's QAPI provisions seem inconsistent with the statutory QAA privilege. The statute provides that QAA privilege applies to the "records of" a QAA committee. While neither the statute, regulations[18] nor guidance further define what constitutes the "records of" the QAA committee, the Proposed Rule would almost certainly require the disclosure of documents subject to the QAA privilege.

QAA committees frequently review and investigate incidents that may lead to litigation, and as such, certain documents and other materials produced by or at the request of QAA committees in furtherance of quality improvement could be valuable to plaintiffs' attorneys as they litigate liability claims against long-term care facilities. As a consequence, it is imperative for facilities to avoid inadvertently waiving the QAA privilege protection, found in either federal law or state law, in order to protect the potential disclosure of such materials during the discovery process of liability litigation. Under the proposed 42 C.F.R. § 483.75, federal or state surveyors could require the disclosure of a wide variety of QAPI documents or other materials. The disclosure of such QAPI documents or other materials to federal or state surveyors would likely waive any federal QAA privilege protection that would otherwise attach to the materials. Therefore, the Proposed Rule's QAPI provisions could chill the very activity that the QAA privilege seeks to encourage: the careful and thoughtful review of safety incidents in LTC facilities.

Finally, the proposed 42 C.F.R. § 483.75(i) relates to sanctions, and states that "[g]ood faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions." This proposal is important because, theoretically, federal and state surveyors could utilize materials obtained in response to compliance with the QAPI requirements to issue other survey citations.

Compliance and Ethics Program The Proposed Rule would add regulatory provisions, found at proposed 42 C.F.R. § 483.85, that would require an LTC facility's operating organization to develop, implement and maintain a compliance and ethics program satisfying certain, specified requirements. Notably, CMS estimates that the compliance and ethics program requirements (not including compliance and ethics training requirements) would cost LTC facilities $139,356,716 for the first year and $120,327,296 for the second and subsequent years. In fact, CMS projects the compliance and ethics program requirements to be the second most costly regulatory requirement resulting from compliance with the Proposed Rule.

Section 6102 of the ACA, codified at 42 U.S.C. § 1320a-7j(b), requires all SNFs and NFs to have in operation an effective compliance and ethics program on or after "36 months after the date of the enactment of this section" (i.e., March 23, 2013). Notably, 42 U.S.C. § 1320a-7j(b)(2) also requires the Secretary, working jointly with the Office of Inspector General of the Department of Health and Human Services ("OIG"), to promulgate regulations for an effective compliance and ethics program for operating organizations no later than two years after the date of the ACA's enactment (i.e., March 23, 2012). To date, neither CMS nor OIG

have promulgated such regulations. However, as CMS explains in the preamble to the Proposed Rule, the agency previously solicited comments regarding the compliance program requirements included in both section 6102 and section 6401(a) of the ACA.[19] Section 6401(a) of the ACA, codified at 42 U.S.C. § 1395cc(j)(8), requires all providers of medical or other items or services or suppliers to establish a compliance program that satisfies certain core elements, to be determined by the Secretary and the OIG. After soliciting comments in September 2010, CMS noted in February 2011 that it intended to propose compliance plan requirements in future rulemakings.[20]

The Proposed Rule indicates that every LTC facility must have a compliance and ethics program in place one year after adoption of the final rule. In addition, pursuant to the Proposed Rule, the compliance and ethics program must satisfy certain specified components, further described below. The Proposed Rule would include two tiers of requirements—one tier of requirements for all operating organizations (including operating organizations that have fewer than five LTC facilities), and one tier of requirements for operating organizations that have five or more LTC facilities.

The Proposed Rule would require all LTC facilities' operating organizations to develop, implement and maintain an effective compliance and ethics program with the following components, among others:

- The establishment of written standards, policies and procedures. Such written standards, policies and procedures must include certain elements, such as the designation of a compliance and ethics program contact for the reporting of suspected or actual compliance and ethics violations as well as an alternative means to report suspected or actual compliance and ethics violations anonymously.
- The assignment of specific, high-level personnel to oversee the compliance and ethics program.
- The effective communication of the standards, policies and procedures to the operating organizations' staff, contractors and volunteers.
- Consistent enforcement of the standards, policies and procedures through appropriate disciplinary mechanisms.
- Performance of an annual review of the compliance and ethics program and revision of the program, as necessary, to reflect changes in applicable laws and regulations.

In addition to the above, among other requirements, operating organizations that have five or more LTC facilities would be required to:

- Perform a mandatory, annual compliance and ethics training program that satisfies certain requirements.

- Designate a compliance officer for whom the compliance and ethics program is a "major responsibility."
- Designate a compliance liaison at each of the operating organization's facilities.

Training Requirements Under the Proposed Rule, LTC facilities must develop, implement, and maintain an effective training program for all staff, independent contractors, and volunteers. The amount and type of such training would be based upon a newly required facility assessment. The training topics are as follows:

- *Communications Training* – All direct care personnel must receive training in effective communications. Such training would be beneficial in reducing unnecessary hospitalizations and improving a resident's quality of life and quality of care.
- *Resident's Rights Training* – All staff members must receiving training on the rights of the resident and the responsibilities of an LTC facility to properly care for its residents.
- *Abuse, Neglect, and Exploitation Training* – All staff members must receive training on the freedom from abuse, neglect, and exploitation.
- *Quality Assurance and Performance Improvement Training* – All staff members must receive QAPI training.
- Infection Control Training – All staff members must receive education on HAIs and the LTC facility's infection control policies and procedures.
- *Compliance and Ethics Training* – Operating organizations for each facility must include, as part of their compliance and ethics program, training for staff outlining the standards, policies, and procedures.
- *Nurse Aide In-Service Training – Dementia and Abuse* – Given the incidence and prevalence of dementia, nurse aides must receive ongoing training in dementia management and abuse prevention.

Binding Arbitration Agreement Limitations According to CMS in the preamble discussion, certain stakeholders have raised specific concerns regarding facilities requiring or pressuring residents to sign binding arbitration agreements. After publication of the Proposed Rule, CMS disclosed, pursuant to a Freedom of Information Act request, that the "stakeholders" at issue was one organization: the American Association for Justice, formerly known as the Association of Trial Lawyers of America. Regardless, CMS states in the preamble discussion that the agency is concerned that, among other things, confidentiality clauses in arbitration agreements prohibit residents from reporting incidents to federal and state surveyors and other health representatives, including the LTC Ombudsman.

In the Proposed Rule, CMS considered an outright prohibition on binding arbitration agreements, but the agency acknowledged that several courts have

upheld such agreements and alternative dispute resolution has advantages for both residents and facilities. CMS nonetheless remains concerned that notwithstanding the Proposed Rule's provisions, residents may still feel coerced into signing binding arbitration agreements. As such, CMS seeks comment regarding whether binding arbitration agreements should be banned entirely.

The Proposed Rule would require that: (1) the agreement is fully explained (the preamble states that such explanation must, at a minimum, notify the resident that they are waiving their right to judicial relief); (2) the resident acknowledges understanding the agreement; (3) the agreement must be entered into voluntarily and admission into the facility may not be contingent upon the patient signing the agreement (the preamble states that readmission and continued stay also must not be contingent upon executing a binding arbitration agreement); (4) the agreement must provide for a neutral arbiter at a venue convenient to both parties; and (5) the agreement may not contain any prohibition or discouragement of residents (or others) from communicating with federal, state, or local health care officials, including the LTC Ombudsman.

In assessing whether the agreement is "voluntary" and "not contingent," the preamble states that the binding arbitration provisions should be separate from any other resident admission documents so patients can affirmatively accept or reject such agreement.

Finally, CMS also attempts to "address concerns" regarding potential conflicts of interest by imposing certain requirements when a party related to the facility acts as the guardian for a patient. In particular, CMS proposes to require that the patient's representative or guardian cannot sign a binding arbitration agreement unless such act is permitted under state law, all other requirements of the Proposed Rule are satisfied, and the representative or guardian "has no interest in the facility."

Conclusion Given the changes in the diversity and clinical complexity of LTC facility residents, CMS clearly believes that these significant revisions in the participation requirements are necessary. Further, since 1991, evidence-based research has improved knowledge regarding resident safety, health outcomes, individual choice, and quality assurance and performance improvement. Given the substantial costs estimated by CMS in the Proposed Rule and the scope and sometimes highly-detailed and burdensome provisions of the Proposed Rule, we recommend that affected parties submit robust comments and specific recommendations on the Proposed Rule's changes. Comments may be submitted until October 14, 2015.

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[1] Centers for Medicare & Medicaid Services, Reform of Requirements for Long-Term Care Facilities, 80 Fed. Reg. 42,168 (July 16, 2015), *available at* http://www.gpo.gov/fdsys/pkg/FR-2015-07-16/pdf/2015-17207.pdf.

[2] 80 Fed. Reg. 55,284 (Sept. 15, 2015), *available at* http://www.gpo.gov/fdsys/pkg/FR-2015-09-15/pdf/2015-23110.pdf.

[3] 80 Fed. Reg. 42,168, 42,174 (July 16, 2015); CMS, Data Compendium, 2002 edition, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/DataCompendium/index.html.

[4] *Id*. at 42,175.

[5] *Id*. *See also* 42 U.S.C. § 1396r(b)(2); 42 U.S.C. § 1395i–3(b)(2).

[6] *Id*. at 42,175-77.

[7] *Id*. at 42,177.

[8] *Id*. at 42,178.

[9] *Id*. at 42,199.

[10] *Id*. at 42199-202.

[11] *Id*. at 42,201-02.

[12] *Id*. at 42,202.

[13] *Id*. at 42,199-202.

[14] 80 Fed. Reg. 42202-203.

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

> Quality assessment and assurance.
>
> (1) A facility must maintain a quality assessment and assurance committee consisting of—
>
> (i) The director of nursing services;
>
> (ii) A physician designated by the facility; and
>
> (iii) At least 3 other members of the facility's staff.
>
> (2) The quality assessment and assurance committee—
>
> (i) Meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and
>
> (ii) Develops and implements appropriate plans of action to correct identified quality deficiencies.
>
> (3) A State or the Secretary may not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section.
>
> (4) Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions. (Emphasis added.)

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

[17] In this Client Alert, we refer to quality improvement/quality assurance committees as "QAA committees," while recognizing that some facilities refer to such committees as quality improvement committees, or QIC.

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

[19] 75 Fed. Reg. 58,204 (Sept. 23, 2015), available at http://www.gpo.gov/fdsys/pkg/FR-2010-09-23/pdf/2010-23579.pdf.

[20] 76 Fed. Reg. 5862 (Feb. 2, 2011), available at http://www.gpo.gov/fdsys/pkg/FR-2011-02-02/pdf/2011-1686.pdf.