

If you have questions or would like additional information on the material covered in this Alert, please contact one of the authors:

Carol C. Loepere

Partner, Washington, D.C.
+1 202 414 9216
cloepere@reedsmith.com

Susan A. Edwards

Associate, Washington, D.C.
+1 202 414 9261
sedwards@reedsmith.com

Kelly Hibbert

Associate, Washington, D.C.
+1 202 414 9226
khibbert@reedsmith.com

Julia Krebs-Markrich

Counsel, Tysons
+1 703 641 4232
jkrebs-markrich@reedsmith.com

Vicki J. Morris

Associate, Philadelphia
+1 215 241 7974
vmorris@reedsmith.com

Yetunde D. Oni

New Associate
Washington, D.C.
+1 202 414 9472
yoni@reedsmith.com

...or the Reed Smith lawyer with whom you regularly work.

CMS Issues Sweeping Final Rule, Significantly Changing the Requirements for Long-Term Care Facilities Participating in the Medicare and Medicaid Programs

The Centers for Medicare & Medicaid Services (CMS) recently issued its first major update to the requirements of participation for long-term care (LTC) facilities participating in the Medicare and Medicaid programs. This update, the first in 25 years, establishes significant new regulatory requirements and modifies existing requirements. Given the potential consequences of failure to substantially comply with the lengthy and burdensome requirements, such as penalties, denial of payment for new admissions, and possible termination from the Medicare and Medicaid programs, we urge all LTC facilities to carefully review, understand, implement, and continue to comply with the newly updated requirements.

Introduction

On September 28, 2016, the Centers for Medicare & Medicaid Services (CMS) issued a final rule comprehensively updating and extensively revising the requirements for participation (ROPs) for long-term care (LTC) facilities participating in the Medicare and Medicaid programs (the [Final Rule](#)).¹ As the first major update to the requirements for LTC facilities in 25 years, the Final Rule will have a dramatic impact on LTC facility operations and finances. The Final Rule adopts numerous changes to the existing ROPs proposed in the [July 16, 2015 proposed rule](#),² and also includes various revisions to the proposed rule, in particular, modifications to the staffing and training requirements, care planning rules, infection prevention and control program provisions, and the prohibition on facilities' use of pre-dispute arbitration agreements.

As an indication of the expected impact of the Final Rule and the differences from the proposed rule, CMS has increased its estimates of the total projected cost of implementation. CMS states that it expects complying with the ROPs to cost

\$831 million in the first year (up from \$729 million), or an estimated \$62,900 per facility (up from \$46,491 per facility), and approximately \$736 million annually in the second and subsequent years (up from \$638 million), or \$55,000 per facility (up from \$40,685 per facility). The Final Rule's projected costs are exceedingly conservative, especially for LTC facilities in certain parts of the country where, for example, hiring and retaining certain facility staff with the required qualifications may be challenging. The cost of compliance will also vary depending on the extent to which facilities already have adopted and implemented certain policies, procedures, and practices covering the requirements. The stakes for a facility's noncompliance are high, as LTC facilities face penalties, denial of payment for new admissions, and possible termination from the Medicare and Medicare programs for failure to achieve substantial compliance with the onerous ROPs.

CMS reports that it received nearly 10,000 public comments on the proposed rule. In response to comments regarding the cost and resources required to achieve compliance with these significant new requirements, CMS will phase-in implementation in three phases. Phase One, which includes many of the health and safety requirements, must be implemented by the effective date of the regulations, **November 28, 2016**. Phase Two and Phase Three require compliance by one year and three years, respectively, from the effective date of the Final Rule (i.e., November 28, 2017 and November 28, 2019), as discussed further below.

Overview of the Final Rule and Phased-In Implementation

In the preamble to the Final Rule, CMS observes that there has not been a comprehensive update to the requirements for LTC facilities since 1991, despite significant innovations in resident care, evidence-based research, and improved knowledge regarding resident safety, health outcomes, individual choice, and quality assurance and performance improvement. Moreover, CMS notes that residents have become more diverse and clinically complex in the decades since 1991. In CMS' view, the revisions to the requirements are intended to improve the quality of life, care and services in LTC facilities, while eliminating duplicative, unnecessary, and burdensome provisions.³

Additionally, the Final Rule, as with the proposed rule, reflects 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. Similarly, the Final Rule addresses certain "cross-cutting" health policy issues, including decreasing the inappropriate use of antipsychotic medications and reducing health care-associated infections.

Finally, the Final Rule codifies certain statutory provisions enacted by the Patient Protection and Affordable Care Act (ACA) for LTC facilities, including requirements to: (1) implement a compliance and ethics program;⁴ (2) establish and implement a Quality Assurance and Performance Improvement (QAPI) program;⁵ and (3) train nursing aides on dementia management and abuse prevention.⁶ In addition, the Final Rule implements an Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) requirement regarding the discharge planning process.⁷

CMS' recognition of the enormous amount of time and resources needed to achieve compliance with the new requirements is reflected by the fact that CMS has agreed to phase-in implementation of the requirements. Specifically, in response to numerous comments, the Final Rule will be implemented in three phases:

- Phase One – by **November 28, 2016**, facilities must be in compliance with the vast majority of the resident rights, quality of care, and health and safety requirements of the Final Rule, including the ban of the use of pre-dispute arbitration agreements.
- Phase Two – by **November 28, 2017**, facilities will be required to implement additional elements of the requirements, including transfer/discharge documentation, baseline care plans, monthly medical chart reviews by a pharmacist, antibiotic stewardship, physical environment smoking policies, and an initial QAPI plan, among others.
- Phase Three – by **November 28, 2019**, facilities will be required to implement their QAPI plan, including integration with other components of the requirements; provide trauma informed care; establish an infection preventionist (IP) and participation of the IP on the QAA Committee; establish and implement the new requirements for a compliance and ethics program; and conduct enhanced training.

The Final Rule includes the following key provisions:

- Banning an LTC facility's use of pre-dispute arbitration agreements after the effective date of the Final Rule, November 28, 2016
- Implementing a "competency based" staffing approach to ensure that LTC facilities are appropriately staffed; note, however, that the Final Rule does not adopt minimum staffing ratios
- Restructuring the residents' rights section and expanding the role of the resident representative
- Specifying that a resident's attending physician must be licensed; however, the agency withdrew its more specific proposed credentialing requirement
- 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 visitation provisions included in the hospital conditions of participation (CoPs), but allows for restrictions for clinical and resident safety
- 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 transferred from a facility, implement a discharge planning process, and follow the discharge planning requirements of the IMPACT Act
- Clarifying what is meant by appropriate coordination of a resident's assessment with the Preadmission Screening and Resident Review (PASARR) program under Medicaid
- Adding a new section requiring facilities to develop a baseline care plan within 48 hours of admission, including instructions needed to provide effective and person-centered care
- 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 QAPI program (which continues to give surveyors and CMS broad access to QAPI-related documents)
- Permitting physicians to delegate dietary orders to qualified dietitians or other clinically qualified nutrition professionals, and therapy orders to therapists
- Requiring facilities to develop an Infection Prevention and Control Program (IPCP) that includes an Antibiotic Stewardship Program and designates at least one IP
- Mandating a pharmacist review of a resident's medical chart every month (rather than every six months), and in instances where the resident is new to the facility, or 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

“Commitment to Person-Centered Care for Long-Term Care Facility Residents”

Throughout the Final Rule, CMS stresses the need to modernize LTC facility requirements, synchronize them with other laws, and implement certain provisions of the ACA and the IMPACT Act. CMS states that these changes are necessary, given the increase in individuals seeking LTC services; the clinical complexity and higher acuity of facility residents; and the increase in the LTC facility resident population requiring behavioral health services for illnesses like dementia and depression.

In light of these developments, one of CMS' goals in the Final Rule is to align its minimum health and safety requirements for LTC facilities with current clinical practices actually applied in the LTC setting for person-centered care. The Final

Rule defines “person-centered care” to mean a “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.” The agency also states that it seeks to “allow flexibility to accommodate multiple care delivery models to meet the needs of the diverse populations that are provided services in these facilities.”⁸ 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.”⁹

The Final Rule’s second goal, as articulated by CMS in the preamble, 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, CMS in 2012 launched the Initiative to Reduce Avoidable Hospitalization among Nursing Facility Residents. CMS states that the Final Rule strengthens the minimum health and safety standards for LTC facilities in hopes of reducing avoidable rehospitalizations.
- *Healthcare-Associated Infections (HAI)* – CMS also has made numerous revisions to the LTC facility requirements to support HHS’ initiatives dedicated to reducing the incidence of HAIs across providers, thereby assisting in reducing overall health care costs (e.g., integrating the IPCP with the facility’s QAPI processes).
- *Behavioral Health* – CMS has made changes to support its initiative aimed at improving behavioral health care and reducing the use of unnecessary antipsychotic medications in LTC facilities.
- *Health Information Technology* – CMS references HHS’ health IT initiatives and the exchange of health information to improve health care generally. CMS explains that the use of such technology can effectively and efficiently help facilities and other providers improve internal care delivery practices, support the exchange of important information across care team members (including patients and caregivers) during transitions of care, and enable reporting of electronically specified clinical quality measures (eCQMs).
- *Trauma-Informed Care* – CMS also intends to assist HHS’ activities designed to support and raise awareness for trauma survivors, including a targeted effort to support the needs of Holocaust survivors. CMS explains that utilization of trauma-informed approaches is an essential part of person-centered care.

Finally, CMS states that it hopes to eliminate unnecessary, outdated, confusing, and/or duplicative regulations. In assessing the benefits of the rule, as compared with the costs for facilities, CMS claims that the Final Rule “creates new

efficiencies and flexibilities for facilities that are likely to reduce avoidable hospital readmissions, increase the rate of improvement in quality throughout facilities, and create positive business benefits for facilities.”¹⁰

In justifying the increased cost of the implementation of and compliance with the Final Rule on LTC facilities of more than \$62,000 in the first year and \$55,000 in each year thereafter, CMS asserts that these costs are significantly less than the amount of Medicare and Medicaid spending for LTC services. According to the 2015 Annual Report of the Medicare Trustees, payments for SNF services from Medicare Part A were \$29.92 billion for fiscal year 2015, and payments for NF services were \$50.6 billion for fiscal year 2013.¹¹ Of course, Medicare and Medicaid payments to LTC facilities are intended to reimburse providers for the costs incurred in the services they furnish, for hiring and contracting with staff to care for residents, for maintaining and operating buildings, for medications and equipment, insurance, and the like. Thus, CMS’ comparison between the costs of implementing and complying with the ROPs and facilities’ reimbursement is illogical. While CMS states that reimbursement issues are beyond the scope of the Final Rule, CMS encourages commenters to address Medicaid reimbursement and public aid concerns to relevant state agencies and departments.¹²

In many ways, the Final Rule reflects the advancements in care for residents of LTC facilities and quality initiatives already underway in many facilities across the country. The focus on person-centered care is one that the long-term care industry has embraced for many years, and continual attention to quality improvement is a laudable and shared goal. Notwithstanding these benefits, the Final Rule imposes detailed, highly prescriptive and, in some areas, paternalistic requirements for providing quality care in LTC facilities. We expect there will be many areas in which health care facilities and their representatives will seek clarification and/or revisions to these requirements. We also understand that CMS will be issuing guidance to surveyors in the State Operations Manual and potentially other guidance documents to clarify how LTC facilities and surveyors should implement the ROPs. As with many regulations, the devil is in the details of how such regulations are implemented, and therefore, we urge facilities and other interested parties to continue to monitor sub-regulatory guidance as they work to respond to and develop policies and procedures to comply with the Final Rule.

Below we discuss the Final Rule’s key provisions and major changes from the proposed rule.

Binding Arbitration Agreement Prohibition

One of the most discussed and controversial provisions in the Final Rule is the prohibition on LTC facilities’ use of pre-dispute, binding arbitration agreements. This prohibition is significant, in part because LTC facilities in certain states rely on arbitration in the dispute-resolution process in order to manage their liability costs, and in part because CMS arguably exceeds the bounds of its statutory authority in adopting a complete ban of pre-dispute, binding arbitration agreements. The

Final Rule also prohibits facilities from requiring a resident to sign an arbitration agreement as a condition of admission to the facility.

While in the proposed rule CMS sought comments regarding whether binding arbitration agreements should be banned entirely, the agency did not expressly propose the prohibition of pre-dispute agreements included in the Final Rule. Instead, the agency proposed that (1) any agreement for binding arbitration between a facility and a resident must be fully explained; (2) the resident must acknowledge understanding of the agreement; (3) the agreement must be entered into voluntarily and admission to the facility may not be contingent upon the patient signing the 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. The proposed rule also would have forbidden a patient's representative or guardian from signing a binding arbitration agreement unless such act is permitted under state law, would have required all other requirements of the proposed rule were satisfied, and that the representative or guardian "has no interest in the facility."

The Final Rule adopted the same five requirements discussed above, with limited changes.¹³ However, the requirements now only apply to agreements for binding arbitration entered into between the facility and a resident *after a dispute has already arisen*; of course, these requirements apply only to post-dispute agreements because the Final Rule prohibits pre-dispute agreements.¹⁴ Further, the resident's continuing rights to remain in the facility must not be contingent upon the resident or the resident's representative signing the agreement.¹⁵ One new requirement under this subsection provides that "[w]hen the facility and a resident resolve a dispute with arbitration, a copy of the signed agreement for binding arbitration and the arbitrator's final decision must be retained by the facility for 5 years and be available for inspection upon request by CMS or its designee."¹⁶

The Final Rule means that, as of the effective date of this rule,¹⁷ November 28, 2016, LTC facilities are prohibited from entering into pre-dispute arbitration agreements with residents or their representatives if the facility intends to participate in the Medicare and Medicaid programs. The Final Rule does not affect any pre-dispute arbitration agreements that were entered into prior to November 28, 2016. Such pre-dispute agreements are valid, enforceable, and will not result in a violation of the requirements for participation as long as it is clear that they were entered into prior to November 28, 2016. Further, the Final Rule does not prohibit facilities and residents from entering into binding arbitration agreements after a dispute has arisen. It does, however, dictate certain requirements for those post-dispute agreements.¹⁸

CMS' suggestion, in the proposed rule, of an outright prohibition on binding arbitration agreements in the LTC setting prompted much concern as evidenced by the significant number of public comments from the LTC industry on the

issue.¹⁹ The public comments focused mostly on whether the Secretary and CMS had authority to enact the proposed provisions pertaining to binding arbitration agreements. Specifically, many of the public comments argued that the proposed rule and CMS' suggestion that binding arbitration agreements should be banned altogether ran afoul of the Federal Arbitration Act (FAA)²⁰, the Non-Delegation and Separation of Powers Doctrines, and the statutory authority granted to the Secretary and CMS.

CMS noted that some commenters "believed that arbitration should not be allowed in LTC facilities under any circumstances."²¹ In support of its decision to include the provision prohibiting pre-dispute arbitration agreements, CMS also cited multiple letters from senators and state attorneys general urging CMS to ban such agreements.²² Arguably bowing to political pressure, CMS adopted a rule that, in our view, clearly contradicts federal policy.

CMS' response that the prohibition of pre-dispute agreements does not implicate the FAA focuses on the fact that the Final Rule's prohibition does not apply to pre-dispute arbitration agreements that existed prior to the effective date of the Final Rule, which is November 28, 2016. In other words, the Final Rule only prohibits future pre-dispute agreements; thus, at least according to CMS, the FAA does not apply because the Act only applies to existing arbitration agreements.²³ This notion – that the FAA only applies to existing arbitration agreements – is a fallacy. In *Marmet Health Care Center, Inc. v. Brown*, which CMS addresses in its preamble to the Final Rule, the United States Supreme Court noted that the FAA "reflects an emphatic federal policy in favor of arbitral dispute resolution." The policy is not limited to enforcement of existing agreements.²⁴ Instead, as highlighted by the Court's holding in *Marmet*,²⁵ it extends to promote the use of arbitration as a legitimate form of adjudication. Therefore, the *Marmet* holding is arguably in direct conflict with the Final Rule's prohibition of pre-dispute arbitration agreements.

In response to comments stating that the Secretary and CMS were without statutory authority to restrict the ability of facilities and residents to enter into pre-dispute agreements, and that the proposed requirements violate the Non-Delegation and Separation of Powers Doctrines, CMS stated that the Social Security Act authorizes her to promulgate rules to protect the health, safety, and well-being of LTC residents, and therefore, provides her with the authority to regulate arbitration agreements. CMS concludes that "it is unconscionable for LTC facilities to demand, as a condition of admission, that residents or their representatives sign a pre-dispute agreement for binding arbitration that covers any type of disputes between the parties for the duration of the resident's entire stay, which could be for many years."²⁶ According to CMS, this supposed unconscionability affects the well-being of the residents. What CMS fails to acknowledge is that unconscionability is a contract defense. As such, if a court of law were to find that the terms of an arbitration agreement were indeed unconscionable, it could invalidate the agreement as a matter of contract law. The

Final Rule takes this important power away from the judiciary by deeming pre-dispute arbitration agreements unconscionable in their entirety.

In summary, the Final Rule's arbitration provision, to be codified at § 483.70(n), prohibits a facility from contracting with its residents to ensure that any disputes that may arise in the future between the facility and the resident are adjudicated efficiently and at a reduced cost through binding arbitration. The Final Rule is a categorical rule (applying only to pre-dispute agreements) that prohibits arbitration of a particular type of claim (claims against LTC facilities).

In response to the arbitration ban included in the Final Rule, the leading trade association for long-term care providers—the American Health Care Association—along with three providers in Mississippi and Texas, filed a complaint for declaratory and injunctive relief requesting that the Mississippi federal court issue an injunction in advance of the November 28 effective date of this provision.²⁷ The providers argue that CMS and the Department of Health and Human Services do not have the authority under the Social Security Act, or any other legislation, to usurp the FAA by restricting patients and nursing homes from entering into legitimate contracts, including a pre-dispute arbitration agreement. We will be closely monitoring this litigation and will publish further updates regarding this case.

Residents' Rights and Facility Responsibilities

The current ROPs 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. In the Final Rule, CMS retains all existing residents' rights, but updates 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 clarifies 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. In doing so, CMS adopts the language of the proposed rule nearly verbatim and emphasizes deference to state law on this issue. Specifically, CMS confirms that: (1) a resident who has been adjudged incompetent under the laws of a state retains the right to exercise those rights not addressed by a court determination; (2) the resident representative can only exercise the rights that devolve to them as a result of the court determination; (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 finalizes 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 his or her person-centered plan of care. For example, in response to commenters and in an effort to further promote a resident's right to be informed while balancing the burden imposed upon facilities, CMS now requires facilities to provide residents and their resident representatives with a summary of their baseline care plan. This summary must include, but is not limited to, the initial goals of the resident, a summary of the resident's medications and dietary instructions, any services and treatments to be administered by the facility and personnel acting on behalf of the facility, and any updated information based on the details of the comprehensive care plan, as necessary. Additionally, while other 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 requires and stresses the importance of the facility to recognize each resident's individuality and provide services in a personalized, patient-centered manner. Specifically, the Final Rule confirms it is the responsibility of the practitioner to discuss the risks and benefits of proposed care, treatment, and treatment alternatives or options with a resident or their representative, and specifies 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 affirms the resident's right set forth in the proposed rule 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. The resident's right 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. Commenters expressed concern that the right of one resident to have a roommate of choice could violate the rights of an existing roommate. CMS has responded that it included the phrase "when practicable" in the regulation, recognizing that such arrangements may not always be possible, or may require some delay in order to accommodate. For example, a move may require waiting until a room is available for both residents who want to be roommates. CMS states it would not expect a facility to accommodate a roommate request when doing so would violate the rights of another resident. Further, the Final Rule requires written notice, including the reason for the change, when the resident's room or roommate in the facility is changed, and clarifies that a room change cannot occur solely for the convenience of staff. Separately, in response to commenters' suggestions, CMS added a new requirement that the facility exercise reasonable care for the protection of the resident's property from loss or theft.

In the proposed rule, CMS also included revisions ensuring that residents can receive visitors of choice at the time of their choosing, among other visitation

rights. Many commenters expressed safety and practicability concerns with regard to open visitation. Some stated that having unexpected visitors entering the facility at any time of day or night is unreasonable, disruptive, and potentially dangerous, but suggested that pre-arranged visits during “off-hours” could be accommodated and felt that, in order for a facility to provide a safe and secure environment for all patients and residents, reasonable parameters must be applied to “open” visitation. Other commenters noted that around-the-clock visitation would require increased staffing and financial burden to the facility. In response, CMS revised the language related to the resident’s right to receive visitors in the Final Rule, establishing that the facility must have written policies and procedures for visitation that includes restrictions, clarifying that restrictions on visitation apply only to those categories of visitors where such restriction is permitted by regulation, acknowledging that the facility may need to place clinical or safety restrictions on visitation rights and should explain the reasons for the restriction or limitation, and require the facility to inform each resident not only of any limitation, but also to whom the restrictions apply.

The Final Rule also updates and expands provisions related to the resident’s right to access facility-specific information, personal and 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 (without making available identifying information about complainants or residents), and other notices and information that the facility is required to provide the resident. In response to comments on the proposed rule, CMS clarifies that while residents or their representatives may wish to do so, they are not required to inspect a record prior to purchasing it. Additionally, CMS takes 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, so long as the use of the internet, or any form of communication, is in compliance with other legal limitations and restrictions relating to those devices or systems. 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 Final Rule requires that the facility establish a grievance policy to ensure the timely resolution of grievances and to identify a Grievance Officer. Specifically, the Final Rule confirms that the resident has a right to receive information and contact information for filing grievances or complaints, and the facility must post similar information, in a form and manner accessible and understandable to residents and resident representatives. CMS expands the scope of grievances in the Final Rule to include those related to care and treatment that has been furnished, as well as that which has not been furnished, the behavior of staff and of other residents, and other concerns regarding their LTC facility stay. In addition, the facility is required to take a number of specified

actions in response to a grievance. CMS clarifies, however, that it is not, at this time, requiring prescriptive timeframes to resolve grievances, and defers to sub-regulatory guidance to suggest what constitutes a timely response to a grievance. Additionally, CMS clarifies that a facility need not hire a new, full-time individual to perform a grievance function, but, instead, that every facility have a designated individual to serve this function, consistent with the needs of that facility.

With regard to issues related to resident funds and charges, the facility, under current requirements, must hold, safeguard, manage, and account for the personal funds of the resident deposited with the facility, including establishing and maintaining 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, and providing the individual a financial record through a quarterly statement, as well as on request. According to CMS, current interpretive guidance establishes that "hold, safeguard, manage and account for" means that the facility must act as fiduciary of the resident's funds, report at least quarterly on the status of these funds in a clear and understandable manner, and include, in such report, money that an individual gives to the facility for the sake of providing a resident with a non-covered service. Accordingly, CMS strengthens its regulations to state that the facility must act as a fiduciary of a resident's funds in the Final Rule. Specifically, CMS includes new requirements focusing on the facility's responsibility related to the protection of resident funds. For example, CMS prohibits a facility 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 Final Rule further clarifies that a facility may 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.

Finally, based on commenter concerns, CMS withdrew its proposed language that would have required physicians furnishing care to facility residents to meet facility credentialing requirements. However, the agency finalizes the requirements that the physician must be licensed to practice medicine,²⁸ and must meet applicable regulatory requirements. In the event that it becomes necessary for a facility to seek alternate physician participation, the facility must discuss this with the resident and honor the resident's selection of a new attending physician.

The effective date of the resident rights and facility requirements is the effective date of the final rule, November 28, 2016, with one exception: 42 C.F.R. § 483.10(g)(4)(ii)-(v), which will be implemented in Phase Two, or November 28, 2017.

Freedom from Exploitation, Neglect and Abuse

CMS redesignates the current 42 C.F.R. § 483.13, "Resident Behavior and Facility Practices" to "Freedom from Abuse, Neglect and Exploitation." In the preamble,

the agency indicates that ensuring that residents of long-term care facilities are protected is an important purpose of the ROPs, a goal that is facilitated by this section. In the Final Rule, CMS modifies a current prohibition on the employment of individuals who: (1) have been found guilty of abuse, neglect, exploitation, or mistreatment of residents by a court of law; or (2) had a finding of abuse, neglect, exploitation, mistreatment of resident or misappropriation of property reported into a state nurse aide registry, to prohibit “otherwise engag[ing]” such individuals, and also to prohibit employing or otherwise engaging individuals who have (3) have a disciplinary action in effect against a professional license by a state licensure body as a result of a finding of abuse, neglect, exploitation, or mistreatment of residents, or a finding of misappropriation of property. In the Final Rule, CMS modified the proposal related to disciplinary actions taken against a professional license to include only such actions currently in effect to allow facilities some flexibility with potential employees with previously resolved disciplinary actions. In the preamble, CMS also indicates that it does not expect facilities to query all 50 states for information on each licensed individual; but instead the agency expects that the facility will check with the state in which the facility is located, and potentially bordering states or other states where the individual is known to have been licensed.²⁹ CMS also indicates that it will provide further information and discussion regarding this requirement in sub-regulatory guidance.

The Final Rule also requires 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 Final Rule requires 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.

Admission, Transfer, and Discharge Rights

Under the Final Rule, the section designated “Admission, Transfer, and Discharge Rights,” found at 42 C.F.R. § 483.15, includes a number of notable provisions. First, this section prohibits LTC facilities 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 provision may not adequately account for residents’ personal responsibility with respect to safeguarding their own personal property. In the preamble, CMS indicates that “[t]his provision does not make the facility automatically liable for every loss of personal property, nor preclude the facility from having policies that establish when the facility is liable.”³⁰

Second, facilities are required to disclose and provide current residents or potential residents with notice of any special characteristics or service limitations at the facility. For example, any religious affiliations impacting resident care must be disclosed. Similarly, notice is 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 Final Rule allows a resident to be discharged when the safety of other individuals is endangered because of the clinical or behavioral status of the resident. Importantly, in a significant change from the current regulations, LTC facilities are prohibited from transferring or discharging a resident when a resident exercises his or her appeal rights to challenge a transfer or discharge, unless the failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility. In that instance, the facility must document the danger that failure to transfer or discharge would pose. In the preamble to the proposed rule, 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 read this provision to effectively mean that an LTC facility could discharge a resident if an appeal is pending only in limited circumstances (which could take months, and possibly even years, in certain instances).

Noting the importance of effective communication between providers during transitions of care, CMS finalizes certain proposals regarding transfers from the facility. As noted below regarding physician services, CMS withdrew the proposal to require an in-person physician visit prior to a resident's unscheduled transfer from a facility. Nonetheless, transfers and discharges must 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 are now 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 is required to provide certain information to the receiving entity, such as contact information of the practitioner responsible for the care of the resident; resident representative information including contact information; Advance Directive information; all special instructions or precautions for ongoing care, as appropriate; comprehensive care plan goals; and all other necessary information, including a copy of the resident's discharge summary and any other documentation, as applicable, to ensure a safe and effective transition of care. CMS indicates that it made changes from the proposed rule's specific data elements to "a more flexible list of elements to be documented in the resident's clinical record and communicated to the receiving health care institution or provider."³¹ While CMS is not mandating a certain form, format, or methodology for this communication, the agency indicates in its preamble discussion that it will consider the development of a specific form in future rulemaking.³²

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, rather than the facility's judgments, should guide facility decision-making.

Lastly, through the care planning process, CMS encourages 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, the Final Rule requires 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, and to the extent practicable, the resident and resident representative. In addition, the facility must provide the resident and his or her representative with a summary of the baseline care plan that includes, but is not limited to: (1) the initial goals of the resident; (2) a summary of the resident's medications and dietary instructions; (3) any services and treatments to be administered by the facility and personnel acting on behalf of the facility; and (4) any updated information based on the details of the comprehensive care plan, as necessary.

Given CMS' desire to ensure safe transitions of care across all providers, the Final Rule seeks to strengthen LTC facility requirements for discharge planning. Specifically, the Final Rule adds a requirement that LTC facilities develop and implement an effective discharge planning process that focuses on the resident's discharge goals, the preparation of residents to be active partners and effectively transition them to post-discharge care, and the reduction of factors leading to preventable readmissions. Such a process must ensure that the discharge goals and needs of each resident are identified. Further, residents' discharge plans must be re-evaluated on a regular basis to identify and implement changes to the plan.

Physician Services, Nursing Services, Behavioral Health Services

Physician Services

As part of its reorganization of the regulations setting for the ROPs, CMS moved requirements for physician services from 42 C.F.R. § 483.40 to re-designated § 483.30. Requirements for physician services previously found at § 483.40 were largely retained with some modification. In the Final Rule, CMS declined to adopt

the most controversial proposal in this part of the proposed rule, which would have required an in-person evaluation of a resident to be conducted prior to an unscheduled transfer to a hospital.

Re-designated § 483.30 continues the requirement that a physician must personally approve, in writing, a recommendation that an individual be admitted to a facility, and that every resident remain under the care of a physician while in the facility. The Final Rule makes explicit, however, that upon admission to a facility, a physician, physician assistant, nurse practitioner or clinical nurse specialist must provide orders for the resident's immediate care needs. CMS explains that the rationale behind this requirement is to ensure that an individual resident receives care for his/her specific needs until a comprehensive assessment and care planning can be completed.³³

CMS retains former 483.40(f), now re-designated as § 483.30(g), which permits states to give nursing facilities the discretion to allow a nurse practitioner, clinical specialist or physician assistant who is not an employee of the facility but working in collaboration with a physician, to perform tasks that the regulations specify must be performed by a physician. In the preamble, CMS states it has no authority to modify the language of re-designated 483.30(g).

The Final Rule does, however, authorize physicians who are responsible for the care of the resident to delegate certain tasks to dietitians and therapists, who may or may not be facility employees. Under § 483.30(e)(2), an attending physician may delegate to a qualified dietitian or another clinically qualified nutrition professional the task of writing dietary orders, as long as this is permitted under state law. Similarly, under new § 483.30(e)(3), an attending physician may delegate to a qualified therapist the task of writing therapy orders, as long as such delegation is permitted under state law. CMS explains that therapists may have more frequent direct contact with residents and therefore may be better able to be more responsive to resident needs. However, only the attending physician has authority to delegate such activity, and the resident's care must remain under the supervision of the attending physician.³⁴

Nursing Services

The Final Rule relocates the requirements for nursing services to 42 C.F.R. § 483.35. Recognizing the potential for unintended adverse consequences and that one size does not fit all, the Final Rule does not impose minimum staffing ratios or mandate the presence of a 24/7 registered nurse.³⁵ The Final Rule does, however, require that a facility have "sufficient nursing staff" with "appropriate competencies and skills" necessary to assure resident safety and to attain or maintain the "highest practicable physical, mental and psychosocial well-being of each resident."

For an individual facility, the determination of what constitutes "sufficient nursing staff" with "appropriate competencies and skills" will require the facility to undertake the "facility assessment" described at § 483.70(e) and make staffing

decisions that take into account the number of residents in the facility, the residents' acuity and diagnoses, and the skill sets necessary to provide the care needed. Perhaps gratuitously, the preamble to the Final Rule emphasizes that its facility-specific approach for regulating staffing is to "preclude facilities from making staffing decisions based solely on fiscal considerations without taking resident specific factors into account" as well as to preclude staffing decisions "from being made solely at a corporate level based on fiscal considerations and without taking facility- and resident-specific factors into consideration."³⁶

Along similar lines, the Final Rules requires at 42 C.F.R. § 483.35(a)(3) and (4) that a facility "ensure" that licensed nurses have the specific competencies and skill sets necessary to care for resident needs as identified through resident assessments and described in the plan of care. Providing care is described as including, but not limited to, assessing, evaluating, planning, and implementing resident care plans and responding to resident needs.

The Final Rule also expressly includes nurse aides in the term "other nursing personnel" under § 483.35(a)(1)(ii). Under § 483.35(c), a facility must ensure that nurse aides are able to demonstrate competency necessary to care for residents' needs as identified through resident assessment and described in the plan of care. The term "minimum" was added to § 483.35(c)(3) to signal that this section identifies minimum competency requirements for nurse aide. Non-permanent care givers are required to meet competency, knowledge, and skill requirements to the same extent as permanent personnel.

Behavioral Health Services

The Final Rule adds a new section § 483.40, regarding requirements for behavioral health services and social workers. The intended purpose of this new section is to "ensure that assessment and treatment of behavioral health issues are viewed with the same importance as the physical and receive the resources necessary to provide appropriate treatment to residents in need of behavioral health services."³⁷ The comment to the rule emphasizes that the new requirements neither mandate specific techniques or care, nor require facilities to forgo the use of any medically acceptable drugs or techniques.³⁸

Specifically, § 483.40 requires LTC facilities to have sufficient direct care staff with the appropriate competencies and skills—as determined by resident assessments, individual plans of care, and the number, acuity, and diagnoses of the facility's resident population—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. The competencies and skill sets include knowledge of and appropriate care and supervision for:

- (1) caring for residents with mental and psychosocial disorders, as well as residents with a history of trauma and/or post-traumatic stress disorder;
- (2) implementing non-pharmacological interventions;

- (3) ensuring, based on a resident’s comprehensive care plan: (a) “that a resident who displays or is diagnosed with mental or psychosocial adjustment difficulty receives appropriate treatment and services to correct the assessed problem or to attain the highest practicable mental health and psychosocial well-being,” or (b) in the case of a resident whose assessment does not reveal or who does not have a diagnosis of a mental or psychosocial adjustment disorder, or history of trauma or post-traumatic stress disorder, ensuring that such resident does not develop a pattern of decreased social interaction, or withdrawn, angry or depressive behaviors unless the resident’s clinical condition demonstrates that development of such pattern was unavoidable;
- (4) ensuring that a resident who displays or is diagnosed with dementia receives appropriate treatment and services to maintain or attain his /her highest practical physical, mental, and psychosocial well-being;
- (5) providing required services for residents with mental disorders or intellectual disability whose care plan requires rehabilitative services directly or from qualified outside resources; and
- (6) providing medically related social services for each resident to attain or maintain the highest practical physical, mental, and psychosocial well-being.

In the preamble to the Final Rule, CMS states its view that “LTC facilities should already be complying with many of the requirements of this rule and that this should minimize the costs associated with complying with the rule.”³⁹

Pharmacy Services

The current regulations related to pharmacy services require that each resident’s drug regimen be reviewed by a pharmacist at least once a month.⁴⁰ Specifically, previous LTC requirements required the pharmacist who conducted the monthly drug regimen review (DRR) to report any irregularities to the attending physician and the director of nursing. The Final Rule requires 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.

According to CMS, the Final Rule provides clarity and strengthens the protections for residents from the use of inappropriate drugs. For example, the Final Rule requires: (1) that each resident’s medical record be reviewed in conjunction with the monthly DRR; (2) that the pharmacist copy the facility’s medical director on the report of irregularities, in addition to the attending physician and the facility’s director of nursing; (3) that the attending physician document his or her review

and actions be taken for any identified irregularity (ensuring that the irregularity is reviewed, and that medication errors and potential adverse events related to medications are minimized); and (4) expanded protections related to psychotropic drugs in an effort to enhance protections for residents prescribed drugs that have an increased potential for being prescribed inappropriately.

Notably, in response to commenters suggesting that the rule as proposed was so burdensome that practitioners would be discouraged from using any psychotropic medication, even when appropriate, CMS modified its proposed language. Specifically, the Final Rule requires that the facility must establish and maintain policies and procedures that address the monthly DRR, including, but not limited to, timeframes for the various steps in the process and procedures a pharmacist is to take when he or she believes immediate action is required because of potential harm to the resident. While CMS agrees with commenters that physicians should not be required to repeatedly document the same rationale in the resident's medical record (once a clinically acceptable rationale is already documented in the medical record for a specific medication), the agency grants flexibility to each facility to determine the best manner in which to handle this situation, and encourages facilities to establish policies and procedures to address psychotropic drugs. CMS also modifies the definition of "psychotropic drug." The Final Rule narrows the broad scope of the definition as proposed, and removes "opioid analgesic" and "any other drug that results in effects similar to the drugs listed" from the definition of psychotropic drug.

Lastly, in response to comments on the use of PRN, or as needed, orders for psychotropic drugs 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, CMS modifies the limitation for PRN prescriptions of psychotropic drugs by extending the timeframe for PRN prescriptions to 14 days. Per the new 14-day limitation, each resident who is taking a psychotropic drug will have his or her prescription reviewed by the physician or prescribing practitioner every 14 days and also by a pharmacist every month. The agency also establishes an exception to this limitation. Specifically, for psychotropic drugs that the attending physician believes a PRN prescription for longer than 14 days is appropriate, the attending physician can extend the prescription beyond 14 days for the resident by documenting his or her rationale in the resident's medical record. However, this exception does not apply to anti-psychotic drugs. Under the Final Rule, if the attending physician believes that the resident requires an anti-psychotic drug on a PRN basis for longer than 14 days, he or she will be required to write a new PRN prescription every 14 days after the resident has been evaluated.

The changes specified in this section are generally effective on the effective date of the Final Rule, November 28, 2016. There are, however, a few exceptions, namely: 42 C.F.R. §483.45(c)(2) and §483.45(e), both which have a Phase Two, or November 28, 2017, implementation date.

Food and Nutrition Services

In this section of the Final Rule, CMS finalized its intention to improve the quality of life and health outcomes of LTC facilities' residents by requiring each facility to take each resident's preferences into consideration when providing meals to its residents. As described in the proposed rule, the meals provided must be nourishing, palatable, and well-balanced to meet each resident's daily nutritional and special needs. Some of the topics discussed, finalized or modified in this section of the Final Rule include: (1) staff sufficiency and credentials; (2) menus and nutritional adequacy; and (3) food procurement and residents' food storage; and implementation deadlines.

Staff Sufficiency and Credentials

CMS finalized the requirement in 42 C.F.R. § 483.60(a) that each facility employ sufficient staff. In complying with this requirement, CMS expects that each facility will use the newly required facility assessment to determine not only the number of staff needed, but also the level of competencies and skills required to carry out the services. CMS does not advocate a one-size-fits-all approach to food and nutrition services, and notes that facilities have some flexibility in determining how best to meet their residents' needs. However, at the very least, each facility must designate a director of food and nutrition services.

Further, CMS finalized its proposal for an attending physician to be able to delegate the task of prescribing a resident's therapeutic diet to a qualified dietician or other clinically qualified professional. The credentials these qualified professionals must have were also finalized, but with some revisions to the proposed rule. The definition of a qualified dietitian was changed to be more consistent with the definition of a "registered dietitian" or "nutritional professional" in section 1861(vv)(2) of the Social Security Act. In the proposed rule, a "registered dietitian" was defined as one who is registered by the Commission on Dietetic Registration of the Academy of Nutrition and Dietetics, or who meets state licensure or certification requirements. The Final Rule now defines a qualified dietitian or clinically qualified nutrition professional more broadly as one who: "(i) holds a bachelor's degree or higher...with completion of the academic requirements of a program in nutrition...; (ii) has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or professional; or (iii) is licensed or certified as a dietitian or nutrition professional by the state in which the services are performed." In addition, the Final Rule now requires that for a dietitian with a hospitality degree to be qualified, he or she must have taken a hospitality degree curriculum that "included food service management/restaurant management in [the] degree program."

Menus and Nutritional Adequacy

Although CMS finalized its proposal in § 483.60(c)(1) to require facilities to provide menus reflecting religious, cultural, and ethnic preferences of its residents, it also clarifies in the preamble that this requirement is not mandatory for every facility.

CMS states that the menu should only reflect, based on a facility's reasonable efforts, the religious, cultural and ethnic needs of the resident population. CMS also modified the standard that menus provided by facilities must only meet national guidelines.

Likewise, in re-designated § 483.60(f) of the proposed rule, CMS attempted to modify the strict meal frequency requirement of the current rule by withdrawing the requirements that: (i) "facilities provide three meals per day at regular times; or (ii) there must be no more than 14 hours between a substantial evening meal and breakfast the following day, or up to 16 hours when a nourishing snack is served at bedtime and a resident group agrees to this meal span." However, CMS only finalized the proposal to eliminate the first section of this requirement to state that, "meals [must] be served at times in accordance with resident needs, preferences, requests and the plan of care." CMS retained the existing requirement regarding the frequency of meals.

Food Procurement and Residents' Food Storage

Finally, CMS finalized its proposal that facilities may procure food directly from local producers in accordance with state and local laws, as well as its proposal that facilities have policies regarding use and storage of foods brought by residents' visitors.

Implementation Deadline

The changes specified in this section are generally effective on the effective date of the Final Rule, November 28, 2016. There are, however, a few exceptions:

- (i) services linked to Facility Assessment (implemented one year following the effective date, November 28, 2017);
- (ii) qualified dietitians or clinically qualified nutrition professional hired prior to the effective date have five years following the effective date (i.e., November 28, 2021) to achieve compliance;
- (iii) directors of food and nutrition services designated to serve prior to the effective date have five years following the effective date (i.e., November 28, 2021) to achieve compliance; and
- (iv) dietitians designated to serve after the effective date have two years (i.e., November 28, 2018) to achieve compliance.

CMS explains that it is carving out these exceptions for implementing the qualified professionals because it understands that there are many highly capable professionals with many years of food service experience without the specific credentials required by CMS. Thus, the later dates of implementation in these cases will allow for these professionals to continue to provide services in LTC facilities without the additional credentials specified by the Final Rule.

Infection Control

In this section of the Final Rule, CMS updates and strengthens the current requirements for infection control. Some of the topics discussed, finalized or modified comprise: (1) the Infection Prevention and Control Program, including the Antibiotic Stewardship Program; (2) Infection Preventionist; and (3) Implementation Deadlines.

The Infection Prevention and Control Program (IPCP)

CMS finalized, without major modifications, the requirements set forth in 42 C.F.R. § 483.80(a) of the proposed rule relating to the elements of the IPCP. The Final Rule, like the proposed rule, requires that the IPCP must include: (1) a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases; (2) written standards, policies, and procedures; (3) an Antibiotic Stewardship Program that includes a system for monitoring antibiotic use; and (4) a system for recording incidents identified under the facility's IPCP, as well as corrective actions taken by the facility. CMS finalized most of these requirements despite comments and concerns by the industry regarding the scope and level of detail required to develop and maintain the IPCP.

CMS specifically addressed the concern that the detail in the scope and components in the IPCP went well beyond what is required in hospitals' Conditions of Participation. CMS defended the detailed requirements of the IPCP on the basis that LTC facilities, as compared with hospitals, have residents who stay much longer, and LTC facilities' residents usually require care for chronic conditions. Further, CMS stated that such level of detail will help the public, and LTC facilities know what is expected for compliance.

Notwithstanding CMS' response to these concerns, it made a modification, in § 483.80(a)(2)(iv), relating to written policies and procedures for residents' isolation when there is an infection or communicable disease. CMS changed the language in this section to reflect concerns raised by commenters about how facilities' policies for residents' isolation have in the past, led to facilities barring visitors from gaining access to residents for a significant period of time. Commenters also raised concerns regarding how such isolations could have an adverse psychological impact on residents. The Final Rule now requires facilities to use "the least restrictive means" approach to infection control. Thus, § 483.80(a)(2)(iv) of the Final Rule now requires facilities' written procedures to include: "when and how isolation should be used for a resident, including but not limited to, (A) the type and duration of the isolation depending upon the infectious agent or organism involved, and (B) that the type and duration of the isolation should be the least restrictive possible for the resident under the circumstances."

The requirement for having an Antibiotic Stewardship Program in the IPCP was also finalized despite concerns raised by commenters. One commenter stated that efforts to comply with the criteria for giving antibiotics are usually undermined by certain scenarios, explaining that there is a disconnect in trying to comply

with the criteria of the Society for Healthcare Epidemiology of America (SHEA) for administering antibiotics, and the standard used by hospital emergency departments or state survey agencies regarding when antibiotics should be given. CMS responded to this concern by stating that it would work on developing sub-regulatory guidance and training for surveyors. Further, CMS referred stakeholders to a proposed rule with requirements for antibiotic stewardship programs for hospitals. This proposed rule updates the conditions for participation for hospitals for infection control and prevention.⁴¹

Infection Preventionist

CMS made some modifications to the requirement in the proposed rule that each facility have an Infection Prevention and Control Officer (IPCO). The IPCO is to be responsible for the IPCP and must have received specialized training in infection prevention and control. First, the Final Rule modifies the proposed rule by changing the title of the individual responsible from IPCO to Infection Preventionist (IP), and also allowing an LTC facility to designate more than one person to be responsible for the facility's IPCP. Thus, facilities have more flexibility in evaluating how many individuals and which individuals to designate as the IP.

Second, CMS relaxed the criteria for the type of training required by the IPCO (now IP). In § 483.80(b) of the proposed rule, CMS required that the individual designated as the IP must have received specialized training in infection prevention and control. However, in response to concerns raised by commenters regarding what specific trainings would qualify and the difficulty in finding qualified staff, CMS modified the proposed rule such that IPs need only have primary trainings in “nursing, medical technology, microbiology, epidemiology or other related field.” The IP can also be qualified by education, training, experience or certification.

Further, in response to comments, CMS did not finalize the requirement that the IPCP be a “major responsibility” for the IP. Some of the concerns included the burden such a responsibility would impose on nursing facilities, as well as the fact that the hospital CoPs do not specify such a requirement even though hospitals might have an even higher risk of infection. CMS, however, emphasized the need to have at least one individual designated as the IP. It also finalized the requirements that the IP be a member of the facility's Quality Assessment and Assurance (QAA) committee, and work at the facility at least part-time.

Finally, CMS finalized the requirements for influenza and pneumococcal immunizations as set forth in § 483.80(d) of the proposed rule without any modifications despite many concerns raised by commenters regarding the details of the requirement. Some of the commenters' concerns relate to the specific date ranges that CMS requires for providing these immunizations, and the very detailed requirements, including documentation, for these vaccines, which are not required for other vaccines. Other commenters requested justifications on why a different process of immunization is required for these vaccines in LTC facilities compared with other types of health care facilities. Most commenters, however, wanted

LTC facilities to have the option of developing their own policies and procedures for ensuring that residents are offered and receive the vaccines. CMS justified its position by explaining that, given the higher morbidity and mortality rates in LTC facilities, the influenza and pneumococcal vaccines are more important. Consequently, there is a need to have a greater level of detail, including dates and documentation required by the Final Rule.

Implementation Deadlines

Each facility is required to implement its IPCP upon the effective date of the Final Rule. Exceptions to this requirement include: (1) services linked to Facility Assessment (implemented in Phase Two, by November 28, 2017); (2) Antibiotic Stewardship (implemented in Phase Two, by November 28, 2017); (iii) designation of IP (implemented in Phase Three, by November 28, 2019); and (iv) IP participation on the QAA committee (implemented in Phase Three, by November 28, 2019).

QAPI Requirements

The Final Rule significantly modifies the QAA-related provisions included in the current ROPs imposed on LTC facilities, but includes only minor modifications from the proposed rule. As in the proposed rule, CMS explains in the preamble to the Final Rule that proposed 42 C.F.R. § 483.75 establishes “standards relating to facilities’ QAPI program and provide technical assistance to facilities on the development of best practices in order to meet these standards” required by Section 6102 of the ACA.⁴²

The statutory language CMS intends to implement through the 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 Final 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, such as 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 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. This may include, but is not limited to, systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of

adverse events; and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities;

- (2) Present its QAPI plan to the state survey agency no later than one year after the effective date promulgation 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.

Notably, the 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.

The Final Rule indicates that a facility may have to "present documentation and evidence of its ongoing QAPI program," which may require a facility to present the following to state survey agencies: "systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events; and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities."

While 42 C.F.R. § 483.75(h) 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 documentation and evidence of a facility's ongoing QAPI program contemplated by 42 C.F.R. § 483.75(a) may require the disclosure of QAA committee records that would be unnecessary to demonstrate compliance with 42 C.F.R. § 483.75. Significantly, depending on how State Survey Agencies implement the Final Rule's QAPI provisions, such implementation could prove 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, nor guidance further define what constitutes the "records of" the QAA committee, the Final Rule could require the disclosure of documents subject to the QAA privilege. While CMS, in the preamble to the Final Rule, states, "it is not our intent that a facility lose existing protections for QAA documents, including those established under state law, nor do we intend to create a punitive environment or increase litigation," the agency also notes that, "in some cases, [QAA committee's records] will be necessary to evaluate compliance." CMS further comments that, "much information relating to the implementation of the QAPI plan could be available outside of the QAA committee's records."⁴³ We find CMS' commentary

on this topic, which indicates that QAA committee's records, and potentially materials protected by the QAA privilege, may be required to demonstrate compliance with 42 C.F.R. § 483.75 troubling. In addition, if implemented incorrectly, the requirement that facilities disclose the materials listed in 42 C.F.R. § 483.75(a) could have a detrimental effect on open and honest evaluation of areas of quality concern in LTC facilities.

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 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, prior to providing surveyors with documents that may have QAA privilege protection in order to show compliance with § 483.75, LTC facilities should consult with legal counsel to ensure that the facility is not inadvertently waiving the QAA privilege.

Finally, 42 C.F.R. § 483.75(i), which relates to sanctions, 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 provision 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. CMS indicates in the preamble to the Final Rule that "nothing in this section would preclude a surveyor from citing a concern that is identified based on a review of materials or on observations separate and apart from an assessment of QAPI compliance," but notes that the agency has and will continue "to educate surveyors on the parameters of this provision and the need to not inappropriately request or use QAPI documentation."⁴⁴

Compliance and Ethics Program

The Final Rule adopts the proposed rule's compliance and ethics program provisions with only one modification: the implementation date. The Final Rule adds regulatory provisions, found 42 C.F.R. § 483.85, that 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 operating organizations ~\$134,790,000 for the first year and ~\$114,980,000 for the second and subsequent years, at an estimated recurring cost of \$15,721 per facility. CMS projects the compliance and ethics program requirements to be the third-most costly regulatory requirement resulting from compliance with the Final Rule.

As reiterated by CMS in the preamble, 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 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.⁴⁵ 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.⁴⁶

Pursuant to the Final Rule, every LTC facility must have a compliance and ethics program in place by November 28, 2017 (Phase Two). In addition, pursuant to the Final Rule, the compliance and ethics program must satisfy certain specified components, further described below. The Final Rule includes 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. CMS explains in the preamble that the agency includes additional requirements for organizations with five or more facilities because of a provision codified at 42 U.S.C. § 1320a-7j(b)(2)(B), which states, “[s]uch regulations with respect to specific elements or formality of a program shall, in the case of an organization that operates 5 or more facilities, vary with the size of the organization, such that larger organizations should have a more formal program and include established written policies defining the standards and procedures to be followed by its employees.”⁴⁷

The Final Rule requires 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. In the preamble to the Final Rule, CMS explains that it is critical that contractors and volunteers, in addition to staff, understand the compliance and ethics program's policies, procedures, and standards. However, the agency also indicates that operating organizations have certain flexibility in determining how to train and disseminate information regarding compliance and ethics. CMS then suggests that an operating organization can coordinate with a contracting organization to conduct and require training and dissemination of compliance and ethics program information.⁴⁸
- 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 must:

- Perform a mandatory, annual compliance and ethics training program that satisfies specific requirements.
- Designate a compliance officer for whom the compliance and ethics program is a "major responsibility." CMS notes in the preamble to the Final Rule that it will provide additional sub-regulatory guidance regarding who can and cannot serve as the compliance officer of an operating organization.
- Designate a compliance liaison at each of the operating organization's facilities. In the preamble to the Final Rule, CMS explains that "[c]ompliance liaisons are not compliance officers," and that the agency "believe[s] that each operating organization needs the flexibility to determine what the qualifications, duties, and responsibilities" of such liaisons will be.⁴⁹

In its discussion of the compliance and ethics program requirements, CMS indicates that it will be developing and publishing additional sub-regulatory guidance before surveyors begin to survey LTC facilities for compliance with the compliance and ethics program requirements. Such guidance will include not only further information regarding who can and cannot serve as a compliance officer, as required for operating organizations that have five or more LTC facilities, but will also provide guidance regarding how to determine reasonableness for the purposes of the compliance and ethics program requirements.

Training Requirements

The Final Rule adds a new 42 C.F.R. § 483.95 requiring facilities to 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. The amount and type of training is to be based on the required facility assessment, as specified in § 483.70(3).

Training topics must include:

- (1) Communications training;
- (2) Resident's rights and facility responsibility;
- (3) Abuse neglect and exploitation, which must include training on activities that constitute neglect, exploitation and misappropriation of resident property; procedures for reporting incidents of abuse, neglect, exploitation or the misappropriation of resident property, as well as dementia management and resident abuse prevention;
- (4) Quality assurance and performance improvement training;
- (5) Infection control;
- (6) Compliance and ethics (requires annual training if the training organization operates five or more facilities);
- (7) In-service training for nurse aides. The focus of this training is to ensure the continuing competence of nurse aides and must be at least 12 hours per year. The training must include dementia management training and resident abuse, and address areas of weakness as determined in individual performance reviews, and the facility assessment required at § 483.70(e). In addition, nurse aides providing services to individuals with cognitive impairment must receive training that addresses the care of the cognitively impaired;
- (8) Training for feeding assistance; and
- (9) Behavioral health.

Outpatient Rehabilitative Services

In the Final Rule, CMS *withdrew* its proposed new section on "Outpatient Rehabilitative Services." In the preamble, CMS notes that the majority of commenters supported the addition of requirements regarding facilities that provide outpatient rehabilitation services, and that many had commented on the ability to provide outpatient therapy to individuals in a home, such as an independent senior living or assisted living facility. CMS acknowledges that these services may be paid for under Medicare Part B. However, noting "additional complex issues" involved in LTC facilities providing outpatient rehabilitative services, CMS decided to withdraw this proposal and consider the proposals for future rulemaking.⁵⁰

Conclusion

The sweeping Final Rule establishes significant new regulatory requirements and modifies existing requirements imposed upon LTC facilities participating

in the Medicare and Medicaid programs. In order to implement and continue to comply with such new and revised requirements, providers must expend considerable time, energy, and resources. Given the potential consequences of failure to substantially comply with the requirements included in the Final Rule, such as penalties, denial of payment for new admissions, and possible termination from the Medicare and Medicaid programs, we urge all LTC facilities to carefully review, understand, implement, and continue to comply with the Final Rule's requirements. In addition, we advise LTC facilities to monitor additional guidance published by CMS related to the ROPs, which may expound upon the agency's and state surveyors' expectations for facilities' implementation of the requirements, and surveyors' review of LTC facilities' compliance.

We would be pleased to answer any questions you have on the Final Rule, or to assist you in assessing and responding to the operational or legal implications of the new requirements adopted by the Final Rule.

¹ Centers for Medicare & Medicaid Services, Reform of Requirements for Long-Term Care Facilities, 81 Fed. Reg. 68,688 (Oct. 4, 2016), available at <https://www.gpo.gov/fdsys/pkg/FR-2016-10-04/pdf/2016-23503.pdf>.

² 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>.

³ 81 Fed. Reg. at 68,688-689.

⁴ Section 6102 of the ACA, codified at 42 U.S.C. § 1320a-7j(b).

⁵ 42 U.S.C. § 1320a-7j(c).

⁶ 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 81 Fed. Reg. at 68,689.

⁸ *Id.* at 68,691.

⁹ *Id.* See also 42 U.S.C. § 1396r(b)(2); 42 U.S.C. § 1395i-3(b)(2).

¹⁰ *Id.* at 68,690.

¹¹ *Id.*

¹² *Id.* at 68,695.

¹³ 81 Fed. Reg. 68,688. The limited changes require the facility to ensure that the agreement is explained not only to the resident, but also to his or her representative in a form and manner that both the resident and his or her representative understand. They also require that the agreement must provide for the selection of a neutral arbitrator "agreed upon by both parties." *Id.* at 68,867 (to be codified at §§ 483.70(n)(2)(i)(A), (n)(2)(ii)(B)).

¹⁴ *Id.* (to be codified at § 483.70(n)(2)).

¹⁵ *Id.* (to be codified at § 483.70(n)(2)(iii)).

¹⁶ *Id.* (to be codified at § 483.70(n)(2)(vi)).

¹⁷ The Final Rule provides that § 483.70(n) will be implemented in Phase 1, meaning upon the effective date of the Final Rule. See *id.* at 68,696-697.

¹⁸ See *id.* at 68,867 (to be codified at § 483.70(n)(2)).

¹⁹ See *id.* at 68,790-800 (summarizing the public comments and providing responses thereto).

²⁰ 9 U.S.C. §§ 1-16. Section 2 of the FAA provides that "[a] written provision in any...contract evidencing a transaction involving commerce to settle by arbitration a controversy arising out of such contract... to perform the whole or any part thereof, or an agreement in writing to submit to arbitration an existing controversy arising out of such a contract...shall be valid, irrevocable, and enforceable, save upon such grounds as exist at law or in equity for the revocation of any contract."

²¹ 81 Fed. Reg. at 68,790.

- ²² *Id.*
- ²³ *Id.* at 68,791 (“[T]he plain language of the FAA applies only to existing arbitration agreements voluntarily made between private parties....”).
- ²⁴ 132 S.Ct. 1201, 1203 (2012) (quoting *KPMG LLP v. Cocchi*, 132 S.Ct. 23, 25 (2011)).
- ²⁵ The Supreme Court held that “West Virginia’s prohibition against predispute agreements to arbitrate personal-injury or wrongful-death claims against nursing homes is a categorical rule prohibiting arbitration of a particular type of claim, and that rule is contrary to the terms and coverage of the FAA.”== 132 S.Ct. at 1203-04.
- ²⁶ 81 Fed. Reg. at 68,792.
- ²⁷ *American Health Care Association, et al. v. Burwell, et al.*, No. 3:16-cv-00233, filed in the United States District Court for the Northern District of Mississippi (Oct. 17, 2016).
- ²⁸ The Final Rule requires the physician to be licensed to practice medicine; it does not require licensure in the state in which the facility is located. See 42 C.F.R. § 483.10(d)(1).
- ²⁹ 81 Fed. Reg. at 68,728.
- ³⁰ *Id.* at 68,732.
- ³¹ *Id.* at 68,823.
- ³² *Id.* at 68,733.
- ³³ 81 Fed. Reg. at 68,752.
- ³⁴ 81 Fed. Reg. at 68,753.
- ³⁵ *Id.* at 68,755-756.
- ³⁶ *Id.* at 68,756.
- ³⁷ *Id.* at 68,760-761.
- ³⁸ *Id.* at 68,761.
- ³⁹ *Id.* at 68,765.
- ⁴⁰ 42 C.F.R. § 483.60(c).
- ⁴¹ *Id.* at 68,809 (referencing 81 Fed. Reg. 39 448, 39,454-459 (June 16, 2016)).
- ⁴² 81 Fed. Reg. at 68,802.
- ⁴³ *Id.* at 68,806.
- ⁴⁴ *Id.* at 68,806-807.
- ⁴⁵ 75 Fed. Reg. 58,204 (Sept. 23, 2010).
- ⁴⁶ 76 Fed. Reg. 5862 (Feb. 2, 2011), available at <http://www.gpo.gov/fdsys/pkg/FR-2011-02-02/pdf/2011-1686.pdf>.
- ⁴⁷ 81 Fed. Reg. at 68,815.
- ⁴⁸ *Id.* at 68,815.
- ⁴⁹ *Id.* at 68,816.
- ⁵⁰ *Id.* at 68,784.

This *Alert* is presented for informational purposes only and is not intended to constitute legal advice.

© Reed Smith LLP 2016.
All rights reserved. For additional information, visit <http://www.reedsmith.com/legal/>