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Long Term Care Facility Requirements Set for Massive Overhaul

By
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Every skilled nursing facility (SNF) and nursing facility (NF)[1] in the U.S. will face tremendous new regulatory obligations under a long-awaited proposed rule ("the Proposed Rule") released by the Centers for Medicare & Medicaid (CMS) on July 13, 2015.[2] The Proposed Rule, Medicare and Medicaid Programs: Reform of Requirements for Long-Term Care Facilities, adds new requirements, reorganizes various other existing regulations, and would substantially change the requirements that these facilities must meet to participate in the Medicare and Medicaid programs. Industry and other stakeholders filed almost 10,000 comments prior to the September 14, 2015 closing of comments on the Proposed Rule. Because the Proposed Rule is such a comprehensive revision and recreation of the current regulations, discussion of each provision is not feasible in this article. This article will begin with an overall summary of the major provisions and then provide a more detailed discussion of certain important areas. Understanding the Proposed Rule will be essential for long term care facilities as they prepare to comply with its complex potential requirements.

Background on the Proposed Rule

As CMS notes in its rulemaking discussion, the changes proposed represent the first comprehensive change to the requirements of participation (RoPs) in over twenty-five years. CMS explains that the population of nursing homes has changed substantially since the last revision in 1991—becoming more diverse and more clinically complex. The long term care population now includes an increased number of elderly with chronic conditions, younger individuals with intellectual or developmental disabilities, and adults who seek post-acute rehabilitation and rehabilitation on a short term basis and then return home. CMS also noted the significant number of residents who now have behavioral and mental health needs.

CMS developed and crafted the Proposed Rule over an extensive period of time, and explains its efforts to obtain significant input in advance of the publication last July. CMS took input from the public and various LTC stakeholders prior to the development of the Proposed Rule. The rule itself also reflects that CMS reviewed significant scientific literature and other studies as the impetus for some of the proposed changes. CMS states stakeholders, prior to the development of the Proposed Rule, pointed out two consistent themes that they believed should be addressed in the Proposed Rule: (1) the need to address facility staffing, and (2) the need to ensure revised requirements were "person centered" in their design. CMS feels both points are incorporated extensively into the published Proposed Rule.

Interestingly, CMS notes their Proposed Rule may already fail to reflect the realities of the current long term care facility.[3] That reality is characterized increasingly by a dichotomy between a "home-like residence" for chronic long term residents and the more medical/rehabilitation model focused on short-stay residents, who are largely Medicare beneficiaries. CMS also acknowledges that providers describe the challenges of serving the divergent needs of these two increasingly diverse long term care populations in a single model of care.[4] In the

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[1] The terms skilled nursing facility "SNF", nursing facility "NF", "nursing home", "facility" and "provider" are all used interchangeably in this article to refer to those entities regulated under the Proposed Rule.

[2] 80 Fed. Reg. 42168 (July 16, 2015). A copy of the Final Rule is available at https://www.federalregister.gov/articles/2015/07/16/2015-17207/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities.

[3] 80 Fed. Reg. at 42177.

[4] *Id.*

Proposed Rule, CMS solicited comments on how the requirements could more effectively acknowledge the special needs of both the long and short stay resident and make serving one or the other population difficult or less effective.[5]

Major Additions and Revisions in the Proposed Rule

In broad summary, the Proposed Rule includes the following major provisions:

- Adoption of a new "competency" requirement for determining sufficient nursing and other staff based on a facility assessment. A new requirement mandates a facility-wide assessment to determine what resources are necessary to care for the facility's residents competently during both day-to-day operations and emergencies. That assessment includes, but is not limited to, the number of residents, resident acuity, range of diagnoses and the content of care plans. All facilities must employ sufficient staff with the appropriate competencies and skills to meet resident needs.
- Requirements for comprehensive person-centered care planning as part of the pre-admission screening and resident review (PASARR) and preparation of a baseline care plan within 48 hours of admission, along with related requirements for an interdisciplinary team and discharge planning.
- New compliance program requirements (implementing Section 1128 of the Affordable Care Act), that impose extensive programmatic obligations.
- Addition of a new behavioral health services requirement, including mental and psychosocial illnesses and non-pharmacological interventions, which focuses on the requirement to provide the necessary behavioral health care and services to residents in accordance with their comprehensive assessment and plan of care.
- Substantial additional changes related to pharmacy services, including the requirement that a pharmacist review a resident's medical chart at least every six months, when the resident is new to the facility, when a prior resident returns or is transferred from a hospital or other facility, and 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 Committee has requested be included in the pharmacist's monthly drug review. Physicians would be required to review issues identified by the pharmacist.
- Requirements on the use of psychotropic medications, including a prohibition on such medications unless medically necessary, strict time limits on "as needed" orders, obligation to try (unless clinically contraindicated) gradual dose reductions and behavioral interventions. The purpose of each requirement is to limit use of psychotropic drugs.
- New and more stringent personnel requirements for food and nutrition staff, including specific credentials for qualified dieticians and directors of food service. Employment of dietary staff would have to meet the "competency" test with the appropriate competencies and skills sets to carry out the functions of the dietary service based on resident assessments. Other new dietary requirements (individual plans of care, religious requirements, and personal preferences) are also added.
- "Clarifications" regarding what constitutes rehabilitative services for mental illness and intellectual disability and an addition of respiratory services to those services identified as specialized rehabilitative services and establishment of new health and safety standards for facilities that choose to provide outpatient rehabilitative therapy services.
- A new Infection Prevention and Control Program (IPCP) requirement. The IPCP would require a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under an arrangement based upon its facility and resident assessments that is reviewed and updated annually. Facilities would have to identify an

[5] *Id.*

Infection Prevention and Control Officer (IPCO).

- New requirements around transitions of care from one facility to another, including an in-person evaluation prior to transfer.
- Increased requirements around employment and contractor relationships designed to protect residents from abuse, neglect, mistreatment or misappropriation of property.
- Specific limits on the use and content of binding arbitration agreements between a facility and residents.
- A requirement that facilities develop, implement, and maintain an effective comprehensive, data-driven Quality Assurance and Performance Improvement (QAPI) program.
- New limits of no more than two (2) residents sharing a bedroom and requirements regarding access to private, in-room toilet facilities.
- Extensive and specific requirements around training of new and existing staff, individuals providing services under a contractual arrangement, and volunteers.
- New requirements for policies regarding smoking, including tobacco cessation, smoking areas, and safety.

Discussion of Particular Sections of the Proposed Rule

The sections below discuss in more detail certain sections of the Proposed Rule that are likely to have the most significant operational or financial impacts on SNFs if implemented as proposed. While all provisions of the Proposed Rule are important, these sections are likely those that will demand the consideration by SNFs and their counsel.

1. Resident Rights

The Proposed Rule leaves the existing provisions around resident rights largely intact; however, CMS proposes to revise the existing 42 C.F.R. § 483.10 to include only those provisions specifying resident rights, including moving certain resident rights provisions from other sections of the existing rules to 42 C.F.R. § 483.10.[6] CMS also proposes a new section 42 C.F.R. § 483.11 (Facility Responsibilities), which would focus on the responsibilities of the facility towards residents, including relevant provisions currently included in 42 C.F.R. § 483.10 and 42 C.F.R. § 483.15. Emphasizing the "person-centric" theme within the revisions, the residents' rights provision would ensure that a facility must afford a resident's representative only those decisions that either the resident or applicable state law confers.[7] The revisions emphasize that health care decision making for or by residents needs to be anchored in the resident's choices. The Proposed Rule also makes clear that a court-appointed representative or legal surrogate has the right to make decisions for residents in the event of incapacity or incompetency.

The Proposed Rule makes a number of other important modifications or additions to existing residents' rights regulations, including:

- Explicitly including same-sex spouses as decisions makers if the marriage is valid in the jurisdiction in which it was celebrated.
- Emphasizing the resident's right to person-centered care and the obligation that the resident and individuals identified by the resident be actively involved in the care planning process. This includes giving residents the right to see their plan of care and to sign the plan of care in the event of changes to interventions.
- While allowing involvement in care planning and ensuring understanding of treatments, the proposal adds specific language to limit a resident's rights to only medically necessary or appropriate treatment. This provision may be helpful when facilities face requests or demands for nontraditional or clinically unsound interventions.
- Adding a right to be able to choose who one lives with in the facility, including a new right to select roommate(s) of choice when it can reasonably be accommodated.
- Expanding the right to an individualized activities program that incorporates an individual's interests and hobbies, and a new right to participate

[6] *Id.* at 42181-42184.
[7] 80 Fed. Reg. at 42181-42182.

in community activities of their choice outside of the facility.

- Enhanced requirements for the access to information, including a right to receive notices verbally and in writing (including Braille), and in a format and language the resident understands.
- Residents would have to be provided reasonable access to the internet if it is available to the facility.

The Proposed Rule makes additional changes and adds new requirements by including a new section 42 C.F.R. § 483.11 (Facility Responsibilities) that outlines the facilities' responsibilities related to residents' rights.[8] The SNF must recognize each resident's individuality and provide services in a person-centered manner. Specific obligations include:

- Planning and implementing care that places much more emphasis on person-centered care and the inclusion of residents in the care planning process.
- Requirements for affirmative action by the facility to inform residents in the event of a change of physician.
- Written policies and procedures regarding visitation rights and restrictions.
- New requirements regarding deposit of residents' funds and notices to residents regarding balances.
- Retention and availability of the prior three (3) years of survey and complaint documents.
- Posting of a list of agencies and advocacy groups, including Medicaid Fraud Units, and contact information including email addresses.
- Sixty (60) days advance notice when there are changes in facility charges.

Lastly, the Proposed Rule attempts to strengthen existing regulations around the residents' freedom from abuse and neglect. SNFs are currently required to address complaints, and specifically investigate and respond to any allegations of mistreatment or abuse. The Proposed Rule would go further to require that the facility establish a grievance policy to ensure the prompt resolution of grievances and identify a grievance officer.[9]

2. Transitions of Care

The Proposed Rule re-designates the current 42 C.F.R. § 483.12 (Admission/Transfer/Discharge) as new section 483.15, which outlines transition of care requirements.[10] These changes reflect CMS's initiative to update regulations to align and keep pace with CMS's objective of strengthening and modernizing the nation's health care system to provide access to high quality care and improved health at lower cost. The new provisions apply to all instances where care of a resident is transitioned between care settings.

The proposed 42 C.F.R. § 483.15 adds new requirements on admissions, transfers and discharges. SNFs may not request or require residents or potential residents to waive potential financial liability for losses of personal property. At or prior to admission, a facility must give notice regarding any special characteristics or service limitations and notice of composite distinct parts and policies and procedures that apply to distinct parts. With respect to discharges, the proposed changes specify that discharges cannot take place while appeals are pending. Facilities also cannot discharge a resident for nonpayment "unless the resident does not submit the necessary paperwork for third party payment" or until the third party, "denies the claim for payment and the resident refuses to pay for his or her stay."[11]

The Proposed Rule also keeps current language that allows facilities to discharge residents who endanger other residents, but adds as a result of the "clinical or behavior status of the resident."[12] This slightly revised language may assist facilities faced with the dilemma of fighting a discharge appeal from an individual resident when in the facility's belief they must discharge to protect other residents. Language allowing a facility the opportunity not to readmit a resident who is hospitalized or on therapeutic leave if the facility "determines that the resident cannot be

[8] *Id.* at 42184-42187.

[9] *Id.* at 42187-42188; *proposed* 42 C.F.R. § 483.11(h).
[10] *Id.* at 42189-42191.
[11] *Id.* at 42254.
[12] *Id.*

readmitted . . . " also may be helpful in those difficult facility and resident situations.[13]

CMS proposes several revisions based on the importance of effective communication between providers during transitions of care. The new requirements detail what must be documented in the clinical record related to a transfer or discharge. Those requirements include the basis for the transfer, the specific needs that cannot be met, the attempts made to meet the needs, and documentation that the services available at the receiving facility will meet the resident's needs. The proposed 42 C.F.R. § 483.15 also requires details regarding documentation that must be made by the physician in the event of a transfer or discharge, requiring a dedicated "Transfer Summary" document including at least demographic information, resident representative contact information, advance directives, history of illness and reason for transfer, diagnoses and diagnostic test results, cognitive status, medications, and comprehensive care plan goals.[14]

3. Physician Services

The Proposed Rule makes significant changes to the expectations placed on physicians and SNFs in their care and interaction with residents, and moves requirements for physician services to a newly designated section 42 C.F.R. § 483.30.[15] Overall, these new requirements increase the responsibilities of physicians within the SNF, and include new tasks that must be done by physicians, or in some cases physician extenders.

The requirement for an in-person evaluation prior to any unscheduled transfer is one of the more controversial additions. A new 42 C.F.R. § 483.30(e) would require that "prior to an unscheduled transfer of a resident to a hospital, [a facility] must provide or arrange for an in-person evaluation of a resident, to be conducted expeditiously, by a physician, a physician assistant, nurse practitioner, or clinical nurse specialist prior to transferring the resident to a hospital, unless the transfer is emergent and obtaining the in-person evaluation would endanger the health or safety of the individual or unreasonably delay the transfer."[16] CMS explains that the new requirement "will help ensure that the decision to transfer a resident to an acute care facility is made on the basis of a clinical assessment and the best evidence available." It intends to improve clinical decision-making and transitions of care between acute and long term care settings and reduce unnecessary rehospitalizations. CMS's requirement is sound in concept, however, many commenters on the Proposed Rule have requested its removal because sufficient physicians (or other professionals) are not available to every SNF to meet this requirement, and the breadth or narrowness of "non-emergency care" could end up delaying access to needed treatment if residents are kept waiting before transfer. Those criticisms add to the concern that meeting the requirement may impose significant costs on SNFs.

For the first time, CMS addresses the unanswered issue of physician credentialing in SNFs. The proposed 42 C.F.R. § 483.10(c) includes new language stating that while a resident has freedom of choice of their attending physician, that physician must "meet professional credentialing requirements of the facility."[17] If the physician does not agree and/or comply with those requirements, a SNF can to seek an alternate physician for resident. With increasing resident acuity, many SNFs have sought to ensure quality physician care is delivered to their residents. This provision offers them a basis to do so, explicitly acknowledging that a resident's freedom of choice of physician is not absolute.

CMS also added increased physician responsibilities for medication review. A new proposed 42 C.F.R. § 483.45 would to require the attending physician to document regularly their review of any pharmacy irregularities identified by the SNFs consultant pharmacist, including what, if any, action they have taken to address it.[18] The physician must record their rationale if there is no action to change a medication that was identified by the pharmacist. Commenters have questioned whether this level of detailed burden on physicians is necessary or effective, though others

[13] *Id.* at 421191 and 42256.
[14] *Id.* at 421190-42191.
[15] *Id.* at 421199.
[16] *Id.*
[17] *Id.* at 42182.
[18] *Id.* at 42204.

have identified it as another valuable enhancement to the physician's oversight of the care to residents.

Lastly, 42 C.F.R. § 483.30(f)(2-3) in the Proposed Rule would allow the physician to delegate therapy and dietary orders to a registered dietitian or licensed therapist to the extent allowed by state law.[19]

4. New Training and Staffing Requirements

The Proposed Rule introduces a new section 42 C.F.R. § 483.95 (Training Requirements) that would set forth mandatory facility training requirements.[20] CMS proposes that a facility must develop, implement, and maintain an effective training program for all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles.[21] This new training requirement dovetails with requirements at 42 C.F.R. § 483.35 that adds a "competency requirement" for sufficient nursing staff at a facility.[22] Under this proposed competency requirement for determining sufficient nursing staff, a facility must ensure that staff have the appropriate competencies and skills for the residents and services required. Those resident needs must be based on a facility assessment including, but not limited to, the number of residents, resident acuity, range of diagnoses, and the content of care plans.

Mandatory components of this annual training are set forth in the Proposed Rule. Training topics must include:

- Communication: Effective communication for direct care personnel.
- Resident Rights and Facility Responsibilities: Staff must know how to properly care for its residents and requirements of regulations.
- Abuse, Neglect, and Exploitation: What is "abuse, neglect, exploitation, and misappropriation of resident property" and procedures for reporting incidents.
- QAPI & Infection Control: Must educate staff on the written standards, policies, and procedures for each program.
- Compliance and Ethics: All staff must know and understand the compliance program and that training is part of the program. It would be required annually for companies with five or more facilities.
- In-Service Training for Nurse Aides: Requires dementia management and resident abuse prevention training to be a part of twelve (12) hours per year in-service training for nurse aides.
- Behavioral Health Training: Behavioral health training to all facility staff, consistent with the residents' facility assessment under 42 C.F.R. § 483.70(e).

The proposed training requirements are likely to have broad implications for facilities. While commenters have opposed these requirements, they acknowledge that it is difficult to oppose better training and education for staff members; some of which will likely be beneficial. However, do new training requirements open yet another area for "tag along" survey deficiencies against facilities? Will the failure of a nurse to perform an action also be presumed to be a training issue? Determining how to maintain compliance with training requirements for contractors and volunteers will also pose a challenge for providers. The requirements may also impact the skill sets of the individuals (both licensed and otherwise) that SNFs and NFs need.

5. Quality Assurance and Performance Improvement (QAPI)

Section 6102 of the Affordable Care Act requires that the Secretary establish and implement a QAPI program requirement for SNFs and NFs, including those that are part of a multi-unit chain of facilities. Under the QAPI provision, the Secretary must establish standards relating to facilities' QAPI program and provide technical assistance to facilities on the development of best practices in order to meet these standards. At proposed § 483.75(a), CMS would require that every facility develop, implement, and maintain an effective, comprehensive, data-driven

[19] *Id.* at 42199.
[20] *Id.* at 42222-42225.
[21] *Id.*
[22] *Id.* at 42199-42202.

QAPI program, reflected in its QAPI plan, that focuses on systems of care, outcomes and services for residents and staff.[23]

Similar to the existing quality assurance requirements now at 42 C.F.R. § 483.75(o), the QAPI program would monitor and evaluate performance of all services and programs of a facility, including services provided under contract or arrangement. Unlike quality assurance, however, QAPI should optimize quality improvement activities and programs comprehensively and proactively, even in areas without any specific deficiencies. The QAPI program should include standards for quality assurance, active feedback systems to monitor performance, and continuous efforts to optimize program design through quality improvement activities and proactive strategies. The QAPI program must use a systematic approach to study and review objective data to continually make improvements in all aspects of an organization's operations and services. The QAPI requirements would not replace the QAA committee requirements but would enhance and be coordinated with these requirements.

One concern identified by some commenters is the new requirement in proposed 42 C.F.R. § 483.74(a)(4) requiring a facility to maintain and present on a recurring basis its documentation and evidence of an ongoing QAPI program upon request of a State Agency, federal surveyor, or CMS. Even some commenters supportive of the QAPI approach have cited the necessity to keep QAPI documentation privileged and protected. Those commenters felt that without such protection, a candid and thorough review of identified concerns and efforts to improve is unlikely to occur.

6. Compliance and Ethics Programs

The Proposed Rule requires operators to develop, implement, and maintain a comprehensive compliance and ethics program in order to participate in the Medicare and Medicaid programs. The proposed costs of this requirement are significant. CMS's projections estimate an overall first year cost of over $141 million for the program and training, followed by an annual ongoing cost of over $122 million dollars.[24]

A new 42 C.F.R. § 483.85 would require all Medicare and/or Medicaid certified facilities to have a compliance and ethics program in place one year after adoption of the final rule. In addition, the Proposed Rule goes into specifics about the elements of an "effective" compliance and ethics program that must be included. Those components, which are similar to those in the CPG include:

- Development and distribution of written standards of conduct, as well as written policies, procedures and protocols that cover topics such as reporting suspected violations.
- Assignment of high-level personnel to oversee the compliance and ethics program.
- Communication of the written compliance standards, policies and procedures to the facility's staff, contractors and volunteers.
- Enforcement of the standards, policies and procedures through consistent disciplinary mechanisms.
- An annual program review to update as indicated by changes in applicable laws and regulations.
- A mandatory compliance and ethics training program on an annual basis.
- Identifying a compliance officer whose job duties include a "major responsibility" for the compliance program.
- Appointment of a compliance liaison at each individual facility.

It should be noted the last three requirements apply only to companies or operators that have five or more facilities, at least as proposed.

7. Use of Arbitration in SNFs

While a relatively small portion of the Proposed Rule, one topic generating enormous controversy is the proposal to adopt requirements for the use of predispute arbitration agreements between residents and a facility. For the first time, CMS includes specific requirements for the facility and for the agreement itself. CMS's stated intent is "to ensure that if a facility presents binding arbitration agreements to its residents that the agreements be explained to the residents and they acknowledge that they understand

[23] *Id.* at 42212-42215.
[24] *Id.* at 42239 and 42240-41.

the agreement."[25] Previously, CMS's only statement was that although the decision to have a binding arbitration agreement is an issue between the resident and the nursing home, no current resident could be forced to sign a new admission agreement that contains binding arbitration as a condition of continued stay in the facility.[26]

CMS states in the commentary to the Proposed Rule that it "believes that nursing home residents need to be fully aware of the right they are waiving (the right to seek relief in a court for a dispute between the resident and the facility) if a nursing home requests they sign an agreement for binding arbitration." To that end, CMS proposed specific requirements for an agreement for binding arbitration that include:

- The nursing home must explain the agreement to the resident in a form and manner that he or she understands.
- The resident must acknowledge that they understand the agreement.
- Must be entered into voluntarily.
- Must be explained and understand rights waived.
- Cannot be a condition of admission.
- Must be a separate document.
- Neutral arbitrator in mutually convenient a location.
- Cannot prohibit or discourage the resident or anyone else from communicating with federal, state, or local health care or health-related officials or ombudsman.
- A patient representative can only sign/bind the agreement if allowed by state law and all requirements met and they have no interest in the facility.[27]

CMS stopped short of trying to ban arbitration outright in the Proposed Rule, but states " . . . we are also soliciting comments on whether binding arbitration agreements should be prohibited."[28]

Given the national debate over consumer arbitration in all settings, CMS's comment has set off a firestorm of criticism in provider comments. Provider commenters take the position that the proposed requirements, as well as inference of a prohibition, exceed CMS's legal agency authority and would violate the Federal Arbitration Act. Others, including consumers and some members of Congress, are equally forceful in their opinions, supporting a complete prohibition on SNF arbitration agreements.

Costs, Timing and Other Considerations of the Proposed Rule

It should be no surprise that individual long term care providers and their professional associations have commented quite critically on the cost burdens to be imposed by the provisions of the Proposed Rule, as well as the need for long extended timeframes for implementation. CMS estimates that the new requirements would cost nursing facilities $729,495,614 for the first year, and $638,386,760 for the second year and thereafter.[29] That equates to about $46,500 and $40,000 ongoing for each certified SNF and NF. However, in its comment letter, the American Health Care Association expressed concern that CMS's economic impact statement for the costs associated with implementation and ongoing compliance with the Proposed Rule are unrealistically low and grossly understate the actual economic impact on facilities. From the provider's perspective, this proposal comes at a time when CMS is making massive changes across the post-acute community, including in the skilled nursing facility payment system. Medicare sequestration is giving nursing homes a likely cut in reimbursement for 2016, and value-based purchasing will result in another 2% "withholding," which will, at best, only be partially returned to those nursing homes achieving the lowest rates of rehospitalizations. Medicaid, which provides the largest share of nursing home revenue, is still grossly underpaying in most states. The new requirements are likely to challenge the SNF/NF provider community, especially given significant reimbursement cuts a few years ago.

Most providers and provider groups also expressed the opinion that the new provisions/requirements in

[25] 80 Fed. Reg. at 42241-42242.

[26] CMS, Binding Arbitration in Nursing Homes, S&C-03-10 (Jan. 9, 2003), *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCletter03-10.pdf (last visited Mar. 21, 2016).

[27] 80 Fed. Reg. at 42241-42242.

[28] *Id.*

[29] *Id.* at 42241-42242.

the Proposed Rule must be implemented more slowly and deliberately to permit providers and CMS to develop adequate systems and guidance for implementation and enforcement. However, recently long term care industry leaders speculated that the Obama Administration is likely to promulgate the Final Rule implementing these revisions before the conclusion of their administration.

In conclusion, long term care facilities and their counsel will benefit if they become familiar with the major new requirements that have been proposed, and, where possible, identify gaps between their current operations and the Proposed Rule. It may also be wise to consider how to implement operational changes that are consistent with the proposed new requirements.