Monday, January 9, 2017

On October 4, 2016, the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) published the final rule revising the conditions of participation that Long-Term Care facilities must meet to participate in the Medicare and Medicaid programs. The effective date of the regulations is November 28, 2016. The regulations will be implemented in phases. The regulations in Phase 1 must be implemented by November 28, 2016; the regulations in Phase 2 must be implemented by November 28, 2017; and the regulations in Phase 3 must be implemented by November 28, 2019. These new conditions and the comments are well over a hundred pages long, and facilities must review the entirety of the rule for compliance. Here, we highlight several significant changes.

Phase 1

§ 483.70-Administration

One big change that must be implemented in Phase 1 is contained in the section of Administration (§ 483.70). Under this section, facilities must not enter into an agreement for binding arbitration with a resident or their representative until after a dispute arises between the parties. Pre-dispute binding arbitration agreements are prohibited.

Commenters from the long term care facility industry to the proposed rule wanted HHS and CMS to withdraw the proposal. Others, including members of the public, wanted a prohibition on pre-dispute arbitration agreements. Some believed that arbitration should not be allowed in long term care facilities under any circumstances. Not surprisingly, a complaint for declaratory and injunctive relief was filed in the U.S. District Court for the Northern District of Mississippi, Oxford Division, on October 17, 2016. The complaint was filed by the American Health Care Association (AHCA), along with the Mississippi Health Care Association (MHCA), and AHCA/MHCA members, Great Oaks Rehabilitation and Healthcare Center, Heritage House Nursing Center and Pavilion at Creekwood. The complaint asserts that the arbitration regulation banning pre-dispute arbitration agreements violates the Federal Arbitration Act (FAA) and exceeds HHS and CMS authority under the Medicare and Medicaid Acts. On November 18, 2016, the court granted the preliminary injunction, indicating that the ban on agreements for pre-dispute arbitration will likely not take effect as scheduled on November 28, 2016. This preliminary injunction is simply one ruling by one district court, but it should stay the enactment of that provision of the rule.

§ 483.35-Nursing Services

The regulations contained in the section of Nursing Services (§ 483.35) must also be implemented in Phase 1. According to this section, the facility must have sufficient nursing staff with the appropriate competencies and skill sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity, and diagnoses of the facility’s resident population. However, specific usage of the Facility Assessment (§ 483.70) in the determination of sufficient number and competencies for staff does not need to be implemented until Phase 2.
Commenters to the proposed rule advocated mandating 24/7 Registered Nurse (RN) staffing. The current conditions of participation mandate that facilities use an RN for eight continuous hours each day, seven days a week. The Response from HHS and CMS to the commenters was that while they agree that RN’s are a valuable resource in long term care facilities, 24/7 RN presence in each facility is not mandatory at this time. They agree that sufficient staffing is necessary, along with the need for that staff to be competent in delivering the care that a resident requires. They agree that all of those factors are associated with quality of care, but did not agree that they should establish minimum staffing ratios at this time.

§ 483.12 -- Freedom from Abuse, Neglect and Exploitation

The rule grants a resident the right to be free from abuse, neglect, misappropriation of resident property, and exploitation. This regulation is not entirely new and portions of the regulation existed prior to the 2016 changes. The new language implicates several important issues, only a portion of which are discussed here.

The first issue involves the addition of a right to be free from physical or chemical restraints which are not required to treat the resident’s medical symptoms. Illinois law already requires that a nursing home have physician orders in place for all treatment, and in Illinois, a resident has the right to refuse treatment. Thus, the use of physical or chemical restraints should already be ordered by a physician in Illinois. Therefore, it may require additional documentation to assure that the physician is not ordering restraints for purposes of discipline or convenience, but rather, that the restraint is part of the treatment as required by the federal regulations.

The ban on employment for certain offenses is now extended beyond nursing assistants to all licensed professionals. The caveat is that a conviction for abuse, neglect, exploitation, misappropriation of property (hereinafter ANEM), or mistreatment will permanently disqualify the individual from employment. In contrast, if the individual has a finding on their license relating to abuse, neglect, exploitation, mistreatment of residents or misappropriation of property, the disciplinary action must be in effect at the time the employee is reviewed. The facility must also develop written policies to prohibit and prevent ANEM.

The comments indicate that confirmation of license status must be reasonable and do imply that if someone has recently moved from out-of-state, further investigation of licensure status might be appropriate. At this time, the regulations do not contain any appeal or dispute rights. However, the comments indicate that HHS will give future consideration to the following issues: the benefits of a national background check, the ability to appeal or dispute the accuracy of information obtained, and an individual’s ability to demonstrate rehabilitation and the relevancy of a particular incident. However, at this time, evidence of a conviction or disciplinary action in effect means the individual cannot be employed.

Finally, a facility is required to report any suspicion of ANEM within two hours if there is serious bodily injury or no later than 24 hours if there is no serious bodily injury. The facility must perform an investigation and report its findings within five working days. These reporting requirements arose in the Affordable Care Act and the regulations codify the requirement and add detail. Again, written procedures to address these issues are required and reports must be made to the state survey agency (Illinois Department of Public Health) and licensed professionals are also required to report to adult protective services (Illinois Department of Aging Elder Abuse Hotline).

Phase 2

§ 483.21-Comprehensive Person-Centered Care Planning

The section of Comprehensive Person-centered Care Planning (§483.21) requires that a facility create a baseline care plan for a resident within 48 hours of that resident’s admission. The section lists information that would, at a minimum, be necessary for inclusion in a baseline care plan, but this would not limit the contents of the care plan to only that information. A facility may develop a comprehensive care plan in place of the baseline care plan if the comprehensive care plan is developed within 48 hours of the resident’s admission and meets the requirements of the comprehensive care plan with certain exceptions (also contained in the section). Discharge planning is also now part of the comprehensive care plan.

Some commenters indicated that the 48 hour timeframe for completing the baseline care plan may be problematic if an individual is admitted on a Friday afternoon or on a holiday. One commenter indicated that staff with specific or specialized training would be required to complete the baseline care plan and that would have a negative financial impact on facilities. The Response indicated that the information necessary to complete the baseline care plan will be readily available or accessible through discussions and follow-up upon admission. HHS and CMS also did not agree that additional staff with specialized or specific training is necessary to complete the baseline care plan. The purpose of the baseline care plan is to serve as an interim care plan within the initial period of residency to avoid poor quality care and reduce the risk of hospital readmission as a result of missing
information. The comprehensive care plan is a more detailed and exhaustive plan of care for each resident that is person-centered and includes a resident’s needs and preferences. Furthermore, the provisions at § 483.35 require the facility to use the services of a registered nurse for at least eight consecutive hours a day, seven days a week. Therefore, at a minimum, a registered nurse will be available to develop a baseline care plan regardless of whether it is a holiday or a weekend.

**Phase 3**

**§ 483.85 – Compliance and Ethics Program**

The changes to the conditions of participation for long-term care facilities in the areas of compliance and ethics serve to bring the requirements closer to those of other types of health care facilities. Facilities have until November 28, 2017 to implement their new compliance program. In 2008, the Office of Inspector General (OIG) set forth the elements of an effective compliance plan for nursing home facilities. See, 73 Fed. Reg. 56832. The practical use of the 2008 regulation was, in the face of an OIG investigation, to mitigate penalties and perhaps to avoid criminal penalties by demonstrating that the facility had an effective compliance plan. So, while this regulation existed, nursing facilities have traditionally focused their efforts on the elements contained in state and federal regulatory surveys. The Affordable Care Act, sect. 1128(b) requires all health care facilities who participate in federally funded health care programs to have an effective compliance program. Thus, compliance plans have now moved from a recommended program for long-term care facilities to a required element in order to participate in the federal program. The practical effect of this change is that surveyors will now receive training and tools to assess whether long-term care facilities are properly implementing and following a compliance plan.

The changes in the Compliance and Ethics section of the rule specifically require a long-term care facility to “develop, implement, and maintain an effective compliance and ethics program” that has written compliance and ethics standards, policies, and procedures “that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act and promote quality of care.” The facility must designate a program contact. High level personnel must be involved in the compliance program. All staff, contractors, and volunteers must be trained with respect to the compliance program. In addition, the facility is to take “due care not to delegate substantial discretionary authority to individuals who the operating organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under the Social Security Act.” § 483.85(c)(4). These regulations appear to provide a substantial basis for citing violations of § 483.85 any time there is a regulatory violation. It will be important to review the interpretive guidance on these issues as it is released to the public.

Organizations with five or more facilities have additional compliance and ethics requirements that include the following: designate a compliance officer for the organization; each facility in the organization must have a designated compliance liaison; hold an annual training that communicates the program’s standards, policies, and procedures; and, annually review their compliance and ethics program.

In the end, long-term care facilities will be well served to have compliance and ethics policies and procedures drafted or reviewed by counsel competent in both the regulations and the nuances of Illinois law.

**Conclusion**

In conclusion, these new regulations represent the most extensive and sweeping changes to the conditions for participation since the enactment of the OBRA regulations in 1987. The final rule is available [here](https://www.natlawreview.com/article/cms-publishes-sweeping-changes-to-snf-conditions-participation).  

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