CMS PROPOSES ONE-YEAR DELAY FOR CERTAIN PHASE 3 SKILLED NURSING REQUIREMENTS – CHANGES MADE TO COMPLIANCE AND ETHICS PROGRAMS AND QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT PROGRAMS

On July 16, 2019, the Centers for Medicare & Medicaid Services ("CMS") released a pre-publication copy of the revisions ("Proposed Rule") to Part 483 to Title 42 of the Code of Federal Regulations the Requirements for States and Long-Term Care Facilities ("RoPs"). CMS stated that it identified a number of existing skilled nursing facility requirements that could reduce unnecessary burdens on facilities if they were simplified or eliminated.

The Proposed Rule would alter a over dozen sections of the RoPs, including: (1) resident rights; (2) admissions transfers and discharges; (3) quality of care; (4) nursing services; (5) behavioral health; (6) pharmacy services; (7) food and nutrition services; (8) facility assessments; (9) physical environment; (10) compliance and ethics programs; (11) Quality Assurance and Performance Improvement ("QAPI") programs; and (12) infection control. The Proposed Rule also proposes to delay implementation to some of these Phase 3 provisions until one year following the effective date of the Proposed Rule.

Several of the areas significantly impacted by the Proposed Rule include Facility Assessments (§483.70), Quality Assurance and Performance Improvement (§483.75), Infection Control (§483.80) and Compliance and Ethics Program (§483.85).

FACILITY ASSESSMENTS (§483.70)

The RoPs at Section 483.70(e) require each facility to conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents during both day to-day operations and emergencies. The facility assessment requirement is intended to be used by the facility for multiple purposes, including, but not limited to, activities such as determining staffing requirements, establishing a QAPI program and conducting emergency preparedness planning.

The Proposed Rule clarifies that data collected under the facility assessment requirement must be utilized to adjust policies and procedures and other skilled nursing facility requirements. In addition, CMS proposes to change the review of the facility assessment from annually to biannually.

QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT (§483.75)

Section 1128I of the Social Security Act, added by section 6102 of the Patient Protection and Affordable Care Act, required CMS to establish and implement a QAPI program for LTC facilities.

CMS believes that the level of specificity and detail in the QAPI requirements limits a facility's ability to design their QAPI program to fit their individual needs and hinder a facility's QAPI program from being a valuable tool in promoting quality care. CMS proposed to revise the requirement for facilities to implement a QAPI program by removing regulatory requirements to allow facilities greater flexibility in tailoring their QAPI program to the specific needs of their individual facility.

CMS proposes revisions to Sections 483.75(b), (c) and (d) that would remove the subparagraphs found in each section. The Proposed Rule would only require that the QAPI program be ongoing, comprehensive and address the full range of care and services provided by the facility. The Proposed Rule would also only require that facilities establish and implement written policies and procedures for feedback, data collection systems and monitoring, including adverse event monitoring. The Proposed Rule would also only require that facilities take actions aimed at performance improvement and, after implementing those actions, measure its success and track performance to ensure that improvements are realized and sustained.

INFECTION CONTROL (§483.80)

Section 483.80 requires facilities to, among other things, establish and maintain an infection prevention and control program ("IPCP") designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. Under Reg. 483.70(f), each facility must conduct an annual review of its IPCP and update its program as necessary

(§483.80(f)).

The Proposed Rule proposes to remove the requirement that the infection preventionist ("IP") work at the facility "part-time" or have frequent contact with the IPCP staff at the facility. The Proposed Rule instead requires that the facility must ensure that the IP has sufficient time at the facility to meet the objectives of its IPCP.

COMPLIANCE AND ETHICS PROGRAM (§483.85)

Section 1128I of the Social Security Act requires the operating organizations for skilled nursing facilities and nursing facilities have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil and administrative violations under the Act and in promoting quality of care consistent with regulations. In the RoPs, CMS finalized this requirement along with additional training and personnel requirement that were not expressly required in the Act.

CMS proposes to remove many of the requirements from this section not expressly required by statute. The Proposed Rule includes the following proposed changes:

- Removing the requirement that each facility designate a compliance officer and a designated compliance liaison for operating organizations with five or more facilities. Instead, CMS proposes that organizations develop a compliance and ethics program that is appropriate for the complexity of the organization and its facilities and that each facility assign a specific individual within the high-level personnel of the operating organization with the overall responsibility to oversee compliance.
- Removing the annual review requirement and propose that each organization undertake a periodic assessment of its compliance program to identify any necessary changes with a biennial review.
- Eliminating the requirement for a "compliance and ethics program contact person" to which individuals may report suspected violations. CMS confirmed that it is important for individuals to report suspected violations, but it will not specify the staff person for this task.

DELAY IMPLEMENTATION OF CERTAIN PHASE 3 ITEMS

The Proposed Rule proposes to delay implementation of portions of the Phase 3 provisions related to:

- Designation and training of the infection preventionist (§483.80);
- QAPI (§483.75); and
- Compliance and ethics program (§483.85) until one year following the effective date of the Proposed Rule.

CMS believes that the delay will avoid unnecessary work, confusion and burden associated with implementing provisions that are proposed to be changed in the Proposed Rule.

EFFECTIVE DATE AND IMPLEMENTATION DATES

Comments to the Proposed Rule are due no later than 5 PM on September 16, 2019, 60 days after publication of the Proposed Rule. We expect CMS to review those comments quickly given the proposed delay in the effective date of some of the upcoming RoP revisions. The Proposed Rule will become effective once the Final Rule is published. The one-year delay in implementation would end one year after the effective date of the Final Rule.

PRACTICAL TAKEAWAYS

- Consider submitting comments to the proposed rule to increase clarity in the rules and decrease the burden on providers;
- Facilities should carefully review and revise their policies and practices on each of the twelve areas that are revised and update them to comply with the proposed changes;
- While QAPI and compliance and ethics programs requirements have been modified, most of those program requirements remain and facilities need to continue to create and maintain those programs; and
- While many of the Proposed Rules are revisions to current regulations, facilities should keep in mind that many of the other Phase 3 components of the RoPs have changes that impact facility operations.

If you have questions or would like assistance preparing comments to the Proposed Rule, please contact:

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