Federal Requirements of Participation for Nursing Homes

Issued September 2016
Summary of Key Changes in the Rule - Part III

On September 28, 2016, the Centers for Medicare & Medicaid Services (CMS) issued updated federal nursing home regulations (Requirements of Participation for Long-Term Care Facilities). This is the first comprehensive revision to the regulations since they were issued in 1991. The updated rule (also referred to as the "final rule") is being implemented in three phases: Phase 1 - November 28, 2016, Phase 2 - November 28, 2017, and Phase 3 - November 28, 2019.

This summary sheet is designed to provide an overview of key changes in regulations going into effect as part of Phase 3. The purpose of the summary is to highlight what is different (new or modified) between the prior rule and the final rule.

Changes in the rule are indicated in two ways:

- **NEW** means that the language is completely new.
- **MODIFIED** means that a prior regulation has been revised in some way. Some language has either been deleted or revised, or new language has been added.

Instances where the content of the prior and final rule are the same, but there is a slight variation in phrasing, have not been included. Only those requirements that go into effect in Phase 3 are included.

§483.12 FREEDOM FROM ABUSE, NEGLECT, AND EXPLOITATION

(b) The facility must develop and implement policies and procedures about abuse, neglect, and exploitation

NEW

(4) The nursing home's policies and procedures must ensure that abuse, neglect, and exploitation are integrated into the Quality Assurance and Performance Improvement (QAPI) program.

§483.21 COMPREHENSIVE PERSON-CENTERED CARE PLANNING

(b) Comprehensive care plans

NEW

(3)(iii) The services a resident receives based on his or her person-centered care plan must be both culturally-competent and trauma-informed.

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§483.25 QUALITY OF CARE

NEW

(m) The facility must care for residents who are trauma survivors in a culturally-competent and trauma-informed way that eliminates or reduces triggers that could retraumatize them. This care must meet professional standards and take into consideration the resident's experiences and preferences.

§483.40 BEHAVIORAL HEALTH SERVICES

MODIFIED

(a)(1) Staff must have the competencies and skills sets to care for residents with a history of trauma and/or post-traumatic stress disorder in addition to those with mental and psychosocial disorders.

MODIFIED

(b)(1) The facility must now also provide residents who have a history of trauma and/or post-traumatic stress disorder with treatment and services to address any problems that have been identified or to help them reach and maintain their highest level of mental and psychosocial functioning.

MODIFIED

(b)(2) The facility must prevent residents with a documented history of trauma and/or post-traumatic stress disorder, as well as residents with a diagnosed mental or psychosocial adjustment difficulty, from becoming less socially interactive or more withdrawn, angry or depressed unless these behaviors cannot be prevented due to a clinical condition.

§483.70 ADMINISTRATION

NEW

(d)(3) The facility's governing body is responsible for all aspects of the QAPI program. *See also Quality Assurance and Performance Improvement §483.75 (f).*

§483.75 QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT

(a) Quality assurance and performance improvement (QAPI)

NEW

Every facility must have a QAPI program that is comprehensive, focused on outcomes of care and quality of life, and based on data. This applies even if the facility is part of a multi-facility chain.

NEW

(1) The facility must have documentation and demonstrate evidence of its QAPI program.

NEW (3) The facility must provide its QAPI plan to:

- A State or Federal surveyor at each annual survey
- A State or Federal surveyor during any other survey (e.g. complaint survey, revisit, etc.) upon request
- CMS upon request

NEW (4) Upon request, the facility is required to show documentation and evidence of its ongoing QAPI program and its compliance with the QAPI regulations to a State Survey Agency, Federal surveyor, or CMS.

(b) Program design and scope

NEW The facility must create a program that is ongoing and designed to address the full range of its services. The program must:

NEW (1) Address all systems of care and management practices.

NEW (2) Always include clinical care, quality of life, and resident choice.

NEW (3) Use the best available data to define and measure its performance goals.

NEW (4) Reflect the uniqueness of the facility.

(c) Program feedback, data systems and monitoring

NEW A facility must establish systems that are governed by policies and procedures. The policies and procedures must address how:

NEW (1) Feedback from residents, their representatives, direct care staff, and other staff will be obtained and used to identify problems and areas for improvement.

NEW (2) Other data (e.g. data from all departments) will be identified, collected, and used. This includes how the data will be used to set and monitor performance goals.

NEW (3) Performance indicators will be developed, monitored, and evaluated.

NEW (4) Adverse events will be tracked, investigated, analyzed, monitored, and prevented.

(d) Program systematic analysis and systemic action

NEW (1) The facility must take systemic action to improve its performance. This includes tracking and measuring how well it has done so that improvement can be sustained.

NEW (2) The facility must develop and then implement policies for how to:

- Identify the causes of systemic problems
- Correct those problems at a systems level
- Monitor the effectiveness of the improvement in order to continue the improvement

(e) Program activities

NEW (1) The facility must set priorities for performance improvement activities that focus on resident health, safety, autonomy, choice, and quality of care, as well as on high-risk, high-volume, and/or problem-prone areas. In selecting its activities, the facility must also factor in how severe, widespread and prevalent the problems are.

NEW (2) All performance improvement activities must track medical errors and adverse resident events. The facility must analyze the cause of these errors and events and then put in place a system or systems to prevent them from happening.

NEW (3) Performance improvement activities must include a certain number of performance improvement projects (PIPs). There is no required number or frequency of PIPs; how many and how often the facility conducts a PIP should be determined by the type of facility and its unique scope of services. Each year, at least one PIP must focus on high-risk or problem-prone areas.

(f) Governance and leadership

NEW The governing body and/or executive leadership has full accountability for the entire QAPI program. *See also Administration §483.70 (d)(3)*. It must ensure that the QAPI program:

NEW (1) Is created, carried out, and addresses identified priorities.
NEW (2) Is sustained during transitions of leadership and staffing.
NEW (3) Has sufficient resources (e.g. staff time, equipment, training etc.).

NEW (4) Targets problems or areas for improvement that are:

- Representative of facility operations and resident services
- Based on performance indicators, resident and staff input, and other information

NEW (5) Corrects gaps in systems.

NEW (6) Sets expectations around rights, quality, choice, safety, and respect.

(g) Quality assessment and assurance

NEW (1)(iv) The infection control and prevention officer has been added as a member of the quality assessment and assurance (QAA) committee. *See also Infection Control §483.80 (c)*

MODIFIED (2) The duties of the QAA committee have been increased to include coordinating and evaluating all QAPI activities.

The QAA is now also responsible for reviewing and analyzing data collected under QAPI and data from monthly drug regimen reviews, and then taking action to make improvements based on that data.

Given its expanded role, the QAA is required to continue to meet quarterly and to also meet as needed.

§483.80 INFECTION CONTROL

(b) Infection preventionist

NEW For the first time, facilities are required to have at least one individual serve as a designated Infection Preventionist (IP). The IP is in charge of the facility's infection prevention and control program (IPCP). One or more people can serve as IP.

To be an IP, an individual must meet certain requirements. He or she must:

- Have been trained primarily in nursing, medical technology, microbiology, epidemiology, or other related field
- Be qualified by one of the following: education, training, experience or certification
- Work at least part-time
- Have received specialized training in infection prevention and control

(c) IP participation on quality assessment and assurance committee

NEW

The IP must serve on the QAA committee and report on the IPCP. If more than one person serves as the IP, at least one of these individuals must be on the committee. *See also Quality Assurance and Performance Improvement §483.75(g)(1)(iv).*

§483.85 COMPLIANCE AND ETHICS PROGRAM

(a) Definitions and (b) General rule

NEW

For the first time each facility will be required to have a compliance and ethics program. The person or entity that operates the facility – called the operating organization – has to ensure that the facilities under its control have a program in place.

The purpose of the compliance and ethics program is to:

- Prevent and detect criminal, civil, and administrative violations
- Promote quality care

(c) Required components for all facilities

NEW

Each facility's compliance and ethics program must consist of eight basic components. These eight elements are:

NEW

(1) Written standards, policies, and procedures. These must at minimum include:

- A designated contact to whom individuals can report violations or suspected violations.
- A means of reporting anonymously
- Disciplinary actions that the entire staff, contractors and volunteers will face for committing violations

NEW

(2) High level personnel charged with overseeing compliance with those standards, policies, and procedures. High level personnel are considered to be individual(s) with substantial control over the operating organization or who play a substantial role in making policy within the operating organization. Examples of individuals considered "high level personnel" are provided.

NEW

(3) Sufficient resources and authority for high level personnel to ensure compliance.

NEW

(4) Due care not to give authority to individuals the operating organization knew or should have known were predisposed to commit violations.

NEW (5) Communication of the program's standards, policies, and procedures to the entire staff, contractors and volunteers. Facilities must communicate their policies and procedures through a training program (*See also Training Requirements 483.95(f)*) or the dissemination of information.

NEW (6) Reasonable efforts to comply with the standards, policies, and procedures. These efforts include:

- Use of monitoring and auditing systems
- Establishing and publicizing a system for reporting anonymously without fear of retribution
- Safeguarding the integrity of reported information

NEW (7) Enforcement of the standards, policies, and procedures using the disciplinary mechanisms set forth in the program. This includes taking disciplinary measures against any person or persons who fail(s) to detect and report a violation.

NEW (8) Appropriate response to the violation and prevention of future similar violations. This involves making changes to the compliance and ethics program when necessary.

(d) Additional required components for operating organizations with five or more facilities

In addition to the eight components listed above, the compliance and ethics programs for operating organizations with five or more facilities must include these 3 elements:

NEW (1) Mandatory annual training on the program

NEW (2) A compliance officer who reports directly to the operating organization's governing body. Responsibility for the compliance and ethics program must be a major part of the officer's job.

NEW (3) Compliance liaisons at each of the operating organization's facilities

(e) Annual review

NEW The compliance and ethics program must be reviewed on an annual basis and revised to incorporate any changes in laws or regulations, or changes within the operating organization.

§483.90 PHYSICAL ENVIRONMENT

(g) Resident call system

MODIFIED (1) The facility must have a communication system that sends a resident's call for assistance directly from their bedside to a staff member or to a centralized work area. Previously, the call system had to operate from the resident's room and not from the resident's bedside.

§483.95 TRAINING REQUIREMENTS

NEW For the first time, facilities must have an organized training program for all new and current staff as well as individuals working under a contractual arrangement and volunteers based on their roles. The amount and type of training are not specified, but are to be determined by the facility based on its facility assessment. However, the training topics are mandated. Topics of training include but are not limited to:

NEW (a) Communication. This is required for direct care staff.

NEW (b) Resident's rights and facility responsibilities

NEW (d) Quality assurance and performance improvement

NEW (e) Infection control

NEW (f) Compliance and ethics

- This training must be held annually if the operating organization has five or more facilities. *See also Compliance and Ethics Program §483.85(d)(1).*

*Note: * Abuse, neglect, and exploitation is also a required topic but was implemented in Phase 1*

(g) Required in-service training for nurse aides

MODIFIED (3) The facility assessment must now be considered in addition to nurse aides' performance reviews in determining what areas of weakness to address in in-service training.

NEW **(h) Behavioral health services**