LeadingAge Comments on Nursing Home Final Rule

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Washington -- CMS released the final rules revising the nursing home requirements of participation, which will be published October 4, 2016. This rule represents the most significant changes to the delivery of nursing home care since OBRA ‘87.

LeadingAge is pleased that CMS has recognized the enormous complexity of this rule and allowed for a phase-in for some of the components. We are also encouraged by:

- The continuing focus on more person-centered approaches, including many elements of resident rights and quality of care.
- The recognition of potential unintended consequences of requiring in-person evaluation by an attending clinician prior to non-emergency transfers; as a result, CMS did not include that proposal in the final rule.
- The 48-hour limit on as needed orders for psychoactive medications was changed from the proposed rule language, and that CMS recognized that the 48-hour limit would potentially lead to disrupted care and resident harm.

However, after an initial read-through, there are a few sections of the rule that we believe could be detrimental to our nursing homes members.

“One of the most significant elements in the final rule is the new requirement for facility-wide assessment,” said Dr. Cheryl Phillips, senior vice president of public policy and health services. “While we support the concept of aligning staff levels and expertise with the needs of the residents, rather than looking at fixed staffing levels, we remain concerned that we have yet to fully understand what this assessment will include and how CMS will use it for assessing quality of care.”

LeadingAge is also concerned with the amount and degree of staff training that will be needed to implement the new requirements successfully. The impact on an already stretched and resource-strapped workforce will be further challenged unless both Medicare and Medicaid include the necessary staff resources into payments and population health shared savings models.

With regards to arbitration, LeadingAge has always supported arbitration agreements that are properly structured and allow parties to have a speedy and cost-effective alternative to traditional litigation. We are therefore disappointed that CMS has exceeded its authority and banned all pre-dispute arbitration agreements. Arbitration agreements should be enforced if they were executed separately from the admission agreement, were not a condition of admissions, and allowed the resident to rescind the agreement within a reasonable time frame.

Over the next several days LeadingAge will be providing in-depth analysis of the entire rule. We also recognize that much of the needed details will come out of the accompanying guidance language, and we look forward to working with CMS as such guidance is developed.
Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities

CMS has issued the Final Rule: Medicare and Medicaid Programs: Reform of Requirements for Long-Term Care Facilities. It is currently on display in PDF format at https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-23503.pdf. The final rule will be published in the Federal Register on Tuesday, October 4.

*We’ll provide the Federal Register link at the point of publication.

- This final rule adds new requirements and reorganizes or eliminates existing language and/or requirements as determined appropriate.
- There is a 3-stage phase-in for implementation of these regulations:
  - The regulations included in Phase 1 must be implemented by November 28, 2016.
  - The regulations included in Phase 2 must be implemented by November 28, 2017.
  - The regulations included in Phase 3 must be implemented by November 28, 2019.

The following is essentially a ‘laundry list’ of the provisions in the final rule; it highlights key changes and timeframes for implementation and will provide an overview/indication of the breadth of revisions to current requirements. Further details and in-depth analyses will follow.

PART 483 – REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

§483.5 Definitions.
- Added and/or revised definitions including “adverse event”; “documentation”; “resident representative” “abuse”; “sexual abuse”; “neglect”; “exploitation”; “misappropriation of resident property”; resident representative; and “person centered care”.

§483.10 Resident rights.
- All existing residents’ rights retained, including, e.g., the right to privacy and confidentiality, notification responsibilities and services, right to be informed, voice grievances, facility maintenance of funds upon request, participate in resident/family groups, exercise legal/citizen rights, etc., but updates language and organization to include, e.g., electronic communications. Revisions include elimination of language, such as “interested family member”; replacement of “legal representative” with “resident representative.”
- Requires that facilities provide equal access to quality care regardless of diagnosis, severity of condition, or payment source; maintain identical policies and practices for transfer, discharge, provision of services.
• Residents not adjudged incompetent may designate representatives in accordance with State law who may exercise residents’ rights within state law; residents may exercise rights not delegated to a representative, including the right to revoke a delegation, except as limited by State law.

• Same-sex spouses must be afforded treatment equal to that afforded to opposite sex spouses if the marriage was valid in the jurisdiction in which it was celebrated.

• To the extent practicable, facilities must facilitate and support and provide opportunities to participate in the [person-centered] care planning process; including the right to identify participants and/or their roles in the process; to be informed of and participate in treatment; care to be furnished and the type of caregiver/professional furnishing care; risks and benefits of proposed care; alternatives or options.

• Residents have the right to a roommate of choice when practicable and the right to receive written notice before a room or roommate change.

• Self-determination includes activities, schedules, health care and providers, choices about aspects of life in the facility; interaction with members of the community and participation in community activities.

• Residents may receive visitors of choice at the time of their choosing, subject to reasonable clinical and safety restrictions, in a manner that does not impose on rights of other residents; facilities written policies and procedures must include any clinically necessary or reasonable restriction or limitation.

• Facilities must designate an ‘approved’ staff person responsible for providing assistance and responding to resident or family groups.

• Facilities must facilitate residents’ right to communicate within and external to the facility, e.g., reasonable access to telephone services and internet to the extent available.

• Composite distinct part facilities must specify the policies that apply to room changes between its different locations.

• Facilities must allow representatives of the State Long-Term Care Ombudsman to examine residents’ medical, social, and administrative records within State law.

• Facilities must exercise reasonable protection of residents’ property from loss or theft.

§483.12 Freedom from abuse, neglect, and exploitation.

• Expanded to prohibit employment of individuals with a disciplinary action in effect against their professional license by a state licensure body as a result of a finding of abuse, neglect, exploitation, mistreatment of residents or misappropriation of resident property; and to require reporting of allegations of abuse, neglect or exploitation immediately, but within 2 hours of the allegation or not later than 24 hours if suspicion of neglect or exploitation does not result in bodily injury.

§483.15 Admission, transfer, and discharge rights.

• Facilities must provide notice of special characteristics or service limitations prior to admission.

• Composite distinct part facilities must disclose physical configurations, including locations and the policies that apply to room changes between these locations.

• Facilities may not transfer or discharge residents while appeals are pending unless failure to discharge or transfer would endanger resident health or safety.

• Documentation by a physician for facility transfers or discharges must include the basis for the transfer; specific resident need(s) that cannot be met and related facility efforts; the service available at the receiving facility.
• Information to the receiving provider must include contact information of the responsible practitioner; resident representative; advance directive information; special instructions or precautions; comprehensive care plan goals; discharge summary.

• Written notice before transfer must include reasons for the move; contact information and a copy to the State Long-Term Care Ombudsman; effective date; receiving location; appeal rights.

• For residents with intellectual and developmental disabilities or a mental disorder or related disabilities, the mailing, email address, and telephone number of the protection and advocacy agency.

• For facility closure, the administrator must provide prior written notification to the State Survey Agency, State Long-Term Care Ombudsman, residents/representatives, and the transfer plan and relocation of residents.

• Facilities must implement a written policy on permitting residents return to the facility following hospitalization or therapeutic leave.

§483.20 Resident assessment.
• Requires direct observation and communication with the resident, as well as communication with licensed and non-licensed direct care staff members on all shifts for discharge planning.

• Clarifies appropriate coordination of resident assessment with PASRR.

• Adds exceptions to PASRR requirements for mental illness and intellectual disabilities for admission with respect to transfers from a hospital with an expected stay of less than 30 days, or to or from a hospital after the initial admission.

• Requires notification of state mental health or intellectual disability authorities promptly after a significant change in the mental or physical condition of a resident with a mental illness or intellectual disability.

§483.21 Comprehensive person-centered care planning.
• Requires development of a baseline care plan for each resident within 48 hours of admission, including instructions needed to provide effective and person-centered care meeting professional standards; identifies the minimum healthcare information necessary, e.g., initial goals based on admission orders; physician orders; dietary orders; therapy services; social services. A copy must be provided to the resident/representative.

• Facilities may develop a comprehensive care plan in place of the baseline if the comprehensive care plan is developed within 48 hours of the resident’s admission and meets all comprehensive care plan requirements, e.g., services to be provided; residents’ goals, residents’ preference and potential for future discharge.

• Requires the care plan to include any specialized services or specialized rehabilitation services the facility will provide as a result of PASRR; a rationale for disagreement with PASRR findings must be documented in the medical record.

• Adds a nurse aide, food and nutrition services, and a social worker to the interdisciplinary team (IDT) that develops the comprehensive care plan.

Discharge Planning [as part of Comprehensive Person-Centered Care Planning]:
• Requires facilities to document and update residents’ goals for discharge; assess potential for future discharge; involve and inform the resident/representative; document the resident has been asked about their interest in receiving information regarding return to community.
• If discharge to the community is determined not feasible, facilities must document who made the determination and why.
• For residents transferred to another SNF or discharged to a HHA, IRF, or LTCH, facilities must assist in selecting a post-acute care provider using data that includes, but not limited to, SNF, HHA, IRF, or LTCH standardized patient assessment data, quality measures, and resource use to the extent data is available.
• Discharge summaries include a recapitulation of the resident's stay; a final summary of the resident's status; reconciliation of all pre-discharge medications and post-discharge medications; a post-discharge plan of care.

§483.24 Quality of life.
• Clarifies that quality of life is an overarching principle in all care and services.
• Based on the comprehensive assessment and consistent with residents’ needs and choices, facilities must provide the necessary care and services to ensure that residents’ abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that such diminution was unavoidable.
• Clarifies the requirements regarding a resident’s ability to perform ADLs, i.e., a resident who is unable to carry out ADLs receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene; personnel provide basic life support, including CPR, to residents requiring such emergency care prior to the arrival of emergency medical personnel, subject to related physician orders and residents’ advance directives.
• Includes requirements related to activities programs / choice of activities.

§483.25 Quality of care.
• Quality of care applies to all treatment and care provided to facility residents. Based on the comprehensive assessment, the facility must ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the resident’s choices, including but not limited to the following: Vision and hearing; Skin integrity: Pressure ulcers, Foot care; Mobility; Accidents; Incontinence; Colostomy; Assisted nutrition and hydration; Modifies requirements for nasogastric tubes to reflect current clinical practice; includes enteral fluids in requirements for assisted nutrition and hydration; Parenteral fluids; Respiratory care, including tracheostomy care and tracheal suctioning; Prostheses; Pain management; Dialysis.
• Trauma-informed care: Trauma survivors must receive culturally-competent, trauma-informed care in accordance with professional standards of practice, accounting for residents’ experiences and preferences to eliminate or mitigate triggers that may cause re-traumatization.
• Bed rails: Facilities must attempt appropriate alternatives prior to use.

§483.30 Physician services.
*CMS eliminated the proposed requirement for in-person evaluation by a practitioner before an unscheduled transfer to a hospital.
• Allows physicians to delegate dietary orders to qualified dietitian or other clinically qualified nutrition professionals.

§483.35 Nursing services.
• Adds a competencies/skill set requirement for determining sufficient nursing and direct care staff based on the [new] facility-wide assessment, including but not
limited to: # of residents, acuity, range of diagnoses, resident assessments and care plan content.

§483.40 Behavioral health services.
- Focuses on provision of necessary behavioral health care and services to residents in accordance with their comprehensive assessment and plan of care.
- Requires staff to have appropriate competencies to provide behavioral health care and services, including care of residents with mental and psychosocial disorders, trauma and/or post-traumatic stress disorders, dementia, and implementing non-pharmacological interventions.
- Includes, but is not limited to prevention and treatment of mental and substance abuse disorders.

§483.45 Pharmacy services.
Drug Regimen Review
- Requires the monthly DRR to include review of residents’ medical record.
- Requires the pharmacist to document any irregularities noted during the DRR, including at minimum, a resident’s name and the relevant drug and irregularity identified to be sent to the attending physician, medical director, and director of nursing.
- Requires the attending physician to document the identified irregularity has been reviewed and what, if any, action has been taken. “Irregularities” include “unnecessary drugs.”
- Requires facilities to ensure that residents who have not used psychotropic drugs not be given these drugs unless medically necessary; and receive gradual dose reductions and behavioral interventions unless clinically contraindicated.
- “Psychotropic drug” includes any drug that affects brain activities associated with mental processes and behavior, including: anti-psychotics; anti-depressants; anti-anxiety; hypnotics.
- PRN orders for psychotropic drugs are be limited to 14 days unless the primary care provider reviews/evaluates and documents the rationale for extension.
- Facilities must implement policies/procedures for DRR, including timeframes for the process and procedures for the pharmacist when immediate action is required.

§483.50 Laboratory, radiology, and other diagnostic services.
- Clarifies that a PA, NP, or CNS may order laboratory, radiology, and other diagnostic services in accordance with state and scope of practice laws.
- Clarifies that the ordering practitioner be notified of results that fall outside of clinical reference ranges in accordance with facility notification policies and procedures.

§483.55 Dental services.
- Prohibits SNFs from charging a Medicare resident for the loss or damage of dentures determined to be the facility’s responsibility.
- Requires NFs to assist eligible residents to apply for reimbursement of dental services under the Medicaid state plan.
- Clarifies that a referral for lost or damaged dentures “promptly” means within 3 days absent documentation of any extenuating circumstances.

§483.60 Food and nutrition services.
• Requires employment of sufficient staff with appropriate competencies to carry out dietary services in accordance with resident assessments, individual care plans, and facility census.
• Requires a qualified dietitian or other clinically qualified nutrition professional either full-time, part-time, or on consultant basis. Dietitians hired or contracted prior to 11/28/16 have 5 years from 11/28/16 to meet the requirements or as required by state law.
• A director of food and nutrition service must be a certified dietary manager, certified food service manager, or be certified for food service management and safety by a national certifying body or have an associate’s or higher degree in food service management or hospitality; has to meet any state requirements for food service managers.
• Requires menus to reflect religious, cultural and ethnic needs and preferences, be updated periodically, and reviewed by the qualified dietitian or other clinically qualified nutrition professional for nutritional adequacy while not limiting residents’ right to personal dietary choices.
• Requires facilities to consider resident allergies, intolerances, and preferences and ensure adequate hydration.
• Allows attending physicians to delegate prescribing resident diets to registered or licensed dietitians, including therapeutic diets, in accordance with state law.
• Requires availability of nourishing alternative meals and snacks for residents who want to eat at non-traditional times or outside of scheduled meal times in accordance with the plan of care.
• Requires documentation in the care plan of the clinical need for a feeding assistant and the extent of dining assistance needed.
• Clarifies that facilities may procure food items directly from local producers and may use produce grown in facility gardens.
• Clarifies that residents are not prohibited from consuming foods not procured by the facility.
• Requires a policy regarding use and storage of foods brought to residents by family and other visitors.

§483.65 Specialized rehabilitative services.
• Adds respiratory services to specialized rehabilitative services.
• Requires that services obtained from an outside resource be a provider of specialized rehabilitative services not excluded from participating in any federal or state health care programs.

§483.70 Administration.
• Requires that the governing body appoint the administrator who reports to and is accountable to the governing body
• Requires the governing body as responsible and accountable for the QAPI program.
  - Facility assessment.
    • Requires a facility-wide assessment to determine resources are necessary to care for residents day-to-day and in emergencies.
    • The assessment must be reviewed and updated as necessary and at least annually.
    • The facility assessment must address the resident population including number; capacity; care required; staff competencies physical environment; ethnic, cultural, or religious factors; resources; services; all personnel including managers, staff and volunteers; contracts; health information technology resources; a facility- and community-based risk assessment utilizing an all-hazards approach.
- **Clinical Records**
  - Establishes safety and confidentiality requirements that mirror some found in the HIPAA Privacy Rule (45 CFR part 160, and subparts A and E of part 164).

- **Binding Arbitration Agreements**
  - Requires that facilities not enter into a pre-dispute agreement for binding arbitration with residents or representatives nor require that residents sign an arbitration agreement as a condition of admission.

§483.75 **Quality assurance and performance improvement.**
- Requires all LTC facilities to develop, implement, and maintain an effective comprehensive, ongoing, data-driven QAPI programs that focus on systems of care, outcomes of care and quality of life.
- Facilities must submit their QAPI plan at the 1st standard survey after 1 year from the final rule effective date of 11/28/16; and at each subsequent standard survey upon request; evidence of ongoing implementation also required upon request.
- Facilities must maintain effective feedback systems from staff, residents/resident representatives; establish priorities; have a process for identifying, reporting, analyzing, and preventing adverse/potential adverse events; systematic determination of underlying causes; measure/monitor the success of actions taken and track performance for sustainability; and include Performance Improvement Projects (PIPS).
- QAA Committee requirements are maintained with amendment

§483.80 **Infection control.**
- Requires a system (Infection and Control Program – IPCP) for preventing, identifying, surveillance, investigating, and controlling infections and communicable diseases for residents, staff, volunteers, visitors, and other individuals providing services based upon facility and resident assessments as reviewed and updated annually; also requires incorporation of an antibiotic stewardship program.
- Requires designation of an Infection and Preventionist (IP) who are responsible for the IPCP and who serves as a member of the facility’s quality assessment and assurance (QAA) committee. More than one IP may be designated within a facility.

§483.85 **Compliance and ethics program.**
- Requires the operating organization for each facility to have in operation a compliance and ethics program with established written compliance and ethics standards, policies and procedures capable of reducing the prospect of criminal, civil, and administrative violations in accordance with section 1128I(b) of the Act.
- Required components: established written standards, policies, procedures; assignment of high-level personnel; sufficient resources and authority for these individuals; due diligence to prevent delegation to individuals with propensity for criminal, civil, administrative violations; effective communication and mandatory training; reasonable steps, e.g., monitoring/auditing systems, to achieve compliance; consistent enforcement; appropriate response to correct and prevent future occurrences.
- Organizations with 5 or more facilities must include mandatory annual training; designated compliance officer; designated compliance liaisons at each facility; annual review.

§483.90 **Physical environment.**
• Facilities initially certified after the effective date of this rule (11/28/16) are limited to two residents per bedroom.
• Facilities receiving approval of construction or newly certified after the effective date of this rule (11/28/16) each resident room must have a bathroom equipped with at least a commode and sink.
• Requires a call system from each resident’s bedside.
• Requires policies, in accordance with applicable federal, state and local laws and regulations, regarding smoking, smoking areas and safety that take into account non-smoking residents.

§483.95 Training requirements.
• Sets forth all requirements of an effective training program for new and existing staff, contract staff, and volunteers. Topics include effective communication; resident rights and facility responsibilities; dementia management and abuse prevention; freedom from abuse, neglect, and exploitation; QAPI & infection control; compliance and ethics.
• Annual training is required for organizations operating five or more facilities.
• Requires dementia management and resident abuse prevention training as part of the 12 hours per year in-service training for nurse aides.

TIMELINES FOR IMPLEMENTATION

Phases:

Phase 1: Implementation by November 28, 2016.

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| §483.12 Freedom from abuse, neglect and exploitation. | Phase 1 except for: 
  - (b)(4) Coordination with QAPI Plan— Phase 3 
  - (b)(5) Reporting crimes/1150B— Phase 2 |
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| §483.60 Food and nutrition services | Phase 1 except for: 
- (a) As linked to Facility Assessment at §483.70(e)—Phase 2 
- (a)(1)(iv) Dietitians hired or contracted prior to effective date—5 years from the final rule effective date 
- (a)(2)(i) Director of food & nutrition services designated to serve prior to effective—5 years from the final rule effective date 
- (a)(2)(i) Dietitians designated to after the effective date—1 year from the final rule effective date | |
| §483.65 Specialized rehabilitative services | Phase 1 | |
| §483.70 Administration | Phase 1 except for: 
- (d)(3) Governing body responsibility of QAPI program—Phase 3 
- (e) Facility assessment—Phase 2 | |
| §483.75 QAPI | Phase 3 except for: 
- (a)(2) Initial QAPI Plan must be provided to State Agency Surveyor at annual survey—Phase 2. 
- (g)(1) QAA committee—Phase 1 except for subparagraph (iv), the addition of the ICPO—Phase 3 
- (h) Disclosure of information—Phase 1 
- (i) Sanctions—Phase 1 | |
| §483.80 Infection control | Phase 1 except for: 
- (a) As linked to Facility Assessment at §483.70(e)—Phase 2 
- (a)(3) Antibiotic stewardship—Phase 2 
- (b) Infection preventionist (IP)—Phase 3 
- (c) IP participation on QAA committee—Phase 3. | |
| §483.85 Compliance and ethics program | Phase 3 | |
| §483.90 Physical environment | Phase 1 except for 
- (f)(1) Call system from each resident’s bedside—Phase 3. 
- (h)(5) Policies regarding smoking—Phase 2 | |
§483.95 Training requirements  
Phase 3 except for:
-(c) Abuse, neglect, and exploitation training—Phase 1
-(g)(1) Regarding in-service training;
(g)2) dementia management & abuse prevention training; (g)(4) care of the cognitively impaired—Phase 1
-(h) Training of feeding assistants—Phase 1
LeadingAge Wisconsin
Full Day Program on the Mega Rule

The Final Rule: Requirements for Participation, DQA Guidance, and Key Changes from an Operator's Perspective -- December 2 in Eau Claire, December 6 in Pewaukee, and December 7 in Kimberly (Fee: $95 including lunch and materials).

This full-day seminar will provide an update and overview from the Wisconsin Division of Quality Assurance, an in-depth review of the RoP, interpretive guidance, and highlights of the survey process changes. There are key areas for system updates to include Resident Rights, Resident Assessments, Comprehensive Person-Centered Care Planning, Quality of Care and Quality of Life, Infection Prevention and Control and more! Additional key updates for facility implementation include Facility Assessment, QAPI, Transitions of Care, Compliance and Ethics Program, as well as the individual interdisciplinary service components. This informational program will address key changes and operational strategies on how to prioritize these changes and put excellent processes in place for both quality and compliance.

Learner Objectives:

- Outline an overview of the new regulations from the perspective of Wisconsin's Division of Quality Assurance (DQA).
- Discuss tips and tools from DQA for managing the new regulations.
- Outline updates to the State's new survey process coming in late November 2017.
- Analyze the key changes in the new Requirements of Participation for skilled nursing facilities.
- Discuss the interpretive guidelines and survey process changes that will directly impact your operations.
- Identify three key strategies for QAPI in facility systems.
- Outline three key leadership implementation strategies for operational

Presenters--

Patricia (Pat) Virnig, RN: Pat Virnig is the Director of the DHS Bureau of Nursing Home Resident Care within the Division of Quality Assurance. Pat has more than 40 years in health care (the last 28 in the Division of Quality Assurance) protecting the health, safety, and welfare of Wisconsin citizens through the survey, certification, and licensure of health care organizations.

Karolee Alexander, RN: Karolee Alexander, Director of Reimbursement and Clinical Consulting at Pathway Health, has over 25 years of nursing leadership in long-term care, including 12 years as a director of nursing services for various facilities and six years in various MDS Coordinator positions. In these roles, she has established herself as an expert in the management of nursing operations, reimbursement systems and performance improvement.
LeadingAge Webinar on the
CMS Requirements of Participation:
A Comprehensive Overview Webinar
October 13, 2016, 2:00 – 3:00 p.m. ET
Fee: $99
Registration Information available here.

CMS has issued a final rule revising the current Requirements of Participation for nursing homes providers. This “mega rule” promises to have a profound effect on the field and includes provisions for compliance and ethics programs, quality assurance and performance improvement (QAPI) processes as well as many other important changes to nursing home operations.

Join LeadingAge experts for an overview of the final rule and what critical steps skilled nursing providers should be taking in preparation for compliance with the new regulations.

- Gain a clear understanding of the provisions of the new requirements and how they differ from existing regulations.
- Explore key areas of importance within the final rule and their impact on staff resources, resident care and quality of life.
- Consider what the changes mean for nursing home providers’ day-to-day operations and care delivery.

Speakers: Cheryl Phillips, Senior Vice President of Public Policy and Health Services; Evvie Munley, Director of Health Regulations and Policy, LeadingAge