

The New Nursing Facility Long Term Care Requirements For Medicare and Medicaid Participation *Report on Phase 1*

THE ENVIRONMENT

As we all know, health care providers -- including hospitals, physicians, skilled nursing facilities, long term care facilities, home health agencies, hospice, DME, and others -- have all been grappling with the challenges of meeting increased scrutiny from a spectrum of HHS centers and offices, including CMS and the OIG, and from increased regulatory mandates.

Facilities providing both long term care and skilled nursing facility care -- which constitute the majority of facilities -- have been coping with both Medicare SNF policies and state and federal Medicaid policies addressing a broad array of regulatory issues and federal legislative mandates provided, for example, in PAMA¹ and the Impact Act. The issue of quality care is being addressed by so many different initiatives, measures and implementation deadlines that one would expect facilities to be reeling in the effort to meet the myriad of quality indices including more than one rehospitalization policy. And perhaps they are reeling.

But then, to this mix, CMS added a “mega” regulation applying to both LTC and SNF facilities. On July 16, 2015 published a proposed rule which provided an extensive revision of the facility “Conditions for Participation” in the Medicare and Medicaid programs.² CMS published the Final Rule on September 28, 2016.³

THE RULE AND THE CMS RATIONALE FOR THE RULE

Consolidated Medicare and Medicaid requirements for participation (requirements) for long term care (LTC) facilities were first published in the Federal Register on February 2, 1989, 54 Fed Reg 5316. These regulations have been revised and added to since that time, principally as a result of legislation or a need to address a specific issue. However, they have not been comprehensively reviewed and updated since 1991, 56 Fed Reg 48826, September 26, 1991, despite substantial changes in service delivery in this setting.

According to CMS, since the current requirements were developed, “...significant innovations in resident care and quality assessment practices have emerged. In addition, the population of LTC facilities has changed, and has become more diverse and more clinically complex.”

Further, CMS states that over the last two to three decades, extensive, evidence-based research has been conducted and has enhanced knowledge about resident safety, health outcomes, individual choice, and quality assurance and performance improvement. In light of these changes, CMS recognized the need to evaluate the regulations on a comprehensive basis, from both a structural and a content perspective. Therefore, CMS “...reviewed regulations in an effort to improve the quality of life, care, and

¹ Congress enacted the SNF VBP legislation in section 215 of the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93); The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT ACT) is a Bi-partisan bill introduced in March, U.S. House & Senate, passed on September 18, 2014, and signed into law by President Obama October 6, 2014. .

² 80 Fed Reg 42168, Proposed Rule, July 16, 2015

³ 81 Fed Reg 68688, Final Rule, October 4, 2016

services in LTC facilities, optimize resident safety, reflect current professional standards, and improve the logical flow of the regulations.”⁴

THE BREADTH AND DEPTH OF THE RULE

The bottom line is that the new regulatory requirements **are significant and challenging**. CMS had received many comments on the necessity of a delay or some phase-in for the regulations. CMS itself recognized the significance of the changes and in the Final Rule agreed to a Phase-in .

It stated in the Final Rule that, “Given the comprehensive nature of the regulatory revisions, it agreed that a longer period of time is necessary to implement the changes outlined in this final rule.”⁵

It acknowledged that facilities would need more time to comply BUT ALSO that CMS would need such!

LTC facilities may find the comprehensive revision to the LTC requirements *overwhelming* and want to avoid any unintended consequences or unanticipated risks to both facilities and residents. We believe that allowing for a longer implementation period will allow LTC facilities the time necessary to come into compliance with the new Requirements. *In addition, we anticipate that additional time will be needed [for CMS!] to develop revised interpretive guidance and survey processes, conduct surveyor training on the changes, and implement the software changes in the Quality Indicator Survey (QIS) system.*⁶

Thus, CMS provided a phased approach with three phases. They are as follows:

- **Phase One – by November 28, 2016:** Facilities must be in compliance with almost all of the resident rights, quality of care, and health and safety requirements of the Final Rule. The one exception is the ban on the use of pre-dispute arbitration agreements. The Rule barred nursing homes from requiring patients to agree to binding arbitration at admission, though facilities and residents could still agree to use the process after a dispute arises. This issue is now in the courts. The American Health Care Association, AHCA, sued to reverse the arbitration curbs. A district court judge in Mississippi blocked the ban while the dispute is being litigated. He agreed with AHCA that CMS exceeded its legal authority by halting the practice, a decision that he said should be left to Congress. It is understood that CMS will not attempt to enforce the ban until the injunction is lifted.
- **Phase Two – by November 28, 2017:** Facilities will be required to implement additional elements of the requirements, including transfer/discharge documentation, baseline care plans, monthly medical chart reviews by a pharmacist, antibiotic stewardship, physical environment smoking policies, and an initial QAPI plan, among others.
- **Phase Three – by November 28, 2019:** Facilities will be required to implement their QAPI plan, including integration with other components of the requirements; provide trauma

⁴ Proposed Rule at 42169.

⁵ Final Rule at 68696.

⁶ Ibid.

informed care; establish an infection preventionist (IP) and participation of the IP on the QAA Committee; establish and implement the new requirements.

PROJECTED COST OF THE RULE TO THE FEDERAL GOVERNMENT AND NURSING FACILITIES

- **The Cost To The Federal Government**

CMS will incur the costs of updating the interpretive guidance, the survey process, and making IT systems changes. The agency anticipates that the majority of the system costs will be incurred between FY17 and FY18. CMS anticipate initial federal start-up costs between \$15 and \$20 million In order to implement these new standards. Once implemented, improved surveys to review the new requirements will require an estimated \$15 to \$20 million annually in federal costs.⁷

- **The Cost to Facilities**

- **This is an incredibly costly regulation for facilities!!** CMS itself provides some devastating data. CMS had high estimates of the impact of the Proposed Rule but had to **increase** them in the Final Rule.
- CMS states that it expects that complying with the updated requirements for participation will cost \$831 million in the first year (up from \$729 million in the proposed rule), or an estimated \$62,900 per facility (up from \$46,491 per facility), and approximately \$736 million annually in the second and subsequent years (up from \$638 million), or \$55,000 per facility (up from \$40,685 per facility).⁸ (See Table 2 in Appendix to the memo.)
- According to more than one analyst, the Final Rule's projected costs are exceedingly conservative. They cite that for LTC facilities in certain parts of the country hiring and retaining certain facility staff with the required qualifications may be challenging.
- The Cost of Facility Non-Compliance -- It is likely that the massiveness and complexity of the Final Rule will result in compliance issues and problems. The cost of failing to comply can be very high. Facilities can face penalties, denial of payment for new admissions, and possible termination from the Medicare and Medicare programs for failure to achieve substantial compliance with the overwhelming updated regulation.

A REPORT FROM THE FRONT – HOW DID PHASE ONE GO?

We believe that there is no clear picture as yet regarding the ability of facilities to meet the demands of the modified and new requirements. CMS determined it would not provide Interpretive Guidance (IG) for specific F-tags (used to cite deficient practice) in Phase 1. The approach that was taken was to incorporate new requirements into existing F-tags without additional guidelines and to provide

⁷ Final Rule at 68844.

⁸ Ibid.

education for surveyors to help them to determine compliance with the new requirements.⁹ For Phase 1, CMS provided training to surveyors via webcast and provided questions that surveyors could ask/investigate to determine compliance with the Phase 1 requirements.

It is important to recognize that nursing centers receive their standard survey annually, within a time frame of 9 - 15 months. There have been a relatively small percentage of centers surveyed to the Phase 1 requirements. However, we understand that a few requirements have been cited, including requirements for a discharge summary for each discharged resident and a grievance policy being developed and implemented in each center.

In November 2017, CMS will implement Phase 2, and also implement new IGs. In addition, CMS will introduce a new survey process. According to CMS, the new survey process will combine “the best approaches” of both the standard survey process and the Quality Indicator Survey process.

The impact on providers of all these changes is expected to be significant. Until the final IGs are made available to surveyors and providers (anticipated in summer or early fall 2017), it is unclear exactly how this will all come together, be implemented and ultimately impact providers.

However, it is an inescapable conclusion that, as the additional mandates of Phases 2 and 3 are triggered, the challenges for facilities in meeting the Final Rule will escalate. We are not yelling “the sky is falling,” and we certainly hope it does not. But we are following this development and will continue to report what we learn.

⁹ See brief account of the initial SOM edits at <http://www.ltcpharmacynews.com/docs/PDF%20Docs/CMS%20Publishes%20Advance%20Copy%20of%20the%20State%20Operations%20Manual.pdf>

Appendix Table 1.¹⁰
Details on Phased Implementation¹¹

Phase	Primary Implementation
<p>Phase 1</p> <p>(Entries with asterisks are partially implemented in Phase 2 and/or Phase 3)</p>	<ul style="list-style-type: none"> • Rights and Facility Responsibilities* • Freedom from Abuse Neglect and Exploitation* • Admission, Transfer and Discharge* • Resident Assessment • Comprehensive, Person-Centered Care Planning* • Quality of Life • Quality of Care* • Physician Services • Nursing Services* • Pharmacy Services* • Laboratory, radiology and other diagnostic services • Dental Services* • Food and Nutrition* • Specialized Rehabilitation • Administration (Facility Assessment – Phase 2)* • Quality Assurance and Performance Improvement* -QAACommittee • Infection Control –Program* • Physical Environment*
<p>Phase 2</p> <p>(Entries with asterisks are partially implemented in other phases.)</p>	<ul style="list-style-type: none"> • Behavioral Health Services* • Quality Assurance and Performance Improvement* - QAPI Plan • Infection Control – Facility Assessment and Antibiotic Stewardship ** • Compliance and Ethics* • Physical Environment- smoking policies *
<p>Phase 3</p> <p>(Entries with asterisks are partially implemented in other phases.)</p>	<ul style="list-style-type: none"> • Implementation of QAPI•Infection Control – Infection Control Preventionist* • Compliance and Ethics* • Physical Environment-call lights at resident bedside * • Training

¹⁰ A video presentation of the Final Rule with detail and citations for all the updated and new regulations is available at: http://www.ltcpharmacynews.com/Learning%20Resources_CMS%20LTC%20Final%20Rule.html

¹¹ MLN Connects National Provider Call Presentation, CMS Learning Network, *Final Rule to Reform the Requirements for Long-Term Care Facilities*, Karen Tritz – Division of Nursing Homes Director Clinical Standards Group Long-Term Care Team Survey & Certification Group, Division of Nursing Homes, October 27, 2016.

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Appendix Table 2.

CMS Estimates of the Cost to the Industry of the new LTC Requirements				
	First Year Projected Total Cost to Facilities	First Year Projected Average Cost Per Facility	Second Year Projected Total Cost To Facilities	Second and Subsequent Years Projected Average Cost Per Facility
Proposed Rule <i>80 Fed Reg 42168 at 42241, July 16, 2015</i>	\$729 million	\$46,491	\$638 million	\$40,685
Final Rule <i>81 Fed Reg 68688 at 68844, October 4, 2016</i>	\$831 million	\$62,900	\$736 million	\$55,000