Rule Overhaul to Save Health Industry Up To $640 Million, Medicare Says

Sandra M. DiVarco

On May 7, 2014, the U.S. Centers for Medicare & Medicaid Services (CMS) issued a long-awaited final rule in response to President Obama's Executive Order (EO) 13563, "Improving Regulation and Regulatory Review," which set as its goal reduction of health care delivery costs by streamlining Medicare and Medicaid regulations for hospitals and other providers. Following the proposed rule, which had been issued in early 2013, the final rule significantly affects regulations that impact a variety of health care facility types. The final rule was published in the Federal Register on May 12, 2014, and will become effective 60 days after publication, July 11, 2014 (but for one provision, which became effective upon publication).

The final rule "Medicare and Medicaid Programs; Part II—Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction" (Final Rule) contains reforms to existing Medicare regulations applicable to hospitals, ambulatory surgical centers (ASCs), intermediate care facilities for individuals who are intellectually disabled (ICF/ID), transplant centers and organ procurement organizations, long-term care (LTC) facilities, critical access hospitals (CAHs), rural health clinics (RHCs), federally qualified health centers (FQHCs) and laboratories [under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations] in order to improve efficiency, improve transparency and reduce regulatory burdens for these provider types. The overall cost savings in the proposed rule is estimated to be $640 million per year.

A brief summary of the main Final Rule provisions affecting each provider type is set forth below. Additional changes, including information on technical corrections, can be found in the Final Rule itself, available via the above weblink,

Hospitals

A significant number of the proposed rules apply specifically to hospitals, and cover a wide variety of issues for that provider type.

MEDICAL STAFF MATTERS: DIRECT CONSULTATION BETWEEN GOVERNING BODY AND MEDICAL STAFF LEADERS

The Final Rule provides for regulatory changes that are of great importance to hospital medical staffs. In formally rescinding a prior final rule regarding mandatory medical staff membership on the governing body, the Final Rule requires that a hospital's governing body "directly consult" with the individual responsible for the organized medical staff of the hospital (or their designee) periodically (at least twice) during the fiscal or calendar year regarding the quality of medical care provided to patients. This requirement is designed to ensure that the "medical staff perspective" on quality of care is communicated to the governing body. The Final Rule defines "direct consultation" as the governing body (or a subcommittee thereof) meeting with medical staff leaders either face to face or via telecommunications system that permits immediate, synchronous communication. Factors to consider in determining the frequency of such communications would include the scope and complexity of hospital services offered, specific patient populations served by the hospitals and any

issues of patient safety and quality of care that a hospital's quality assessment and performance improvement program might identify.

For multi-hospital systems with a unified governing body, this consultation requirement will apply to the governing body and each hospital within the multi-hospital system. CMS acknowledges that there are many ways in which the direct consultation requirement can be met, including (for multi-hospital systems with a unified governing body) simultaneous communications with medical staff leaders or the use of a committee structure to facilitate the process.

Hospitals that have members of the medical staff on their governing body will meet the direct consultation requirement by virtue of that position only where the medical staff member so serving is the same individual responsible for the organization and conduct of the medical staff, and only where their governing body position includes meeting with the board periodically during the fiscal or calendar year and discussing matters relating to the quality of medical care provided to patients of the hospital. Simply having a medical staff member on the governing body will not suffice in the absence of these qualifying criteria.

MEDICAL STAFF MATTERS: OPTION FOR UNIFIED AND INTEGRATED MEDICAL STAFF FOR MULTI-HOSPITAL SYSTEMS

Of surprise to some in the hospital community, the Final Rule also reverses CMS' prior position that each hospital must have an organized and individual medical staff that is distinct to that particular hospital (*i.e.*, one medical staff per hospital provider number/CMS Certification Number). In the proposed rule issued in 2013, CMS acknowledged historical arguments of the hospital industry in favor of combined medical staffs among affiliated hospitals, and proposed that separate medical staffs be retained as the best model for overseeing care delivery and moving forward with quality improvement initiatives. In the Final Rule, CMS noted that it reviewed a large number of comments on the matter and pivoted its commentary to focus on the significant benefits that a "unified and integrated" medical staff can provide to multi-hospital systems. Specifically identified were the standardization of evidence-based "best practice" information among hospitals, increased opportunity to improve the peer review process, improved patient safety through shared credentialing and privileging, and coordination for Accountable Care Organization (ACO) and related clinical integration planning. CMS noted that hospitals that had implemented this model successfully—and in the process reduced hospital-acquired conditions and hospital-acquired infections—helped convince the agency that the ability to structure in that manner was appropriate.

Consistent with this view, the Final Rule revises the condition of participation (CoP) to include provisions that will hold a hospital responsible for "showing that it actively addresses its use of a unified and integrated staff model" and works in tandem with the medical staff in this regard (*i.e.*, there can be no "unilateral" determination to use this model). The CoP will include provisions that address: (1) medical staff members of each separately certified hospital in a system have voted by majority (in accordance with their respective bylaws) to accept a unified and integrated medical staff (the terms of which shall be included in the medical staff bylaws) or to opt out of such a structure and remain separate; (2) that the unified and integrated medical staff, through its bylaws, rules and regulations, describe their governance process and processes for privileging, credentialing, appointment, peer review and oversight, as well as the process for medical staff members at a particular hospital to be advised of their rights to opt out of the structure upon majority vote of the members of the medical staff at that hospital; (3) the need for a unified and integrated medical staff to take into account each hospital's unique circumstances and differences in populations; and (4) the establishment of mechanisms for the unified and integrated medical staff to ensure that local issues are appropriately considered and addressed.

The Final Rule again emphasizes that within a multi-hospital system, each separately certified hospital must continue to independently meet all of the other CoPs for hospitals. While collaborative approaches among multi-hospital system members are acknowledged, each hospital in the system must still be able to demonstrate that it meets the CoP requirements.

MEDICAL STAFF MATTERS: NON-PHYSICIAN MEMBERS OF THE MEDICAL STAFF

The Final Rule adopts the proposed rule that a hospital's medical staff may include, in accordance with state laws,

categories of non-physician practitioners determined to be eligible for appointment by the hospital's governing body. Such non-physician practitioners could include advanced practice nurses, physician assistants, registered/licensed or otherwise qualified dieticians (QDs) and pharmacists.

OTHER AREAS OF IMPACT: DIETETIC SERVICES, NUCLEAR MEDICINE SUPERVISION, OUTPATIENT SERVICES AND SWING BED ACCREDITATION

Dietetic Services

The Final Rule addresses aspects of a hospital's food and dietetic services program, and provides that hospitals may, if state law allows, extend order-writing privileges to QDs or other "qualified nutrition professionals." This avoids a redundant process that required QDs or similarly situated nutrition professionals to have physicians take this step. This change gives hospitals the flexibility to either appoint certain dieticians to the medical staff and grant them specific privileges to write orders or to authorize such ordering privileges, provided by the medical staff bylaws, rules and regulations, without appointment. Dietary needs may then be ordered by the practitioner responsible for the care of the patient or by the QD, in conformance with state law.

Nuclear Medicine

The Final Rule reflects the proposed rule in permitting the preparation of radiopharmaceuticals under the supervision (rather than the "direct" supervision) of an appropriately trained pharmacist or physician, thus reducing the burden of having a trained individual physically present for such preparation on a 24-hour basis.

Outpatient Services

The Final Rule revises current regulations to permit orders for outpatient services to be made by any practitioner who is responsible for the care of the patient, licensed in the state to provide care, acting within his or her scope of practice and is authorized by the medical staff (and approved by the governing body) to order such services and not limit such orders to the those who have privileges at the subject hospital. Hospitals maintain control over this process inasmuch as it is up the hospital to authorize—or not authorize—practitioners outside of their medical staff to order such services. This issue would also be addressed in the medical staff bylaws and/or hospital policy and procedure. The Final Rule carries with it the expectation that hospitals would not permit a practitioner who does not have privileges and whom the hospital has not previously credentialed to perform a verification prior to any order being accepted.

Swing Beds

The Final Rule adopts the proposed rule to permit hospitals with long-term care swing beds to have such beds evaluated during a deemed status survey by an accrediting organization, rather than through a separate survey by the state agency acting on behalf of CMS. This change is accomplished in part by moving the requirement to another section of the federal regulations (to locate it with "optional" services that may be so accredited) and has the effect of streamlining the survey process for those bed types.

Critical Access Hospitals, Rural Health Clinics and Federally Qualified Health Centers

POLICY DEVELOPMENT

The Final Rule adopts the proposed rule that removed the requirement for CAHs to develop policies and procedures in consultation with a non-CAH staff member, with the goal of easing potential compliance challenges for CAHs.

PHYSICIAN PRESENCE AND OVERSIGHT

In addition, the Final Rule finalizes proposed regulations that would remove the requirement that a physician be present at a CAH, RHC or FQHC at least once every two weeks. CMS now requires physician involvement as appropriate and necessary given the services provide at the facility. Similar flexibility not previously detailed in the proposed rule was also included in the Final Rule. Specifically, the standardized interval for physician review and co-signing a sample of mid-level provider outpatient records was changed to instead require only that such a sample be reviewed "periodically," so long as there are no specific timeframe requirements set by state law for such review and co-signature, and need not be reviewed where there is no state law requirement for this type of oversight. Changing these requirements was noted to allow RHCs and FQHCs to have flexibility to manage patient care in

a way that maximizes staff time to provide patient access to care.

DEFINITION OF PHYSICIAN

The Final Rule differs from the proposed rule's provision regarding an expansion of the definition of physician in RHCs and FQHCs. In the proposed rule, CMS noted that it would conform to the definition used more broadly by the Medicare program and thereby include doctors of dental surgery or dental medicine, doctors of optometry, doctors of podiatry and surgical chiropody and chiropractors, in addition to doctors of medicine and osteopathy. In the Final Rule, CMS provides that physician has a bifurcated definition: medical doctor or doctor of osteopathy for purposes of supervision, collaboration and oversight; and for specific services furnished by specialty providers, the term includes doctor of dental surgery or dental medicine, doctor of optometry, doctor of podiatry, surgical chiropody or chiropractor.

Ambulatory Surgical Centers

The Final Rule largely follows the proposed rule and streamlines the requirements that ASCs must meet in order to provide radiologic services. Specifically, under the Final Rule, ASCs need not comply with hospital requirements for supervision of radiologic services, which require supervision by a radiologist. Rather, while ASCs remain limited to performing radiologic procedures that are integral to the services it otherwise provides at the facility, it may have radiologic services supervised by an "individual with appropriate qualifications" (in accordance with state law and ASC policies). The proposed rule had provided for such supervision to be provided by an MD or DO; however, the Final Rule took into account concerns raised that limiting this to an MD or DO would be too restrictive or burdensome for some ASCs (such as those that are limited to dental or podiatric procedures and do not regularly work with MDs or DOs).

Long-Term Care Facilities

Of great interest to LTC facility providers (both hospitals with LTC units and freestanding LTC facilities), the Final Rule adopts, with some revisions, the proposed rule regarding extension of the August 2013 deadline to have all buildings containing LTC facilities equipped with automatic sprinkler systems. The August 2013 deadline, which was imposed by regulation in August 2008 after in-depth analysis of fire safety issues in LTC facilities, faced significant pushback from the LTC provider community due to the expense of equipping—and in many cases, retrofitting older buildings—with automatic sprinkler systems.

Despite the pushback, the Final Rule does not change the basic elements of the requirement for LTC facilities to be fully sprinklered; rather, it provides an extension mechanism for those "relatively small number" of facilities that face "extenuating circumstances" that have resulted in delayed compliance. These extenuating circumstances must meet each of the following requirements: (A) The facility is in the process of replacing its current building or undergoing major modifications in all unsprinklered living areas that involve significant structural work (such as moving structural walls, corridors or supports); (B) the facility demonstrates that is has made the necessary financial commitments to complete the project; (C) the facility has submitted construction or modification plans to the state and local authorities necessary for approval of replacement or modification of the building; and (D) the facility agrees to complete "interim steps" to improve fire safety, as determined by CMS. Interim steps may include efforts with which facilities are familiar if they have implemented "interim fire safety measures" during temporary construction or fire alarm maintenance projects. Interim steps may include fire watches, installation of temporary exits, staff training, signage and additional permanent or temporary smoke detection systems.

This aspect of the Final Rule became effective upon publication, May 12, 2014. As of the effective date, CMS will continue to cite LTCs without automatic sprinkler systems as noncompliant; however, in such cases, LTCs that meet the criteria for extenuating circumstances may apply for an extension of the sprinklering requirement for up to two years (with a potential for one, one-year renewal) as part of the survey response. While the specific process of applying for an extension and specifics on interim steps will be further described in subregulatory guidance from CMS, the Final Rule generally describes what CMS will require such facilities to submit to their regional office and state survey agency, including: organization information, information on the qualification for the extension (*i.e.*, replacement facility or

major modification to existing facility), timeframe, milestones, financial commitment, construction documentation and interim fire safety information.

Of interest, the Final Rule provides that all applications for extension shall be posted by the CMS central office on a CMS website, along with contact information, to permit public input on the request. The CMS regional office, once "satisfied" that the information submitted is complete, will (1) consult with the state survey agency and make a recommendation to the CMS central office on the request and (2) recommend interim steps to improve fire safety at the requesting facility. The CMS central office will then review the material from the regional office and consult with the state fire marshal and ombudsman programs to make a final determination as to the request for extension and implementation of interim fire safety measures, which will then be communicated to the facility. The decision of whether or not an extension is granted is not appealable.

CMS specifically notes in the Final Rule that it intends for the extension to be "narrowly-construed." As such, and given the intricacies that the Final Rule describes as part of the extension application process, the extension permitted by the Final Rule may not be the panacea that affected facilities had hoped for.

Transplant Centers and Organ Procurement Organizations

ELIMINATION OF THREE-YEAR RE-APPROVAL PROCESS

Welcome news to the transplant center community, the Final Rule finalizes the proposed rule to remove the automatic three-year re-approval process and on-site review of CoPs for such centers. CMS emphasized its previously stated belief that transplant center compliance is effectively monitored and enforced through the current offsite surveys, on-site complaint surveys and, when appropriate, on-site full re-approval surveys. This more "flexible" method of oversight is preferred by CMS to mandated three-year re-approval. The Final Rule also notes that CMS will establish policy identifying a maximum time interval between onsite surveys for transplant centers. Regardless of survey timing, CMS emphasized that compliance with its requirements is expected to be "continuous" for all providers and suppliers.

ELIMINATION OF BORDERLINE TRANSPLANT AND SURVIVAL RATES; OTHER RATE REPORTING

Through the Final Rule, CMS also eliminates the requirement for transplant centers to report to CMS when the number of transplants or survival rates could result in non-compliance with transplant center CoPs. It noted that this information is already reported to CMS through other data sources (in the case of transplant numbers) or not always known to the transplant center at the time when notification is required (in the case of survival rates), and that requiring additional reports is "unnecessary, confusing and burdensome" for transplant centers.

CMS also made final its proposed rules to clarify reporting requirements related to review of lung transplant outcomes and the reporting period for transplant volume and clinical experience to conform the regulations to current review and reporting practices.

Intermediate Care Facilities for Individuals Who Are Intellectually Disabled

For ICF/ID facilities, the Final Rule carries through and makes consistent language regarding a previously revised change to remove the concept of a time-limited certification, instead replacing such certifications with open-ended agreements and thereby putting ICF/ID facilities on equal footing with nursing facilities and other providers with such certification periods.

Laboratories

The Final Rule provides for a narrow, one-time exception to the prohibition on sending proficiency testing samples to other laboratories for additional or confirmatory testing. Under the exception, alternative sanctions are imposed in lieu of revocation of the CLIA certificate. These alternative sanctions may include a directed plan of correction, a civil monetary penalty, state monitoring and suspension of Medicare payments. Repeat issues within a certain survey timeframe will otherwise be deemed "intentional" and subject to sanctions.

The Final Rule also adds a definition of "distributive testing" to address concerns about how testing performed by multiple laboratories on the same specimen would be handled.

Of note, the Final Rule works to reconcile its provisions with the Taking Essential Steps for Testing Act of 2012, which was passed around the time of the proposed rule. CMS stated its support of implementing that act as soon as possible, while acknowledging that such implementation may lead to additional regulatory changes in this area.

If you have questions regarding the proposed rule, please contact the author or your McDermott Will & Emery lawyer.

AUTHORS

For more information, please contact your regular McDermott lawyer, or:

Sandra M. DiVarco
+1 312 984 2006
sdivarco@mwe.com