Easing the Burden of Medicare Regulations: Round-Up of New Final and Proposed Rules

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Pursuant to Executive Order 13563, “Improving Regulation and Regulatory Review,” President Obama required federal agencies to review existing regulations and propose changes to eliminate obsolete, unnecessary, or unduly burdensome rules. In response, the Department of Health and Human Services, which includes the Centers for Medicare and Medicaid Services (“CMS”), drafted an agency plan for updating its regulations.

In follow-up, on October 24, 2011, CMS finalized or proposed changes to Medicare Conditions of Participation or Conditions for Coverage for participating providers, including hospitals, and also proposed additional rule changes to remove, clarify or amend obsolete, redundant or burdensome regulatory provisions associated with the Medicare program. Among the key provisions are proposed rules that would allow hospitals to grant privileges to physicians who are not members of the medical staff and to use standing orders, including those for drugs and biologicals, under certain circumstances. CMS has also requested comment on whether health systems with more than one hospital should explicitly be allowed to have a single medical staff. Based on CMS estimates, the new rules would save the health care industry over $5 billion over the next five (5) years.

Hospital and Critical Access Hospital (CAH) Conditions of Participation

Hospital/CAH Final Rule

In May 2011, CMS made changes to the Conditions of Participation to provide hospitals and CAHs with a new streamlined mechanism for credentialing of telemedicine providers. In brief, the new final rule allows hospitals and CAHs to rely on the credentialing decisions of a “distant-site” hospital or telemedicine entity where the physician or practitioner is already credentialed, as long as certain requirements are met. Specifically, where the distant-site location is a hospital, the arrangement must be memorialized with a written agreement, and the distant-site hospital must be a Medicare-participating hospital (and therefore responsible for meeting the Medicare Conditions of Participation regarding a governing body’s oversight of the medical staff). Where the distant-site location is a telemedicine entity, its credentialing process must meet the Medicare standards, such that the hospital is able to remain in compliance with these standards. In both cases, the distant-site location must

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1 E.O. 13563, Jan. 18, 2011.
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provide a current list of the practitioner’s privileges; the practitioner must be licensed in the state where the patient is located; and the hospital utilizing the telemedicine service must have evidence of an internal review of the practitioner that it also sends to the distant-site location. The Joint Commission has made corresponding changes to its accreditation requirements to conform to the new Conditions of Participation. While this final rule was issued several months in advance of CMS’s regulatory review plan, recent proposed changes cite this change as included in its plan for reducing regulatory burdens.

Hospital Proposed Rules

- Multi-hospital systems could be governed by a single governing body. Under current rules, each hospital within a multi-hospital system must have a separate governing body.
- Hospitals would explicitly be allowed to grant privileges to physicians and non-physicians within their applicable state law scopes of practice, regardless of whether these individuals are also members of the hospital’s medical staff. CMS commentary suggests that this practice was already permitted, but notes that stakeholders identified a lack of clarity on this point, potentially limiting the privileging and use of allied health professionals in hospital settings. Podiatrists would also be added to the list of physicians able to serve in medical staff leadership roles.
- Standing orders, including standing orders for drugs and biologicals, would be allowed under certain circumstances. Specifically, they would have to be approved by the medical staff; based on nationally recognized, evidence-based guidelines; regularly reviewed; and authenticated promptly upon use. CMS states that it would expect to see clear and specific criteria for the applicability of a standing order and thorough documentation of the creation, use and review of standing orders. Hospitals would not have to follow the typical notification rules for patient deaths under seclusion or restraint if the death occurred with the use of soft two-point wrist restraints only. Because these restraints are often medically necessary in critical care settings to prevent patients from removing medical equipment, these patient deaths would only have to be reported within seven (7) days via a log entry that would be available to CMS. Under the current rules, all such deaths must be reported on the next business day by telephone. The new rule would also allow electronic reporting mechanisms for seclusion-and-restraint death reports.
- The hospital nursing care plan could be prepared as a part of the interdisciplinary care plan and would not have to be a separate document. Current rules require a nursing plan to be established as a free-standing document even though incorporated into the interdisciplinary care plan.
- Drugs could be administered on the orders of non-physician practitioners, as allowed by state law and medical staff privileges. Similarly, verbal orders could be authenticated by these mid-level practitioners.
- Hospitals could develop policies and procedures to allow patients to self-administer hospital-issued medications and the patient’s own medications brought to the hospital. This proposed rule would require the hospital to (i) assure that a practitioner’s order is in place for self-administration of the medication; (ii) conduct an assessment of the patient or caregiver’s capacity to self-administer the medication; (iii) instruct the patient or caregiver in the proper administration of the medication as

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to self-administered hospital-issued medications; (iv) ensure the security of the medication; (v) identify the patient’s medication and visually inspect it for integrity as to medications brought to the hospital; and (vi) document the administration of the medication in the patient’s medical record. In light of these numerous requirements, it is unclear whether the new process would actually reduce the burden on hospitals.

- Verbal orders would not have to be authenticated within 48 hours, but authentications would still be subject to state law and hospital policy. Under current rules, absent a state law dictating a specific timeframe for authentication, verbal orders must be authenticated within 48 hours. Nevertheless, CMS still explicitly discourages the use of verbal orders, and as a practical matter, in many jurisdictions, state law may require authentication within a specific timeframe. As to the authentication itself, CMS does propose to make permanent the temporary rule allowing authentication by either the ordering practitioner or another practitioner responsible for the patient’s care, rather than allowing that rule to “sunset” on January 25, 2012.

- While retaining the requirement that a hospital have an infection control tracking system, a separate infection control log would no longer be required. In commentary, CMS clarified that problems with infection control and pharmaceutical services must be monitored via the hospital-wide quality assessment and performance improvement program.

- Hospitals would be allowed to assign more than one person responsibility for outpatient services. Under current rules, one person is required to oversee all outpatient services, often leading to two layers of administration over outpatient service lines.

- Certain redundant rules regarding transplant blood type verification documentation would be eliminated.

CAH Proposed Rules

- CAHs would be allowed to offer required services (such as laboratory services) through contractors rather than employees.

- Surgical services would not be a required service of a CAH. CMS commentary notes that this change merely clarifies existing policy on this issue.

Other Areas Under Review

In proposing the above change, CMS also sought comment on the following issues related to the Conditions of Participation for hospitals:

- Single organized medical staff: CMS states in commentary that it does not believe that a single and separate medical staff is required for each hospital within a multi-hospital system. CMS is requesting comment, however, on whether clarification is necessary in regard to this requirement.

- Updating a patient history and physical examination: CMS is asking whether clarification is necessary for the rule requiring an update to a patient history and physical examination that is performed within 30 days prior to a hospital admission. The commentary clarifies that under these circumstances only an update note is necessary, not a full examination.

- Appointment of department leaders: CMS is considering whether to reorganize the Conditions of Participation such that there would be a single general requirement to appoint departmental
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leadership. Under the current format, appointment of leaders is required under the rules for each specific department of the hospital.

- Life Safety Code: CMS is seeking comment on which version of the Life Safety Code should be the standard for the Conditions of Participation. The 2000 edition is codified into the current regulations, despite the fact that there are more recent versions, including a new 2012 edition that was recently released.

Ambulatory Surgery Center (“ASC”) Conditions for Coverage

Final Rule

The current Medicare Conditions for Coverage for ASCs require notice of a patient’s rights to be provided “in advance of the date of the procedure,” which has caused problems for facilities when an urgent procedure needed to be performed on the same day it was ordered. A new final rule issued October 24, 2011 instead requires notice to be provided “prior to the start of the surgical procedure,” thereby allowing notice to be provided on the same day as a surgery.\(^8\)

The final rule also includes a number of other reorganizing and technical changes to the patient rights Condition for Coverage, including clarifying that grievance decisions may be provided to the patient, patient’s representative, or patient’s surrogate, not just the patient.

In addition, the Condition for Coverage now explicitly incorporates the Medicare Program Integrity provision requiring written disclosure of physician financial interest or ownership in the ASC, where applicable.\(^9\)

All of the above provisions will become effective on December 23, 2011.

Proposed Rule

In separate rulemaking, CMS also proposed the following changes to ASC Conditions for Coverage:\(^{10}\)

- The current pre-determined list of emergency equipment required for an ambulatory surgery center would be deleted. Instead, the governing body and medical staff of the ASC would be allowed to determine which types of emergency equipment are necessary, as long as current acceptable standards of practice for these facilities are met.

- The standard-level requirements for infection control under the ASC’s Condition for Coverage for “Environment” would be deleted, because infection control is now its own condition-level requirement.

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\(^9\) The Medicare Program Integrity regulations appear at 42 C.F.R. Part 420.

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Enrollment and Coverage Appeals

**Proposed Rule**

CMS has also proposed the following changes to its Medicare enrollment and claim determination appeal rules:11

- The Medicare re-enrollment waiting period would not be imposed if a provider or supplier’s billing privileges are revoked based solely on the failure of the provider or supplier to respond in a timely fashion to a revalidation request or other request for information. The current rule is that any provider or supplier whose billing privileges have been revoked may not re-enroll in Medicare for at least one year.

- CMS may but would not be required to deactivate the billing privileges of a physician or practitioner who has not submitted a claim for 12 consecutive months.

- CMS would be allowed to deactivate, rather than revoke, Medicare billing privileges for a provider or supplier who fails to respond within ninety (90) calendar days to a request from CMS to submit requested enrollment documentation.

- Provisions describing the former appeal procedures for Medicare claim determinations would be deleted. The old process at Part 405, Subparts G and H, applied to claims from before the effective date of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000. The commentary describes how any unresolved appeals from that period would be handled. The remaining provisions of Subparts G and H would be moved to Subpart I, where the current appeals process appears.

Other Proposed Rule Changes

Among other changes, CMS has also proposed the following revisions to the Medicare rules:12

- E-prescribing transaction standards would be updated to reflect new software versions.

- A new definition of “organ donor document” would allow use of “any documented indication of an individual’s choice that was executed by the patient, in accordance with any applicable State law, before his or her death, and that states his or her wishes regarding organ and/or tissue donation.” The intent of the new definition is to allow for more flexibility in how a person may validly express his or her wishes regarding organ donation.

- Most end-stage renal disease facilities would no longer be subject to certain provisions of the National Fire Prevention Agency’s Federal Life Safety Code.13 CMS noted that some of these requirements would otherwise require structural changes to facilities where the Federal Emergency Management Agency has documented that the risk of fire is low. Therefore, the proposed rule would only require dialysis facilities to comply with these fire safety requirements if they are located adjacent to “high hazardous” facilities (defined to include those where certain flammable chemicals or activities are located) or if patient treatment areas are not located at ground level with

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11 *Id.*
12 *Id.*
13 *Id.*
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direct access out of the building. Dialysis facilities would still have to comply with state and local fire codes, and certain buildings would still require sprinkler systems.

- Intermediate care facilities for the intellectually disabled (formerly “mentally retarded,” as described below) would no longer have time-limited provider agreements and instead would have open-ended agreements that would remain in effect until the facility no longer met the Medicare requirements. There would also be increased flexibility in the survey schedule, with a survey required every 12 months on average (up to a maximum interval of 15 months), as opposed to the current fixed schedule of 12 months.

- There would be two broad nomenclature changes in the regulations: a Medicaid “recipient” would instead be a “beneficiary,” and the phrase “mental retardation” would be replaced with “intellectual disability.”

Conclusion

The deadline to comment on all of the proposed rules described above is December 23, 2011, which is also the date when the ASC final rule goes into effect. Health care providers should consider the potential impact of these changes and provide feedback to CMS as appropriate.

In addition, CMS has invited comment on other changes to the Conditions of Participation and Conditions for Coverage that might reduce the regulatory burden on the health care industry. Commenting to CMS on other areas where the Conditions of Participation or Conditions for Coverage are outdated, duplicative or overly burdensome may result in further beneficial rulemaking. To the extent that these changes could make it easier for a provider to remain in compliance with Medicare Conditions of Participation and other requirements, they will be very helpful and timely. For instance, these changes come on the heels of the implementation of the Patient Protection and Affordable Care Act requirement that a finding of immediate jeopardy will result in exclusion from the incentives available under the new Hospital Value-Based Purchasing Program.

Finally, as these new rules are finalized in the months to come, providers should review these rules and seek to reduce or eliminate redundant processes accordingly, so as to achieve some portion of the projected $5 billion in savings that could result from these rule changes. In this regard, providers should also monitor the standards of The Joint Commission and other accrediting bodies for possible changes in accordance with the new rules.

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