Health Care Alert: CMS Issues Rules Targeted At Reducing Compliance Burdens on Providers

Related Attorneys

J. Liam Gruzs

Related Industries

Health Care

CLIENT ALERT | 5.15.2012

The Centers for Medicare and Medicaid Services (CMS) has issued two rulemakings aimed at alleviating procedural and administrative burdens on providers in response to the president's Executive Order 13563, *Improving Regulation and Regulatory Review*. The Executive Order directs each executive agency to reduce outmoded or unnecessarily burdensome rules in an effort to increase the ability of providers to devote resources to providing high quality patient care. The rules are slated to be published in the *Federal Register* on Wednesday, May 16, 2012, and will become effective July 16, 2012.

Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction

The first rule removes unnecessarily burdensome and obsolete requirements from the Medicare regulations. Some changes apply broadly to Medicare beneficiaries, providers and suppliers (e.g., removing obsolete claim determination and appeals provisions), while others are more specific to certain provider types (e.g., ESRD facilities and ASCs). CMS projects the overall cost savings to exceed $200 million in the first year, and approximately $630 million in the next five years. The major changes are set forth below.

Removes Unnecessarily Burdensome Requirements

- *ESRD Facilities*: Limits mandatory compliance with the Life Safety Code to those Medicare-participating end-stage renal disease (ESRD) facilities located adjacent to high hazardous occupancies, and clarifies that the requirement for sprinklers in facilities housed in high rise buildings applies to buildings constructed after January 1, 2008. See 42 C.F.R. § 494.60.
- *ASC Emergency Equipment*: Removes the detailed list of emergency equipment that must be available in Ambulatory Surgery Center (ASC) operating rooms. The current list includes outdated terminology and equipment not suitable for ASCs that furnish minor procedures that do not require anesthesia. See 42 C.F.R. § 416.44.

- *Re-Enrollment Bar for Providers and Suppliers*: Eliminates as unnecessarily punitive the enrollment bar for providers and suppliers when the bar is based on the failure to respond timely to revalidation or other requests for information. See 42 C.F.R. §§ 424.535 and 424.540(a)(3).
- *ICFs/IID (referred to in current regulations as ICFs/MR)*: Eliminates the requirement for time-limited agreements for Intermediate Care Facilities for Individuals who are Intellectually Disabled (ICFs/IID) and replaces the requirement with an open-ended agreement which will remain in effect until the secretary or a state determines that the ICF/IID no longer meets the ICF/IID conditions of participation (CoPs). Adds a requirement that a certified ICF/IID must be surveyed, on average, every 12 months with a maximum 15-month survey interval. See 42 C.F.R. §§ 442.15–442.109.

Removes Obsolete Regulations

- *Appeals of Parts A and B Claims Determinations*: Removes obsolete regulations that apply to initial determinations, re-openings and appeals of claims. This will eliminate confusion by Medicare beneficiaries, providers and suppliers regarding which appeals rights and procedures apply. See 42 C.F. R. §§ 405.701–405.877.
- *ASC Infection Control Program*: Removes the obsolete requirement that an Ambulatory Surgery Center (ASC) establish a program for identifying and preventing infections, maintaining a sanitary environment and reporting the results to the appropriate authorities. See 42 C.F.R. § 416.44.
- *E-prescribing*: Retires older versions of e-prescribing transactions for Medicare Part D and adopts the newer versions to be in compliance with the current e-prescribing standards. See 42 C.F.R. § 423.160.
- *Physical and Occupational Therapist Qualifications*: Removes the outdated personnel qualifications in the current Medicaid regulations and refers to the updated Medicare regulations. See 42 C.F.R. § 440.110.
- *Organ Procurement*: Updates definitions related to Organ Procurement Organizations (OPOs), and removes duplicate regulations related to OPO administration and governance. See 42 C.F.R. §§ 486.302 and 486.324.

Reform of Hospital and Critical Access Hospital Conditions of Participation

The second rule also reduces unnecessary provider regulatory obligations, but focuses specifically on hospital and critical access hospital (CAH) Medicare CoPs. The rule seeks to permit flexibility while eliminating unnecessarily burdensome CoPs. CMS projects that these changes will reduce the total regulatory burden for hospitals and CAHs by nearly $940 million initially, and by almost $5 billion over the next five years. Set forth below is a summary of the major provisions.

- *Single Governing Body for Multiple Hospitals*: Allows one governing body to oversee multiple hospitals in a multi-hospital system, and requires a member, or members, of the hospital's medical staff to be included on the governing body as a means of ensuring communication and coordination between a single governing body and the medical staffs of individual hospitals in the system. See 42 C.F.R. § 482.12.
- *Reporting of Restraint-Related Deaths*: Replaces the requirement that hospitals report deaths that occur while a patient is in soft, 2-point wrist restraints with a requirement that hospitals maintain a log of all such deaths. See 42 C.F.R. § 482.13.
- *Medical Staff*: Broadens the concept of "medical staff" and allows hospitals the flexibility to include other practitioners (e.g., APRNs, PAs, pharmacists) as eligible candidates for the medical staff with hospital

privileges to practice in the hospital in accordance with state law. Allows podiatrists to be responsible for the organization and conduct of the medical staff. See 42 C.F.R. § 482.22.

- *Nursing Care Plan*: Allows hospitals the option to have a stand-alone nursing care plan or a single interdisciplinary care plan that addresses nursing and other disciplines. See 42 C.F.R. § 482.23.
- *Patient Self-Administration of Medications*: Allows hospitals to have an optional program for patients/support persons on self-administration of appropriate medications. See 42 C.F.R. § 482.23.
- *Administration of Blood Transfusions and Intravenous Medications*: Eliminates the requirement for non-physician personnel to have special training in administering blood transfusions and intravenous medications, and revises the requirement to clarify that those who administer blood transfusions and intravenous medications do so in accordance with state law and approved medical staff policies and procedures. See 42 C.F.R. § 482.23.
- *Orders by Other Practitioners*: Allows for drugs and biologicals to be prepared and administered on the orders of a non-physician practitioner, and allows orders for drugs and biologicals to be documented and signed by non-physician practitioners, in accordance with hospital policy and state law. See 42 C.F.R. § 482.23.
- *Standing Orders*: Allows hospitals the flexibility to use standing orders, and requires medical staff, nursing and pharmacy to approve written and electronic standing orders, order sets and protocols. See 42 C.F.R. § 482.24.
- *Verbal Orders*: Eliminates the requirement for authentication of verbal orders within 48 hours and defers to applicable state law to establish authentication timeframes. See 42 C.F.R. § 482.24.
- *Authentication of Orders*: Makes permanent the temporary requirement that all orders, including verbal orders, must be dated, timed, and authenticated by either the ordering practitioner or another practitioner who is responsible for the care of the patient and who is authorized to write orders by hospital policy in accordance with state law. See 42 C.F.R. § 482.24.
- *Infection Control Log*: Eliminates the obsolete requirement for a hospital to maintain an infection control log as unnecessarily duplicative of other various required surveillance methods. See 42 C.F.R. § 482.42.
- *Outpatient Services Director*: Removes the burdensome and outdated requirement for a single director of outpatient services position that oversees all outpatient departments in a hospital as duplicative of the separate directors for individual outpatient departments. See 42 C.F.R. § 482.54.
- *Transplant Center Process Requirements*: Eliminates a duplicative requirement for an organ recovery team working for the transplant center to conduct a "blood type and other vital data verification" before organ recovery when the recipient is known. See 42 C.F.R. § 482.92.
- *CAH Provision of Services*: Eliminates the burdensome requirement that CAHs must furnish diagnostic and therapeutic services, laboratory services, radiology services, and emergency procedures directly by CAH staff, which will allow CAHs to provide such services under arrangement. See 42 C.F.R. § 485.635.

This newsletter is for general information purposes and should not be regarded as legal advice. As always, please let us know if you want more information or have questions about how these developments apply to your situation.

IRS CIRCULAR 230 DISCLOSURE: In order to ensure compliance with requirements imposed by the U.S. Internal Revenue Service, we inform you that any federal tax information contained in this communication (including any attachments) is not intended or written to be used, and it cannot be used, by any taxpayer for the purpose of (i) avoiding penalties that may be imposed under the U.S. Internal Revenue Code; or (ii) promoting, marketing, or recommending to another person, any transaction or other matter addressed herein.