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Client Alert
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Reform of Hospital and Critical Access Hospital Conditions of Participation and Ambulatory Surgery Center Conditions of Coverage

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The Centers for Medicare and Medicaid Services (CMS) recently released a series of proposed and final rules revising and clarifying the Medicare and Medicaid conditions of participation governing hospitals, the conditions for coverage governing ambulatory surgery centers (ASCs) and regulatory requirements affecting non-hospital providers and suppliers. The rules were promulgated in response to Executive Order 13563 issued by President Barack Obama on Jan. 18, 2011, that called for a reduction in needless and outdated requirements mandated by federal rules. The proposed changes to hospitals and ASCs reflect thoughtful consideration of the conditions of participation and coverage. If adopted, the proposals could streamline certain processes, allowing these providers to more efficiently deploy resources. The proposed changes to non-hospital providers and suppliers seeks to eliminate federal rules found to be duplicative, overlapping, outdated and conflicting for many health care providers.

Hospital Conditions of Participation

Hospitals participating in the Medicare program must meet CMS's statutory and regulatory requirements designed to ensure high-quality care for all patients. These requirements are commonly known as Conditions of Participation (CoPs). In its attempt to reduce unnecessary burdens and costs imposed upon hospitals, CMS issued proposed rules revising certain CoPs. CMS anticipates that these revisions will result in upwards of $942 million in annualized savings. Each of the revisions is briefly discussed below.

Hospital Governance. CMS currently requires each hospital facility to have a separate governing body. CMS recognizes that a single, system-wide governing body could oversee care in a more efficient and effective manner. However, in the Proposed Rule, CMS would allow a single governing board to oversee multiple hospital facilities in a health system.

Patient Death Reporting. Recognizing that patients needing soft, two point wrist restraints are individuals in critical settings such as ICUs where such restraints are necessary to prevent patients from removing various medically necessary devices and equipment, CMS proposes to modify the reporting requirements for patient deaths that occur during or after the use of such restraints. Hospitals would be required to log the deceased patient's name, date of birth, date of death, attending physician, primary diagnosis(es) and medical record number within seven days. This log must be made accessible to CMS upon request.

Medical Staff. To clarify that a hospital may grant privileges to both physicians and non-physicians (practicing within their scope of practice) regardless of whether the physician or nonphysician is appointed to the hospital's medical staff, CMS proposes to change the CoPs to clarify that technical membership on a hospital's medical staff is not a prerequisite for the hospital's governing body to grant an individual hospital privileges. CMS intends that those physicians and non-physicians who are granted privileges without appointment to the medical staff be subject to the same hospital requirements, medical staff bylaws and medical staff oversight as appointed medical staff members. Alternatively, CMS suggests that a separate category of medical staff appointment could be created for these types of providers. CMS believes that this change will provide more flexibility to small hospitals and critical access hospitals (CAHs) and regions with a limited supply of primary and specialty physicians while encouraging appropriate use of non-physician providers. Finally, CMS proposes to add doctors of podiatric medicine to the list of those practitioners permitted to serve as president or its equivalent of a hospital's medical staff.

Nursing Services. CMS proposes to make four significant changes to the CoPs governing Nursing Services. First, the Proposed Rule would allow for an interdisciplinary team to complete one comprehensive care plan per patient, rather than maintain separate care plans for each discipline. Second, to more fully integrate nonphysician practitioners into the provision of care, CMS proposes to allow these practitioners to order and/or administer drugs and biologicals in accordance with their state scope of practice laws and hospital privileges. CMS also proposes to allow for the preparation and administration of drugs and biologicals based upon standing orders, order sets and protocols. Finally, CMS proposes to allow hospitals the flexibility to develop and implement policies and procedures for hospital patients and/or their caregivers/support persons to self administer certain medications, including those for chronic conditions, such as nitroglycerine tablets or inhalers and selected non-prescription medications such as lotions and eye drops.

Authentication of Verbal Orders. Recognizing that computerized order entry (CPOE) systems have not been adopted as rapidly as CMS initially anticipated, CMS proposes to revise the requirements associated with documentation of verbal orders by removing the 48 hour requirement and adding language allowing authentication by either the ordering practitioner or another practitioner who is responsible for the care of the patient and authorized to write orders pursuant to hospital policy.

Infection Control. CMS proposes to eliminate the current requirement of maintenance of a separate infection control log.

Outpatient Services. CMS acknowledges that, as more and more specialized services are provided on an outpatient basis, the requirement that the hospital assign one individual

to be responsible for all outpatient services may result in unnecessary staff costs, increased administrative burden and confused chains of commands. Consequently, CMS proposes to allow hospitals to assign one or more individuals to be responsible for outpatient services. Additionally, CMS proposes to allow hospitals to make their own personnel decisions with regard to staffing of outpatient services based upon the scope and complexity of outpatient services offered at each outpatient location.

Transplant Services. CMS proposes to eliminate the requirement that the transplant team to verify blood type before organ recovery.

CMS invites comments on these proposed revisions to the Hospital CoPs. All comments are due by Dec. 23, 2011.

ASC Conditions for Coverage

CMS also proposed changes to the ASC conditions for coverage (CfC) that require a detailed list of emergency equipment to be available in the ASC's operating room. The proposed revisions will permit ASCs to develop policies and procedures that will detail the emergency equipment necessary for the facility's patient population. CMS estimates a one-time savings of $18.5 million to ASCs through the reduction of unnecessary emergency equipment.

CMS recognizes that a potential disadvantage to allowing ASCs to determine the necessary emergency equipment is increased variation in emergency preparedness between ASCs. Thus, as an alternative, CMS proposes to categorize ASCs by the major services they provide and specify a minimum list of equipment required by ASCs in each category. CMS invites comments on the alternative proposal, as well as additional proposals submitted by commenters. Comments are due by Dec. 23, 2011.

In addition to the proposed rule applicable to ASCs, CMS published a final rule that regulates the patient's rights notice given by ASCs. CMS previously published a proposed rule on April 23, 2010, that required ASCs to provide notice of patients rights in advance of the date of a procedure. CMS removed the requirement for advance notice; the final rule requires notice to be given in verbal and written form to the patient, the patient's representative or the patient's surrogate prior to the start of the surgical procedure.

The final rule clears the way for same-day surgeries without a need to document an emergency procedure for these patients. CMS anticipates that this final rule will result in savings for both patients and facilities by reducing provider and patient time spent on additional visits for procedures that can be completed the same day. CMS estimates a savings of $35 million a year for patients and $17.5 million for providers.

Non-Hospital Providers and Suppliers

CMS issued a proposed rule to address regulatory adjustments that can promote Medicare and Medicaid program efficiency, transparency and burden reduction for non-hospital providers and health care suppliers. The rule contains specific reforms grouped into three categories:

1) removing unnecessarily burdensome requirements; 2) removing obsolete regulations; and 3) responding to stakeholder concerns. The following is a summation of the recommended adjustments to providers, suppliers and programs as outlined in the proposed rule:

- Clarifying higher-risk End Stage Renal Disease (ESRD) facilities are required to comply with the full federal Life Safety Code requirements based on proximity to "high hazard" occupancies;
- Revising ASCs Conditions for Coverage (CfCs) emergency equipment requirements by removing the list of required emergency equipment and allowing ASCs flexibility in developing appropriate emergency equipment policies and procedures;
- Changing revocation of enrollment and billing privileges in the Medicare program to eliminate re-enrollment requirements in instances when providers and suppliers have not responded to timely requests for revalidation of enrollment or other requests for information initiated by CMS;
- Eliminating the current Medicare requirement that automatically deactivates a provider or supplier who has not submitted a claim for 12 consecutive months;
- Replacing time-limited agreements that govern Intermediate Care Facilities for the Intellectually Disabled participation in Medicaid with open-ended agreements and reducing inspection of these facilities to once a year;
- Removing from regulation the following: obsolete provisions related to initial determinations, appeals and re-openings of Part A and Part B claims and entitlement determinations; ASC infection control regulations that are also contained in other regulations; outdated Medicaid physical and occupational therapy qualifications language (and instead cross references to updated Medicare qualifications); inadvertent duplicative language in the Conditions for Coverage for Organ Procurement Organizations final rule;
- Updating certain Medicare Part D e-prescribing requirements for consistency with the current HIPAA transaction standards and other e-prescribing regulations;
- Replacing the current definition of donor documents with a broader definition; and
- Updating nomenclature by replacing the term "recipient" with "beneficiary" and terms "mental retardation" and "mentally retarded" with "intellectual disability" and "intellectually disabled" throughout 42 CFR title IV.

CMS invites comments on these proposed revisions; comments are due by Dec. 23, 2011.

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