HEALTH CARE

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CMS Issues 2008 Physician Fee Schedule Proposed Rule, Makes Other Changes – Part I

On July 12, 2007, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule for the 2008 Physician Fee schedule, and proposed rules on a number of Part B programs including Independent Diagnostics Testing Facilities (IDTFs), Physician Quality Reporting Initiatives (PQRIs), Anemia Quality Indicators, Physician Pathology Services, and the Physician Assistant and Quality Initiative Fund (PAQI).

IDTF Issues

In the 2007 Physician Fee Schedule final rule, CMS established 14 performance standards for IDTFs. In this 2008 proposed rule, CMS clarifies several of the performance standards and proposes several new ones:

- Under the final rule, CMS imposed a requirement that IDTFs maintain comprehensive liability insurance with at least $300,000 of coverage per incident carried by a nonrelated-owned company. CMS proposes to add to this a requirement that the applicable Medicare contractor be listed as a "certificate holder" on the policy to allow for prompt notice to the contractor of any policy changes or cancellations. The new requirements would provide that failure to maintain the insurance would result in revocation of the IDTF's billing privileges, retroactive to the date the insurance lapsed. The IDTF also would be responsible to provide CMS with the contact information for the issuing insurance agent and the underwriter. In the commentary, CMS acknowledges that self-insurance may be used to satisfy the comprehensive liability insurance requirement so long as CMS or the Medicare contractor can verify the policy and its coverage provisions with an independent underwriter.
- IDTFs now are required to report changes of the information submitted on its enrollment application within 30 days of the changes. CMS proposes to clarify, and relax this requirement, by requiring that changes in ownership, changes of location, changes in general supervision, and adverse legal actions must all be reported within 30 days of the change, but all other reportable changes may be reported within 90 days of the change.
- The performance standards would be revised to fix what CMS characterizes as an "oversight in drafting" of the standard that now states: "Answer beneficiaries' questions and respond to their complaints." The new standard would state: "Answer, document,

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and maintain documentation of beneficiaries' questions and responses to their complaints at the physical site of the IDTF." The commentary makes clear that IDTF's are expected to maintain and document a thorough complaint management system on all oral and written complaints, including telephone complaints, which includes the name, address, telephone number, and health insurance claim number of the beneficiary; a summary of the complaint, the date it was received, the name of the person receiving the complaint, and a summary of the actions taken to resolve the complaint; and, if an investigation was not conducted, the name of the person making the decision not to investigate and the reason for the decision. This information must be stored at the physical site of the IDTF, which, for mobile IDTFs, is the home office.

- Correcting an unintended consequence of its prior rulemaking, CMS clarifies that the supervising physician does NOT have overall administrative responsibility for the IDTF and therefore proposes to delete from the supervising physician's responsibilities "…is responsible for the overall operation and administration of the IDTF…". CMS also clarifies the limit (to only three IDTF sites) placed on supervising physicians. CMS defines the limitation as applying to both fixed and mobile sites, which means that a supervising physician can supervise only a total of three sites, whether fixed or mobile.
- A new proposed standard would establish an initial enrollment date for IDTFs. Under the new proposed standard, Medicare would establish an initial enrollment date of an IDTF that would be the later of (1) the date of filing of a Medicare enrollment application that was subsequently approved, or (2) the date an IDTF first started rendering services at its new practice location. This change limits the retrospective payments that an IDTF may obtain from Medicare.
- Another new proposed standard would eliminate the ability of a fixed site IDTF to share space with another individual or organization. The standard states "[An IDTF] does not share space, equipment, or staff or sublease its operations to another individual or organization." The commentary makes clear that the intent of the standard is to eliminate any kind of space, equipment, or staff-sharing arrangements, including, but not limited to, shared waiting rooms, supervising physicians, receptionists, or other non-physician personnel due to the perceived circumvention of the Medicare enrollment and billing requirements (as well as concerns under the physician self-referral and anti-kickback provisions) associated with these kinds of arrangements. CMS also is seeking comment on whether a similar prohibition should apply to mobile IDTFs and should be interpreted to preclude a motel or hotel from being an appropriate site for an IDTF.

PQRI

The proposed rule also identifies the 74 quality measures (66 original measures posted to the CMS Web site on December 5, 2006 plus eight new ones) that apply to 2007. A list and description of these 74 measures is available for download from the PQRI Measures/Codes page of the PQRI section of the CMS Web site at www.cms.hhs.gov/PQRI. The commentary to the proposed rule describes, in detail, the process that will be used to identify the 2008 PQRI measures, which must be determined and published by November 15, 2007. The commentary also discusses the process that will be used to allow for reporting the PQRI measures through registries (such as the Society of Thoracic Surgeons (STS) National Database registry) and through electronic health records. Evaluation of these other reporting options will be conducted in 2008.

Anemia Quality Indicators

In a more direct approach to regulating the quality of care through payment policy, the United States Congress (Congress) expanded the clinical reporting necessary for the administration of Erythropoiesis stimulating agents (ESA), used to treat anemia, from patients undergoing End Stage Renal Disease (ESRD) to patients experiencing anemia from cancer therapy. Noting that recent research "…has raised concerns that these drugs may be associated with significant adverse effects including a higher risk of mortality in some populations..," Congress amended section 1842 of the Social Security Act by adding a new subsection (u) that reads: "Each request for payment, or bill submitted, for a drug furnished to an individual for the treatment of anemia in connection with the treatment of cancer shall include (in a form and manner specified by the Secretary) information on the hemoglobin and hematocrit levels for the individual." In addition to proposing rules to implement this new provision in the Medicare law, CMS also is seeking public comment on whether this reporting requirement for ESAs should be expanded to all uses of the drug.

Physician Pathology Services

Since 2000, CMS has indicated its policy to pay only the hospital for the technical component of physician pathology services furnished to inpatients. This policy was enacted to eliminate the potential that

Medicare could pay twice for the technical component of pathology services for inpatients; once through the prospective payment system and again to an independent laboratory that could bill the carrier globally for both the technical and professional component. The policy enacted in 2000, however, was delayed by section 542 of the Medicare, Medicaid, and SHIP Benefits Improvement and Protection Act of 2000 and section 732 of the Medicare Modernization Act. This proposed rule now states that, after December 31, 2007, an independent laboratory may not bill the carrier for the physician pathology services furnished to a hospital inpatient or outpatient.

PAQI Fund

Congress established the PAQI Fund to make funds available for physician payment and quality initiatives. The amount of the fund for 2008 is $1.35 billion, which may be spent by CMS to either buy down the negative update to the fee schedule or for quality improvement initiatives. In this proposed rule, CMS makes clear that it will use the fund only for quality improvement initiatives and not to minimize the cuts to the physician fee schedule. Although it is not able to predict precisely the exact percentage for the bonus payment for 2008 (and paid in 2009), CMS estimates that it will be 1.5-2 percent of allowed charges for the participating professionals, subject to an aggregate cap of $1.35 billion.

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