

HEALTH LAW

Update

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

An Autumn Cornucopia of Reimbursement Updates

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What better way to welcome fall than to settle into a comfortable chair and read about some of the latest reimbursement updates from the Centers for Medicare & Medicaid Services (CMS)? In this *Health Law Update*, we offer our readers a smattering of recent noteworthy developments:¹

Complex Medical Reviews

CMS Transmittal 303,² effective October 13, 2009, provides authority to Affiliated Contractors (ACs), Medicare Administrative Contractors (MACs), Recovery Audit Contractors (RACs), and the Comprehensive Error Rate Testing (CERT) contractor to apply an exception to the clinical "reasonable and necessary" requirements described in a local coverage determination (LCD). Ordinarily, ACs, MACs, RACs, and CERT must follow LCDs when reviewing claims, but Transmittal 303 states that, in "rare and unusual circumstances," these entities may apply exceptions to single claims "after a thorough review of the patient's medical record and a comprehensive analysis of the evidence in the medical literature."

ACs and MACs may apply exceptions during all complex reviews, including redeterminations, and ACs, MACs, and CERT may use the exceptions process to approve or deny a claim. However, RACs may use the exceptions process only to avoid a claim denial. Only the contractor medical director has the authority to apply the exception, and no reviewing entity may make an exception to national coverage determinations (NCDs), CMS manuals, or MAC articles. Note that exceptions cannot be made for missing or insufficient documentation.

¹ Portions of this *Health Law Update* have previously appeared in e-mail alerts authored by Bass, Berry & Sims member Claire F. Miley for the American Health Lawyers Association's Regulation, Accreditation and Payment (RAP) Practice Group.

² Transmittal 303, which was issued September 25, 2009 and is effective October 13, 2009, rescinds and replaces Transmittal 302, issued earlier in September.

CMS stipulates that the reviewer shall document the specific claim and detail the rationale for the exception in a log maintained at the contractor. The log must include relevant citations to the evidence-based literature used in the decision and must be available to the AC and MAC appeal units as well as to RACs, CERT, and CMS upon request. On an annual basis, the contractor must create an exceptions report and provide it to the applicable project officer if requested. If exceptions to the LCDs ultimately prove to be more than "rare," then the contractor must reevaluate the LCD clinical criteria.

Provider and Supplier Re-Enrollment

On September 14, 2009, CMS issued three new transmittals—Transmittals 556, 557, and 558—which rescind and replace three earlier transmittals regarding CMS' provider revalidation effort. The three new transmittals focus on organizational Part B suppliers, individual Part B practitioners, and skilled nursing facilities (SNFs).

The new transmittals do not alter the revalidation efforts' basic process. For each of the three categories of suppliers or providers addressed by the new transmittals, all carriers, FIs, and A/B MACs will compile a list of the top fifty billers (by dollar value of submitted claims) within each state that do not have an established record in the Provider Enrollment, Chain, and Ownership System (PECOS). CMS has deleted what it called an erroneous reference to Electronic Funds Transfer (EFT) in the three earlier transmittals, so that now its focus in selecting suppliers and providers for revalidation is apparently solely based on the absence of a PECOS record.

The Division of Provider and Supplier Enrollment (DPSE) expects that each carrier and A/B MAC will mail initial revalidation packages to the selected organizational Part B suppliers and individual Part B practitioners within thirty days of the new transmittals' issuance. The FIs and A/B MACs shall mail initial revalidation letters to the selected SNFs on October 14, 2009.

CMS notes that with respect to SNFs, contractors with multiple states may stagger the mailings at the rate of one state every thirty days, once implemented. CMS also notes that SNFs' revalidation of enrollment information does not require a new state survey, and that SNFs that initially enrolled or that have been revalidated in the past five years will not be solicited at this time.

Recoupment of Provider and Supplier Overpayments

On September 16, 2009, CMS published in the *Federal Register* a final rule implementing certain limits mandated by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) on CMS' ability to recoup overpayments from a provider or supplier. The final rule provides that a provider or supplier has forty-one days to file the first level of appeal, i.e., the redetermination, before the Medicare contractor can begin recoupment. If the request for redetermination is timely filed, CMS must stop recoupment during the redetermination process.

The final rule also provides that a provider or supplier has sixty days to appeal at the second level, i.e., an appeal to a Qualified Independent Contractor (QIC), before the Medicare contractor

can begin recoupment. If the provider or supplier files a timely appeal at the QIC level, CMS must stop recoupment during the QIC process.

In addition to changing the recoupment process, the final rule changes how CMS pays interest to providers or suppliers who are successful in having an overpayment determination fully or partially reversed at the latter stages of the appeal process, i.e., above the QIC appeal level. Previously, if a CMS overpayment decision was reversed on appeal, CMS owed interest only if it failed to pay the underpayment to the provider or supplier within thirty days of the final determination and then such interest accrued only from the date of final determination. The date of "final determination" was the date following the appeal when the Medicare contractor would issue a written determination of underpayment implementing the results of the appeal. Now, if an overpayment is overturned on appeal above the QIC level of appeal, CMS is liable for interest on recouped overpayments based on the entire period that the CMS contractor recouped and held the provider's or supplier's funds.

The final rule, which takes effect November 16, 2009, leaves all other interest calculation regulations intact. Thus, for example, if the provider or supplier takes advantage of the limitation on recoupment and ultimately loses on appeal, the provider or supplier is still liable for all interest that would otherwise have accrued from the date of the original notice of overpayment.

End-Stage Renal Disease Facilities – Proposed New Prospective Payment System

In the *Federal Register* for September 29, 2009, 2009, CMS published a proposed rule in which it proposed a new prospective payment system for end-stage renal disease (ESRD) facilities. Currently, ESRD facilities receive what CMS calls a "partial bundled rate," i.e., a composite reimbursement rate that covers many of the services in a dialysis session, and also receive separate reimbursement for a variety of ESRD-related items such as injectable drugs and non-routine laboratory tests. The proposed system replaces the current system with a single, "fully bundled" payment rate covering all services related to the dialysis session, including those that are currently billed separately.

This migration to a fully bundled system is mandated by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). CMS notes that the single payment rates would be adjusted for factors such as the patient's age, gender, body size, and time on dialysis. In addition, adjustments would be made for specific conditions or co-morbidities that CMS states will result in higher payments to those facilities with the most costly patients (CMS is also proposing an outlier policy that would make an adjustment for particularly expensive cases). There are also special adjustments for pediatric patients, geographic differences in labor costs, and low-volume facilities.

Along with the new payment system, the proposed rule includes three proposed quality measures, based on data currently used on CMS' "Dialysis Facility Compare" website, and provides a conceptual framework for a new quality incentive program (QIP) that would tie dialysis facility payments to their performance on the three proposed quality measures. CMS notes that it will adopt the QIP through a separate rulemaking process.

CMS will accept comments on the proposed rule through November 16, 2009. The final rule will be published in 2010, with the new payment system applying to dialysis services furnished to Medicare beneficiaries on or after January 1, 2011.

If you have any questions about the topics covered in this *Health Law Update*, please don't hesitate to contact any of the attorneys in our Healthcare Practice Group listed below. Happy autumn!

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