G-2 Compliance Report

WASHINGTON G-2 REPORTS

Vol. X, No. 5, May 2008

For Hospitals, Laboratories and Physician Practices

Court Ruling Bolsters Case for Repeal of Lab Competitive Bidding

An April 8 ruling granting a motion for a preliminary injunction to halt the Medicare laboratory competitive bidding project in San Diego appears to bolster the case for Congressional repeal of the project.

The ruling by federal court judge Thomas Whelan enjoins the Department of Health and Human Services (HHS) from announcing winners in the demo project, otherwise implementing and carrying out the demo in San Diego, or further disclosing information included in the bid applications. The injunction remains in place until further order of the court.

HHS had anticipated announcing winning bidders on or around April 11, with the actual demonstration to begin July 1. Peter Ashkenaz, an HHS spokesman, says the agency is disappointed with the court's injunction because it believes it followed Congress's direction in implementing the demonstration.

"CMS [the Centers for Medicare & Medicaid Services] was careful in designing the demonstration to ensure the quality of clinical laboratory services to Medicare, particularly the most vulnerable who reside in nursing homes and underserved areas," he tells *GCR*. "Throughout the development of the laboratory competitive bidding demonstration, CMS has communicated with and sought input from the laboratory industry and other stakeholders to address the issues outlined in the suit." *Continued on p. 2*

Preliminary Injunction Temporarily Blocks Enforcement of Anti-Markup Rule Provisions

A federal district judge has temporarily blocked the Centers for Medicare & Medicaid Services (CMS) from enforcing a provision in a November 2007 rule that would have made substantial changes to the way physicians bill for anatomic pathology diagnostic testing services (*Atlantic Urological Associates PA v. Leavitt*).

Judge Rosemary Collyer, with the U.S. District Court for the District of Columbia, entered a preliminary injunction March 31 enjoining the enforcement of a provision in the anti-markup rule that applied to anatomic pathology diagnostic testing services provided in a centralized building, as defined in physician self-referral *Continued on p. 9*

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Lab Competitive Bidding, *from page 1*

The lab industry's focus now turns to Capitol Hill, where legislation to repeal the project altogether is gaining steam. A repeal bill introduced in the House (H.R. 3453) has 40 cosponsors, while a similar Senate bill (S. 2099) has eight cosponsors.

Alan Mertz, president of the American Clinical Laboratory Association (ACLA), believes the repeal legislation could be rolled into a broader Medicare measure that Congress is likely to consider in June. "We're optimistic that we're going to be part of the package this time."

> ***"The Secretary [of HHS] cannot identify hardships that even remotely rival those identified by plaintiffs. At most, implementation of the demonstration project will be delayed for a period of months. Given that roughly five years have passed since Congress authorized the project, it is doubtful that a short delay will have a significant impact on the ultimate long-term goal of reducing Medicare costs."***
> ***—Thomas Whelan***

Irreparable Injury

In filing their request for an injunction, the three plaintiff laboratories—Sharp HealthCare, Scripps Health, and Internist Laboratory of Oceanside—argued that the competitive bidding demonstration "threatens to cause severe and irreparable injury" to the labs, as well as to their employees and patients. For example, Scripps estimated that it would lose a minimum of $1.9 million in revenue, which would lead to a reduction in services and laying off numerous employees.

In his ruling, Whelan agreed with the plaintiffs' contention that the competitive bidding demonstration could cause "irreparable injury to laboratories and patients," in effect rejecting the federal government's argument that because no winners or losers had been established in the demonstration, no one could have been harmed yet.

"The judge was crystal clear in finding that both laboratories and patients could be hurt," said Mertz. "ACLA applauds the court for recognizing the harm this project will cause and for highlighting the fatal flaws in the project."

Whelan also noted that even if the plaintiffs could not have established irreparable injury, injunctive relief would be appropriate because the plaintiffs identified significant hardships that would flow from losing the bidding competition.

"Aside from the economic injuries, Sharp and Scripps have identified severe challenges to their integrated medical network," Whelan wrote. "Internists' employees will be required to find other employment, and its owners would lose their livelihood. And the quality of patient health care (for Medicare beneficiaries and others) will diminish.

"The Secretary [of HHS] cannot identify hardships that even remotely rival those identified by plaintiffs," Whelan continued. "At most, implementation of the demonstration project will be delayed for a period of months. Given that roughly five years have passed since Congress authorized the project, it is doubtful that a short delay will have a significant impact in the ultimate long-term goal of reducing Medicare costs."

Merits of Case

Whelan also ruled that the plaintiffs were likely to prevail on a number of merits of the case, which also supported the tempo-

rary injunction. For example, the plaintiffs alleged that HHS violated the notice and comment requirements of the Administrative Procedures Act (APA). Although HHS contended that its notice and comment activities were sufficient, Whelan believes the plaintiffs have established a likelihood of success on that count.

The plaintiff laboratories also argued that HHS violated the controlling statute by expanding the scope of the demonstration projects. According to the plaintiffs, the statute authorizes the secretary of HHS to conduct a demonstration project only with respect to clinical laboratory tests. The secretary, however, is also requiring laboratories to bid on the price charged for collecting and handling laboratory specimens.

While HHS argues that it has broad authority to conduct the demonstration project, Whelan agreed with the plaintiffs that Congress did not intend the term "laboratory test" to include specimen collection. Thus, the plaintiffs have established a likelihood of success on this claim as well, Whelan said.

Pathologists Fight United Healthcare for Nonpayment in Class-Action Suit

More than 51 pathology groups representing approximately 300 pathologists have been granted approval to seek a class action judgment against United Healthcare of Illinois for millions of dollars of damages relating to nonpayment, according to Greg Brodek, a partner at Duane Morris LLP, the law firm representing the plaintiffs.

"We remain committed to achieving two goals: one, to recover those dollars that we will prove have been underpaid to the pathologists and two, to get a recognition of these payments going forward in some manner."
—Greg Brodek

The lead plaintiff, Associated Pathology Consultants, S.C. (APC; Naperville, Ill.), contends that beginning in July 2004, United Healthcare of Illinois unilaterally stopped paying for the professional component of clinical pathology work.

"United contends that we do not have a role in the provision of those services and that we are paid by the hospital for the provision of these services, which is factually inaccurate," said Richard Anderson, M.D., president of APC and the client representative. "There was not only no negotiation, there was no prior notification. One day we are getting paid for these services, and the next day we are not." While APC continues to provide services to United Healthcare patients, it has not been reimbursed for these services.

All attempts to contact United—by attorneys, APC, and related billing companies—have been unsuccessful. "What made this incredibly frustrating was that United took a national position that it would no longer pay for these services, period, end of discussion," said Brodek.

Moving forward, there will be a hearing scheduled to decide the merits of the case. In the meantime, Brodek is working on quantifying the plaintiff's monetary damages. He currently estimates the shortfall damages to be in the tens of millions of dollars. But in addition to recovering these payments, the plaintiffs are also seeking a judgment for United to restore the payment for the professional component. "We remain committed to achieving two goals: one, to recover those dollars that we will prove have been underpaid to the pathologists and two, to get a recognition of these payments going forward in some manner," said Brodek.

Confusion Over Physician Signature Requirements Creating Problems for Clinical Laboratories

Language included in a transmittal issued by CMS in January is creating significant difficulties for clinical laboratories with respect to the agency's long-standing policy that orders for clinical laboratory services do not require physician signatures.

In the past month, several laboratories have reported receiving requests from the contractor overseeing the Comprehensive Error Rate Testing (CERT) program for an original requisition slip signed by the ordering physician, according to the American Clinical Laboratory Association (ACLA). At issue is Transmittal 80 (Change Request 5743), issued Jan. 11, 2008, which defines a test order, in part, as "a written document signed by the treating physician/practitioner, which is hand-delivered, mailed, or faxed to the testing facility."

The transmittal also deleted a provision of the Medicare Carriers Manual that specifically reflected CMS's long-standing policy that physician signatures are not required on orders for clinical laboratory services.

CLIA regulations, which govern laboratory testing, have historically required only that the physician's name, not his or her signature, be provided on the test requisition. As part of the Balanced Budget Act of 1997, Congress required a negotiated rulemaking process to simplify administrative requirements for clinical diagnostic laboratory services. Over the course of a year, representatives from CMS and 18 different laboratory and medical groups met nine times.

One of the issues discussed in the course of the process was whether or not a physician signature was required on a laboratory requisition, notes ACLA. "As a result of those meetings, and with the full and complete agreement of HCFA [now CMS], it was determined that a physician signature was not required on a laboratory requisition," writes ACLA in an April 1 letter to CMS. This policy has since been restated in a number of *Federal Register* notices and transmittals.

As a result of this confusion, the CERT contractor is now threatening to recoup millions of dollars from clinical laboratories because it believes the orders received by laboratories were invalid since they lacked a physician signature, notes ACLA. The association has asked CMS to clarify the issue by reinserting the deleted language.

COMPLIANCE PERSPECTIVES

Medicare Part A Proposed Rules Near Finalization


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After several years of deliberation, the Centers for Medicare & Medicaid Services (CMS) is likely to finalize new and restrictive Medicare Part A appeal requirements in the near future. These rules will dramatically limit the historical practices of hospitals and other providers challenging cost report-based intermediary determinations found in the Medicare Notice of Program Reimbursement (NPR). Providers will need to implement new and different management approaches in order to rapidly respond to NPRs once these rules are in effect.

CMS stated that it expected that revisions to the appeal regulations would lead to a more effective and efficient appeal process and would help the PRRB reduce its backlog of approximately 10,000 cases.

Background

On June 25, 2004, CMS issued proposed rules that would update, clarify, and revise various provisions of the regulations governing the Medicare Part A provider appeal process. Normally, CMS is required to publish final rules within three years after publication of proposed rules. However, the agency stated that it was unable to meet the three-year deadline due to the complexity of the policy and legal issues raised in the public comments that it received, and it extended the deadline for publication of the final rule for an additional year, until June 25, 2008. The proposed rules are currently before the Office of Management and Budget (OMB) for its review, which is typically the last step before proposed rules are issued as final rules. Depending on the OMB's action, the proposed rules may be issued in final form in the near future.

The proposed rules would make a number of significant changes to the appeal process before the Provider Reimbursement Review Board (PRRB). Most of the regulations governing the appeal process at the PRRB are approximately 30 years old. CMS stated that it expected that revisions to the appeal regulations would lead to a more effective and efficient appeal process and would help the PRRB reduce its backlog of approximately 10,000 cases.

What follows are some of the most significant changes in the proposed rules.

Limitation on the Addition of Issues to the Appeal

The most controversial aspect of the rules is the proposal to limit the right of pro-

viders to add issues to an existing PRRB appeal. Under current regulations, a provider may add a specific matter to the original hearing request at any time before the commencement of the hearing. This permits providers to add issues that come to light based on further review of the cost report or the fiscal intermediary's audit report. Under the current rules, providers are not required to explain why they did not include the issue in the original hearing request, and there is no penalty for adding issues after the hearing request has been submitted.

If the provider is unable, at the time of filing an appeal, to make a final decision as to whether an issue should be appealed, it most likely will include the issue in the hearing request in order to preserve its appeal rights. Thus, it is questionable whether the proposed time limit on adding issues will have the desired effect of expediting the PRRB appeal process.

Often providers do not learn about important legal and reimbursement developments until years after the issuance of the NPR. The current rules allow providers to incorporate those developments into their PRRB appeals as they learn of favorable decisions by the PRRB or the courts in other cases.

Furthermore, at the time an appeal is filed, providers may not possess all of the facts or documentation with which to determine whether a particular issue should be appealed. Indeed, some providers may avoid appealing certain issues because they are not certain that an appeal would be meritorious, but may do so once further research or factual development confirms that an issue is suitable for appeal. *Under the proposed rules, providers would be allowed to add issues to their original hearing request only within 60 days after the expiration of the time limit for making the original appeal request*.

As under current regulations, providers would have 180 days from the date on which the fiscal intermediary issues its NPR to file their appeals. Thus, providers would be barred from adding issues to an appeal later than 240 days after issuance of the NPR. There are no exceptions to this time limit, whether for good cause or for any other reason.

As justification for this proposal, CMS states that permitting the addition of issues at any time before the hearing is untenable and that the availability of a long period for adding issues has become a major obstacle to the PRRB's efforts to reduce its case backlog.

In fact, there are many reasons for the PRRB's backlog, and it is questionable whether the addition of issues to existing appeals is a significant factor contributing to the backlog. Furthermore, in light of the fact that appeals are not scheduled for hearing for at least several years after the appeal is filed, there is little justification for the proposed 60-day time limit for adding issues. Indeed, the current rules use the hearing date (which is set by the PRRB and not by the provider or the intermediary) as the deadline for adding issues.

If the proposed time limit on adding issues to an appeal is adopted, providers will be required to conduct a comprehensive review of the cost report and the NPR in order to identify all of the issues that should be appealed. The proposed rules likely would result in providers appealing more issues in their hearing requests as "protective filings" or placeholders.

If the provider is unable, at the time of filing an appeal, to make a final decision as to whether an issue should be appealed,

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CMS did not explain in the proposal how the rules would apply to existing appeals, and it is unclear how they would apply retroactively to existing appeals. CMS also might include a provision limiting the time period for providers with existing appeals to add issues to their appeals. While there would be grounds to challenge such an application on due process grounds or as retroactive rulemaking, providers should be aware that this is a possibility.

In light of the possibility that the right to add issues may be restricted if and when the proposed rules are finalized, providers should evaluate whether there are additional issues that should be added to their existing appeals and should include all likely appeal issues in future hearing requests.

Failure to Follow PRRB Rules

CMS proposes to add a new regulation that would specify that the PRRB has authority to take appropriate actions for failure to follow established procedural requirements or for inappropriate conduct during hearings. If the provider fails to meet any filing or procedural deadlines or other requirements established by the PRRB, the PRRB could dismiss the appeal, issue an order requiring the provider to show cause why the PRRB should not dismiss the appeal, or take other appropriate action.

There are a number of areas in which the draft instructions overlap or are inconsistent with provisions of the proposed rules. The PRRB has indicated that it will not finalize the provisions of the draft instructions until the proposed rules are finalized.

If the intermediary fails to meet any filing or procedural requirements set by the PRRB, the PRRB could issue a decision based on the written record submitted up to that point or take other appropriate action. The express statement that the PRRB may issue a decision even though the intermediary has not filed a position paper or taken other action is an important reminder.

Currently, intermediaries that delay filing position papers in PRRB cases suffer little consequence, other than formal reprimands from the PRRB to the CMS. If the PRRB would rule regularly in favor of providers' substantive positions when the intermediaries fail to participate actively in the appeal process, it would do much to facilitate the prompt resolution of appeals.

Reopening Procedures

The proposed rules would provide that a change of legal interpretation or policy by the CMS in a regulation, CMS ruling, or CMS general instruction is not a basis for reopening a CMS, PRRB, or intermediary decision. Thus, reopenings would not be permitted based on a change in legal interpretation or policy. Prior court rulings have made it clear that providers have no right to appeal a refusal to reopen.

This restriction on reopenings is a significant statement to providers that underscores the importance of filing appeals to protect their rights through the formal appeal process and not to rely on the pos-

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PRRB Draft Instructions

Subsequent to publication of the proposed rules, the PRRB in February 2005 issued draft instructions that would further restrict the procedures for PRRB appeals. These draft instructions were not promulgated in accordance with the notice and comment provisions of the Administrative Procedure Act and are separate from the proposed rules. There are a number of areas in which the draft instructions overlap or are inconsistent with provisions of the proposed rules. The PRRB has indicated that it will not finalize the provisions of the draft instructions until the proposed rules are finalized.

The most significant and controversial aspect of the draft instructions concerns the appeal information and documentation that must be submitted with the provider's hearing request. *Under the draft instructions, providers in their initial hearing request would be required to provide the explanation and documentation that currently is required in the provider's preliminary position paper*.

In the hearing request, the provider would be required to state, in numbered paragraphs, the material facts supporting the provider's claim. If any documents necessary to support the appeal were not furnished previously to the intermediary, the provider would be required to send those documents to the intermediary with the hearing request. The provider would have to describe any legal issues in dispute and the authorities upon which it relies. This would constitute a major change to the current notice filing for appeals and would greatly increase the burden on the provider in the early stages of the appeal.

In light of the impending rule changes, it is advisable that providers take steps now to prepare for significant restrictions in their abilities to challenge NPR determinations in the event that the proposed rules or draft instructions are issued in final form.

Action Steps for Providers

As noted above, neither the proposed rules nor the draft instructions are currently in effect. Given that the proposed rules are now at the OMB for review, it is likely that the proposed rules (or some variation of them) could be issued as final rules in the near future. It is unknown whether or when the draft instructions might be finalized. In light of the impending rule changes, it is advisable that providers take steps now to prepare for significant restrictions to their abilities to challenge NPR determinations in the event that the proposed rules or draft instructions are issued in final form. These steps include:

- Assessment of existing appeals already filed with the PRRB, with the goal of determining whether there are additional issues that need to be included in the appeal and what information or research is necessary to make a decision regarding those issues. If the restriction on adding issues to the proposed rule is retroactively applied to existing appeals, providers will need to be prepared to include additional issues in their appeals within a short time.
- Evaluation of providers' internal processes and resources for prompt review and analysis of NPRs. If the draft instructions are finalized, providers will need to file a thorough appeal brief within 180 days of the issuance of the NPR. Providers should assess whether additional internal or external resources will be needed to accomplish this.

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Anti-Markup Rule, *from page 1*
regulations (known as the Stark rules).

The outcome of the ruling means physicians and other providers can continue, for now, billing for such services as they did before the November 2007 rule. The injunction holds until either a trial based on the merits of the case or until further action is taken by the court.

CMS published the final anti-markup rule in November 2007. However, in January, the agency delayed the effective date for one year except in two circumstances, one of those being the application of the rule to anatomic pathology diagnostic testing services furnished in a centralized building.

The court said the plaintiffs had shown a likelihood of success based on the merits and that the government would not suffer significant harm if the injunction were granted.

At that time, CMS said those testing services, often delivered through so-called pod lab arrangements, were a chief concern because physician lab owners used a perceived loophole in the Stark rule to profit from referrals to such labs.

The second exception to the January delay of the anti-markup rule pertained to the technical component of purchased tests. The March 31 preliminary injunction did not cover that exception, and the anti-markup rule continues to apply in those claims.

The case was brought against Health and Human Services Secretary Michael Leavitt by three urology physician group practices that own and operate pathology laboratories: Atlantic Urological Associates PA, Urology Center of Alabama PC, and Urology Care Inc. Also named in the lawsuit were Sam Michaels, a self-employed pathologist; Uropath LLC, a company that manages various pathology laboratories; and Uropath's director, Rebecca Page.

Likelihood of Success

The court said the plaintiffs had shown a likelihood of success based on the merits and that the government would not suffer significant harm if the injunction were granted.

Attorney Dan M. Peterson, Fulbright & Jaworski LLP, Washington, who represented the plaintiffs, said one form of relief the case sought was a delay in the anti-markup rule for anatomic pathology diagnostic services in the same way CMS had delayed most other provisions in the rule.

Peterson said the plaintiffs also asked that the anti-markup rule be struck down in so far as it applied to anatomic pathology services. However, he noted that CMS had said it would engage in new rulemaking or provide clarifying guidance on the November rule later this year.

He further said that the case did not contest the delay of the anti-markup rule provisions as they may apply to other services, such as radiology diagnostics.

No Comment Period

The court also said that the HHS secretary had issued the January final rule that delayed the November anti-markup rule without formal notice and comment period, although the secretary said the rule was issued pursuant to an "informal" comment period.

"The court thus finds that this constitutes evidence in support of a finding of arbitrary and capricious rulemaking, evidence sufficient to support a preliminary injunction," Collyer wrote.

HHS argued to the court that the provider plaintiffs lacked standing to bring the lawsuit because provider claims under the Medicare Act must be channeled through HHS's administrative process. However, the plaintiffs countered that the exception to the rule permits federal jurisdiction where the statute's application would result in no review at all. Furthermore, the court determined it need not decide the jurisdictional issues before entering a preliminary injunction.

Clinic Exec Gets Prison Term for Upcoding Claims

A former executive of a medical clinic in Texas is to serve a 30-month prison term for filing fraudulently coded claims and diagnosis codes to Medicare, Medicaid, and private insurance companies in order to receive higher payments than those authorized by the payers, U.S. Attorney for the Northern District of Texas Richard B. Roper announced March 14 (*United States v. Edwards*).

Judge Sam R. Cummings of the U.S. District Court for the Northern District of Texas also ordered defendant Angela Michelle Edwards to pay $370,657 in restitution. Edwards is the former chief executive officer of Oasis Medical Clinic in Plainview. The clinic is now in bankruptcy. Edwards pleaded guilty in November 2007 to one count of health care fraud.

From approximately January 2002 until August 2005, Edwards admitted that she upcoded and improperly coded claims that were submitted to the health care benefit programs. Although Edwards knew that only clinicians were authorized to make diagnoses and determine the level of a patient visit for payment purposes, she personally changed bills submitted by the clinicians.

The defendant also admitted that she taught her billing staff to routinely change bills by filing claims with the payers for visits with added higher-level encounters.

The indictment alleged that Edwards added diagnoses, laboratory tests, and/or symptoms that were not listed or indicated on the original claim form by the clinician.

In one January 2003 medical invoice described in the information, a clinician assigned a visit code of 99201, a code for a first-time patient encounter of 10 minutes that involved a problem-focused history, a problem-focused examination, and straightforward medical decisionmaking, according to court documents. However, Edwards directed the code be changed to 99203 for that of a first-time patient encounter of about 30 minutes, involving a detailed medical history, a detailed examination, and medical decisionmaking of low complexity.

The upcoded claim caused Medicaid to wrongfully pay an additional $68.74 for the patient visit, Edwards admitted in her plea agreement.

Edwards also admitted that she caused poor banking and accounting records to be kept. In addition, she admitted taking money from Oasis's accounts for personal expenses during her tenure as chief executive officer.

Florida Lab Settles False Claims Allegations

A Sarasota, Fla., laboratory and its owner will pay $461,000 to settle civil allegations they submitted false claims to Medicare, federal authorities announced March 17 (*United States ex re. Jane Doe v. Acculab Laboratories Inc.*).

Under a settlement of a qui tam lawsuit originally brought under the False Claims Act by a "Jane Doe" plaintiff, the payment by Acculab Laboratories Inc. and its president and owner, Joseph T. DeGregorio, will settle allegations the company submitted claims to Medicare for laboratory services that were not ordered, not provided, not medically necessary, or improperly unbundled, the Department of Justice said in a written statement. Of the settlement amount, the unidentified whistleblower/relator will receive $92,200, the statement said.

In the complaint, the relator questioned Acculab's procedure for recording patient medical information on requisition forms. Under standard procedures, the physician diagnosing a patient determines the medical diagnosis (ICD-9) code for the patient, the complaint said.

Acculab management, however, directed the relator to enter ICD-9 diagnosis codes on patient requisition forms when there was no diagnosis code listed and to change ICD-9 diagnosis codes when the diagnosis code had been rejected as not payable, the complaint stated.

"The relator alleges that the Acculab phlebotomy draw stations were provided with 'cheat sheets' that listed all of the various payable ICD-9 diagnosis codes that the phlebotomist could use to fill in the patient medical history on the requisition forms instead of contacting the referring doctor," the complaint stated.

ACLA Challenges Medicare Ruling on Ionized Calcium

The American Clinical Laboratory Association (ACLA) is challenging a recent transmittal issued by the Centers for Medicare and Medicaid Services (CMS) establishing ionized calcium as a test to be included in the automated multichannel chemistry (AMCC) panel payment algorithm.

For 2008, the American Medical Association (AMA) created a new CPT code for a new Basic Metabolic Panel that includes ionized calcium, notes ACLA. This code, CPT 80047, includes seven common chemistry tests, plus an ionized calcium (CPT 82330). Ionized calcium is not a commonly ordered test, but it was included in this panel because a new point-of-care, hand-held instrument—the I-Stat, developed by Abbott—is capable of performing all of these tests at the bedside.

Another similar panel, also called a Basic Metabolic Panel (CPT code 80048), has existed for quite some time, and that panel includes a regular, total calcium, rather than an ionized calcium. The I-Stat is not able to perform the regular, total calcium.

Transmittal 83 (Change Request 5874) creates a new automated test panel (ATP) code to designate that the new Basic Metabolic Panel with ionized calcium would be paid under the AMCC panel payment algorithm. Basically, this means that new code 80047 is paid for as an automated chemistry panel composed of eight tests.

In addition, CMS has also indicated that for ESRD dialysis patients, the new Basic Metabolic Panel will be considered a composite rate test when the ionized calcium is done to replace the serum calcium. What's more, CMS included the ionized calcium in the calculation of the 50/50 rules applicable to ESRD patients. Under the 50/50 rule, if half or more of the tests in a chemistry panel are included in the ESRD composite rate, then the entire panel is considered part of the composite rate and will not be paid for.

"ACLA believes that the new policy of CMS is erroneous on several fronts," writes ACLA in a March 14 letter to CMS. "First, it is incorrect to consider the ionized calcium included in 80047 as an automated chemistry test as it does not meet the criteria for such test. As a result, it is also incorrect to pay for it based on the AMCC payment algorithm.

"Further, it is inappropriate to consider the ionized calcium as an ESRD test because it is not routinely or commonly used for ESRD patients. Finally, it is incorrect to include ionized calcium in the 50/50 rule." ACLA has asked CMS to withdraw Transmittal 83.

False Claims Amendments: The Senate Judiciary Committee April 3 unanimously approved an amended version of the False Claims Act (FCA) Correction Act of 2007 (S. 2041), containing a number of revisions to the original bill as recommended by the Department of Justice. Sen. Chuck Grassley (R-Iowa) introduced the bill in September 2007 to fix what he called misinterpretations by federal courts of the 1986 whistleblower amendments that prevented government employees from acting as qui tam relators.

Stark Guidance: The Centers for Medicare & Medicaid Services (CMS) may begin issuing more interpretive and subregulatory guidance to hospitals and doctors on the physician self-referral rules, according to CMS Technical Payment Division Director Donald Romano. Speaking at the American Conference Institute's Symposium on Healthcare Fraud Investigations, Romano said he would like to see the agency communicate to health care providers and institutions about the Stark regulations beyond formal rulemaking to address uncertainties and questions that arise about the complex rules. Among ideas CMS is considering are special Stark alerts that would address specific self-referral issues as they arise, such as common questions from providers or questionable arrangements in place at multiple facilities. The alerts would be similar to special fraud alerts occasionally issued by the Department of Health and Human Services Office of Inspector General (OIG).

Advisory Opinion Payment: The Department of Health and Human Services Office of Inspector General (OIG) has eliminated the $250 down payment for advisory opinions and has changed payment procedures for requesters seeking advisory opinions. Requestors are still required to pay a fee equal to the cost of preparing an advisory opinion. However, the OIG will no longer require an initial payment at the time of the request. Advisory opinions will be released after requestors pay the full fee appropriate for their opinions. The OIG said the changes would streamline the advisory opinion process and make the system more efficient. The new procedures become effective April 25.

G-2 Compliance Report (ISSN 1524-0304) is published by Washington G-2 Reports, 1 Washington Park, Suite 1300, Newark, NJ 07102-3130. Tel: 973-718-4700. Fax: 973-622-0595. Order line: 212-629-3679. Web site: www.g2reports.com.

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