

# G2 Compliance Report



For Hospitals, Laboratories and Physician Practices

Kimberly Scott, Managing Editor, [kscott@G2Intelligence.com](mailto:kscott@G2Intelligence.com)

Issue 12-09 • September 2012



## COMPLIANCE PERSPECTIVES



*George B. Breen, Esq., and Daniel E. Gospin, Esq., are attorneys in the health care and life sciences division of Epstein Becker & Green.*



### Preparing for and Living Through a RAC Audit: A Guide for the Clinical Laboratory

**T**here is no doubt about it—government enforcement is on the rise and with the expansion of the Recovery Audit Contractor (RAC) program, more providers, including clinical laboratories, will be faced with the proposition of navigating the often complex world of a government audit. In this day and age, RAC audits are virtually impossible to avoid; however, providers can take proactive steps to prepare for and to better address a RAC audit once the government is at the door.

#### Background on the RAC Program

The Centers for Medicare and Medicaid Services (CMS) first implemented the RAC program in 2005 as a pilot program in five states (California, Florida, Massachusetts, New York, and South Carolina). After three years, the program was expanded to a permanent national program. With the passage of health reform, the RAC program has once again been expanded to include all Medicare claims, not just Part A and B claims. CMS also has begun implementation of Part C and D RACs, as well as the Medicaid RAC program.

Currently, there are four RAC regions, each handled by a different contractor. RACs have historically been tasked by CMS with detecting and correcting past improper payments (over- and underpayments). However, this is changing. Later this month, CMS is expected to implement a new demonstration project that will allow RACs to conduct prepayment reviews on certain types of Medicare claims. The new project will permit RACs to review selected claims to determine compliance with Medicare requirements *before* Medicare makes a payment to the provider. At least initially, the demonstration project is limited to a list of diagnosis-related groups relative to an observed problem by CMS surrounding short hospital stays.

#### By the Numbers

RACs began reviewing claims as part of the permanent national program in October 2009. Fiscal year (FY) 2010 was the first year in which the RACs began actively identifying and correcting improper payments under the permanent program. Since the permanent program began, \$1.27 billion in overpayments has been recovered and \$184 million in underpayments has been returned to providers. In FY 2010, the RACs identified and corrected \$92.3 million in combined overpayments and

underpayments. In FY 2011, RACs recovered \$797 million in overpayments. In the first quarter of 2012, RACs collected \$588.4 million in overpayments and returned \$61.5 million in underpayments. By all accounts, RACs are getting better at what they do. The dramatic increase in recoveries can be attributed to a number of factors, including more sophisticated data collection and mining techniques, better communication between federal and state agencies to target error-prone providers, and an increase in financial resources being allocated by the federal government for enforcement.

### **RACs and Clinical Labs—What Is the Government Looking At?**

Guidance from various government contractors and CMS suggests that contractors have focused their attention on auditing certain issues such as the improper use of the 59 modifier, performance of a CBC differential when the physician's order does not specifically include this test, and routine performance of direct-measure LDL tests when such tests may not be medically necessary. Notably, the 2012 Office of Inspector General (OIG) Work Plan discusses the OIG's plan to review Medicare's contractors' procedures for screening the frequency of clinical laboratory claims for glycated hemoglobin A1C tests and determining appropriateness of Medicare payments for these tests.

In addition, the work plan reflects an intent to review trends in laboratory utilization under Medicare with respect to the types of laboratory tests and the number of tests ordered by physicians. This review will include an analysis of how a physician's laboratory test ordering is impacted by medical specialty, diagnosis, and geographic differences. In the near term, clinical labs may also see increased scrutiny surrounding quality measures that are used within the lab to ensure that services are rendered in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA). A lack of quality-control procedures could create exposure under CLIA as well as under the False Claims Act.

### **Getting and Staying Ahead of the Curve**

What can clinical laboratories do to prepare for, and respond to, a RAC audit? The pressure placed on clinical laboratories in having to respond to RAC audit requests (prepayment and post-payment) may raise issues related to staffing, budgeting, and the organization's internal process for coordinating responses to RAC requests and managing appeals. There are certain steps that a clinical laboratory can take to help minimize the impact of responding to RAC audit requests in the first instance and then limit exposure when actually faced with such an audit in the second.

First, it is critically important that clinical laboratories develop and adopt a robust compliance program that contemplates the elements of an effective program described by the U.S. Department of Health and Human Services, OIG, and the Federal Sentencing Guidelines. A tailored compliance program will

help cement a culture of compliance and position your organization to proactively address risk areas that are the focus of RACs and other government enforcement bodies.

***There are certain steps that a clinical laboratory can take to help minimize the impact of responding to RAC audit requests in the first instance and then limit exposure when actually faced with such an audit in the second.***

Moreover, an effective compliance program will improve quality of services and provide a central system for disseminating information and guidance to your organization's employees and contractors. It is not simply enough to have a set of policies and procedures maintained in a binder within the laboratory. The compliance program should be tailored to contemplate issues that are specific

to clinical laboratories, and the program must be implemented at all levels of the organization. While developing and implementing an effective compliance program requires substantial commitment of resources, the long-term benefits of having such a program in place will ultimately outweigh the costs.

The auditing function of your organization's compliance program is an important one to highlight when discussing ways to prepare for post-payment and prepayment RAC audits. Organizations should ensure that the compliance program audit work plan is reviewed and updated on at least an annual

basis. The work plan should reflect those issues that came to light during prior audits as well as newly identified risk areas contemplated by the OIG, CMS, or one of its contractors. Your lab's audit function should be updated as frequently as necessary in order to address significant changes in the regulatory landscape and focus of the government or its contractors. Therefore, it is essential that the compliance team for your clinical laboratory stay current with national and local trends in enforcement as well as the types of claims that the RACs are authorized to review for purposes of determining whether overpayments or underpayments have been made.

In this regard, your organization's compliance department should regularly monitor the guidance issued by the regional RAC, including the RAC's Web site, CMS, and the OIG's annual work plan. In fact, someone within the organization's compliance department should register with the local RAC's list serv as well as CMS's list serv to receive relevant updates. Staying current with government and contractor issuances will allow your compliance team to focus and tailor the compliance program on risk areas that the government deems significant in the clinical laboratory and pathology context.

In anticipation of increased audit activity from the RACs, clinical laboratories should also consider staging mock audits to replicate the RAC review process and use the results of the audit as an opportunity to improve operational and clinical areas that may be the source of detected weaknesses.

***In anticipation of increased audit activity from the RACs, clinical laboratories should also consider staging mock audits to replicate the RAC review process and use the results of the audit as an opportunity to improve operational and clinical areas that may be the source of detected weaknesses.***

At a minimum, a mock audit will give your organization a series of benchmarks by which you can measure improvement over the course of many audits. To maximize the value of a mock audit, various operational functions, such as billing, coding, and documentation should be included in the internal review.

RAC audit requests will many times require the submission of documentation that is not within the care, custody, or control of the laboratory. However, the documentation requested substantiates the claim and must be provided to the RAC in response to the audit request. In these situations, clinical laboratories have found themselves reaching out to referring providers (e.g., physicians' offices, nursing homes, and hospitals)

to request the necessary documentation. This can create a delay in responding to the RAC, and it also may have the unintended effect of frustrating referral sources. Both of these potential consequences can be avoided.

First, be transparent with other providers from whom you are requesting documentation. Let them know the circumstances under which you are asking for the documentation and this may provide the necessary support for the urgency of their response. To the extent that your clinical laboratory enters into professional services agreements with other providers for rendering clinical laboratory services, consider incorporating a provision in the agreement that contemplates a request for documentation received by a third party (e.g., a RAC). With such a provision, all parties will start the relationship on the same page as it relates to the fulfillment of these requests.

### **Challenging the RAC's Findings**

Invariably, labs are faced with a decision on how to respond to an overpayment demand stemming from a RAC audit. One option is to appeal the RAC's determination. Historically, providers, including clinical laboratories, have underutilized the appeal process, and in so doing potentially forgo a favorable decision to overturn the overpayment determination. CMS recently released aggregate data for FY 2011 that sheds light on some very interesting statistics regarding RAC appeals. In FY 2011 there were 903,372 claims with an overpayment determination by a RAC. Of these claims, only 56,620 were appealed at any level. Of these, 24,548 claims' decisions were reversed on appeal in the provider's favor.

## Extrapolation

Clinical laboratories should be mindful that RACs are authorized to use an extrapolation methodology to calculate and project overpayment amounts when it is determined that a “sustained or high level of payment error” exists or where there is “documentation that educational intervention has failed” to correct payment errors and it is necessary to calculate the overpayment amounts that may be due

***The use of extrapolation by RACs presents a key issue for appeal. A provider may appeal the statistical methodology used to determine the sample size, as well as the sample selection.***

to the Medicare program. Extrapolation uses statistical sampling to calculate and project overpayment amounts to be recovered by recoupment, offset, or otherwise. A “sustained or high level of payment error” may be identified through a variety of means including, but not limited to, data analysis, probe samples, provider history, and information from law enforcement.

When extrapolating, a RAC must use the services of a qualified statistician and the sampling methods used must be well-documented.

After the sample size and selection methodology are determined, a RAC staff member will request selected records from the lab and review them. The RAC will calculate the average per-claim overpayment amount in the sample and multiply this by the number of claims in the review population to determine the total overpayment amount.

## Should We Appeal?

There is clear evidence that (1) providers are not appealing overpayment determinations with any regularity and (2) there is a high success rate on appeal for providers. Organizations should carefully consider the strategic value of appealing (or not appealing) certain denials. There may be value in appealing what appears to be a relatively low dollar amount of denied claims; however, these decisions should be discussed internally and with outside advisers who understand the nuances of the appeal process.

The use of extrapolation by RACs presents a key issue for appeal. A provider may appeal the statistical methodology used to determine the sample size, as well as the sample selection. A provider also may appeal the rationale for the overpayment determination and the application of the statistical finding to the entire population of claims.

In any event, providers should carefully evaluate the appeal process, paying particular attention to the many deadlines that are imposed throughout the appeal. It is also beneficial to develop a tracking mechanism to manage appeals and establish a coordinated approach to uniformly and accurately manage the process.

As RAC activities continue to increase and as CMS and its contractors become more coordinated, clinical laboratories will need to take a hard look at their compliance program and audit response process to ensure the effectiveness of both. The current RAC climate suggests that the prudent course is for clinical labs to make the up-front investment in an effective compliance program in order to help mitigate future risk and prepare for the RAC requests and demand letters.

*George Breen can be reached at [gbreen@ebglaw.com](mailto:gbreen@ebglaw.com).*

*Daniel Gospin can be reached at [dgospin@ebglaw.com](mailto:dgospin@ebglaw.com).* 