G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

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Inside this issue

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Compliance Priorities for Laboratory-Developed Tests

The Food and Drug Administration (FDA) set off a storm of written and oral comments when it notified Congress, via a letter dated July 31, of its intent to issue two draft guidance documents regarding oversight of laboratory-developed tests.

The 60-day notification is required by Section 1143 of the Food and Drug Administration Safety and Innovation Act. The guidance was long awaited and destined to be controversial as soon as announced. The purpose of this article is to provide some guidance for laboratory compliance officers concerning how to prioritize their response to the guidance documents among all their other compliance issues.

Industry newsletters and various laboratory industry associations and trade groups, bloggers, and allied industries, such as instrument and reagent manufacturers and lawyers and consultants, are responding

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Comparative Billing Report Identifies Special Stain Outliers

Approximately 5,000 individual providers of tissue exams by pathologists in August received a comparative billing report (CBR) that compared their billing patterns for immunohistochemistry (IHC) and special stains procedures with a national average of their peers.

The providers were chosen because their billing pattern differed in some way from national billing patterns. The CBR was developed, issued, and disseminated by Palmetto GBA and eGlobalTech (eGT), a Centers for Medicare and Medicaid Services contractor specializing in providing services to the federal government. The report was disseminated by fax or regular mail with fax numbers or addresses obtained from the National Plan and Provider Enumeration System and Provider Enrollment, Chain and Ownership System. Providers should make certain their information in these databases is correct.

While the CBR, identified as CBR201407, is meant as an educational tool that can alert providers to potential problems that could result in increased scrutiny, it can also be a tool used to identify providers that may be committing fraud or abuse. This particular CBR was focused on IHC and special stains to educate providers about the proper units of service to bill for the new Healthcare Common

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Comparative Billing Report Identifies Special Stain Outliers, *from page 1*

Procedure Coding System (HCPCS) level II codes that went into effect in January 2014. The codes used for this report are:

- 88305—Tissue exam by pathologist;
- 88312—Special Stains—group I, for microorganisms;
- 88313—Special Stains—group II, other than those for microorganism or enzymes; and
- 88342—IHC.

Sample CBR Allows Providers to Preview a Report

A sample CBR is available to all providers as part of the education aspect of issuing CBRs. The sample report consists of mock (deidentified) data and includes the language and all other information that was provided to the 5,000 providers who received CBRs specific to their practice. The sample includes the same language that was included in the actual CBRs, which explains not only the results of the data analysis but also the various policies and regulations that govern billing for these procedures.

The policies come from a variety of sources, including the Internet Only Manuals, the Correct Coding Initiative policy manual, and the Pathology Service Coding Handbook®. The existing policies and documentation requirements are outlined for the reader. The report explains that "the information provided does not supersede or alter the coverage and documentation policies as outlined in the Medicare Administrative Contractor (MAC) local coverage determinations (LCDs) and Policy Articles." It also instructs the reader to seek answers to specific questions from their local MAC.

What Metrics Are Being Measured

The report specifically examines billing for the above listed HCPCS codes performed on gastric and colon biopsies. The metrics are:

- Average allowed charges per episode of care;
- Average services per episode of care; and
- Percentage of episodes of care with an IHC or special stain.

The report lists the specific references for the various regulations, rules, audit reports, and LCDs used to make determinations about the data on the claims.

The report examines claims with allowed services for the HCPCS codes with dates of service from Jan. 1, 2013, through Dec. 1, 2013. The population of claims was restricted to beneficiaries that had gastric biopsies on the same date of services as the pathology claims. The gastric services are identified with HCPCS. Episodes of care are defined as a provider's distinct interaction with a beneficiary on a date of service. The average allowed charges were broken down by state and across the nation so a provider is compared to similar providers in their state as well as nationally.

There are four possible outcomes for the comparison tables included in each report to a specific provider. Each table contains columns that identify the provider's data and what they are being compared to. Here is an example from the sample report:

Average Allowed Services by CPT® Code Per Episode of Care January 1, 2013 - December 31, 2013					
CPT® Code	Your Average Services Per Episode	Your State's Average Services Per Episode	Comparison with Your State's Average	National Average Services Per Episode	Comparison with the National Average
88305	1.70	1.99	Does Not Exceed	2.27	Does Not Exceed
88312	1.69	1.27	Significantly Higher	1.44	Higher
88313	1.74	1.35	Higher	1.74	Does Not Exceed
88342	N/A	1.35	N/A	1.44	N/A

Note: A t-test was used in this analysis, alpha = 0.05.
Source: Sample comparative billing report.

There is a table for each of the metrics mentioned previously in this article. The four possible outcomes for the comparison columns in each table are:

- **Significantly Higher**—Provider's value is higher than the peer value and the statistical test confirms a significance;
- **Higher**—Provider's value is higher than the peer value but the statistical test does not confirm a significance;
- **Does Not Exceed**—Provider's value is not higher than the peer value; and
- **N/A**—Provider did not have any allowed charges in this category.

Other Resources for Providers

In addition to the references embedded in a specific CBR and the sample report, eGT and Palmetto GBA have also provided a frequently asked questions (FAQ) file about this CBR at *www.cbrinfo.net*. The FAQ provides more links and detailed explanations about various aspects of the report and the methodology used to collect and analyze the data. eGT and Palmetto will hold a one-hour webinar on the comparative billing report Aug. 27 starting at 3 p.m. Eastern time. Recordings will be available five business days after the live presentation.

What Is Next?

If your practice or laboratory is one of the 5,000 that received a CBR on this topic, you should conduct a self-audit. eGT provides guidance on conducting such an audit on its Web site. The CBR is one of nine reports released so far this year covering a variety of topics from all disciplines in health care, and there are more to come. Even if your lab did not receive one of these CBRs, it should review the sample report and other related information and at least review coding and billing for the tests involved. Another action step for labs related to the CBR is to establish a protocol to monitor eGT for lab-related reports. Labs should also document these steps as part of their compliance program annual review and update.

***Takeaway:** The CBR on immunohistochemistry and special stains is another example of the government using data to identify potential billing, coding, and utilization problems. Providers need to become familiar with such reports and develop policies addressing how to respond to them.* G2

Discounts and the Anti-Kickback Statute: Mobile X-Ray Company Survives Challenge

A mobile X-ray company has survived a whistleblower suit based on a discounting arrangement with a skilled nursing facility (SNF) (*U.S. ex. rel. McDonough v. Symphony Diagnostic Services.*).

The U.S. District Court for the Southern District of Ohio, Eastern Division, on Aug. 12, 2014, granted the defendants' motion for summary judgment and denied the relator's motion for partial summary judgment, saying that the relator was unable to establish a sufficient factual basis to support his "chain of inferences."

In a recent LinkedIn posting, Robert Mazer, a health care payment, compliance, and regulatory attorney with Ober|Kaler in Baltimore, discussed the case, noting that it addresses such questions as when is a discount too low, what is fair market value, and what measures are built into the cost of services. For instance, it is a common belief that a laboratory, or any other provider such as the mobile X-ray company involved in this case, should not discount below its costs to provide a service. What is not addressed in previous documents and pertinent advisory opinions issued by federal agencies is what costs should be used—"fully loaded costs" or some other expression of costs.

According to the court documents, in order to prove a violation of the AKS, the relator must show that remuneration was offered or paid in order to induce referrals of government-funded business, and this must be done knowingly and willfully.

This case involved a whistleblower's allegation that the mobile X-ray provider was swapping deep discounts on the Part A services it provided to SNF patients in exchange for the referral of the Part B services that the mobile X-ray company could bill directly to the Medicare program and be reimbursed at the fee schedule amounts. The Part A services are billed directly to the SNF, which then billed them to the Medicare program under the consolidated payment provision; the SNF is then reimbursed in a bundled payment.

The relator argued that the mobile X-ray company had violated the anti-kickback statute (AKS) because it did not use "fully loaded costs" when determining if its pricing was above its cost to provide services. The X-ray company argued that it was providing the Part A services at a rate it had negotiated in a competitive market and it therefore represented the fair market value for Part A services.

This is a very brief description of a case that has been ongoing since the original complaint was filed in February 2008. There are 191 individual documents in the docket file for this case and testimony of experts about calculating costs and defining what are fully loaded costs.

In this case, the court disregarded previous advisory opinions and other opinions and documents and focused on the issue of proving the basic elements of intent as it applies to the AKS. According to the court documents, in order to prove a violation of the AKS, the relator must show that remuneration was offered or paid in order to induce referrals of government-funded business, and this must be done knowingly and willfully. The court states that the relator was unable to provide any direct evidence such as e-mails, memos, comments, or other evidence of a bribe or kickback that would prove the defendants acted knowingly and willfully. The court ruled in favor of the defendants and dismissed the case.

If one takes the time to review some of the more detailed documents and court records of testimony in this case, it can be very instructive and enlightening. It shows that the court can be very unpredictable in its view of concepts we take for granted.

Takeaway: It is very important that a laboratory be careful what documents and memos it creates when making discounting and contractual arrangements with referral sources.

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COMPLIANCE PERSPECTIVES

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Compliance Warning: Watch Out for 2015 Laboratory Drug CPT® Code Changes

The American Medical Association (AMA) and the Centers for Medicare and Medicaid Services (CMS) have posted the preliminary new, revised, and deleted CPT® codes for 2015. The Drug Testing and the Therapeutic Drug Assay sections of the CPT book are being completely revamped. Whenever we see changes of this magnitude, we know there will be compliance problems in the transition from the old way to the new. This article will highlight the upcoming changes, contrast them with the way drugs have been coded in the past, and offer compliance warnings for the new codes.

The AMA CPT Editorial Board received a request to add numerous new CPT codes for drug testing. The board created a Quantitative Drug Task Force, which consisted of members of the Pathology Coding Caucus (the group that normally proposes laboratory CPT changes), pharmacists, reference laboratories, insurance representatives, and physicians, including pain medicine doctors. It took almost two years to create the new codes.

The actual CPT codes have not been released as of the publication date of this article, but instead placeholder codes have been provided by the AMA until the codes are officially published in September. There are 65 new codes, seven revised codes, and 34 deleted codes in the drug testing section. There are now two sections: the qualitative, presumptive drug screens and the quantitative, definitive drug analysis section, which includes confirmations. Previously confirmation and quantitation of drugs were spread out between the drug section, the therapeutic drug assays, and the chemistry section of the CPT book.

Qualitative Screening

All of the current drug screening codes 80100, 80101, and 80104 are being deleted. There has been quite a bit of confusion with the AMA CPT codes and the CMS Healthcare Common Procedure Coding System (HCPCS) codes (G0431 and G0434) in the past. The two sets of coding had different descriptions and usage, which created the confusion and compliance problems. Recently other payers have started requesting that laboratories bill drug screens using HCPCS codes instead of the AMA codes. This has created compliance issues because the units of service between CPT and HCPCS are not the same. The new drug codes were created with the hope that they would be compatible with all payers, including Medicare. The 80101 was billed for each drug or drug class with a typical claim containing seven to nine units of service. The G0431 was once per day of service, and then only for high-complexity testing. The 80104 was for point-of-care drug screening, but the description didn't adequately describe that usage. The G0343 was a mix 80101 and 80104 but had the additional confusion of having CLIA complexity in the description of the code.

The new codes separate the drugs into Class List A and B. There is also provision for the methodology used in the testing, whether it is a simple point-of-care cup or matrix-assisted laser desorption/ionization-time of flight technology. Class A drugs are those that are included in the point-of-care methods and are also available on the multichannel chemistry analyzers. Class B drugs are those that are usually single-test procedures or are not typically screened with every Class A drug. The two tables are appended at the end of this article.

2015 CPT	2015 Description	Notes on Usage	2014 Code(s) that Are Replaced
801XXX1	Drug screen, any number of drug classes from Drug Class List A; any number of non-TLC devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation including instrumented-assisted when performed (e.g., dipsticks, cups, cards, cartridges), per date of service	Point of care dipsticks and cups. Can bill only once per date of service.	80104, G0434
801XX2A	Drug screen, any number of drug classes from Drug Class List A; single drug class method, by instrumented test systems (e.g., discrete multichannel chemistry analyzers utilizing immunoassay or enzyme assay), per date of service	Drug screening performed on larger instruments. Bill this code once, no matter how many drugs in this class were performed. This differs from the 80101, which was billed once for each drug or drug class.	80101, G0434
801XX4A	Drug screen, presumptive, single drug class from Drug Class List B, by immunoassay (e.g., ELISA) or non-TLC chromatography without mass spectrometry (e.g., GC, HPLC), each procedure	These are drugs not typically found on dipsticks or on multichannel chemistry analyzers.	Various
801XXX6	Drug screen, any number of drug classes, presumptive, single or multiple drug class method; thin layer chromatography procedure(s) (TLC) (e.g., acid, neutral, alkaloid plate), per date of service	Close to 80100 description, but instead of each procedure, it is each date of service.	80100, G0431
801XXX7	Drug screen, any number of drug classes, presumptive, single or multiple drug class method; not otherwise specified presumptive procedure (e.g., TOF, MALDI, LDTD, DESI, DART), each procedure	A catch all code for other methodology that does not fit into one of the previous codes.	

There are five new drug screen CPT codes for 2015 as defined in the preceding table.

Quantitative or Confirmation Drug Testing

The drug confirmation code of 80102 (Drug confirmation, each procedure) is being deleted in 2015. This code was too general, which created problems for payers not knowing what they were paying for, and for laboratories that need reimbursement better matched to the cost of the confirmation. One size did not fit all anymore. The new CPT codes are more defined by having a code for each drug and drug class. Some of them are tiered depending on the number of metabolites that are being quantified. There still are the not otherwise specified codes that have the description of "Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 1 to 3, 4 to 6, and 7 or more (801XY45 – 801XY47)." Laboratories will need to be careful and selective in their use of correct codes in 2015.

Some drugs that previously had their own CPT code, such as salicylate (80196), are now part of a larger drug class (Analgesics, non-opioid). A different code would be used to screen for salicylate, which is in the Class B screening list.

Several codes in the drug section are being renumbered. For example, benzodiazepines were 80154. They now have two codes, 801XY5 and 6, depending on the number being reported. Some drugs that previously had their own CPT code, such as salicylate (80196), are now part of a larger drug class (Analgesics, non-opioid). A different code would be used to screen for salicylate, which is in the Class B screening list. Some codes that were in the chemistry section are being deleted and moved and renumbered in the drug section. An example of that is 83925, Opiate(s) drug and metabolites, each procedure. A table of all of the definitive drug codes follows at the end of the article.

Class A Drugs Reference List	Class B Drugs Reference List
Alcohol (Ethanol)	Acetaminophen
Amphetamines	Carisoprodol/Meprobamate
Barbiturates	Ethyl Glucuronide
Benzodiazepines	Fentanyl
Buprenorphine	Ketamine
Cocaine metabolite	Meperidine
Heroin metabolite (6-monoacetylmorphi)	Methylphenidate
Methadone	Nicotine/Cotinine
Methadone metabolite (EDDP)	Salicylate
Methamphetamine	Synthetic Cannabinoids
Methaqualoe	Tapentadol
Methylenedioxymethamphetamine (MDMA)	Tramadol
Opiates	Zolpidem
Oxycodone	Not otherwise specified
Phencyclidine	
Propoxyphee	
Tetrahydrocannabinol (THC) metabolites (marijuana)	
Tricyclic Antidepressants	

Changes in the Chemistry Section of CPT

The chemistry section of the CPT codes is from 82000 to 84999. There were 20 drug testing codes in the chemistry section. They are being renumbered or deleted and in some cases renamed and now will reside with the rest of the drug codes in the drug testing section of CPT.

Codes that Have Description Changes

A handful of codes retain their current number but have had description changes that either clarify the use of the code or change entirely the use of the code. A few of the significant changes are:

- **80162**—Digoxin now is Digoxin, total, and a new code is created for Digoxin, free.
- **80299**—This previously was for quantitation of any drug, not elsewhere specified. It now is only to be used for quantitation of a *therapeutic* drug, not elsewhere specified.
- **82541**—Column chromatography/mass spectrometry has added verbiage to indicate this code is for use only in *nondrug* analysis.
- **84600**—This is the volatiles code. The alcohols have been removed because they now will be coded using the new Alcohol CPT code in the drug section.

Compliance

All of these changes have potential to create coding and compliance issues. The correct qualitative drug screen must be selected, based on methodology, to avoid

upcoding. Care must be taken when selecting the new quantitative CPT codes as to the correct class and correct tiers. Codes that have been used for years now may have changed meaning and purpose. There are several codes that are very similar to each other and caution must be exercised when selecting the correct CPT.

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Definitive Drug Assays					
801XY2	Alcohol biomarkers; 1 to 2	801XY36	Antiepileptics, not otherwise specified; 7 or more	801XY10	Methadone
801XY3	Alcohol biomarkers; 3 or more	801XY31	Antipsychotics, not otherwise specified, 1 to 3	801XY17B	Methylenedioxyamphetamines
801XY1	Alcohols	801XY32	Antipsychotics, not otherwise specified, 4 to 6	801XY17C	Methylphenidate
801XY44	Alkaloids, not otherwise specified	801XY33	Antipsychotics, not otherwise specified, 7 or more	801XY7	Opiates, one or more
801XY18	Amphetamines; 1 to 2	801XY4	Barbiturates	801XY15	Opioids and opioid analogs; 1 to 2
801XY19	Amphetamines; 3 to 4	801XY5	Benzodiazepines; 1-12	801XY16	Opioids and opioid analogs; 3 to 4
801XY20	Amphetamines; 5 or more	801XY6	Benzodiazepines; 13 or more	801XY17	Opioids and opioid analogs; 5 or more
801XY44A	Anabolic steroids; 1 to 2	801XY12	Buprenorphine	801XY8	Oxycodone
801XY44B	Anabolic steroids; 3 or more	801XY37	Cannabinoids, natural	801XY21	Phencyclidine
801XY28	Analgesics, non-opioid; 1 to 2	801XY38	Cannabinoids, synthetic; 1 to 3	801XY13A	Pregabalin
801XY29	Analgesics, non-opioid; 3 to 5	801XY39	Cannabinoids, synthetic; 4 to 6	801XY7A	Propoxphene
801XY30	Analgesics, non-opioid; 6 or more	801XY40	Cannabinoids, synthetic; 7 or more	801XY7B	Sedative hypnotics (non-benzodiazepines)
801XY27A	Antidepressants, not otherwise specified	801XY43	Cocaine	801XY14	Skeletal muscle relaxants; 1 to 2
801XY22	Antidepressants, serotonergic class, 1 to 2	801XY45	Drugs or substances, definitive, qualitative, or quantitative, not otherwise specified; 1 to 3	801XY14A	Skeletal muscle relaxants; 3 or more
801XY23	Antidepressants, serotonergic class, 3 to 5	801XY46	Drugs or substances, definitive, qualitative, or quantitative, not otherwise specified; 4 to 6	801XY17A	Stereoisomer analysis, single drug class
801XY24	Antidepressants, serotonergic class, 6 or more	801XY47	Drugs or substances, definitive, qualitative, or quantitative, not otherwise specified; 7 or more	801XY41	Stimulants, synthetic
801XY25	Antidepressants, tricyclic and other cyclicals, 1 to 2	801XY13	Fentanyl	801XY42	Tapentadol
801XY26	Antidepressants, tricyclic and other cyclicals, 3 to 5	801XY13B	Gabapentin, non-blood	801XY48	Tramadol
801XY27	Antidepressants, tricyclic and other cyclicals, 6 or more	801XY9	Heroin metabolite	8XXX13	Digoxin; free
801CY34	Antiepileptics, not otherwise specified; 1 to 3	801XY9A	Katamine and norketamine	80XXX11	Valproic acid (dipropylacetic acid); free
801XY35	Antiepileptics, not otherwise specified; 4 to 6				

Compliance Priorities for Laboratory-Developed Tests, *from page 1*

publically and privately to the guidance documents. The two documents are titled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)." Experts are continuing to analyze them and organize their response.

As compliance officers, our real concern is what do we have to do and when do we have to have it done. In many cases, the laboratory compliance officer is not going to be expert in either FDA regulation or the more technical aspects of highly complex LDTs, but they still have the responsibility to make certain their laboratory does what needs to be done to meet any regulatory or billing requirements for its LDTs.

The Compliance Officer's Duties Regarding the Draft Guidance

One of the first things a compliance officer will need to do is read the FDA documents to gain a basic understanding of what they entail and identify critical dates and deadlines they will have to meet. Many times, third parties will publish various articles and summaries of these very facts, and that can also be helpful to the compliance officer. In fact, G2 has published such articles in its newsletters, including *National Intelligence Report* (Aug. 14), *Diagnostic Testing and Emerging Technologies* (August), and *Laboratory Industry Report* (Aug. 7).

The framework guidance defines the term* laboratory-developed test *as an in vitro diagnostic device intended for clinical use and designed, manufactured, and used within a single laboratory.

The next thing for the compliance officer to consider is that these are draft documents, and all of the deadlines and timelines associated with them begin when the drafts are finalized. According to early reviews of the drafts, there are still critical questions that have not been answered. Further, it is almost certain that there will be legal challenges to the authority of the FDA to regulate LDTs. However, with pressure being applied to getting these drafts finalized by a variety of sources, including Congress, there may be enough push to move them along faster than our experience with the FDA would imply is possible.

In any case, the compliance officer will need to monitor the progress of these draft guidance documents. One way to accomplish that is to sign up for an appropriate newsfeed or listserv. Another, if the resource is available, is to assign the monitoring to an appropriate interested party in the laboratory, such as the medical director or the technical director for the department where the LDTs are performed.

Complex New Regulations for the Compliance Officer

The framework document is 28 pages with an additional 13 pages of appendix and frequently asked questions. It describes a risk-based approach to regulating LDTs, which is no surprise to anyone following this issue. The FDA for years has been saying it wants to take a risk-based approach to oversight of LDTs. The framework guidance defines the term *laboratory-developed test* as an in vitro diagnostic device intended for clinical use and designed, manufactured, and used within a single laboratory. This is an important definition for the compliance officer to understand because at some point, he or she will have to identify those devices that are LDTs and those that are not.

In order for a test to be considered an LDT, all aspects of it must have been developed within the laboratory using general-purpose reagents and analyte-specific reagents and general laboratory instruments. Among the examples provided by the FDA as devices that are not LDTs is a case where an entity that owns several laboratories develops a test in one site and then exports it to another of its laboratories for use there.

According to the framework guidance, there will be three groups of LDTs that will be subject to regulation. There will be LDTs that will be subject to enforcement discretion, LDTs subject to partial enforcement discretion, and LDTs that will be subject to full FDA regulation. The latter are the riskiest tests in terms of potential harm to patients if they are not used correctly. For our purposes, enforcement discretion means essentially very limited FDA enforcement as we see in today's LDT regulation. From the compliance perspective, it will be necessary to learn new regulations or, if the lab does a lot of higher-risk LDTs, hire a compliance officer already versed in FDA regulations.

Time Frames, Deadlines, and Notification Requirements

The second guidance concerning medical device reporting (MDR) and notification requirements contains the earliest deadlines that will have to be met. These requirements will take effect six months after the framework guidance is finalized. The intent of this guidance is to explain to laboratories how to notify the FDA that they perform LDTs and what LDTs they are performing. FDA has said that it will exercise enforcement discretion if the laboratory notifies the FDA of their LDTs within six months of the finalization of the framework guidance. That makes this guidance the one that compliance officers should focus on. Understanding what information the MDR includes is essential to meeting those early deadlines.

FDA has said that it will exercise enforcement discretion if the laboratory notifies the FDA of their LDTs within six months of the finalization of the framework guidance.

If the laboratory performs a lot of LDTs, the need to understand and monitor the progress of these guidance documents becomes more important. The kinds of potential changes that a laboratory doing a lot of LDTs will have to plan for and budget for are extensive, and executive-level leadership will want to know how they should prepare. They will need to understand which of their tests will be subject to which level of enforcement and what needs to be done first. The compliance officer will be the person who will have to answer those questions and thus needs to be prepared.

Takeaway: While there may be relatively long delays before these guidance documents are finalized, compliance officers should take steps now to help their laboratories prepare to meet these requirements.

Arizona Hospital Network Agrees to $35 Million FCA Settlement

In the largest settlement ever in Arizona for a violation of the False Claims Act, Carondelet Health Network, an Arizona nonprofit corporation doing business as Carondelet St. Mary's Hospital and Carondelet St. Joseph's Hospital (Tucson) has paid $35 million to settle allegations that it had submitted false claims for inpatient rehabilitation facility (IRF) services.

Whistleblower Jacqueline Bloink, a Carondelet employee who worked as a corporate responsibility coordinator, filed the lawsuit in November 2011. Bloink will receive $5.95 million for her part in the suit in addition to payment for her attorneys' fees and related costs.

Corporate Compliance Office Knew About the Overpayments

What makes this case interesting and important for compliance officers working in large health systems is that Carondelet had a corporate compliance program in place and that the corporate compliance officer has known about the problems since at least 2008, according to court documents. Carondelet had conducted audits in 2008, 2009, 2010, and 2011 that consistently identified the problem claims and the overpayments due the Medicare and other government programs as a routine part of the audit pro-

visions of their own compliance program. The results of these audits were discussed among management-level employees and corrective actions were put into place.

Carondelet is a member of the Ascension Health system and uses the Corporate Responsibility Program Effectiveness Assessment protocol designed by the Ascension Health Corporate Responsibility Department. While the audits are required by Ascension's corporate responsibility department, Ascension does not see the results of the audits. In 2010, Corporate Responsibility Coordinator Rachel Harnish completed an IRF audit. This was prior to the audits conducted by Bloink. Harnish's audits revealed error rates similar to Bloink's. One problem area was with the intensity of therapy. Intensity requirements must be met unless there is a patient related reason to miss a therapy session. According to the court documents, the majority of cases lacking intensity were due to staffing issues, not patient inability to participate.

According to the court record, "Carondelet knowingly and willfully failed to notify Medicare of the results of its audits, and further knowingly and willfully failed to reimburse Medicare for services that did not meet Medicare's requirements."

Despite the consistent failure of the corrective actions and the repeated audits that demonstrated that overpayments were being received, Carondelet failed to repay Medicare until 2010 when it refunded $24 million, just prior to becoming aware of the whistleblower lawsuit. Even though it was a substantial amount, it was too little and it was way too late. Further, a subsequent audit conducted in 2011 by Bloink revealed the problem persisted and overpayments were still being received. Even faced with that, Carondelet did not make any more repayments.

Knowing and Willful

The overpayments occurred because Carondelet provided IRF services for patients that did not warrant inpatient services and hence were not properly reimbursable as inpatients. According to the court record, "Carondelet knowingly and willfully failed to notify Medicare of the results of its audits, and further knowingly and willfully failed to reimburse Medicare for services that did not meet Medicare's requirements."

The court documents seem to describe a health system that had a compliance program in place and was following its audit protocols. It was examining itself on a regular basis and was reporting the results to upper management. The compliance program was developing and implementing, or so it thought, corrective actions that should have resolved the issue but never seemed to have worked. In fact, it appears that the only part of the compliance program that was not working was the part where Carondelet refunded acknowledged and documented overpayments.

From the prosecutor's perspective, as surmised from the announcement regarding the disclosure and refund that occurred just prior to Carondelet becoming aware of the lawsuit, there was concern that Carondelet's disclosure and repayment was not timely, complete, or adequate. In spite of this, the government gave some consideration to Carondelet regarding its compliance efforts when deciding on the settlement amount. It could have been a lot worse, especially with the current requirements that repayments be made within 60 days.

Takeaway: There is a lesson here for all compliance officers and executive-level administrators. The most important part of a compliance program is taking effective action to fully and properly resolve discovered problems and promptly repay any overpayments identified.

Compliance Corner

Do you have a question about laboratory billing and coding or other compliance concerns? Send your question in and it may be addressed in a future Compliance Corner. Please send questions to *cyoung@G2intelligence.com*.

News-At-A-Glance

PROGRAM TRANSMITTAL MEANT TO CLARIFY *HOMEBOUND* DEFINITION: Program transmittal R192BP, issued Aug. 1, defines the criteria necessary for a patient to be considered homebound allowing a clinical laboratory to charge for a travel allowance to collect blood specimens from the patient. The transmittal says that in order for patients to be eligible for home health services, which includes a travel allowance for a phlebotomist to travel to their home or place of residence to collect a blood sample, they must meet certain criteria to be certified as homebound. The transmittal clarifies the criteria and eliminates the use of vague terms like "generally speaking." Eventually, the language in the transmittal will reside in Chapter 15, Section 60.4.1 of the Medicare Benefit Policy Manual (Publication 100-02). This includes patients in assisted-living facilities or other similar settings, as well as in their own home. Laboratories that provide phlebotomy services to patients receiving benefits under the Medicare home health regulations and charging a travel allowance, in addition to blood collection fees, may want to institute a policy that documents their attempt to determine if the patient is certified as homebound under Medicare regulations.

NORIDIAN ISSUES MOLECULAR AND GENETIC TEST LCDS: Noridian Health Solutions (NHS), one of the largest Part B Medicare Administrative Contractors (MAC), has issued draft Part B local coverage determinations (LCDs) for certain molecular and genetic tests. NHS released draft policies for public comments for CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing; MolDx Breast Cancer Genetic Assay (PBT22); MolDx Prostate Cancer Genetic Assay (ZBE44); and MolDx Genetic Assay for Refractory Depression. The comment period starts Sept. 3 and ends Nov. 3. The reason for issuing the LCDs, as stated in the policies, is to create uniform LCDs with other MAC jurisdictions. The three MolDx LCDs are derived from policies that have been posted on the Palmetto GBA Web site for MAC Jurisdiction 11. NHS covers Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming. Clinical laboratories that file claims for the listed tests in this MAC's jurisdiction should review the policies and comment on them if there are any problems or issues. A hospital that must file claims for its inpatients or outpatients for tests performed in reference labs should forward the policies to the reference lab for any comments they may have regarding the tests and to make them aware of the diagnostic requirements.

OPTIM HEALTHCARE AGREES TO $4 MILLION SETTLEMENT: Improperly inflated claims, upcoded claims, and violations of the physician self-referral laws (Stark) are among the allegations leveled against Optim Healthcare (Savannah, Ga.). The settlement was announced Aug. 11 by the U.S. Attorney's Office in the Southern District of Georgia. According to the announcement, the case was initiated by complaints from patients who live in the Savannah area but had to travel to Optim Healthcare's rural hospital to undergo major surgical procedures. The government alleges that the patients were sent to the rural facility based on reimbursement issues rather than anything to do with patient care. The allegations that were resolved through this settlement were also part of a federal whistleblower suit.

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