G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

G2 INTELLIGENCE
A Bloomberg BNA Business
Bloomberg BNA

December 2014

Inside this issue

www.G2Intelligence.com

Embattled Laboratory Seeks Dismissal of Cigna Lawsuit

Health Diagnostic Laboratory Inc. (HDL) is seeking dismissal of an $84 million lawsuit filed against it in October by Connecticut General Life Insurance Co. (Cigna).

In a Dec. 8 motion seeking dismissal of the Cigna suit, HDL alleges the claims are not properly founded in Employee Retirement Income Security Act (ERISA) law, claiming that the suit is instead motivated by Cigna's desire to limit out-of-network providers. ERISA is a group of federal laws designed to protect retirement plan funds.

In a 43-page memorandum of law in support of its motion to dismiss, HDL alleges that Cigna brought the complaint in the guise of its purported role as an administrator of certain ERISA-based insurance plans when its real motivation is the support of its own business strategies to control costs by limiting out-of-network providers such as HDL.

HDL Paid Referral Sources Collection Fees to Garner Referrals

In the original complaint, reported in the October issue of *G2 Compliance Advisor*, Cigna alleges that HDL operated a scheme to circumvent safeguards designed to prevent unreasonable and excessive charges by forgiving patient copays, coinsurance, and deductibles if they used HDL. Further, Cigna alleges that HDL also paid physicians kickbacks disguised as collection fees if they referred patients to HDL.

Continued on page 9

A Pattern or Practice of Submitting Improper Claims Could Cost Labs Their Billing Privileges

Under a new final regulation published by the Centers for Medicare and Medicaid Services (CMS) in the Dec. 5 *Federal Register*, laboratories could be at higher risk than other kinds of providers because of the large number of claims they submit.

Under the rule, CMS can revoke billing privileges if a laboratory exhibits a "pattern or practice of submitting claims that fail to meet Medicare requirements." Labs could potentially exhibit such a pattern or practice sooner than other kinds of providers because of the sheer number of individual claims they routinely submit.

CMS already has the authority to revoke billing privileges of a laboratory that abuses its privileges, but this regulation expands that authority. Currently, CMS can revoke a laboratory's billing privileges if it submits

Continued on page 2

A Pattern or Practice of Submitting Improper Claims, *from page 1*

a claim or claims for services that could not have been furnished to a specific individual on a specific date of service—for instance, if the beneficiary is deceased or the physician is in a different state or country on the claim date. Under the new rule, titled "Requirements for the Medicare Incentive Reward Program and Provider Enrollment," CMS can revoke billing provisions for reasons such as unpaid Medicare debt or a previous felony conviction of a managing employee. However, this article will focus on the pattern or practice criteria because this area potentially creates greater risk for laboratories than for other kinds of providers. The effective date for the new provisions is Feb. 3, 2015.

New Authority Sets Criteria CMS Will Use

Under the expanded authority, CMS will make the determination of what constitutes billing privilege abuse mainly through measuring claims submissions to detect a pattern or practice of submitting improper claims. Claims denial is the metric, and the pattern of abuse is based on predetermined criteria based in part on provider and supplier input to an April 29, 2013, proposed rule. The new criteria to measure a lab's improper claims submittal patterns will include:

- The percentage of submitted claims that were denied;
- The reasons for the claim denials;
- Whether the provider or supplier has any history of final adverse actions (as that term is defined under §424.502) and the nature of any such actions;
- The length of time over which the pattern has continued;
- How long the provider or supplier has been enrolled in Medicare; and
- Any other information regarding the provider's or supplier's specific circumstances that CMS deems relevant to making its determination.

In the proposed rule, CMS sought input on criteria by seeking comments from stakeholders. Some of the key comments raise valid concerns on the part of providers such as laboratories. Commenters asked CMS to include only claims that have been fully adjudicated in its measure of improper claims, excluding claims under appeal. The logic of these commenters is that if a claim denial is overturned in the appeals process, it should not be counted as an improper claim. CMS did not agree with these commenters, saying that excluding claims that are in the appeals process may spark providers to file unmerited appeals to circumvent the application of this rule.

Another group of commenters said that CMS's proposal is arbitrary and subjective and grants too much discretion to CMS and its contractors. These commenters also said that the proposed criteria were not fully discussed and that CMS does not adequately define "pattern or practice." Further, there is nothing in the rule that limits CMS and its contractors' authority under the rule, they noted. While CMS stated in the proposed rule's preamble that it or its multiple contractors would not use this provision to revoke a provider's privileges for isolated and sporadic claim denials or innocent billing errors, there are no safeguards to prohibit that.

Commenters also noted that CMS contractors' errors in interpreting Medicare rules and billing guidelines can lead to inappropriate claims denials. CMS did not agree with these commenters either, stating that sporadic billing errors would not result

in inappropriate revocation of billing privileges and that CMS, not its contractors, will be making all revocation decisions. The agency also said that it did not define pattern or practice on purpose "to maintain flexibility to address a variety of factual scenarios." CMS said that providers should be reassured that the revocation authority would be applied fairly because it is listing factors that it would consider when making determinations and promised to apply revocation only in situations where provider behavior could not be considered sporadic. Further, CMS said it would revoke billing privilege only after "the most careful and thorough consideration of the relevant factors."

In this response, and in other sections of the rule, CMS reminds providers that they have the responsibility to "diligently seek and obtain clarification of Medicare policies should there be a misunderstanding or confusion." Also, providers and suppliers have the responsibility to submit only claims they are certain are correct and meet Medicare requirements.

Similar comments were received by other stakeholders with essentially the same response from CMS. Providers have the responsibility to submit accurate claims, and they receive ample notification from CMS or its contractors of the reasons claims are denied. CMS again makes the oft-repeated statement that honest providers have no reason to worry because this rule is not intended to punish them, only providers who consistently and continually submit claims that do not meet Medicare requirements.

Reinstatement After Revocation

Provider or suppliers, such as laboratories, that have their billing privileges revoked under this rule will be barred from participating in the Medicare program for at least one year after they receive the mailed notice of the revocation. The same bar may also be applied to managing employees or owners. The re-enrollment bar can be up to three years based on the severity of the basis for the revocation.

Revoked billing privileges can be reinstated through the use of a corrective action plan (CAP) only in the limited circumstances. A CAP cannot be used when the provider is determined to be not in compliance with the enrollment provisions. CMS notes in the rule that "providers and suppliers generally should not be exonerated from failing to fully comply with Medicare enrollment requirements simply by furnishing a CAP, for it is the duty of providers and suppliers to always maintain such compliance."

Actions Laboratories Should Seriously Consider

Laboratories must ensure that claims they have reason to suspect will be denied are not submitted to Medicare or other government payers until they are corrected. Laboratories should also institute a post-claims submittal review of their remittance advice from Medicare and Medicaid for denied claims and aggressively address repeated denials for the same reasons. This can be as simple as reviewing 10 or 20 pages of a remittance advice report and noting the kind and frequency denials. However, many laboratory billing systems will produce reports that group and summarize claims denials, and using such a system is a much better option. Compliance officers should make sure those tools are being appropriately applied to claims submittals.

Laboratories should also conduct monthly comparative analysis to make sure they detect any changes in denial patterns as early as possible. In addition, reviews of

claims denials over longer periods may have the added benefit of detecting longer-term trends on claims denials and the reasons for those denials.

A critical component of reviews and analysis of claims is to correct any detected patterns of denials and document the outcome. Any contact with Medicare contractors to attempt to get clarification of claim submittal requirements to address denials should be thoroughly documented in case they are needed to demonstrate good-faith effort to address denials.

Takeaway: It is incumbent on laboratories and other providers to use all tools and reviews necessary to prevent claims that will be denied from being submitted or face revocation of their Medicare billing privilege for at least one year.

CMS Changes Time Frame for Prepayment Documentation Requests

Providers will have 45 calendar days, instead of the current 30 days, to respond to additional documentation requests (ADRs) during prepayment reviews from Medicare auditors, or their claim will be denied, according to a recent transmittal from the Centers for Medicare and Medicaid Services.

The transmittal, R554PI (change request 8583), originally issued on Nov. 14, was revised on Nov. 18 to make corrections in the prepayment review section concerning ADRs.

This transmittal applies to Medicare contractors such as Medicare Administrative Contractors (MACs), Zone Program Integrity Contractors (ZPICs), Recovery Auditors, Comprehensive Error Rate Testing contractors, and Supplemental Medical Review Contractors in different circumstances. In prepayment reviews, MACs and ZPICs should not extend the 45-day time frame for providers who need more time and "shall" deny the claim on day 46. Use of the term *shall*, according to the transmittal, means the requirement is mandatory.

Documentation Requests Should Include the 45-Day Deadline

In cases where a Medicare contractor does not receive sufficient information to adjudicate a claim based on the information it received with the claim or that may be available in the billing history or in the common working file, it will solicit additional information from the provider or supplier that submitted the claim. The contractor is authorized to collect additional medical documentation to determine the correct amount due to the provider submitting the claim under Section 1833(e) of the Social Security Act. According to Chapter 3, Section 3.2.3.2 of Pub 100-08, Medicare Program Integrity Manual, the ADR must include the 45-day deadline.

It is important to note that the changes describe in this transmittal are applicable to prepayment reviews conducted by MACs and ZPICs only and do not include post-payment reviews. Post-payment reviews are not affected by this transmittal, so contractors have the discretion to allow an extension of the 45-day deadline completely at their own discretion in that case.

The effective date of this change is April 1, 2015, with an implementation date of April 15, 2015.

Takeaway: Providers will have a little longer to respond to prepayment review additional documentation requests from Medicare contractors.

G2 INTELLIGENCE
A Bloomberg BNA Business
Bloomberg BNA

COMPLIANCE PERSPECTIVES

It's Time to Look Forward: Make a List and Check It Twice

Among the many tasks that a laboratory compliance officer must carry out, planning for upcoming compliance issues and anticipating regulatory challenges is as important as any other. This task is essential for a variety of other interdependent tasks the compliance officers must oversee or plan for, including budgeting, human resources, education and training, and continually upgrading their own skills and knowledge. In some cases, the compliance officer will have to choose whether to develop the necessary expertise internally or hire a consultant to help with some of these tasks. Developing the necessary expertise and skills internally holds far more potential to provide the greatest benefit to the laboratory. If the compliance officer decides to use a consultant or seek help from outside the laboratory, the selection of the person or firm is the next most important decision.

Making a List Is a Good First Step

Often, making a list is a good way to focus on the issues that need to be addressed as a means to make sure all things are covered and nothing is missed. Even better, make the list dynamic so that the compliance officer can add to it or add new information as items develop or change throughout the year. Think of the Health and Human Services Office of Inspector General's (OIG) annual work plan as a template.

Here is a list of newer issues laboratory compliance officers will have to face during 2015 and beyond, in addition to operating and overseeing the existing compliance activities:

- Changes to the way pricing and fees will be determined for clinical laboratory services, with possible significant reductions (this includes continued attacks and revisions to the Physician Fee Schedule for pathology services and molecular and genetic testing);
- Sophisticated use of data mining and intelligent computer technology, including predictive algorithms to detect fraudulent providers or suspicious claims and to deny potential problematic claims before they are paid;
- New cases and prosecutions in the area of anti-kickback and physician self-referral brought mainly by whistleblowers;
- The government's push for transparency in the health care industry, including laboratory services, which brings new scrutiny to the industry from the outside;
- Unrelenting advances in the technology and methods of testing that enable physicians and others to more effectively detect, monitor, and treat disease.

Overview and Methods

In this article, we will discuss each item on the list and provide some guidance to compliance officers concerning how urgent they are and what the complicating issues or challenges are. We will then try to provide some guidance on how to deal with them, keeping in mind that how a particular laboratory deals with any of the items discussed will, to a large part, depend on the laboratory's systems, resources, and knowledge; what kind of laboratory it is; and the setting (hospital or independent, rural, nursing home, etc.).

For our purposes here, there is an assumption that the laboratory has a robust compliance program and the compliance officer is generally aware of the underlying rules and regulations of whatever the issue might be. For instance, when discussing fee schedule changes, there is an assumption that the compliance officer has some idea of the changes that are coming. Further, there is an assumption that the compliance program is active and that the laboratory is operating a comprehensive audit and monitoring program.

One of the general principles or themes throughout this article is its global view of the items or issues presented, with the understanding that it is more than likely that changes to the details may occur before implementation but the general, overall issue will not go away. For instance, there is no doubt that some kind of changes to the laboratory and pathology fee schedules or methods of payment will occur since such changes are required by law. The government expects that whatever changes occur will result in either lower utilization, lower payment, or both. Understanding that as a basic and valid premise will help compliance officers interpret this information correctly as it applies to their own laboratories or responsibilities.

For our purposes, it is not important how a new system will actually work but rather how a change this significant will affect compliance issues and when the compliance officer should expect to have to deal with these changes.

Reimbursement Changes

Options for fee schedule change that the government has expressed an interest in, besides just ratcheting fees down as aggressively as possible, include bundled payments similar to those used for prospective payment systems in hospitals and basing the reimbursements on fees paid by other kinds of payers in the laboratory industry's market. Most likely the changes will result in reduced payment amounts. At this point, regulations have been proposed that provide a general overview of the way this will happen. The Centers for Medicare and Medicaid Services (CMS) intends to rebase the Clinical Laboratory Fee Schedule on fees paid by other payers for laboratory services. However, just last year we were looking at rebasing the fee schedule to account for technological changes that CMS assumes reduced the cost of providing some testing. Many thought that we would be dealing with that in 2015, and yet, here we are today looking at a very different method of rebasing the fee schedule.

For our purposes, it is not important how a new system will actually work but rather how a change this significant will affect compliance issues and when the compliance officer should expect to have to deal with these changes. Reducing the fee schedules will present some challenges in resources available, which often results in budget cuts in the laboratory. Developing a new fee schedule entirely and including data and pricing information provided by laboratories has its own challenges and compliance issues.

Compliance officers will have to deal with the lower reimbursement issues in the first quarter and throughout the year. For the other area of concern, rebasing the fee schedule on market payments, compliance officers should spend the first month of 2015 making certain the current information of the changes are thoroughly understood. Later in the year, but still in the first six months, the first sets of details will be published about the changes and the laboratory will have to begin preparing for whatever is required. Compliance issues will emerge during this time, and the compliance officer can prepare to make certain that all in the laboratory understand them and what needs to be done.

While we are fairly certain that bundled payments in some form are in our future because it is a payment method the government already uses and favors, it is unlikely that there will be much activity in the independent laboratory in 2015.

The Use of Sophisticated Techniques

CMS and the OIG have been touting predictive modeling and data mining techniques as two of the more important tools they have been given to help them meet their responsibilities to prevent fraud and abuse and reduce payment errors. Demonstration projects have given the agencies a way to actually deploy these tools and learn how to best employ them. These tools have allowed them to create some pretty sophisticated reviews of data, such as comparative billing reports, they can ultimately use to find laboratories that are outliers or have aberrant billing patterns. The data can point CMS to areas where lots of billing errors are made by many different kinds of laboratories or to find a single provider who represents a billing outlier that needs to be reviewed more closely. In the first case, the data can be used to determine where improvements need to be made in their own systems. This same data can be used to focus educational efforts for providers, one of CMS's other major areas of responsibility that should lead to fewer claim errors and better compliance. The other side of that coin is the benefits auditors and prosecutors can derive from the data to obtain refunds where claims were improperly paid.

Laboratory compliance officers should plan for adding an information technology expert, or gaining priority access to one, for their compliance team and make sure they have appropriate computers, access, and equipment to allow them to take best advantage of the government's data to compare to their own.

Laboratory compliance officers should use this same data in their own audits and self-monitors to set benchmarks for their laboratories to help keep them in compliance. This is an area of current activity, so the compliance officer needs to get a handle on this as early in 2015 as possible. Laboratory compliance officers should plan for adding an information technology expert, or gaining priority access to one, for their compliance team and make sure they have appropriate computers, access, and equipment to allow them to take best advantage of the government's data to compare to their own. This individual will eventually become a key person to help overturn government demands for refunds and to support the internal auditing and monitoring processes.

Anti-Kickback, Stark, and Whistleblowers

The number of anti-kickback and physician self-referral (Stark) cases has been on the rise for several consecutive years, as was recently reported in a Department of Justice report to Congress. These cases usually are the result of whistleblower activities, but in recent years, more have been a result of self-reporting by the institution or provider involved. These cases become false claims cases with significant settlement amounts and, in some cases, criminal indictments and exclusions. Laboratory compliance officers should review all of the laboratory's practices that have implications for these two sets of regulations, including discounts to referral sources, leases, and rental of space or equipment from referrals sources; placement of laboratory employees in the offices of referral sources; gifts and entertainment for referrals sources; and any contracts for services where the laboratory pays a referral source or physician for a service they are providing. These are generally complex and serious problems, and the laboratory compliance officer should not take this on alone. As a way to prepare for potential problems in this area, compliance officers will need to make certain they have access to competent and knowledgeable legal counsel to help with these issues and a written policy for dealing with whistleblowers. This is ongoing, and

the compliance officer should plan on spending resources with short notice in this compliance area as problems tend to arise with little notice.

Transparency

The new public scrutiny resulting from the government's push for transparency in the health care industry creates both opportunities and challenges. This is an area where the laboratory compliance officer can expect problems beginning in the first quarter and continuing throughout the year. To prepare for issues that may arise out of this, the laboratory compliance officer should review the data already available and analyze their laboratory's data to determine if they represent an outlier in any way. The compliance officer should also monitor the release of new information or reports and analyze those as well. These are likely to be public media kinds of issues in some cases, so the compliance officer needs to understand how the laboratory normally deals with public issues. Finally, the compliance officer should develop benchmarks that can be readily used to help others understand what any given report means for the laboratory. This is a first-quarter item and then ongoing throughout the year as more data becomes available.

New Tests and Methods and the FDA

The field of laboratory testing is developing remarkably fast. New, expensive, and often not well reimbursed tests and methods become available nearly every week. Customers of the laboratory, including patients and other laboratories, sometimes demand the laboratory make a new test available. Generally speaking, the compliance areas that are going to be greatly impacted by this are laboratory-developed tests (LDTs) and reimbursement for new tests.

Selecting the correct code or codes for a new test can be a challenge, and then getting them reimbursed adds another layer. Often, this is not an area where the compliance officer has a lot of technical knowledge, which complicates the problem even further. This is ongoing as the new coding system has been around now for a while, but the compliance officer still needs to make sure there is review for code selection by a technical expert in the methods being used to perform the test.

Being a laboratory compliance officer is a challenging and often thankless job. It requires a person who is willing to look forward and backward all of the time, keep an open mind, and remain calm and self-possessed in the most violent storms.

Compliance officers need to become familiar with the Food and Drug Administration's (FDA) rules and regulations and how they apply to LDTs even if the laboratory does not actually perform them. This is a first of the year item because the FDA's outreach and education on the new guidance for LDTs has already begun. Compliance officers need to be familiar with how the FDA works and what their labs' involvement will be.

Conclusions

Being a laboratory compliance officer is a challenging and often thankless job. It requires a person who is willing to look forward and backward all of the time, keep an open mind, and remain calm and self-possessed in the most violent storms. In many cases, the compliance officer is dealing with problems or issues that are fairly routine and basically benign. In other cases, hopefully very rare cases, the compliance officer is dealing with a problem that ultimately could result in the demise of the laboratory or a person spending time in jail. Compliance officers must be mindful of the business and financial impact on the laboratory, as well as the compliance implications, of their decisions and recommendations when making them. In addition, there are certain conflict of interest issues to be recognized and addressed. It is this two-sided blade that makes the profession constantly interesting and constantly difficult at the same time.

Embattled Laboratory Seeks Dismissal of Cigna Lawsuit, *from page 1*

HDL reportedly is under investigation by the federal government for paying those allegedly disguised kickbacks as well. The federal complaint has not been made public, so there is no way to know exactly what HDL is accused of or if there is any legal action moving forward.

HDL Says Cigna Cannot Use ERISA as Basis for Complaint

In its motion seeking dismissal of the Cigna lawsuit, HDL alleges the following:

- Cigna lacks standing as a fiduciary under ERISA §502(a)(3) because it improperly seeks the return of funds that it paid in its capacity as an insurer and it otherwise fails to adequately allege facts that identify the benefit plans that it purports to represent;
- Cigna has not afforded the plan's beneficiaries with the notice and appeal rights as required by ERISA;
- Cigna does not state a claim for violations of ERISA or any terms imposed by ERISA or any plan document that requires HDL to collect copays, coinsurance, and deductibles;
- Cigna's demand for compensatory damages fails because ERISA allows only equitable relief, which is not established by the Cigna complaint and, according to the HDL memorandum, insurers are not entitled to such relief;
- All of Cigna's state law claims are preempted by ERISA; and
- Cigna's allegations regarding a fraudulent scheme fall short of the particularity required by rule 9(b), which says in part that a party must state with particularity the circumstances constituting fraud. According to HDL, the who, what, when, where, and how of the fraud must be stated clearly.

HDL's memorandum alleges that Cigna's complaint fails to plead the most important details in the case. Those details include the identity of the plans, the number of plans, how those plans are funded, whether those plans are subject to ERISA, what terms the plans contain, which terms were violated, how such terms were violated, who the real party-in-interest is, and what Cigna's interest is.

Why Should Other Laboratories Care?

HDL is a prime example of the state of compliance in health care today and how compliance issues can be affected by other current activities in health care.

A drive by the government to foster transparency in health care payment issues resulted in the release of Medicare claims payment files in April. A review and analysis of those files by the *Wall Street Journal* resulted in a front-page story about HDL and some of the practices that made it a fast-growing health care company. Along the way, the Health and Human Services Office of Inspector General published a fraud alert identifying one of those practices, paying physicians and other referral sources collection fees, as presenting a substantial risk of fraud and abuse under the anti-kickback statute. HDL ceased the practice shortly after the release of the fraud alert, saying the alert constituted new guidance from the government.

Recent reports that HDL CEO Tonya Mallory has resigned and that HDL is reducing its workforce serve to illustrate the impact of transparency and bad press. Finally, the Cigna lawsuit, whether it ultimately fails or not, completes the circle.

Compliance officers must seriously consider how much risk they are willing to allow their companies to take and how they should operate their compliance programs going forward.

Takeaway: The lawsuit by Cigna against HDL demonstrates the creative use of a federal law, ERISA, to recoup money and potentially restrict networks.

Lab Charged With Sending Unsolicited Faxes

A Minnesota laboratory facing a class action lawsuit over unsolicited facsimile advertisements it sent to an Ohio clinic, Sandusky Wellness Center LLC, in February 2012 lost its motion for summary judgment, according to court documents filed on Dec. 5 in a Minnesota district court.

The class is made up of all persons who, on or after four years prior to the filing of the lawsuit, received facsimiles of material advertisement on behalf of Medtox, which did not have prior invitation or permission and whose ads did not contain the required opt-out notice.

Medtox Scientific Inc., Medtox Laboratories Inc., and John Does 1-10, the defendants in the case, may have violated the federal Telephone Consumer Protection Act (TCPA) when they sent an advertisement for blood lead testing without the recipient's prior permission or invitation, which subjects them to statutory damages of at least $500 per violation.

The court may grant summary judgment if the movant, Medtox in this case, shows that there are no material facts in dispute. According to Sandusky's response to the Medtox motion for summary judgment, there are 18 disputed facts in the case.

Consumer Protection Against Unsolicited Facsimile Ads

The TCPA says that unsolicited faxes, referred to as junk faxes, damage recipients because they lose the use of their fax machine and waste paper and ink toner. Recipients also lose valuable time that would have been spent on something else, and their privacy is interrupted. In addition, these faxes prevent the fax machine from being used for authorized purpose and for sending authorized faxes. Finally, determining the source and purpose of the unsolicited fax wastes additional human resources such as labor.

Facts Remain in Dispute

On or about Feb. 21, 2012, Medtox sent a fax to Sandusky's fax machine that was an advertisement for a Medtox blood test for lead. According to Medtox, the number used for the fax belonged to Dr. Bruce Montgomery and was obtained by a sales representative for Medtox from a third party directory called CareSource. The fax was allegedly sent without a cover sheet and did not identify Montgomery as the intended recipient. Neither Sandusky nor Montgomery gave permission for Medtox to use the fax number for advertising its products. Based on information and belief, Medtox also allegedly sent the advertisement to more than 39 other recipients without permission. The facsimiles did not display an opt-out notice as is required by law. All of the above allegations would constitute violations of the TCPA.

The class is made up of all persons who, on or after four years prior to the filing of the lawsuit, received facsimiles of material advertisement on behalf of

Medtox, which did not have prior invitation or permission and whose ads did not contain the required opt-out notice. However, the court denied class certification in an Aug. 5, 2014, ruling. Sandusky retains the right to appeal that ruling at a later date.

In its answer to the first amended complaint in the suit, Medtox "denies each and every statement, allegation, matter, and thing contained in the Amended Complaint except as hereinafter specifically admitted, qualified, or alleged."

Professional Plaintiff Intercepted Fax

In a memorandum of law in support of its motion for summary judgment, Medtox alleges that the plaintiff intercepted the fax intended for Montgomery for the purpose of filing the TCPA legal action. The document further alleges that Sandusky has been involved in at least nine putative TCPA class actions all filed by the same attorney. This same document says that Medtox offered Sandusky a payment in the amount of $3,500 to settle the case but that Sandusky rejected the offer. The letter enclosed with the check does not admit any liability and denies it sent an illegal fax. It also promises not to send "another facsimile to the plaintiff in violation of any law."

The Latest Documents Leave Case in Limbo

The latest document in the case is the plaintiff's response in opposition to Medtox's motion for summary judgment. Still pending is Sandusky's potential appeal of the earlier denial of class certification, which must be resolved before certain other aspects of the case can move forward. In this case, an employee of the laboratory took an action that has the potential to seriously impact the future of the laboratory.

Compliance officers worry about whistleblowers and False Claims Act lawsuits; they should also be concerned with the actions of individual employees. Ongoing compliance training can help minimize this risk.

Takeaway: The variety of potentially applicable laws and regulations to clinical laboratories means that it is more important than ever that employees understand the importance of checking with their compliance officer when they contemplate any new actions.

Compliance Corner

Is there a regulation that requires a hospital to pay pathologists for administrative duties, such as oversight of the laboratory and other traditional duties typically performed by a hospital pathologist?

This is not a simple question, and the answer is often specific to the relationship between the parties. Complications are imposed by the reimbursement policies of government payers for the professional and technical components of services provided by pathologists, part of which are, by regulation, paid to the hospital. To further complicate things, opinions vary about how these arrangements should be structured.

Pathologists perform duties on the hospital's behalf, and the hospital provides items such as space, equipment, and other services for the pathologists, who often operate private businesses and bill for their own professional component work. One regulation of concern is singled out in the Health and Human Services Office of Inspector General's Supplemental Compliance Guidance for Hospitals, published in the Jan. 31, 2005, *Federal Register*. That guidance implies that anti-kickback regulations may affect the arrangements between pathologists and hospitals in cases where the pathologist is not an employee of the hospital.

Some experts point out that because the hospital may be receiving some compensation in various bundled payments for services the pathologists perform on the hospital's behalf, not compensating pathologists at fair market value for such services may be an anti-kickback issue, particularly if the hospital is directing referrals for testing to the pathologist.

The reverse also may exist. In this case, pathologists receive the benefit of referrals of hospital patients for which they receive professional service reimbursements and, as a result, do not charge the hospital for oversight and management duties they provide for the hospital laboratory.

There are also concerns related to the different compensation methods based on the kind of hospital involved in the arrangement, who the patient's payer is, and any state laws that might govern the relationship. In the absence of a specific regulation that governs these relationships, it is important that both parties retain the services of experts and obtain legal advice when negotiating a contract for these arrangements.

News-At-A-Glance

BENEFICIARY INDUCEMENTS: Health care providers can induce beneficiaries to use their services in much the same way that they can induce physicians and other referring parties as evidenced by a recent settlement by a major drug store. Rite Aid Corp. in early December settled with the government for $2.99 million in a case where the chain allegedly used gift cards as a means to induce patients to use their pharmacies instead of others. Using gift cards and other forms of influencing patient decisions to use one provider over another is not new. The Health and Human Services Office of Inspector General issued a special bulletin in August 2002 advising providers not to give cash or cash equivalents, including gift cards. Laboratories should pay attention to this case, which is based on a whistleblower lawsuit, because as patients are allowed more direct access to laboratory services, the issue of beneficiary inducements could become an additional compliance risk for laboratories. In the case of a laboratory, while tests for Medicare and Medicaid patients would not qualify for reimbursement because those programs require a physician to order tests, there may be state-based anti-kickback laws that would be implicated by this scenario.

ANOTHER UPDATE AND CORRECTION FOR HEPATITIS C SCREENING: The Centers for Medicare and Medicaid Services has corrected an important omission that affects professional claims filed by independent laboratories related to hepatitis C screening. Change request 8871, dated Nov. 26, defines and clarifies the professional and institutional billing requirements for the Medicare screening benefit for hepatitis C. In this third revision, place of service code 81 identifying independent laboratories has finally been added as an allowed place of service. Other changes in this latest revision include clarifying information for payment methodologies and adding place of service 50 for federally qualified health centers and 72 for rural health clinics. There are also revisions to Medicare Administrative Contractors claims processing instructions and implementation information. If your laboratory is getting denials for this new screening benefit, it may be useful to refer back to this revised version when talking to your Medicare contractor about the problem.

NEW COVERAGE ANALYSIS FOR CERVICAL CANCER SCREENING: The Centers for Medicare and Medicaid Services (CMS) has accepted a formal request to initiate a National Coverage Analysis (NCA) for screening for cervical cancer using a combination of Pap smear and human papillomavirus testing. As noted on the NCA tracking sheet, this screening pathway is recommended with a grade A by the U.S. Preventive Services Task Force (USPSTF) at intervals of five years for women age 30 to 65. The requester is the board chair of the American Academy of Family Physicians, Jeffrey J. Cain, M.D. CMS currently covers a screening pelvic exam and Pap smear for all female beneficiaries at 12 to 24 month intervals depending on specific risk factors. According to Cain's letter requesting the new benefit, women 30 to 65 years of age may lengthen their screening interval to five years, rather than the three years currently recommended by the USPSTF if the two tests are used in combination. CMS may, under 42 CFR 410.64, cover additional preventive services if it determines through the national coverage determination process that the service is recommended with a grade A or grade B rating by the USPSTF. The public comment period ends on Dec. 25, and the expected NCA completion date is Aug. 23, 2015. The NCA tracking sheet can be found on the CMS Web site (*www.cms.gov*) in the Medicare coverage database section.

 G2 Compliance Advisor (ISSN 2332-1474) is published by G2 Intelligence, 24 Railroad Street, Keene, NH 03431-3744 USA. Tel: 800-531-1026 or +1-603-357-8101. Fax: +1-603-357-8111. Web site: www.G2Intelligence.com.

Kimberly Scott, Managing Editor, kscott@G2Intelligence.com; Christopher Young, Editor; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, President and Publisher