G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

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Study Questions Billing for Part B Laboratory Services

A July study of billing practices in the clinical laboratory industry conducted by the Health and Human Services Office of Inspector General (OIG) may drive laboratory compliance billing policy and audit focus for the coming years.

The OIG's Office of Evaluation and Inspections (OEI) performed the study reportedly due to concerns about increases in Medicare payments that did not align with increases in enrollment. According to the study, from 2005 through 2010 Medicare enrollment increased by 10 percent while lab spending increased by 29 percent. Medicare paid $8.2 billion for Part B lab services in calendar year 2010.

Unfortunately, a study like this—by its own admission—is based solely on claims data and cannot be used to detect fraud and abuse or even criminal activity; it can only point out anomalies in the data

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Overpayment 60-Day-Rule Case Will Set Precedent

In a case that may have implications for clinical laboratories, the U.S. Department of Justice has intervened in a whistleblower False Claims Act (FCA) lawsuit related to failure to return overpayments within 60 days of discovery.

The lawsuit, *State of New York, ex rel. Robert P. Kane v. HealthFirst Inc. et al*, was filed June 27 in the Southern District of New York. It alleges that Continuum Health Partners Inc., Beth Israel Medical Center d/b/a Mount Sinai Beth Israel, and St. Luke's-Roosevelt Hospital Center d/b/a Mount Sinai St. Luke's and Mount Sinai Roosevelt (Continuum) violated federal and state false claims acts when they did not return Medicaid overpayments within 60 days of knowing they existed as is required by New York state law and the Affordable Care Act (ACA). The whistleblower, Robert Kane, was an employee at Continuum and conducted the internal investigation that allegedly identified the extent of the problem.

This case is noteworthy for laboratories and their compliance officers because labs file large numbers of individual claims where the possibility of errors is increased, and audits can be difficult and time-consuming when trying to figure out how much is to be refunded. An important question is when does the 60-day clock on refunding overpayments begin? Perhaps this case will bring some clarity to that question.

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Software Glitch Initiated the Problem

Continuum and the hospitals were contracted with HealthFirst Inc. (HF), a nonprofit managed care organization that covers services for Medicaid-eligible enrollees. The New York Medicaid program paid HF under a capitated arrangement, and HF then reimbursed Continuum and other contracted providers. The providers are not allowed to seek any additional payment from the Medicaid program.

The case began in 2009 when Continuum began to improperly bill Medicaid as a secondary payer after it received payment from HF because of a software glitch related to its remittance advice (RA). The glitch caused HF's RA to generate a billing code that erroneously indicated that Continuum could seek additional payment from Medicaid and other secondary payers, which it did and was paid.

Continuum allegedly failed to take any steps to repay the claims it was aware of through Kane's investigation and did not make Medicaid aware of Kane's spreadsheet.

Eventually, auditors from the state comptroller's office questioned some of these secondary payments and concluded that Continuum had been overpaid. Subsequent investigation that included Continuum and the software vendor identified the cause of the problem as a translation problem between Continuum's software and the vendor's that caused the erroneous claims to be submitted. The vendor sent a computer software patch in December 2010 to correct the problem going forward.

In January 2011, Continuum management asked Kane to analyze billing data and identify the claims involved. Kane produced a spreadsheet that identified over 900 claims totaling over $1 million that contained the billing code that caused the problem and likely were erroneous. However, Kane indicated in a Feb. 4 e-mail to management, which included the spreadsheet with a complete list of the suspect claims, that further study was needed to corroborate his findings. According to the court document, Kane had identified the vast majority of erroneous claims. Four days later, Continuum terminated Kane's employment. Kane filed his sealed complaint 60 days after sending his e-mail to management.

Meanwhile, the state comptroller identified more batches of affected claims and brought them to Continuum's attention. Continuum allegedly failed to take any steps to repay the claims it was aware of through Kane's investigation and did not make Medicaid aware of Kane's spreadsheet. Continuum repaid small batches of claims over the next two years until it received a civil investigative demand from the government in June 2012, when it paid more than 300 of the claims. All of the claims were refunded by March 2013.

Billing Error Vs. False Claim

The FCA establishes civil penalties and treble damages for an individual or entity that "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government."

The ACA made a change to the FCA when it added the 60-day report-and-refund requirement to overpayments. Failure to return an overpayment within 60 days of knowing the overpayment exists constitutes a reverse false claim that is actionable

under the FCA. Such an action can turn a billing error into a false claim with significantly larger fines and penalties than the original overpayment. In Continuum's case, Kane's spreadsheet identified each of over 900 individual claims that were potential improper payments. Under the FCA, each of these would be subject to treble the actual damages (amount of the claim) plus a civil penalty amounting to between $5,500 and $11,000 per claim. According to the complaint-in-intervention, the government is seeking the maximum civil penalty. This has the potential, if the government wins the case, to cost Continuum about $30 million instead of the $1 million identified by Kane had Continuum refunded the overpayments promptly.

Conclusions and Actions

Since the passage of the ACA, the 60-day report-and-return provision has been the subject of legal debate centered around when exactly does a provider know that overpayments exist since the term *identified* is not clearly defined. The Centers for Medicare and Medicaid Services issued a proposed regulation for the 60-day rule but it has not been finalized, leaving health care providers and their consultants and legal advisers in limbo in terms of when the 60-day clock actually starts running.

This case may be the route by which questions about the 60-day reverse false claims provisions of the ACA, and state laws that include such provisions, are defined.

This case may be the route by which questions about the 60-day reverse false claims provisions of the ACA, and state laws that include such provisions, are defined. The Department of Justice is seeking the maximum FCA penalty of $11,000 per claim. It remains to be seen what the state of New York may be able to impose as penalties also, but its law includes a per-claim civil penalty of between $6,000 and $12,000. Had the government chosen to prosecute under the civil monetary penalties provisions, the recently proposed expansion of authority by the Department of Health and Human Services, Office of Inspector General, may impose fines of $10,000 per claim, per day for refunds not returned.

It is important for laboratories and other health care providers to follow this case as it may be the harbinger of things to come. Depending on how the court defines when an overpayment is identified, labs may find themselves doing a lot more internal assessments when potential overpayments are discovered.

Takeaway: Laboratories should review and assess their ability to efficiently and effectively respond to suspected or reported overpayments in light of this case because they file so many claims that errors can escalate into very big problems quickly.

Halifax Hospital Whistleblower Case May Finally Be Over

According to documents filed in a Florida court on July 11, Halifax Hospital Medical Center and false claims relator Elin Baklid-Kunz have reached a $1 million settlement that will end a 5-year-old false claims case, provided the government approves the settlement agreement.

The lawsuit did not specifically involve laboratory claims but because of its size, originally estimated at over $200 million, the allegations brought by the relator and the fact that the relator was Halifax's compliance director, it has been closely followed by legal counsel and compliance professionals from many different segments of the health care industry. The settlement occurred one week before the July 8 trial was scheduled to begin.

Background

Originally, the case involved two separate issues. One involved alleged violations of the Stark and anti-kickback regulations concerning contracts with six medical oncologists and three neurosurgeons, which allegedly included improper incentives and above-fair-market payments. The second part involved the hospital admitting patients to the hospital when they could have been treated as outpatients allegedly because the hospital could receive a larger reimbursement. Part of the case rested on the relator's allegation that there was no specific physician order for the admissions, making them improper and all claims related to the admissions false claims.

The trial for the anti-kickback part of the case was scheduled for March 3 but was settled before the trial began when the hospital and government prosecutors reached an $85 million settlement.

The second part of the case involving the improper hospital admissions was the larger part in terms of the amount of damages involved and was scheduled for trial to begin on July 8. The government declined to intervene in this part of the case, but the relator chose to continue.

Halifax Seeks Summary Judgment

In an eleventh-hour attempt to get the case dismissed, Halifax filed a motion for summary judgment seeking a ruling on three issues. Halifax argued that the relator had not provided sufficient evidence as to the damages suffered by the government and questioned whether a violation of a condition of participation can render claims as false under the False Claims Act and whether some of the claims are barred by the statute of limitations.

A violation of a condition of participation does not make the claim false, and the court ruled that for the time being, the relator was barred from arguing or presenting evidence that the lack of an admission order alone was fraudulent.

Judge Gregory A. Presnell ruled in favor of Halifax on two of the three issues, which essentially dealt a crippling blow to the relator's case. In terms of the damages, Presnell ruled that the relator had not established any evidence a jury could use to determine the amount of damages because she had claimed the entire amount charged for the services provided as an inpatient constituted the damages when the damages were actually the difference between what the government would have paid for the same services provided as outpatient rather than as inpatient.

Perhaps the more significant ruling involved Baklid-Kunz's allegation that the admissions were improper because there was no documentation of a specific admission order present in the medical records. Halifax argued, and Presnell agreed, that even if the allegations are true, they constitute a violation of conditions of participation, not a condition of payment. A violation of a condition of participation does not make the claim false, and the court ruled that for the time being, the relator was barred from arguing or presenting evidence that the lack of an admission order alone was fraudulent.

The court ruled against Halifax on the statute of limitations issue, but the real damage was done. Halifax and Baklid-Kunz are waiting for the government to agree with the terms of the settlement, bringing an end to an important FCA case. It is possible that this case will be cited over and over again in the future for a variety of its rulings.

Takeaway: Every case can provide important information for compliance officers, even if they don't involve their specialty. This case underscores the importance of adhering closely to all federal and state laws.

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COMPLIANCE PERSPECTIVES

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OIG Warns of Anti-Kickback Statute Violations In Laboratory Payments to Referring Physicians

The Health and Human Services Office of Inspector General (OIG) on June 25 issued a special fraud alert titled "Laboratory Payments to Referring Physicians," which should cause any laboratory that compensates referral sources for specimen collection, processing, and packaging or for submitting patient data to a registry or database to carefully review all such arrangements to be certain they are compliant.

Any arrangement found to be noncompliant should be terminated immediately or reconfigured to be compliant. Any laboratory that fails to do so risks both civil monetary penalties and criminal sanctions, as well as exclusion from the federal health care programs, as would the referral source. It is likely that many states will also mirror this guidance in their enforcement of state anti-kickback laws.

A laboratory's arrangements with referring physicians will not just be subject to government scrutiny based upon the guidance in this alert. Other laboratories will review the compliance of competitors, and the alert could serve as a basis for qui tam actions.

The federal anti-kickback statute is implicated when remuneration is paid in order to induce or reward referrals for any items or services reimbursed by a federal health care program. The alert cautions against arrangements that improperly take into account the volume or value of referrals or that compensate referring physicians above fair market value and that may induce a physician to use a particular laboratory. The OIG expresses four principal concerns with these types of arrangements—that they will:

- "Corrupt medical judgment";
- Result in "overutilization";
- Result in "increased costs to the federal health care programs"; and
- Result in "unfair competition."

The OIG highlights certain arrangements for specimen collection, processing and packaging arrangements, and registry payments that are particularly suspect under the anti-kickback statute.

Specimen Collection and Processing

The OIG explains the risks associated with arrangements where a physician is paid by a laboratory (directly or indirectly) for the collection, processing, or packaging of specimens.[1] Certain characteristics that the OIG finds to be evidence that the arrangement may be unlawful include:

- The payment exceeds fair market value;
- The payment is calculated on a per-specimen, per-test, or per-patient method or some other method that takes into account the value or volume of referrals;

1. Specimen collection is reimbursed by Medicare only in certain circumstances where it is customary practice in the region and for that particular physician to charge for specimen collection separately. There are separate CPT codes for processing and packaging specimens for transport to a laboratory.

- The payment is offered on the condition of a certain number or type of test orders, especially where the tests are duplicative, not medically necessary, or not reimbursable;
- The physician is already paid for the services by a third party, such as Medicare;
- The payments go directly to a physician rather than the group practice that employs the physician and that actually bears the cost of the services; and
- The physician is paid for services performed by someone placed in the office by the laboratory.

The OIG makes it clear that its concerns are not abated by limiting the payment arrangement to nonfederal health care program patients, indicating that the amount paid for the nonfederal program patients could still act as a financial incentive to refer the federal health care program patients to the laboratory. There is also a practical issue of completely screening out federal government patients due to incomplete or inaccurate patient coverage information. Although more of an issue under Stark due to the lack of an intent element, a pattern of federal health care patients "slipping through the screen" may raise issues, especially when the safeguards to prevent such "slip through" are inadequate.

Laboratories should also remember that state anti-kickback laws could also create civil and criminal exposure related to patients covered by private and commercial payers.

Registry Payments

Clinical laboratories have been getting involved more frequently in setting up and maintaining registries that collect patient data related to laboratory testing. The OIG states that there is the potential for improper arrangements because physicians may be induced to order unnecessary or duplicative tests to submit more data and thus receive higher payments. Certain characteristics that the OIG considers potentially unlawful include if:

- The laboratory requires or encourages a certain frequency or volume of tests to be performed and reported on in order to receive payment;
- The laboratory collects comparative data for the registry form and bills for multiple tests that may be duplicative (e.g., two or more tests performed using different methodologies that are intended to provide the same clinical information) or that otherwise are not reasonable and necessary;
- The compensation is paid per-patient or in another manner that takes into account the volume or value of referrals;
- The compensation is not fair market value for the services rendered or is not supported by documentation evidencing efforts;
- The research is limited to the laboratory's proprietary tests or only to the laboratory's patients;
- The physicians selected to participate in the registry are only high-volume referrers; and
- The arrangement uses the laboratory requisition form, which steers the physician toward certain ordering practices and overrides independent medical judgment regarding medical necessity.

Research activities like registries are not always improper and can be intended to promote and support clinical research and treatment, but appropriate documentation, including, where applicable, the review and approval of an institutional review board, is important to document the lawful intent of the research. Such documentation and review, however, will not offset an otherwise noncompliant arrangement.

Again, the OIG noted that merely carving out federal health care programs from these arrangements does not remove the risk of an anti-kickback violation. The risk of noncompliance with state law also exists.

Summary

This latest fraud alert highlights the OIG's suspicion of financial relationships between laboratories and physicians that involve either the provision of free or discounted goods, equipment or services, or payments of more than fair market value for services. It is noted that the relationship between a laboratory and a physician is of concern particularly because there is typically no input from patients in the selection of laboratories for tests. The decision is fundamentally made by the referring physician.

Action Steps

Laboratories should:

- Carefully audit all current arrangements to determine if they are compliant and terminate or modify those that are not compliant. Any arrangement must fully comply with a Stark exception and anti-kickback statute safe harbor—fixed, fair market value compensation that does not vary based on the value or volume of referrals. This audit can be conducted by the laboratory itself or an independent party. Regardless of the identity of the auditor, the audit must be conducted in a manner that ensures a comprehensive review of all arrangements.
- Address such arrangements in their compliance plan and make them part of their compliance education and training programs. Be certain that no financial arrangement should be implemented without the consent of a laboratory compliance officer and management.
- Periodically audit arrangements to be certain they remain compliant (audits, no less frequently than annually, are recommended).
- Be prepared to explain to customers what types of arrangements are not compliant and the risks to the customer of a noncompliant arrangement. Ideally, a laboratory should have a written explanation that could be deployed across the entire laboratory platform. This provides written standards for laboratory representatives to follow, is evidence of a laboratory's intent to be compliant, and can serve as an effective means of challenging noncompliant arrangements of competitors.
- Keep apprised of all government pronouncements and enforcement actions involving those types of arrangements and adjust their practices accordingly. A laboratory should remain current not only with respect to the federal government's position on these types of arrangements but should also track state government and private or commercial payer developments.
- Document the compliant arrangement in a written agreement with the referring physician. The agreement, among other things, should specify the functions being performed in exchange for the payment and contain a representation and warranty from the physician that he or she is not being otherwise compensated for such services. The functions should be described in as much detail as possible. It would also be advisable if the contract contained a representation and warranty regarding the actual costs of the referring physician associated with the functions since that will be central to any fair market value assessment.
- Determine fair market value—OIG Advisory Opinion 05-08 states that if the payment is greater than Medicare reimbursement for its activity it could be in excess of fair market value. A payment more than a de minimis amount will likely raise a red flag. The recommended approach is to have the payment amount equal the physician's actual costs so that there is no profit recognized from the payment.

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Study Questions Billing for Part B Laboratory Services, *from page 1*

that may require further scrutiny. The real value of this study will be demonstrated when the identified labs are reviewed and the claims data is evaluated against the actual billing activities of any given lab.

It is unlikely the industry will ever be afforded the opportunity to know if the conclusions of this study really do predict labs that are more likely participating in fraudulent activities than not. Meantime, even though the OIG states very clearly that the study does not actually identify labs that are doing something improper but only labs that may require more scrutiny, the way the results are portrayed to the public and to Congress by the media and others makes it appear as if the lab industry is rife with fraud and abuse and that hundreds of labs are committing some kind of inappropriate billing of government programs. This is an unfortunate outcome at the least.

The purpose of this article is not to rehash and re-report the results of the study. Anyone can read the report for themselves or read articles that summarize the information in the study. The purpose of this article is to point out the meaning and the potential impact this will have on the industry and to give compliance officers and laboratory administrators ideas about how to respond and use the information in the study to prepare for the additional scrutiny labs will be subject to as a result.

A Very Brief Overview

The study consisted of a review and analysis of 145.6 million Part B lab claims for services to 23 million Medicare beneficiaries from 94,609 individual labs representing allowed payments of over $7.25 billion. The study concluded that 1,032 of the labs reviewed exhibited questionable billing and should be subject to further review.

The purpose of this article is to point out the meaning and the potential impact this will have on the industry and to give compliance officers and laboratory administrators ideas about how to respond and use the information in the study to prepare for the additional scrutiny labs will be subject to as a result.

The OIG also cited other reasons for performing the review, including other studies it has performed on lab billing going back to 2000. The report provides details of how the study was conducted, how the measures were applied, and how the conclusions were reached. It also provides examples, using unidentified actual labs, of problematic scenarios uncovered as a result of the study. It may be here that the industry can derive some benefit. If a lab analyzes its own billing data using the criteria detailed in the report, it can determine if its own billing data indicates questionable billing practices.

Measures That Define Questionable Billing

The heart of the study is the metrics or measures used to identify questionable billing. From the claims data reviewed, the OEI reviewers developed 13 measures that could be used to compare lab to lab. If any of the labs reviewed exceeded calculated thresholds for five of the 13 measures, that lab was considered as exhibiting a questionable billing pattern warranting further review. How the calculations were done is included in some detail in the study report. The 13 measures used were as follows:

1. High average allowed amount per claim;
2. High average number of claims per beneficiary;
3. High average allowed amount per beneficiary;
4. High average number of claims per ordering physician;
5. High average allowed amount per ordering physician;
6. High percentage of claims for beneficiaries with no associated Part B services

with the ordering physician;

7. High percentage of claims for beneficiaries living more than 150 miles from the ordering physician;
8. High percentage of duplicate lab tests;
9. High percentage of claims with invalid ordering physician numbers;
10. High percentage of claims with ineligible ordering physician numbers;
11. High percentage of claims with compromised beneficiary numbers;
12. High percentage of claims with compromised ordering physician numbers; and
13. Compromised lab provider number.

Industry Group Responds

The American Clinical Laboratory Association (ACLA) cautions that the report's methodology does not present a clear picture of industry billing practices. ACLA President Alan Mertz contends that several of the metrics used in the study may lead to erroneous conclusions about actual fraudulent activity and can represent legitimate and appropriate use of laboratory services.

One of the questionable measures Mertz specifically addresses concerns physician office visits within six months prior to the lab services. He pointed out that many lab services are ordered on the same day or prior to an office visit. Further, for patients with chronic conditions like diabetes, lab tests are part of routine monitoring and may not be associated with an office visit. This single measure accounted for more than two-thirds of the questionable billing claims, said Mertz.

First and foremost, laboratory compliance officers and administrators must read the study report and objectively analyze what the OIG did and why these measures were considered to be questionable.

Mertz questioned other measures, including one that suggests that billing is inappropriate if the patient lives more than 150 miles from the ordering physician. Mertz points out that in 2009, 5.3 million lab claims represented only 2.5 percent of total Medicare claims. Given that many Medicare patients travel or live in warmer climates in winter or seek out centers of excellence and specialists away from home, Mertz points out that this figure is not surprising and does not necessarily suggest questionable billing by the laboratory.

"While lab services represent less than 2 percent of Medicare spending as noted in the OIG report, it remains important that clinical labs take seriously their responsibility as stewards of taxpayer dollars used to cover the expenses of caring for Medicare beneficiaries," said Mertz, "It is just as important when studies are released that are aimed at identifying questionable, fraudulent, and even criminal activity with regard to Medicare billing, that they utilize appropriate measures and include all information necessary to provide a clear picture for policymakers and taxpayers alike."

How Should Labs Respond

First and foremost, laboratory compliance officers and administrators must read the study report and objectively analyze what the OIG did and why these measures were considered to be questionable. It may be appropriate to create a similar audit to evaluate your own claims to make some kind of determination of where you stand in relation to the criteria outlined in the study. If your lab does actually exceed enough of the measures or exhibits one of the questionable billing scenarios identified by the OIG in the study, you can figure out why. At the very least, you may be able to develop creditable arguments for why your lab may be exhibiting questionable billing patterns.

To combat negative public perceptions that are created by this study, labs should make an effort to publically comment on the study and point out its flaws and its relationship to the realities of the laboratory industry and marketplace. Finally labs must support efforts by professional associations and other labs in undoing the damage a report like this can do to an industry that is populated mostly by honest providers fulfilling a central role and providing essential services to physicians and others who care for Medicare beneficiaries.

Takeaway: While this study may be perceived as negative for the laboratory industry, it does provide insight into how the government perceives labs, what it considers questionable billing, and what labs should use to benchmark their billings from a compliance standpoint. It could serve as a flashpoint for the industry to come together to overcome the negative perceptions generated by the study. G2

Class Action Lawsuit Accuses LabCorp Of Willfully Violating the Credit Card Privacy Act

Court documents filed July 6 allege that Laboratory Corporation of America Holdings (LabCorp) violated the Fair and Accurate Credit Transactions Act (FACTA) by including information on its credit card receipts that expose its customers to increased risk of identity theft. The class action suit, filed in the Southern District of Florida, is seeking statutory and punitive damages, injunctive relief, attorneys' fees, and litigation expenses.

Statutory damages under FACTA include a minimum $100 and can reach $1,000 per violation even if the victim incurs no actual injury. The statute requires willful violations of FACTA. The complaint alleges that is the case here and provides a variety of allegations that attempt to prove that, including the fact that LabCorp complied with the redaction of credit card numbers required under the statute indicating it was aware of the provisions of the law, according to the complaint. LabCorp also engaged the services of an international law firm that allegedly advised it regarding FACTA requirements related to identity theft. The law has been in effect since 2006, but businesses had until 2009 to comply.

According to the court documents, lead plaintiff Christopher Legg alleges that he received services from a LabCorp facility and paid with a credit card. At the point of service he received a printed receipt that included the expiration date for his credit card. Including the expiration date on a printed receipt for a credit or debit card transaction is specifically prohibited by FACTA, which states that "no person that accepts credit cards or debit cards for the transaction of business shall print more than the last five digits of the card number or the expiration date upon any receipt provided to the cardholder at the point of the sale or transaction." According to the complaint, despite the clear language of the statute, LabCorp willfully chose not to comply with the requirements of the law and exposed all customers who paid with a credit or debit card to increased risk of identity theft. The complaint says that all such customers are entitled to an award of statutory damages.

FACTA Can Be Burdensome and Risky

These kinds of lawsuits happen to the full gamut of businesses, from a small mom-and-pop business to very large national corporations. The risks associated with not complying with a law like FACTA increase almost daily because of media reports about identity theft and even advertisements for companies that can help an individual avoid problems. In many cases, the violation or problem identified is something that occurs to many people rather than a few because these problems

tend to be systematic. Many cases end up as class actions, and this case represents just such a situation.

The class in the LabCorp case is defined in the complaint as:

> (i) All persons in the United States (ii) who, when making payment to LabCorp, (iii) made such payment using a credit or debit card, (iv) and within the five (5) years prior to the filing of the complaint (v) were provided with a receipt of the payment (vi) which displayed the expiration date of said credit or debit card.

Depending on the number of credit or debit card transactions, a suit like this can cost a company a lot of money and create a lot of headaches. Labs should monitor this case and they should review their own policies and procedures if they accept payment for services with credit or debit cards.

Takeaway: Any laboratory that allows payment for its services with credit or debit cards should become familiar with the provisions of FACTA or face potentially significant monetary penalties should they violate its provisions.

Laboratory Payments Adjusted for Technological Changes? Forget That

The Centers for Medicare and Medicaid Services (CMS) proposes to rescind the statutory authority in the Social Security Act that allows adjustments to the lab fee schedule based on technological changes. Instead, CMS will add a new Section 1834A of the act requiring a new process for clinical laboratory payments based on private payer rates. These changes and others that will affect clinical lab payments were contained in a proposed rule titled "Revisions to Payment Policies Under the Physician Fee Schedule for CY 2015." This is the "official" rule that rescinds the technological changes proposal from 2014.

After raising an uproar in the lab industry with its proposal to make adjustments to the fee schedule based on technological changes last year, CMS now must change course and develop another process required as part of the Protecting Access to Medicare Act (PAMA). PAMA provided some details on the new process and laboratory administrators and compliance officers await the details that CMS has promised to provide later this year or early next year.

New compliance risks accompany the new process, and laboratory compliance officers must make certain they stay abreast of these changes so they can provide appropriate guidance to laboratory leadership during these changes.

Takeaway: The regulatory and legislative landscape is constantly changing, requiring compliance officers to assess each new rule to determine not only its risks but, in light of the reversals described above, when to take action on a proposed change.

Compliance Corner

Should we charge for an unsatisfactory Pap smear since we had to do the test to determine it was unsatisfactory? If we do charge, would we get paid?

This is a frequently asked question in one form or another, so it is valuable to go over it again. If the payer is Medicare or Medicaid, the government considers a test not medically necessary if it does not produce a clinically useful result that a physician or practitioner can use in the treatment or monitoring of a beneficiary. A laboratory should not charge a government payer for an unsatisfactory Pap, even though the work was done. If you do charge for the test, it is likely that contractors will pay for it because they do not receive test results, only Current Procedural Terminology (CPT) codes and International Classification of Diseases, Ninth Revision (ICD-9) codes. Unless the Medicare system has edits in place to deny claims based on an applicable CPT or ICD-9 code, the test would be paid. It would require a post-payment review or some other kind of audit or review to find out that the test was unsatisfactory. A laboratory may also find itself the subject of a whistleblower case if charging for unsatisfactory Pap smears.

News-At-A-Glance

MINNESOTA TO REQUIRE REFERENCE LAB BILL: Effective Oct. 1, labs in Minnesota who wish to bill for patients enrolled in Minnesota Health Care Programs (MHCP), that refer tests to another lab are not to bill for the tests themselves and instead will be required to provide the necessary information to allow the performing lab to file the claim. This change likely will cause some problems for out-of-state labs because, to be eligible for MHCP payment, they will need to enroll as an MHCP provider. Until the effective date of the new requirement, labs may file the claims themselves or allow the reference lab to bill. If the lab chooses to bill for the reference lab tests, claims should include a 90 modifier, the national provider identifier of the performing lab, and place of service code 81 for independent labs. Claims that include a 90 modifier after Oct. 1 will be denied. Laboratories affected by this change may want to file enrollment applications as soon as possible to avoid a potential backlog if many labs try to enroll at the last minute. Information on enrollment, fee schedules and other important topics, can be found on the MHCP home page at *http://mn.gov/dhs/*. Select "A-Z Topics" in the upper right of the page then select "independent lab providers" from the list.

CLIA GETS IN ON GLUCOSE METER ISSUE: During a July 2 webinar, Ann Snyder, a medical technologist for the Division of Laboratory Services for the Centers for Medicare and Medicaid Services (CMS) in Baltimore said that if a Clinical Laboratory Improvement Amendments (CLIA) surveyor inspects a laboratory and finds it using a glucose meter on patients other than those allowed by the package insert, they will cite the laboratory under existing CLIA standards using a CMS 2567 citation form. Snyder said CMS will not be looking to shut labs down and every lab will have an opportunity to correct any deficiencies noted by the surveyor. She also emphasized that the two recently published Food and Drug Administration documents on glucose meters are intended for manufacturers, not clinical laboratories. If a laboratory wants to use a glucose meter "off label," it must meet the requirements of a high-complexity CLIA lab. Translation: labs can be cited with a CLIA deficiency if they are inspected by a CLIA surveyor today and found to be in violation of the off-label rules.

NEW JERSEY LAB BRIBES FOR REFERRALS SCHEME NETS 29TH DEFENDANT: Peter Deplas, M.D., of Glen Head, N.Y., admitted to taking bribes of more than $100,000 over a 17-month period from a New Jersey lab in return for referring patient tests to the laboratory, according to a July 15 Department of Justice announcement. Deplas is the 29th defendant in the case of the Biodiagnostic Laboratory Services LLC (BLS) massive bribery scheme and faces a potential five-year prison term and a $250,000 fine. Bribes were paid to Deplas in the form of a sham lease agreement in the amount of $5,000 a month and cash payments of as much as $7,000 a month. According to the announcement, BLS collected over $900,000 in reimbursements as a result of Deplas's referrals. Deplas admitted to ordering unnecessary tests in order to justify the BLS bribes. Sentencing is scheduled for Oct. 29, but Deplas has already agreed to forfeit $120,000, which represents the amount of the bribes he received.

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