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Are ABNs a No-Win for Laboratories and Other Health Care Providers?

A case addressing provider knowledge, beneficiary notice and liability for Medicare-denied claims may create confusion concerning proper advance beneficiary notices (ABNs). *International Rehabilitative Sciences v. Burwell*, (W.D. Wash. at Tacoma, No. 08-cv-05442-BJR, 2/13/15), highlights regulatory and Medicare manual instructions regarding ABNs that differ for laboratories as opposed to other providers.

Background

On July 14, 2008, International Rehabilitative Sciences (doing business as RS Medical) challenged, in the US District Court for the Western Division of Washington, four decisions by the Medicare Appeals Counsel (MAC) denying coverage of a device known as the BIO-1000. The district court ruled in favor of RS Medical and against U.S. Department of Health and Human Services Secretary Burwell saying that the Secretary's final decisions denying coverage were arbitrary and capricious and were not supported by the evidence presented by RS Medical. This court never reached the issue of whether RS Medical knew or should have known Medicare

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Aetna Files $120 Million Lawsuit Against Texas Hospital for Fraudulent Billing

More complex than it seems, a lawsuit filed on Feb. 23 in the Southern District of Texas actually involves a hospital and an insurance company fighting over in-network versus out-of-network contracting and billing issues. According to Aetna Life Insurance Company's original complaint, North Cypress Medical Center and its CEO Robert A. Behar M.D. allegedly used fraudulent billing schemes to circumvent patient responsibility copays and paid kickbacks to physicians to garner the referral of Aetna patients to it, an out-of-network physician-owned hospital.

Cypress argues in a motion to dismiss Aetna's suit, however, that it has been the victim of Aetna's alleged scheme to sue out-of-network providers across the country in an attempt to force them into financially disadvantageous contracts with Aetna.

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Aetna Files $120 Million Lawsuit, *from page 1*

Aetna's Original Complaint in the Feb. 23 Case

Aetna claims that North Cypress has been much more successful than other hospitals in its market that have higher patient volumes and a wider array of services, reporting annual gross revenues of $1.5 billion. According to Aetna's complaint, North Cypress marketed itself as having the atmosphere of an upscale five-star hotel. Aetna asserts that this success is not a result of it being a high quality and more efficient facility, but because of its illegal activities. Aetna alleges that North Cypress offered ownership interests in the hospital to physicians who admitted patients, a form of kickback, and that physicians who did not admit a sufficient number of patients were eventually squeezed out of their ownership interest. Aetna also alleges that North Cypress, because of its out-of-network status, recruited patients to use its services by charging them no more than what they would have to pay if they used an in-network hospital, forgiving patient responsibility costs like copays, deductibles and co-insurance. North Cypress then, allegedly, billed Aetna inflated rates and was paid more than in-network providers precisely because it was out-of-network and was not forced to accept Aetna's much lower in-network rates. Aetna, like many other insurance companies, allow out-of-network options for their members but the member must pay higher deductible and co-pays than if they went to an in-network facility. The excessive charges by North Cypress allegedly included such things as $20,000 for treatment of an abscess and near $83,000 for removing a nasal polyp, according to Aetna's complaint.

Aetna also alleges that this was a specific business strategy masterminded by Behar and carried out by others at North Cypress. It asserts that such activity constitutes violations of the Racketeer Influenced and Corrupt Organizations Act (RICO) and seeks $120 billion to recover overpayments North Cypress allegedly received.

North Cypress Files Motion to Dismiss or Transfer

As mentioned earlier, this case has deeper roots than this single complaint. North Cypress and Dr. Behar asked the court to dismiss Aetna's complaint or transfer the matter to another court already handling a lawsuit North Cypress filed against Aetna on Feb. 12, 2013, seeking to collect underpayments and non-payment of medical benefits from Aetna.

That case is *Koenig v. Aetna Life Ins. Co.* (C.A. No. 4:13-cv-00359), filed in the Southern District, Houston Division. North Cypress now alleges that after two years of intense discovery in *Koenig*, involving over 1.4 million pages of documents, Aetna filed a motion for leave to file a first amended counterclaim which eventually was dismissed. According to North Cypress's motion, Aetna's new case discussed above, allegedly covers the identical 66,000 plus claims and the same 3,500 plans and policies as the *Koenig* case—essentially seeking a second shot at that counterclaim amendment. North Cypress claims Aetna is engaging in "judge shopping" in the hopes of finding a court more favorable to its case.

Laboratory Perspective

Issues relating to exclusive insurance contracts have impacted the laboratory industry for many years and such exclusives are a key element in competition between large national laboratories and smaller regional or local laboratories. Insurance companies used this natural market force to commandeer predatory rates from both large and small providers who are hoping to garner a large enough share of a market to be able

to control where discretionary tests are sent. The hope is that a physician will, as a matter of convenience, send all of their testing to the laboratory that he must use for the largest number of patients in his practice. This is known as gaining "pull through" business and it is still a prominent influence on the laboratory market. The idea is that a laboratory can cover its low margins, or in some cases losses, on low-bidded exclusive insurance contracts with revenue on the discretionary testing for which it can charge a higher price.

This strategy, in part, depends on the insurance company being able to keep their members and physicians from using other laboratories, sometimes referred to as "leakage." Insurance companies are well aware of the cost associated with leakage, which can be significant, particularly for a company Aetna's size.

If your laboratory is the excluded laboratory, you could find yourself fighting to stay viable and if you are the laboratory with the low-bid exclusive contract, you may be hoping that you gain control of the market before your ability to live with the marginal pricing expires.

Some laboratories may try to overcome this problem by employing strategies Aetna alleges in this case. The questions compliance officers need to ask are precisely the questions that may be resolved by this case's outcome.

This, and other cases like it, demonstrate the insurance industry's impatience with tactics that undermine cost control efforts by shifting costs to the beneficiary. While the tactics described in these court documents are merely the subject of allegations and are not proven facts, and the parties' allegations of illegal conduct are simply the parties' arguments for how the law should be applied to these facts, nonetheless, these cases provide guidance and raise questions compliance officers should ask when evaluating their laboratory's policies, practices and procedures.

Takeaway: Laboratories should follow this case because it could have far reaching effect on the influence insurance companies can exert on the laboratory industry and health care in general.

Safety Consultant Agrees to $1 Million Settlement for Causing False Claims

According to a March 2 Department of Justice press release, Dr. Charles Denham, from Laguna Beach, Calif. a prominent safety consultant, has agreed to pay a $1 million fine and will be excluded from Medicare, Medicaid and all other government programs to settle allegations he solicited and accepted kickbacks in return for using his influence in promoting a company's products. Two companies that Denham ran, Health Care Concepts Inc. and Texas Medical Institute of Technology, a research organization, are parties to the settlement and are excluded as well.

During 2009 and 2010, Denham was under contract with CareFusion at the same time he co-chaired a National Quality Forum (NQF) committee called the Safe Practices Committee, which reviews, endorses and recommends health care performance measures and practices. As part of his CareFusion contract, initiated in 2008, the DOJ alleged that Denham received monthly payments ultimately worth about $11.6 million. According to the government, the payments were made to induce Denham to use his influence with the NQF committee to recommend a specific CareFusion product called

ChloraPrep. According to an Email Alert, published by the American Health Lawyers Association on March 13, Denham was investigated because of a government investigation of CareFusion that resulted in a $40.1 million dollar settlement concerning false claims and kickback allegations. See the January 2014 issue of *G2 Compliance Advisor* for more information on the government's case concerning ChloraPrep and CareFusion. Although Denham was not specifically named in that suit, the government investigated him personally as a result of it, according to the AHLA Alert.

Non-Disclosure Creates Bigger Issue

Allegedly, Denham did not reveal his relationship with CareFusion to the committee or any other individual. Hiding the financial relationship with CareFusion may have led to more scrutiny of his activities, but there is no way to know whether or not disclosing his relationship would have helped his case. However, he would likely have had to recuse himself from making decisions about ChloraPrep and, as a result, there would be no benefit to CareFusion allegedly paying bribes and kickbacks to him.

The AHLA Alert also points out that the settlement agreement appears to have been reached based on Denham's ability to pay and not on what the government might think is appropriate for his part in the case. Denham self reported his financials used to determine the amount. AHLA says that if the government finds out he understated his net worth by at least $100,000, they can rescind the initial settlement amount.

Comments and Conclusions

There are lessons here for compliance professionals, consultants and health care providers such as laboratories and others. Dr. Denham did not submit any claims nor did he make any referrals—which we are used to seeing as key elements in any false claims case. Instead he was alleged to have caused false claims to be submitted. Under the Anti-Kickback statute, inducing another person or entity to submit a false claim has the same consequence as if the person or entity actually submitted the claim itself.

Theoretically, this same scenario could apply to a reference laboratory making recommendations to a referral source that may be submitting claims for tests it referred but bills itself, such as a hospital laboratory. Hospital laboratories have to submit claims for all of its outpatients, whether the tests are referred or not. Potentially, if a reference laboratory instructs a referring laboratory how it can get paid for tests referred to it, as a way to induce the referring laboratory to make the referral, the reference laboratory could be accused of a false claims violation if the instruction turns out to be improper or illegal.

The same principle applies to a consultant who helps a laboratory get paid for difficult or expensive tests, if the method used is improper or illegal.

Remember: The person or entity submitting the claim is ultimately responsible for its accuracy and thus should exercise some healthy skepticism when taking recommendations from another person, even if that person is considered an expert or seems beyond reproach.

Takeaway: Two best practices when following advice of another person or entity who may have something to gain by your laboratory following his recommendations is to contact your government contractor even if you believe the contractor may not be of help, and document everything so you can demonstrate your good faith effort should there be a problem later. G2

COMPLIANCE PERSPECTIVES

60-Day Deadline for Reporting and Returning Overpayments

The Centers for Medicare and Medicaid Services (CMS) recently delayed publication of a final rule addressing the 60-day overpayment refund requirements. Additionally, two cases involving issues concerning refund of overpayments are working their way through the courts now. While we await final guidance from CMS, *G2 Compliance Advisor* has consulted two health care attorneys for their *Perspective* on the issues raised by this rule.

Background

Section 6402(a) of the Affordable Care Act established a new Social Security Act section 1128J(d). This new section requires a person who has received an overpayment to return that overpayment, along with a written explanation of the reason the overpayment occurred, within 60 days of its identification or the overpayment becomes a "reverse false claim." We'll explain what constitutes a reverse false claim below but note that a reverse false claim carries the same penalties as a traditional false claim, including treble damages and a fine ranging from $5,500 to $11,000 per claim. For a laboratory processing hundreds or thousands of tests each day, the numbers associated with a simple error on one test can be staggering.

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The problem with the statute's requirements is that some of the terminology needs clarification. CMS was to provide that additional clarity in a final regulation and issued a proposed rule on Feb. 16, 2012, attempting to explain the approximately 270-word statute. It's the finalization of that proposed rule that has been delayed one more year, causing frustration for laboratories and other providers doing their best to comply with the 60-day rule despite some uncertainty about the requirements.

We asked attorneys Paul M. Thompson and Laura J. Capotosto from the Washington, D.C., office of the international law firm McDermott Will & Emery to answer some questions concerning the statute and its implementation. Mr. Thompson and Ms. Capotosto authored a February 26, 2015 blog post on this topic, titled *FCA Enforcement Action to Watch: Government Intervened in Reverse False Claims Case*; available online at McDermott's FCA Update Blog,www.FCAUpdate.com.

Q. What exactly are "reverse false claims"? What law first created them?

A. Reverse false claims is a theory of liability under the False Claims Act (FCA), 31 U.S.C. §§ 3729-33. The Fraud Enforcement Recovery Act of 2009 (FERA) broadened the scope of the FCA to include retained overpayments of government funds. Put most simply, a provider knowingly or recklessly failing to return a government overpayment creates FCA liability under a reverse false claims theory. As explained by the DOJ's own FCA primer, "Section 3729(a)(1)(G) is known as the reverse false claims section; it provides liability where one acts

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improperly—not to get money from the government, but to avoid having to pay money to the government."

> *"Five years after the passage of the ACA, however, it remains unclear what it means for an overpayment to be 'identified,' thereby triggering the 60-day clock."*
>
> *—Paul M. Thompson, Esq. and Laura J. Capotosto, Esq., McDermott Will & Emery*

Q. Is there a dollar amount, time limit or other factor a laboratory should be aware of when making decisions about starting their 60-day clock in today's environment?

A. The Affordable Care Act (ACA) modified the FCA's reverse false claims provision, so that a laboratory has 60 days from "identifying" an overpayment to report and return the overpayment to the government. *See* 42 U.S.C. § 1320a–7k(d). Five years after the passage of the ACA, however, it remains unclear what it means for an overpayment to be "identified," thereby triggering the 60-day clock. CMS proposed interpretative rules in February 2012 that provide some guidance concerning when identification occurs. The proposed rule defines "identified" as when the provider or supplier has "actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate indifference of the overpayment." CMS also stated in the preamble that the 60-day clock would not start running until after the provider or supplier had an opportunity to undertake a "reasonable inquiry" into the basis of the alleged overpayment "with all deliberate speed" after receiving information concerning a potential overpayment. While there is normally a three-year deadline for finalizing proposed rules, CMS obtained a one year extension from HHS. The deadline for publishing the final rule is February 16, 2016. The decision in *Continuum Health* will likely provide the first judicial guidance about what the law requires.

As suggested by CMS's preamble discussion, it is important for laboratories, like all providers, to be able to show that they engaged in a reasonable process when they became aware of a potential government overpayment. For instance, the laboratory should show that:

- It took the potential overpayment seriously;
- It approached determining whether there was an actual overpayment in a reasonable way; and
- It determined whether there was an actual overpayment in a reasonable amount of time.

Q. How important is the reporting aspect of the rule's requirements as things stand today?

A. Important. Once an actual overpayment is identified, a provider has an obligation to report and refund it within 60 days to avoid reverse false claims liability. Since 2010, there is no debate that a provider has to refund overpayments.

Q. One of the cases that you wrote about and reference in your answer above, *U.S. ex rel. Kane v. Continuum Health Partners, Inc.*, concerns overpayments to the Medicaid program. I believe that some providers may think the 60-day rule applies to Medicare only. Is there any question that the 60-day rule applies to Medicaid as well as Medicare?

A. In *Continuum Health*, the government takes the position that the 60-day rule applies to Medicaid.

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Q. Also, if it applies to Medicaid, does it also apply to Tricare and Railroad Medicare, or any other government funded programs?

A. The government has taken the position that the reverse false claims theory of the FCA applies to all programs involving reimbursements from a federal payor, including Tricare, Railroad Medicare, and the Veterans Administration.

Q. Another case that may have implications for the 60-day rule is *Keltner v. Lakeshore Medical*, which broaches the subject of deliberate ignorance or reckless disregard of the truth. In that context, if a laboratory is conducting routine auditing and finds one case of a wrong CPT code that caused an overpayment and the code is for a test that is performed on average 10 times per day, should the laboratory do a more expanded audit and investigation? When would the 60-day clock start in that case?

A. Depending on the facts, the government may take the position that the lab had sufficient information to suggest that it may have received an overpayment on other, similar claims, and as discussed in the CMS proposed rule, should undertake a reasonable inquiry.

Q. Are there any cases where it would be okay not to conduct a broader audit when an error that causes an overpayment is discovered through an audit process or other routine compliance process?

A. The answer to this question depends on the facts of a particular situation. When determining how to proceed, a provider should consider the error rate and the size of the sample. That said, we can expect that the government would expect providers to take appropriate steps when obtaining information that suggests a potential overpayment may exist.

Q. Are you aware of other cases that address reverse false claims or obligations to repay in the context of Medicare and Medicaid?

A. Yes. There are a growing number of such cases. The significance of *Continuum Health* is that it is the first reverse false claims case where the United States intervened, and its only allegation involves a failure to timely report and refund overpayments to the government.

Q. Does the rule apply differently in cases where the rule has been violated because of simple administrative oversight or some other innocent cause that delayed the return of owed money?

A. The law requires knowingly and recklessly failing to return an overpayment. In every case, that will be a key question. Once a provider becomes aware of a potential issue, it should investigate the issue and, if the provider determines that a refund is needed, it should repay it within 60 days.

Q. What, if any, is the role of attorney client privilege in 60-day rule cases?

A. The attorney-client privilege operates in these cases the same way it would in any other type of case.

Editor's Note: The issue of attorney-client privilege was addressed in *G2 Compliance Advisor*'s May 2014 *Compliance Perspective*. Generally, the attorney client privilege protects from disclosure communications between an entity's attorneys and employees of the entity when the information communicated is the basis for rendering legal advice. There are

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additional requirements that must be met for the privilege to protect communication from disclosure and laboratories with in-house counsel should take particular note that communications with in-house counsel and outside counsel are treated differently under the privilege. Please consult the May 2014 *G2 Compliance Advisor* for more in-depth coverage.

Sources

Medicare Program, Reporting and Returning of Overpayments; Extension of Timeline for Publication of the Final Rule, *Federal Register*, Vol. 80, No. 31, Feb. 17, 2015, pp. 8247-8248.

U.S. ex rel. Kane v. Continuum Health Partners, Inc., No. 11-2325 (U.S. Dist. S.D.N.Y.).

Keltner v. Lakeshore Medical Clinic, No. 11-cv-00892 (U.S. Dist. E.D. Wisc.).

Understanding the Issues in *Continuum Health* and *Lakeshore Medical*

In our Q & A with Thompson and Capotosto, we mention two cases: *Continuum Health* and *Lakeshore Medical Clinic*. Here are the facts of those cases relevant to the overpayment rule.

In *U.S. ex rel. Kane v. Continuum Health Partners, Inc.*, the government intervened in a whistleblower case brought by a Continuum employee who conducted an internal audit that allegedly identified billing errors involving Medicaid claims. The whistleblower claimed Continuum and others didn't return Medicaid overpayments within the 60-day period required by the Affordable Care Act.

Keltner v. Lakeshore Medical Clinic involves another whistleblower claim alleging reverse false claims liability. The whistleblower alleged that a Lakeshore audit revealed physician upcoding with an error rate of 10 percent but Lakeshore failed to audit additional claims involving those physicians. The issue is knowledge of erroneous payments, similar to the issue of when an overpayment is considered identified under the 60-day repayment rule.

Chris Young, Editor

Editor's Perspective

Note that these cases are fact-specific so laboratory compliance officers will need to make decisions on a case-by-case basis.

The difficulty for laboratories is often not about the overpayments found—which are often the result of simple billing or coding errors—but rather about other potential similar overpayments that are implied by the one found. There is a question of whether those other potential overpayments are actually "identified." The proposed rule references a "reasonable inquiry" with "all deliberate speed" but neither term is well defined. That said, significant delays in investigating the potential overpayments, regardless of the reasons for those delays, could create significant potential liability for the laboratory.

Note too that the proposed rule also expands the look back period to 10 years. If the laboratory discovers a problem that has been going on for a longer period than three or four years, it should definitely seek legal counsel.

Three steps a laboratory can take to proactively address potential overpayment obligations include:

1. Develop a policy and procedure that defines what exactly should be done when an overpayment problem is encountered.
2. Make sure the laboratory's information technology systems can provide the data necessary to conduct overpayment investigations and audits. That will require some flexibility and the ability to conduct unique or custom computer inquiries.
3. Train staff on your policy and procedure for overpayments.

A laboratory that is operating an effective compliance program, with effective policies and procedures and a well trained staff is going to have fewer problems and less significant negative outcomes than a laboratory that does not.

Are ABNs a No-Win for Laboratories and Other Health Care Providers?, *from page 1*

would deny coverage for the BIO-1000 and if it gave adequate notice to beneficiaries to allow it to shift liability to them. The Ninth Circuit overturned the ruling, declaring the Secretary's decision was not arbitrary and capricious and remanded the limitation on liability (ABN) issue.

RS Medical Knew of Past Denials and Issued ABNs Based on That Knowledge

On remand, the District Court faced the following issues:

1. Whether RS Medical knew that the BIO-1000 would not be covered by Medicare, and
2. Whether it provided adequate notice to beneficiaries to shift liability for the cost of services.

When deciding whether to cover a certain procedure or device, CMS contractors review literature and other evidence that providers present to determine efficacy, medical necessity and other issues. In this case, CMS decided that the BIO-1000 was not medically necessary and denied claims for the device. RS Medical argued that it did not know the BIO-1000 would not be covered by Medicare and because it had allegedly never received a notice of non-coverage and it had reason to believe the claims would be covered because of other evidence in the case, it should be paid. According to court documents, this belief was based on four arguments, all of which the court rejected.

The first argument was that prior claims were initially paid by lower end CMS reviewers and RS Medical did not know that the claims would later be denied at the higher level of review. Secondly, RS Medical expressed a belief that when the device received a Healthcare Common Procedure billing code, it was eligible for coverage. The court was not persuaded and explained that the mere fact that a procedure or device receives a billing code does not mean that it will be covered by Medicare. RS Medical also asserted that meetings by Thomas M. Zizic, president of the manufacturer of the BIO-1000 device, with Medicare contractors gave him the impression that the contractors "believed the evidence supported the clinical efficacy of the device." The court ruled that Zizic's subjective belief was not adequate to imply coverage. Finally, RS Medical argued that the approval of the device by the Food and Drug Administration created a reasonable basis to believe the device would be covered but again, the court disagreed.

The ABN and "Adequate Notice"

This case is troubling because the court said the reason noted on the ABN to support its belief that the BIO-1000 would not be covered was insufficient. The court noted RS Medical's ABN stated, "Medicare has not established coverage criteria for this item or does not cover this item." The court ruled that this was a generic notice and did not provide sufficient information to allow a Medicare beneficiary to make an informed decision about whether to receive the service or not. Unfortunately, the court provides a lot of reasons why it thinks this notice is not adequate but provides no information on what it would consider adequate in this case. In a footnote, the court comments that the regulations indicate if a provider notifies beneficiaries that a device will not be covered, the provider cannot then argue that it did not know Medicare would deny coverage.

Analysis and Comment

Some of the comments by the court in this case seem to conflict with current rules concerning the proper administration of ABNs by providers, including laboratories. First, there is an alternative format for laboratories provided on the Medicare Beneficiary Notice Initiatives webpage on the CMS website. This ABN uses somewhat generic reasons similar to the one rejected by this court.

Laboratories are well advised to err on the side of providing more detail rather than relying on a CMS form that is relatively simplified, even if the form has been successfully employed by the laboratory in the past. Laboratories may want to make additions to the ABN in the area designated as the reason box to make the explanation a little more specific to avoid accusations that a beneficiary did not understand what they were signing.

Takeaway: Laboratories may not want to rely too heavily on the ABN as a method to ensure it gets paid for its services, but rather should rely on working to get physicians to submit orders for tests that include appropriate medical necessity documentation. G2

Budget Includes Changes to the Appeals Process

One aspect of the Department of Health and Human Services fiscal year 2016 budget proposal that is sure to impact laboratories addresses changes the Centers for Medicare and Medicaid Services (CMS) want to make in the appeals process. The changes include a multi-pronged comprehensive strategy that includes increased funding, administrative actions and legislative proposals.

The budget makes investments at all levels in the appeals process, focusing on the Office of Medicare Hearings and Appeals (OMHA). The funding adds resources to handle the increasing volume of claims and to alleviate the current backlog in the appeals system, which is estimated to reach over a million appeals by the end of fiscal year 2015.

Changes to the Medicare Appeals Process

Some of the changes are helpful without negatively impacting providers and may bring more efficiency to the process. One proposal would give OMHA and the Departmental Appeals Board authority to retain part of the money from Recovery Audit Contractors recoveries. Another proposes using attorney adjudicators in certain circumstances, reserving Administrative Law Judges (ALJ) for more complex cases. Other proposals designed to ease the bottleneck at the ALJ level include increasing the amounts in controversy thresholds for an ALJ review and returning claims that are in a higher appeal level to the redetermination level if new evidence is provided by the appellant. In the current system, appellants often wait until later in the appeals process to submit critical evidence that would allow the appeal to be resolved earlier, before they reach the ALJ level. This proposal is designed to provide incentive for providers to file all relevant documents as early in the appeals process as possible. When appellants do not provide all the relevant documents in the early stages of an appeal, the appeal may get elevated to later stages or levels of appeal unnecessarily.

One of the more concerning proposals establishes a "refundable filing fee" for each claim at each level of the appeals process. According to HHS, the fee would allow it to invest in the appeals process to make it more responsive and efficient. The fee would be refunded to appellants who "receive a fully favorable appeal determination." There is no mention of what happens to the fee in the case where the final outcome is not fully favorable, or, for that matter, what constitutes "fully favorable."

Laboratories that often submit may find problematic a proposal that allows consolidation of claims and the use of sampling and extrapolation techniques for adjudication purposes. This proposal would allow the Secretary to consolidate claims at all levels of the appeals process. The efficiency provided here benefits CMS in that it only has to make one decision, while each of the claims in any extrapolation or consolidation batch could have unique aspects that would make it payable while some other "similar" claim may not be. In the current process, each claim is considered on its own unique properties such as supporting documentation or diagnosis code. This proposal potentially could help clear the current backlog that causes claims to take as many as 400 days to be resolved, which would benefit laboratories and others. However, there is no mention of what happens after the backlog is cleared. Are these consolidated appeals going to become a permanent part of the appeals process going forward? It may not be good for laboratories or other providers in the long run if some of these proposed solutions become a permanent part of the process.

Impact on Laboratories

For the most part, laboratories should benefit from improving the appeals system. As things stand today, there is effectively no appeals process after the first and second levels because the delays and resources needed do not make it cost effective for laboratories to pursue appeals.

There are other things at work that affect the number of appeals that are filed, not the least of which is the numerous errors and misinterpretations made by CMS auditors, particularly when it comes to laboratories because of the variations in the applicability of some regulations when applied to laboratory claims, or, because Medicare manuals contain incorrect or out-of-date information. The proposals should have included more effective training for auditors to reduce errors and misinterpretations and additional CMS resources to review and correct information in the Internet only manuals, on which many auditors rely when reviewing claims and their support documents.

Takeaway: Laboratories should avoid the upper levels of the appeals process as much as possible until the backlog of appeals is resolved, by submitting all documentation related to the denied claim up front, making it easier for Medicare reviewers to resolve the appeals earlier in the process. G2

G2 Compliance Corner

A laboratory has placed several dozen computers in its clients' offices for the sole purpose of ordering tests and receiving test results. The computers are interfaced with the laboratory information system (LIS). The laboratory replaces its LIS, requiring a rebuild of the interfaces and the test ordering database on the computers in the physician offices, after which the systems will have to be tested. Some clients do not want to take the time to do the testing and have asked the laboratory for help, in some cases, they want the lab to pay the physician for the cost of this work. Is there a way to accomplish this without violating the Anti-Kickback or Stark laws?

The laboratory should offer their clients the use of an outside vendor, paid by the laboratory. The laboratory should not pay the physician office directly for the work because this would create a financial relationship with the physician implicating both the Anti-Kickback and Stark laws and regulations. In this scenario, there is no financial relationship or compensation arrangement with the physician office, significantly reducing the compliance risks. As with any Stark, Anti-Kickback or other compliance issue, the analysis depends on the individual facts of each case and laboratories should always seek guidance from legal counsel familiar with the Stark and Anti-Kickback laws and regulations.

News at a Glance

Medicare Advantage Fraud: A Florida physician is facing eight counts of health care fraud based on allegations that he upcoded claims while operating two Florida clinics. The clinics functioned as primary care physicians, sponsored by Humana Inc. as part of a Medicare Advantage (MA) program. Isaac Kojo Anakwah Thompson, MD, a Delray Beach, Fla. physician operated two clinics in southern Florida— Isaac K.A. Thompson, MD PA in Delray Beach and IM Medical PA in Boynton Beach. The MA program allows private insurance companies to provide services for its beneficiaries. CMS pays Humana a fixed or capitated payment, 80 percent of which it passes on to primary care physicians such as Thompson. The payment amount increases based on the severity of the patient's condition. Thompson allegedly falsified diagnosis information to make his patients appear more ill than they actually were, thereby receiving an increased amount for each patient, costing the Medicare program about $2.1 million in overpayments between 2006 and 2010. Although Humana was the sponsor for Thompson's clinics it was not charged in the case. Thompson faces possible sentences of 10 years for each count and fines up to $250,000 as well as restitution in the amount of the fraudulent payments. The indictments are accusations only and a defendant is presumed innocent until proven guilty.

Fraud Hits Other Entities Besides Medicare: A U.S. Attorney has initiated a health care fraud case in Miami, Fla., involving private insurance companies, not Medicare and Medicaid. According to a March 11 press release by the US Attorney's office in the Southern District of Florida, federal agents arrested 14 suspects in the health care fraud case that allegedly netted over $13 million for the perpetrators. The case names 30 companies based in Miami, Hialeah, Hialeah Lakes, and Doral, Fla., as being involved. The defendants allegedly obtained physician names and licensing information through medical director staffing companies and used the information to submit false and fraudulent claims to the private insurance companies. Four other suspects have not yet been apprehended. The companies allegedly defrauded include insurers such as Blue Cross Blue Shield, United Healthcare and Cigna as well as entities such as Pepsi Co., Macy's and others who were self-insured. Note that an indictment is only an allegation; guilt has not been determined.

GAO Report Says Improper Payments Still Too High: A government accounting office (GAO) report released on March 4, says that for the first time in four years, government-wide improper payments have increased from $105.8 billion in 2013 to almost $125 billion in 2014. The improper payments were attributable to 124 programs—with Medicare at the top of the list and Medicaid listed third. Recommendation for the Centers for Medicare and Medicaid Services in the report included exercising its authority to strengthen enrollment provisions by using surety bonds at enrollment to provide incentive for new providers to be compliant. Also, the report recommended improving pre-payment audits of claims through the use of automated edits that detect aberrant claims filing patterns. For Medicaid, the report recommended requiring states to audit claims as part of its integrity program. The complete report is available on the GAO's website at www.gao.gov under the tab Reports and Testimony. G2

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