G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

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Inside this issue

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Study Highlights Tension Between Physician Orders, Utilization Management of Lab Testing

A recent study on "low-value" medical procedures highlights the need for clinical laboratories to work with referring physicians to educate them about appropriate test ordering.

Medicare spent as much as $1.9 billion on medical procedures, including laboratory tests, considered "low-value," according to a study published online May 12 in the *JAMA Internal Medicine* that examined nearly 1.4 million Medicare beneficiaries' claims data from 2009.

Some of the laboratory services deemed low-value included cervical cancer screening in women over 65 years of age, prostate-specific antigen testing for men 75 years and older, and colorectal cancer screening in older persons of both sexes. In all, 26 services were included in the

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Improper Medicare Advantage Plan Noncoverage Notices May Benefit Labs

Laboratories may be positively affected by changes outlined in a May 5 memo concerning limitations of liability for financial responsibility for providers of services to Medicare beneficiaries covered under Medicare Advantage (MA) plans.

After receiving reports that Medicare Advantage organizations (MAOs) are issuing improper noncoverage notices to Medicare beneficiaries, the directors of two separate Centers for Medicare and Medicaid Services (CMS) groups sent a memo ordering offending MAOs to "immediately cease this practice and instead follow the process for issuing a notice of a denial of coverage in accordance with 42 CFR § 422.568 and 422.572."

In a May 5 memo, Arrah Tabe-Bedward, director of the Medicare Enrollment and Appeals Group, and Danielle R. Moon, director of the Medicare Drug and Health Plan Contract Administration Group, stated that the notices being used by MAOs appear to be similar in purpose and content to advance beneficiary notices of noncoverage (ABNs) used in the original Medicare program. "Such notices are not applicable to the Medicare Advantage program and are not appropriate for use by an MAO with respect to its enrollees."

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Improper Medicare Advantage Plan, *from page 1*

One of the purposes of an ABN is to allow a Medicare beneficiary to determine whether or not a service is covered by Medicare without having to receive the services. According to the memo, Medicare Advantage enrollees have always had the right to an advance determination of whether services are covered prior to receiving the service. Regulations require MAOs to have a procedure for making these determinations.

There Is an Official CMS Form for That

This long-standing policy is in Chapter 4, section 170 of the *Medicare Managed Care Manual*, which states, in part, that services including referrals of a contracted provider to another provider like a laboratory are considered plan-approved unless the enrollee is notified that the services will not be covered. In the case of a laboratory that provides services to an MAO enrollee who identifies as such, the plan is liable for payment if the beneficiary has never been notified, on the appropriate CMS form, that the service is noncovered.

Until Nov. 1, 2013, there were two types of notices that could be used, one for a denial of payments and the other for a denial of coverage. Both were official CMS forms, CMS-10003-NDP and NDMC respectively. In an effort to streamline the notice requirements, CMS combined the forms into a new form called the Integrated Denial Notice (IDN) form (CMS–10003–NDMCP). The form and its instructions can be found on the CMS Web site in the beneficiary notices initiative Web page and is a required form.

In the case of a laboratory that provides services to an MAO enrollee who identifies as such, the plan is liable for payment if the beneficiary has never been notified, on the appropriate CMS form, that the service is noncovered.

Some Medicaid plans are also covered under these regulations. The IDN integrates Medicaid appeal rights for Medicare health plan enrollees receiving benefits under a Medicaid program. Plans administering Medicaid benefits are responsible for including any applicable Medicaid information in the notice.

The IDN is a three-page form that is used for both coverage and payment denials and explains in some detail how the beneficiary goes about appealing the decision of the plan in the case of a denial of coverage or payment. The MAO is required to explain why the coverage or payment has been denied. The form also explains that beneficiaries can have someone else act on their behalf and provides instructions on how to go about accomplishing that.

There is also a mechanism for a "fast appeal" in a case where beneficiaries or their doctors believes their health could be seriously harmed by waiting 30 days for a standard appeal. A fast appeal will provide a decision within 72 hours after the appeal form is received. A fast appeal is automatic if the physician asks for it or supports the beneficiary's request for one. Also, if the MAO denies the appeal, it is supposed to provide a written decision and automatically forward the case to an independent reviewer. In the case of a Medicaid beneficiary, the specific state Medicaid appeal process is to be described on the form.

Benefit for Labs?

Labs may be able to avoid performing tests or having claims denied with no recourse for MA beneficiaries in cases where they believe a test will not be covered. MAOs have denied claims for providers like laboratories and have avoided the stigma of informing enrollees of coverage limitations because these rules are not well known

and MAOs have not followed the correct procedures. Many labs believe that there is not a mechanism to hold the beneficiary liable if a service is not covered by an MA plan, as is the case with an ABN in regular fee-for-service Medicare. That apparently has not been exactly true. The main difference is that the MAO is required to provide the notice, not the lab or other provider.

If the laboratory is willing to create a process for handling MA beneficiaries in cases where it believes a test will be denied, like many of the new genetic and molecular tests, it can avoid having to write off the charges. Here is how that would work. It is the responsibility of a provider, such as a laboratory, to advise the enrollee to request a coverage determination from the MAO in any case where it believes the test will be denied. The provider can request the coverage determination on behalf of the enrollee as is explained in the form and its instructions.

In any case, the notice is required for an MAO to deny coverage or payment. If the MAO notifies the beneficiary that it will not cover the test, the laboratory may hold the beneficiary liable for the payment. If the determination is that the test is covered, the lab should be able to bill the MA plan and receive payment. In the event of a denial, the lab can appeal using the positive coverage determination from the MA to overturn the denial. In the case of a negative determination, the lab can bill the patient for the service. The lab should make sure that it has a copy of the notice of noncoverage and informs beneficiaries that they are responsible for payment for the service provided. Many laboratories include this on their requisition, and the patient signature along with a copy of the MAO notice to the patient should be sufficient to collect payment from the patient or the plan.

Takeaway: Laboratories have options to hold Medicare Advantage plans and beneficiaries liable for payment for denied claims as long as they make adjustments to their process to account for the requirements of noncoverage or nonpayment notices.

CMS Data Dump Reveals Pain for Alabama Clinic

The three top recipients of Medicare reimbursements for unclassified drug injections are at a single clinic in Alabama, according to a *Washington Post* article published May 10 about how recently released Centers for Medicare and Medicaid Services (CMS) Medicare payment data can be used to identify "hotspots" for particular treatments.

The article said that the Alabama Pain Center and its owner, Dr. K. Dean Willis, an anesthesiologist, and two other physicians at the clinic were the top three recipients nationally for Medicare payments for unclassified injections.

The *Post* article went on to describe how the clinic has been the subject of a 16-month audit by a Medicare contractor and a court filing by Blue Cross and Blue Shield of Alabama accusing the clinic of fraudulent billing practices. That intense scrutiny had forced the clinic to the brink of closure after Medicare began denying its payments to the clinic for issues related to the unclassified injections. Two of the physicians have left the Alabama clinic and started pain clinics of their own. The clinic rallied its patients to their cause asking them to write letters to their representatives in the government, and payments were restored.

In the April issue of *G2 Compliance Advisor*, we discussed the CMS data dump and its potential for causing increased scrutiny from the press and the public as the in-

formation is studied by newspapers and others. In this case, the *Post* article revealed the troubles this clinic has experienced after studying the data CMS released.

There is a lesson for laboratories and all other providers in the *Post* article: As the government continues its quest for transparency in how health care services are provided and paid for, many more providers may find themselves the subject of increased scrutiny by not only the government but by their patients and their peers.

Takeaway: Laboratories should study the data contained in the CMS data release that relates to their business and industry to determine potential troublespots.

ABN Deemed Invalid by QIC Because It Used an Abbreviation

A properly executed and signed Medicare advance beneficiary notice (ABN) that used the term *PSA* in place of *prostate-specific antigen* was deemed invalid in an appeal by a hospital laboratory after the patient received a bill from the hospital and won an appeal from his Medicare Administrative Contractor (MAC).

As noted in an article published May 1 by AISHealth.com, Olympic Medical Center in Port Angeles, Wash., appealed the ruling by the MAC to Maximus, a qualified independent contractor (QIC), armed with the signed ABN, but lost the appeal.

QIC Used Incorrect Information in Its Decision

Maximus used information found in section 50.15.4 concerning the use of abbreviations on an ABN by a home health agencies (HHA) when it said "abbreviations were used without explanation" in its denial letter to the hospital. According to the Medicare claims processing manual, Chapter 30, section 50.3, "Information specific to HHA use of the ABN has been added in §50.15.4. The guidelines for ABN use published in this section and the ABN form instructions apply to HHAs unless noted otherwise."

Maximus also ignored the sample lab ABN provided by CMS, which includes the term "PSA Screen G0103" as one of the tests listed on the sample form. It does not even mention prostate-specific antigen. Additionally, the Medicare National Coverage Determinations Coding Policy Manual and Change Report lists PSA as an abbreviation for prostate-specific antigen. It is the information in this manual that triggers the use of an ABN by a laboratory. Maximus commented that the ABN must be "written in lay terms to be understood by the beneficiary." An extensive search of the Internet, where many patients get their medical information these days, did not reveal a single article that does not mention PSA when referring to testing for prostate disease.

Is There a Next Step for Olympic?

The hospital cannot appeal to the next level, administrative law judge (ALJ), because the amount in question is $76 and the threshold for an ALJ hearing in 2014 is $140. Putting that aside, there is no financial gain that comes from expending further resources following the appeals process, even if the hospital met the threshold. One possible course is to complain to the CMS regional office about Maximus's seemingly arbitrary decision, which may have the benefit of obtaining more thoughtful decisions in the future.

Takeaway: Laboratories must make certain they thoroughly explain all of the information on an ABN to their patients and avoid the use of abbreviations alone in any case where they believe the beneficiary may not understand the information on the form or the financial consequences of signing the form.

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COMPLIANCE PERSPECTIVES

Keeping Legal Advice In-House: Protecting the Attorney-Client Privilege

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Given that laboratories operate in a heavily regulated environment, the advice of legal counsel is integral to ensuring compliance with the many laws and regulations that govern the laboratory industry. Luckily the attorney-client privilege[1] protects legal advice from disclosure to regulatory agencies, enforcement authorities, and opposing parties in litigation, including whistleblowers in False Claims Act (FCA) cases. This protection is crucial because it allows laboratories to seek legal guidance on potential compliance issues without fearing that their proactive efforts to comply with the law could later be used against them in a legal proceeding.

The privilege is the bedrock of open and honest communication between attorneys and their clients. It encourages full and frank communication "to protect not only the giving of professional advice to those who can act on it but also the giving of information to the lawyer to enable [them] to give sound and informed advice."[2] The privilege doctrine thus eliminates the possibility that these confidential communications must be disclosed (with some limited exceptions),[3] which means that preservation of the privilege is important when requesting and receiving legal advice.

The practical implications are significant. Legal adversaries might question the application of the privilege if the laboratory seeks to withhold privileged communications from its response to an information request from a regulatory agency, a subpoena from a health care enforcement agency, or a discovery request in litigation. Because the privilege prevents disclosure of otherwise discoverable information, the party invoking the privilege must establish its existence. If the laboratory fails to protect potentially privileged communications at the time they are made, these communications will likely be subject to disclosure.

This article provides an overview of the privilege; examines how the privilege applies (or does not apply) to communications to and from in-house counsel, outside counsel, and compliance professionals; discusses common privilege issues; and offers practical tips for protecting the privilege.

A Primer on the Attorney-Client Privilege

Who Holds the Privilege?

The privilege belongs to the client (or a person or entity seeking to become the attorney's client). When the client is a corporation or other legal entity, such as a laboratory, the entity holds the privilege. Because the client holds the privilege, neither an individual employee (whether current or former) nor an attorney or an attorney's agent may decide to waive the privilege.

1. Though not addressed here in detail, the attorney work product doctrine and the joint or common interest privilege are two other privilege doctrines that may apply to legal advice. The *attorney work product doctrine* protects documents prepared by an attorney, or at the request of an attorney, in anticipation of litigation. The *joint or common interest privilege* prevents a party from waiving privilege when confidential information is shared among joint defendants of a lawsuit.
2. *Upjohn, Co. v. United States*, 449 U.S. 383, 391 (1981).
3. *United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.*, No: 6:09-cv-1002, 2012 U.S. Dist. LEXIS 158944 at *6 (M.D. Fla, Nov. 6, 2012).

The privilege extends to communications between a corporation's attorneys and individual employees where information is needed to supply the basis for legal advice.[4] The information sought must relate to the scope of the employee's duties, and the employee must know that the information is being sought so that the company can obtain legal advice.[5] The privilege also protects communications between employees transmitting legal advice received from an attorney to those who have a need to know about the advice in the scope of their corporate responsibilities.[6]

Is a Communication Privileged?

To assess whether a specific communication is privileged, a laboratory and its attorneys should consider the following factors:

- *Was there a communication?* A communication may be oral or written. Written communications may be in hard copy or electronic form.
- *Was the communication made in confidence?* The party holding the privilege must intend the communication to remain confidential and must reasonably believe that the information will not be shared with a third party.

Although surprising to many, courts treat communications to and from in-house counsel and outside counsel differently when assessing whether the privilege applies.

- *Was the communication made for the purpose of obtaining legal advice?* Only communications made for the purpose of obtaining legal advice are protected. In contrast, communications made for business purposes are not privileged.
- *Was the communication made to or by an attorney or client?* The communication must be made between a client and a duly licensed attorney or an agent of the attorney working under the attorney's supervision and control. Examples of attorney-agents may include assistants and paralegals and, in some cases, experts and consultants.
- *Was the privilege waived?* Clients may inadvertently waive the privilege by, for example, discussing privileged legal advice when a third party is present or by accidentally sending a privileged e-mail to a third party. A client may also make a strategic decision to waive the privilege and defend its position based on the advice of counsel defense.

Common Privilege Considerations

When applying the privilege doctrine in practice, laboratories seeking to protect legal advice from disclosure should be aware of several important privilege-related issues to avoid confusion over whether a communication will be privileged.

Communications With In-House and Outside Counsel Are Treated Differently

Although surprising to many, courts treat communications to and from in-house counsel and outside counsel differently when assessing whether the privilege applies. Some courts have decided that communications between a corporate client and outside counsel (usually a law firm) are presumptively privileged. But communications with in-house counsel are not afforded this same status. Instead, a client must show that the "purpose and intent" of the communication with in-house counsel was to render legal advice because in-house counsel frequently provide nonlegal advice on business, technical, scientific, public relations, and advertising issues. Advice on such matters is not protected by the privilege even if conveyed by attorney to a client because the "purpose and intent is not to communicate legal advice."[7]

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4. *Upjohn Co.*, 449 U.S. at 394.
5. *See Id.*
6. *See Halifax,* 2012 U.S. Dist. LEXIS 158944 at *10.
7. *Id.* at *9.

Compliance Program Documents Are Not Always Privileged

Laboratories often have compliance personnel who are responsible for ensuring compliance with relevant laws and regulations. Internal communications with compliance personnel and documents generated by compliance personnel are not privileged. Where a lawyer serves as in-house counsel and also as a compliance department employee, the lawyer should be clear about the purpose of the communication and his or her role when providing legal advice. That way, if a court later scrutinizes the communication, the privilege will be apparent.

A recent case illustrates the complexities of the privilege as applied to compliance department documents. In *United States ex rel. Baklid-Kunz v. Halifax Hospital Medical Center*, a relator in an FCA case challenged a hospital's assertion of privilege over documents and communications related to audits and reviews performed by the hospital's compliance department. The hospital maintained a log of possible Medicare compliance issues that might require investigation, and it listed each complainant, complaint, and the hospital's corrective action. It also contained an incident sheet for each complaint, addressed to the attention of the general counsel, and all pages were stamped "Confidential Attorney-Client Privileged Information." Among other items, the relator sought disclosure of the compliance logs.

The primary reasons to conduct a privileged internal investigation under an attorney's direction are to preserve the confidentiality of the investigatory record, to allow employees to speak freely, and to enable counsel to provide frank legal advice under the protection of privilege.

The court decided that none of the documents evidenced that the hospital sought or received legal advice concerning the log. In particular, the court explained that no lawyer commented on the compliance log and that employees in the compliance department never indicated that they planned to seek the advice of counsel with respect to the contents of the log. Further, the court characterized some of the information in the log as a recordation of facts, which is not privileged.[8] The bottom line is that merely labeling documents as privileged does not make them so.

Copying Counsel on a Communication Does Not Confer Privilege

Similarly, copying in-house counsel on otherwise nonprivileged communications does not deem those communications privileged. For example, one court recently decided that communications related to a pharmacy's corporate restructuring process, including e-mails copying in-house counsel, were not privileged because they concerned factual matters or business-related considerations rather than requests for legal advice. In that case, the court explained that the company needed to "make a 'clear showing' that the 'speaker' made the communications for the purpose of obtaining or providing legal advice" to protect the communications from disclosure.[9] Because the company could not make the required showing, the court required disclosure of the communications to the opposing party in a lawsuit.

Conducting Privileged Internal Investigations Is Beneficial

Laboratories should carefully consider how best to protect the privilege before undertaking internal investigations of compliance-related issues, such as compliance hotline complaints, potential billing errors, or compliance audit issues. At the outset of the investigation, the laboratory should decide whether to conduct a privileged investigation under the direction of counsel and, if so, whether to work with in-house or outside counsel.

The primary reasons to conduct a privileged internal investigation under an attorney's direction are to preserve the confidentiality of the investigatory record, to allow

8. *Id.* at *21.
9. *Craig v. Rite Aid Corp.*, No. 4:08-cv-2317, 2012 U.S. Dist. LEXIS 16418, at *28 (M.D. Pa. Feb. 9, 2012).

employees to speak freely, and to enable counsel to provide frank legal advice under the protection of privilege.

The laboratory's decision whether to use in-house or outside counsel should be driven by a number of factors. First, the laboratory should consider the fact that courts typically presume that communications with outside counsel are privileged. Working with outside counsel is thus more protective. In addition, outside counsel may have more experience conducting internal investigations and offer the added benefit of having independence. By contrast, in-house counsel will generally know the organization and its politics better than outside counsel.

During an internal investigation, the laboratory or its lawyers may need to call upon an outside consultant to work with counsel on technical issues, such as coding or billing matters. The consultant's work is not privileged unless it is necessary, or at least highly useful, for the effective consultation between the client and the lawyer.[10] Courts have held that the privilege is not waived where a client allows disclosure to an agent assisting the attorney in giving legal advice to the client. To maintain the privilege, counsel should retain the consultant, and the consultant should work under the lawyer's direction.

Tips for Preserving the Privilege

Laboratories and their employees, including legal and compliance department personnel, can take several simple steps to preserve the privileged status of their communication:

- Be explicit about seeking or providing legal advice. Even though it may seem formal, consider clearly stating that a communication's purpose is to request or obtain legal advice.
- Separate business and legal discussions whenever possible so that the two types of advice are clearly distinguishable.
- Only include those who need to know on communications with attorneys.
- Instruct all employees (especially the sales force and others who communicate directly with clients) to be cautious when forwarding e-mails. If a company's legal advice is sent to a third party, the privilege is waived.
- An employee who fulfills legal and compliance roles should clearly state when acting as a lawyer or as a compliance professional.
- Work with outside counsel where appropriate, especially when conducting sensitive internal investigations.
- If documents are created by nonlawyers in connection with an internal investigation, they should be created at counsel's direction and should reference that fact.

Conclusion

Protecting the privilege is critical in an environment of growing government health care enforcement and an exploding number of FCA lawsuits filed by relators, who are often former employees who may be privy to—and may attempt to use—confidential and privileged information in the lawsuit. Fortunately, laboratories can take steps to protect the legal advice the must often seek to comply with a highly complex statutory and regulatory regime governing their operations, provision of services, relationships with physicians and referrers, and billing requirements.

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10. *United States v. Kovel,* 296 F.2d 918, 922 (2d Cir. 1961).

Study Highlights Tension Between Physician Orders, *from page 1*

list of low-value services. Low-value services can be easily considered services that are not medically reasonable and necessary and therefore not payable under the Medicare program.

The value of a service was determined using criteria from the American Board of Internal Medicine Foundation's Choosing Wisely initiative, the U.S. Preventive Services Task Force D recommendations, the National Institute for Health and Care Excellence "do not do" recommendations, the Canadian Agency for Drugs and Technologies in Health Assessments, and peer-reviewed medical literature.

The Sensitivity vs. Specificity Trade-Off

There were two levels considered in the study, and depending on which level is considered, the amount of overall spending on low-value services varied from 0.6 percent to 2.7 percent of Medicare spending during the year studied. If the more sensitive criteria are used, the number of services and the overall spending increases. If the more specific criteria are used, the spending decreases. The study authors indicate that their study may represent only a small fraction of the actual low-value services paid for by Medicare.

There are many somewhat obvious problems and limitations to the analysis of the data because it used claims data and did not include clinically important information on patients.

Most Common Overutilized Tests

Cancer screening and imaging services were the most common overutilized services in terms of the number of claims involved, while cardiovascular testing and procedures accounted for the vast majority of spending. According to the study, 1.9 percent of all Medicare spending was for low-value cardiovascular services when the sensitivity measure is used.

There are many somewhat obvious problems and limitations to the analysis of the data because it used claims data and did not include clinically important information on patients. That means that in some cases services are classified as low-value when they were actually appropriate for the individual patient involved.

The authors wrote, "Despite their imperfections, claims-based measures of low value care could be useful for tracking overuse and evaluating programs to reduce it. However, many direct claims based measures of overuse may be insufficiently accurate to support targeted coverage or payment policies that have a meaningful [e]ffect on use without resulting in unintended consequences."

In an accompanying editor's note, *JAMA Internal Medicine* Deputy Editor Mitchell H. Katz, M.D., and colleagues write, "This article highlights the opportunity for eliminating unnecessary care, and we hope that others will use and improve the methods developed by the authors. Most important, we hope that development of better measures of low-value care will ultimately spur development of interventions to reduce unnecessary care."

What Does This Study Mean for Labs?

Many laboratories are involved in efforts to control utilization of laboratory services deemed unnecessary or inappropriate by the laboratories' medical directors. These efforts create problems when a laboratory deems a test or panel of tests unnecessary or inappropriate but, because its testing services are based on orders from referring physicians, it continues to perform the testing and file claims for it if the ordering physician insists. The auditor could use the lab's own data to support its assertion that the services were unnecessary or inappropriate.

There is the very real potential for "low-value" to be defined as "medically unnecessary" for Medicare claims adjudication processes, particularly in the post-payment

audit case. This could be one of the unintended consequences of this study and others like it. The data could be used to support refund demands for services provided that are determined as low-value, especially when a provider continues to provide the services at a higher rate than other similar providers.

If the Centers for Medicare and Medicaid Services uses study conclusions to develop rational coverage policies, there are obvious benefits to the Medicare and Medicaid programs in terms of reducing unnecessary spending in their programs. If that is the case, Medicare beneficiaries who want to have these services would likely have to bear the burden of paying for them on their own. The impact on providers would include a likely reduction in the number of these services provided or ordered.

In terms of laboratory compliance, labs may find themselves in the middle of conflicts between a physician's determination of the medical necessity of some tests or services and conclusions by payers about the medical necessity of the tests. Since the laboratory files the claim, it suffers the denials and risks of being seen as abusing the Medicare program.

Takeaway: Laboratories need to understand the potential consequences of utilization management efforts and make sure they carefully document their efforts to get their referring physicians to order tests appropriately and only when they are reasonable and necessary as defined by Medicare. G2

Two New Proposed Rules Would Expand OIG Exclusion and CMP Authority

The Office of Inspector General (OIG) of the Department of Health and Human Services published two new proposed rules that would expand its exclusion authority and ability to impose civil monetary penalties (CMPs) and other statutory authority. The combination of the two rules would result in an expansion of the OIG's ability to impose sanctions on entities and individuals that provide services to federal health care programs.

In the May 9 *Federal Register*, the OIG proposed amending its exclusion authority to incorporate statutory changes resulting from the Affordable Care Act (ACA), propose early reinstatement procedures, and clarify existing regulatory provisions. The rule adds exclusion authority in the case of an offense in connection with the obstruction of an audit, failure to supply payment information, or making or causing false statements or omissions in a Medicare enrollment application. The proposed rule also established authority for the OIG to issue testimonial subpoenas in exclusion case investigations. Comments on this proposed rule are due by July 8.

In the May 12 *Federal Register*, a proposed rule would amend CMP rules to incorporate changes required by the ACA and certain other legislation. The proposed rule would allow exclusion and provide for CMPs for:

- Failure to grant OIG timely access to records;
- Ordering or prescribing while excluded;
- Making false statements, omissions, or misrepresentations in an enrollment application;
- Failure to report and return an overpayment; and
- Making or using a false record or statement that is material to a false or fraudulent claim.

The rule also proposes to reorganize the regulations to make them more accessible to the public and to add some clarity. There is also a provision to change the calculation for penal-

ties and assessments where an excluded individual is employed in a position not directly involved with claims submission. Comments on this proposed rule are due by July 19.

These rules serve as notice to providers who would commit fraud against federal programs that the penalties outweigh any gains that might be obtained. However, as with many rules and regulations, in order to penalize the few bent on committing crimes against the government for financial gains, the many honest providers face ever more severe and escalated risks should they inadvertently violate a law or regulation. For instance, it is not that difficult to make an error when completing a Medicare enrollment application, but the penalty for doing so can be harsh and result in the individual or entity being excluded from doing business with the very government program they are applying to participate in.

Takeaway: Laboratories and other providers must take care to ensure they do not accidentally violate any laws or regulations because the potential penalties involved are severe and can result in significant fines or exclusion from federal programs.

OIG Again Demonstrates Its Prowess in Bringing Fraudsters to Justice

Government agencies this month announced a nationwide takedown by Medicare Fraud Strike Force operations that involved six cities and charges against 90 individuals for their alleged participation in Medicare fraud schemes involving approximately $260 million in false billings.

The Department of Health and Human Services Office of Inspector General (OIG) May 13 announcement featured south Florida, long considered a hotbed for Medicare fraud schemes, as ground zero for fraud, with 50 residents from south Florida and more than $65 million in false billings.

The OIG hopes that this announcement, which involved the coordinated efforts of a variety of officials from federal and state enforcement agencies, will serve as a deterrent for others who might think that they can get away with committing fraud against federal programs like Medicare.

"Today's arrests demonstrate the effectiveness of our strike forces in combating Medicare and Medicaid fraud," said U.S. Department of Health and Human Services Inspector General Daniel R. Levinson.

Laboratory compliance officers may view this announcement as a further demonstration of how various federal and state government agencies have learned to work together on a national and local level to detect and prosecute fraudsters. The announcement includes 26 individual cases with descriptions of the charges and enough information to allow an interested person to locate that actual court documents. Reviewing these documents can provide useful insights to compliance professionals.

Takeaway: The risks of being discovered if your laboratory or hospital has violated any laws or regulations increase almost daily, as evidenced by a recent government takedown of offending health care providers.

Compliance Corner

We are seeing more cases where an organ panel is ordered in the morning that contains an abnormal result. After treatment, the panel is followed up by an order later the same day for only the abnormal component. Our system kicks these out because of correct coding initiative (CCI) conflicts. How should we code these to get them to pass the CCI edits in our system and at Medicare?

These follow-up medically necessary laboratory tests require the use of a modifier to bypass the edits. Since these are CCI edits, the most appropriate modifier is 59 (distinct procedural service).

News-At-A-Glance

ESTIMATION OF HBA1C FOR DIABETIC PATIENTS: Labs may find their volume of HbA1c testing drops as methods for calculating glycemic control over time improve. An article published May 6 on *LabMedica.com* describes a data-based model that accurately estimates HbA1c from self-monitored blood glucose readings. The computational demands of the tracking algorithm are not so difficult that they can't be readily incorporated into devices used for monitoring glucose levels like a home glucometer. One of the main problems with diabetic patients is to get them to comply with their treatment regimens, including diet restrictions and regular testing to determine glycemic control. A noninvasive procedure like a running HbA1c value can help motivate diabetic patients to better comply with their treatment regimens. While the article clearly states that the calculated method should not be used in place of periodic HbA1c tests performed in a laboratory or doctor's office, patients may see it differently if the calculation and the actual test results compare favorably and the patients have an aversion to having their blood drawn.

TUOMEY GIVEN GO-AHEAD TO FILE BANKRUPTCY: Filing for bankruptcy as early as this month may be the only option left for Tuomey Healthcare System in Sumter, S.C., if several upcoming legal decisions go against it. According to reports from several newspapers and news agencies, the board of trustees told Chief Executive Officer Michael Schwartz that he could pursue Chapter 11 bankruptcy if needed. The dire financial situation for Tuomey began when a jury found the hospital had violated the Stark law and False Claims Act and entered a $237 million judgment against Tuomey. Last month a federal district court ordered Tuomey to pay $70 million while its appeal was ongoing. Tuomey appealed the ruling saying it would cause the hospital, which is in a rural setting and provides services to local patients, to close its doors. Filing for bankruptcy or posting large financial losses could lower the health system's already poor credit rating. According to a blog post by Pete Strom of Strom Law Firm LLC, Tuomey collected $39 million in false claims and Medicare fraud between 2005 and 2009 based on inaccurate billing for doctors' procedures. A previous trial in 2005 found Tuomey guilty of paying doctors full-time wages for part time employment, which the jury ruled as a kickback.

ILLINOIS COULD PROHIBIT MARKUP OF AP SERVICES: The Illinois Senate has passed a bill, SB 1630, that would require physicians to disclose the name and address of the laboratory that provided the anatomic pathology (AP) service and the amount the physician paid for the service. The bill is essentially a disclosure law and does not actually prohibit physicians from adding fees to the amount the reference lab charges them, according to a posting by the *Pathology Blawg* on May 5. It does, however, prohibit a physician from increasing the amount subject to disclosure, which is the amount charged by the reference lab. It allows additional fees for specimen collection and transport, but such fees must reflect the actual cost of the collection and the additional charges must be separately coded according to the American Medical Association coding policies. If the state passes the new law, it would be the 17th state with a disclosure law for AP services and the eighth state to prohibit marking up the amount paid for those services.

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