

Clinical Laboratory Compliance Issues

While Similar to Other Health Care Services, It Is Important to Note How They Are Different

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Clinical laboratory compliance issues have some similarities to compliance issues that apply to other types of health care services. They also have significant differences from many such services, however. There are at least four reasons for the differences.

1. Clinical laboratory services are subject to unique payment rules. The Medicare statute includes specific provisions stating how clinical laboratory services are paid, including who may bill Medicare for lab services.^{1,2} Anatomic pathology services, generally referred to by Medicare as physician pathology services, are paid under Medicare principles applicable to other physician services but are subject to special rules prohibiting mark-up of diagnostic services.³
2. Clinical laboratory tests are high-volume services. If there is a systemic problem in billing for such services, thousands or tens of thousands of claims could be affected, even if the problem relates only to a single test.
3. Clinical laboratory tests are frequently performed at the request of unrelated physicians. These physicians generally have the only documentation of the test's medical necessity and may hold the only documents demonstrating that the test was ordered.
4. Many physicians believe that clinical laboratory tests are fungible. Some such physicians may attempt to select a clinical laboratory based on the benefits that he or she may receive under the arrangement, resulting in a tension with the federal anti-kickback statute (AKS) and the federal self-referral law (Stark law). Many arrangements with physicians raise issues under the AKS and Stark law that are unique to clinical laboratory services, such as the placement of a phlebotomist in a physician's office to collect specimens from his or her patients.

This article will focus principally on compliance issues of special interest to clinical laboratories, including

application of general prohibitions to providers of clinical laboratory services.

COMPLIANCE WITH RELEVANT RULES

Laboratory compliance arrangements should include at least three elements: (1) an intent to comply with relevant legal, regulatory, and third-party requirements (rules); (2) knowledge of the rules; and (3) a process that results in continuing compliance with the rules, including recognition of ongoing changes that impact their application.

Clinical laboratories are subject to a long list of rules, including federal and state licensure, certification, and enrollment requirements; Medicare, Medicaid, and other third-party payer requirements related to claims for payment; and restrictions related to financial relationships with physicians and other referral sources under federal and state laws. It is impossible to comply with the rules without knowledge of the rules. Therefore, the compliance process requires participation of individuals who know the rules.⁴

Those charged with ensuring compliance must be aware of all relevant facts as they may change over time, *i.e.*, “those who need to know need to know.” For example, to evaluate the potential renewal of a lease arrangement with a medical practice for collection of patient specimens, the individual responsible for the decision should know if the laboratory recently established a patient service center in the same building as the leased space.

Clinical laboratories, like many other health care providers, have submitted many different forms to various federal and state agencies. A laboratory may suffer significant adverse consequences when the relevant agency is not advised of changes to its operations, personnel, or other information that was submitted previously by the laboratory, as required. In one recent decision of the Departmental Appeals Board (DAB), Medicare enrollment and billing privileges of an emergency physicians group (ER Group) were

revoked because a physician listed as one of its managing employees was convicted of health care fraud and the ER Group failed to timely report his conviction, even though, according to the ER Group, the physician had stopped working for them months earlier.⁵ Timely notification of this change would have prevented the imposition of sanctions. Health care compliance is an ongoing responsibility, and related decisions need to be based on the rules and relevant facts, as they change over time.

MEDICARE ENROLLMENT ISSUES

Few providers of clinical laboratory services can survive without the ability to bill Medicare for its services. Medicare regulations permit the Centers for Medicare & Medicaid Services (CMS) to revoke a clinical laboratory's Medicare privileges based on specified bases, including noncompliance with Medicare enrollment requirements.⁶ Revocation may also result from a pattern or practice of submitting claims that do not meet Medicare requirements, including potentially claims for services that are not reasonable and necessary.⁷ Although CMS is required to consider the “reason(s) for the claim denials” in deciding whether or not to revoke Medicare billing privileges, it need not find that there was an improper intent or even negligence before it can do so.⁸

Similarly, Medicare enrollment regulations permit revocation of billing privileges for including false or misleading information on a Medicare enrollment application.⁹ In a recent DAB proceeding, an administrative law judge (ALJ) stated that the signature of an authorized official on the enrollment application made the laboratory responsible for false or misleading information included on the application, even though the laboratory claimed that it reflected negligence of the consulting firm that handled this task. According to the ALJ, the regulation did not require proof that the supplier *intended* to provide false information, only that it *did* certify as true misleading or false information.¹⁰

Medicare enrollment regulations also require that a laboratory be “operational” in order to receive Medicare billing privileges and that it continue to remain operational.¹¹ A laboratory’s enrollment application was denied when it was not open and accessible to the Medicare contractor’s inspector when he attempted to inspect the facility.¹² Similarly, a clinical laboratory had its enrollment revoked when it was found to be not yet operating a few months after its enrollment became effective.¹³ A new clinical laboratory must coordinate filings to avoid an onsite review before it is actually performing tests. Similarly, a laboratory that closes or relocates should promptly advise the Medicare contractor (as well as CLIA authorities) to avoid a determination that it is not operational and resulting adverse consequences.

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988

Generally, a laboratory testing human specimens for the diagnosis, prevention, or treatment of any disease or impairment of an individual or an assessment of his or her health must have a certificate under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).¹⁴ CLIA certification is also a condition for Medicare and Medicaid payments.¹⁵ CLIA regulations specify requirements for performance of testing, depending upon whether the laboratory performs only waived tests, tests of moderate complexity, or tests of high complexity.¹⁶ In the case of a violation of a CLIA “condition” (conditional-level deficiency) by a moderate or high complexity laboratory, CMS can impose sanctions against the laboratory, including revocation of its CLIA certificate, cancellation of its right to receive Medicare payments, or lesser sanctions.¹⁷

CLIA regulations include specific provisions for imposing penalties based on actions of a laboratory’s owner or operator or one of its employees, and for improper referrals

of proficiency testing (PT) samples.¹⁸ CMS may revoke, limit, or suspend a CLIA certificate when the laboratory has refused a reasonable request for permission to inspect the facility during its operating hours.¹⁹ The DAB determined that this occurred when a laboratory delayed scheduling a pre-announced inspection and provided numerous excuses why CMS could not conduct the visit. According to the DAB, when the laboratory failed to respond to requests for information on a timely basis, submit complete responses, return telephone calls, pick up certified mail and appear for scheduled visits, this conduct could be viewed only “as defiant” and “the kind of refusal to permit inspection of the laboratory contemplated under the regulations.”²⁰

If CMS determines that a laboratory has “intentionally” referred its PT samples to another laboratory for analysis, it may impose sanctions including revocation of the laboratory’s CLIA certificate and a prohibition against the laboratory’s owner or operator (including its director) owning or operating another laboratory for one year.²¹ The penalty assessed depends upon whether this was a “repeat” violation, the laboratory reported another laboratory’s PT test results, and whether the lab received the PT results of another laboratory before the PT “event close date.”²² According to CMS, a referral of PT samples is “intentional” if there is a “general intent to act—that is to send a PT sample to another laboratory for analysis.”^{23,24}

In defending challenges to revocation actions, CMS has generally been successful in asserting that the reason for requesting another laboratory to test a PT sample is irrelevant. CMS’ revocation actions, however, have not always been upheld. In *J.B. & Greeta B. Arthur Comprehensive Cancer Ctr. Lab. v. CMS*, DAB No. CR2436, Medicare & Medicaid Guide (CCH) ¶ 122,519 (H.H.S. Sept. 21, 2011), CMS revoked a cancer center’s CLIA certificate after finding that it had improperly referred PT samples to a related hospital

for analysis. The ALJ reversed this determination. The ALJ stated that although the cancer center directed unused portions of its PT samples to the hospital and the hospital tested those samples, the cancer center did not violate the PT referral prohibition because it reported its own results, sent the unused PT samples to the hospital only for storage, and the hospital tested the samples to check its own equipment, not at the cancer center's direction or to verify the cancer center's results.

Hospitals and health systems that operate laboratory facilities under different CLIA certificates have additional PT-referral compliance issues. These laboratories are considered separate labs for PT purposes, even though they may be part of the same hospital department. If PT samples are delivered to one hospital laboratory, but are for a laboratory operating under a different CLIA certificate, CMS could find that this was a prohibited PT referral. Similarly, if PT samples were rotated for testing among laboratories operating under different CLIA certificates, as if they were part of a single laboratory, this would likely be considered a prohibited PT referral by CMS. It would be prudent for a hospital operating laboratories under different CLIA certificates to purchase PT samples from different PT vendors for each laboratory, to the extent possible, eliminating any possibility of sharing PT test results. A hospital may also want to prevent individuals involved with PT testing at one laboratory from having electronic access to PT results of another laboratory with a different CLIA certificate.

CMS has asserted that the prohibition against PT referrals applies to laboratories holding a certificate of waiver, even though such laboratories are generally exempt from CLIA requirements.²⁵ CMS has also asserted that the prohibition against referral of PT samples applies to referrals of waived tests by laboratories that perform tests of moderate and high complexity. This position is questionable as regulations

provide that waived tests are not subject to the subpart of CLIA regulations in which the PT prohibition is included.²⁶

PT referral issues are not limited to clinical laboratories that refer their PT samples to another laboratory for testing. Laboratories are prohibited from engaging in interlaboratory communications regarding PT test results.²⁷ Additionally, a laboratory which receives a PT sample from another laboratory for testing is required to notify CMS.²⁸ Given the severe penalties that may be imposed for certain violations of regulations related to PT testing, laboratories should carefully evaluate their procedures for testing PT samples to ensure that they do not include conduct that might be considered a prohibited PT referral or whether additional safeguards should be put in place.

MEDICARE BILLING ISSUES

A clinical laboratory's submission of an improper claim for payment can result in severe adverse consequences. These can range from an obligation to return these payments to criminal penalties. In most cases, the result will depend upon the laboratory's intent in submitting the improper payment claim. Bad intent, however, is not required before a laboratory can suffer significant adverse consequences. An honest mistake usually results in an overpayment determination, without assessment of penalties. It, however, can also result in a suspension of Medicare payments, other administrative sanctions, or a Medicare recoupment action that can drive a laboratory out of business.

Payment claims submitted with actual knowledge of the false information included on the payment claim, with deliberate ignorance as to whether the information was true or false, or with reckless disregard to whether or not the information was truthful can result in fines and penalties under the False Claims Act (FCA).²⁹ An improper payment claim that was knowingly and willfully made can

result in criminal penalties. Billing violations that may lead to penalties can result from including incorrect information on a payment claim, or a claim for payment that is contrary to Medicare payment principles, such as an independent laboratory's payment claim for a test provided to a Medicare hospital inpatient or outpatient.³⁰ A recent appellate court decision, *U.S. v. Bertram*, 2018 WL 3966510 (6th Cir. Aug. 20, 2018), confirmed that payment claims that reflect "half-truths"—with material facts omitted—can result in penalties. In this case, a laboratory's failure to include information that would have indicated that the laboratory tests billed had been ordered seven to 10 months earlier resulted in criminal sanctions against its owners when the tests were no longer medically necessary.

The Match Game

The most fundamental billing rule for clinical laboratory services is that (1) the test ordered, (2) the test performed, and (3) the test billed must match. This requires careful coordination of laboratory activities. If the laboratory director substitutes a new test for one that has become obsolete, and no corresponding changes are made to the ordering and billing process, the test billed may be different from the test actually ordered and performed. Additionally, each component of the process raises important issues.

Test Order

Medicare regulations require that laboratory tests be ordered by the physician (or an authorized nonphysician practitioner (NPP)) who is treating the patient.³¹ While this statement is relatively clear, what constitutes an acceptable test order is not. In the preamble to the 2012 Medicare physician fee schedule final rule, CMS stated that a test requisition need not be signed, although each clinical laboratory test must be supported by an order *signed* by the physician or NPP.³² Subsequently, consistent

with its interpretive manual, CMS stated that a physician order is *not* required to be signed, but "the physician must clearly document, in the medical record, his or her intent that the test be performed."³³ CMS has also stated that "[u]nsigned physician orders or unsigned requisitions alone do not support physician intent to order."³⁴

CMS Medicare contractor Noridian Healthcare Solutions has stated that a "[s]igned requisition [is] not required, physician intent is required."³⁵ According to Noridian, "[d]ocumentation supporting intent" includes a "signed order or requisition."³⁶ Noridian has also stated that "documentation showing the intent that the test be performed must be authenticated by the author via a handwritten or electronic signature."³⁷

Although the different language used in these pronouncements is confusing, a recent CMS videotape, MLN, Provider Minute: Laboratory and Diagnostic Services Billing Video (Aug. 30, 2018), indicates that CMS *does* require a physician's *signature* (electronic or handwritten) reflecting a test request, whether on the test requisition or in the physician's medical records. In fact, Noridian stated that more than 60 percent of the claims for clinical laboratory services that were deemed to have been improperly submitted by a Comprehensive Error Rate Testing (CERT) contractor did not have required documentation regarding an intent to order the service (another 22 percent was due to missing documentation of medical necessity).³⁸ As discussed below, it may prove difficult to obtain records from physicians if necessary to establish that a test for which payment was claimed was actually ordered. Accordingly, laboratories may wish to consider requiring a signed requisition, even though physicians will undoubtedly tell them that there is no such Medicare requirement.

The lack of a valid test order can be the basis for an overpayment determination or false claims assertion. A laboratory has

been denied payment for biopsies because it could not document that a physician had ordered the procedure.³⁹ Similarly, in a case involving audiology testing, a court upheld Medicare's disallowance of related payment claims because the physician's medical records did not reflect his intent or knowledge that the tests would be performed.⁴⁰ A laboratory also must ensure that it does not perform tests that are different or in excess of those actually ordered. A federal court has held that a *qui tam* relator stated a valid cause of action under the FCA in alleging that a laboratory performed a fluorescence in situ hybridization (FISH) test whenever there was an abnormal result on a cytology test, even though the FISH test had not been ordered by the referring physician.⁴¹

Reflex testing, which is additional testing performed by the laboratory when initial test results are positive or outside normal parameters without a new physician order, may be permissible. The Office of Inspector General (OIG) has stated that in order to avoid performing unnecessary reflex tests, requisition forms should "only allow for the reflex test when necessary" and clearly indicate the condition under which the reflex test will be performed.⁴² The ordering physician should be able to order a test with or without reflex, and a reflex test should be performed only when the physician selects that option.

"Standing orders" can refer to at least two different types of arrangements.⁴³ The first, sometimes referred to as "routine orders," are arrangements in which patients with the same or similar conditions receive a previously established set of tests without regard to factors related to the individual patient.⁴⁴ These tests may not be considered medically necessary and can result in FCA allegations. The second type of arrangement that may be referred to as standing order involves orders for tests to be performed for a particular individual on a specified schedule. These arrangements are frequently

used for residents of skilled nursing facilities (SNFs). The OIG has stated that they are not prohibited in connection with an extended course of treatment but are not usually acceptable documentation of medical necessity and their use is discouraged.⁴⁵ According to the OIG, they should be monitored periodically, should have a fixed term of validity, and must be renewed at their expiration.⁴⁶

Preprinted or electronic lists of potential orders may be acceptable when reviewed and modified, as necessary, by the treating physician.⁴⁷ Standing orders have been subject to greater scrutiny than other test orders for medical necessity purposes.⁴⁸ Medicare contractors and other third-party payers may establish specific requirements for these types of standing orders which should be closely followed.⁴⁹ In the absence of guidance from a clinical laboratory's own Medicare contractor, it may be prudent to comply with guidelines issued by a different contractor.

Tests may be ordered as part of a "custom profile," a profile developed for a particular physician that includes tests that reflect the needs of a particular group of patients that he or she treats. The OIG is suspect of these test order arrangements, and its compliance program guidance provides for special procedures for their use involving notices to physicians.⁵⁰ Custom profiles can be subject to abuse, such as ordering tests which are not medically necessary or to maximize third-party payments, *e.g.*, creation of a profile that excludes a test from a recognized organ or disease panel for the sole purpose of receiving payments for individual tests rather than the lesser amount paid for the profile. Clinical laboratories that continue to offer custom profiles should follow the procedures developed by the OIG. Compliance with these procedures does not mean, however, that related claims will be paid by the third-party payer to which the claim for payment is submitted. Clinical laboratories should confirm that

relevant third-party payers will accept tests requested as part of a custom profile as having been validly ordered and medically necessary.

Several of these issues are illustrated in a single case. As part of an FCA action against a family medical center, the U.S. government alleged that the center tested patients using custom profiles that included excessive test components. It also alleged that the center had developed “standing orders” that required staff to automatically perform certain tests without a physician’s order. The court found that these practices potentially resulted in FCA violations. In denying the defendant’s motion to dismiss, the court stated that it “cannot say that allegedly routine testing made without reference to the patient’s needs or a physician’s request constitutes a difference of opinion so as not to state a claim under the FCA.”⁵¹ The court did not reach a final decision in this matter. The action was subsequently resolved, with the defendants required to make a payment of \$2 million as part of the settlement.

Test Performed

A test that is not performed should not be billed. The OIG has stated that if a laboratory did not perform a test, for example, because of a laboratory accident or an insufficient specimen, a claim for payment “could subject a provider to sanctions under administrative, civil, or criminal law.”⁵² A laboratory must have a system in place that prevents submission of a claim for payment for a test that was not performed.

Test Billed

The test billed should reflect the procedure that was actually performed and related payment rules. This includes use of the correct Current Procedural Terminology (CPT)[®] code. Incorrect coding can result in recoupment claims and even FCA actions. In *U.S. ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, Medicare & Medicaid Guide (CCH)

¶ 304,600 (8th Cir. 2013), *qui tam* relators asserted that Mayo violated the FCA when it billed for a surgical pathology claim on the permanent slide but did not prepare a separate report when it would have been the same as the report reflecting review of the frozen slide. Finding no such requirement in either the AMA’s CPT[®] or Medicare regulations, the Court dismissed the FCA claim.

Improper coding is not limited to “upcoding,” *i.e.*, selection of a code for which a greater amount would be paid than for the CPT[®] code that best reflects the test actually performed. When the CPT[®] code reflecting the test that was actually performed was not a covered code, a test may be “downcoded” to a CPT[®] code for which payment would be made, and such downcoding could result in an FCA violation.⁵³ Additionally, improper coding claims are not limited to misuse of CPT[®] codes but can include allegations related to use of modifiers. For example, modifier 91 is to be used only when it is necessary to perform the same test more than once during a single day, when it is necessary to obtain multiple results in the course of treatment.⁵⁴ Other uses of the modifier may be improper, such as to receive payment for a confirmatory test.

MEDICAL NECESSITY

Medicare Payment Authorities

The Medicare statute includes two provisions that have been interpreted to require documentation of medical necessity in order for a clinical laboratory to receive payment for a lab test. The statute provides that Medicare will not pay for an item or service that is “not reasonable for the diagnosis and treatment of illness or injury.”⁵⁵ It also prohibits any payments without information necessary to determine the amount due.⁵⁶

The statute also includes two provisions which potentially protect clinical laboratories from loss of Medicare payments based

on medical necessity. Medicare limitation of liability provisions state that where payments cannot be made based on the medical necessity requirement and neither the patient nor the provider knew or could have been expected to know that payments would be denied, “payments shall... be made.”⁵⁷ Similarly, statutory “without fault” provisions state that a previous payment that is later determined to have been incorrectly made should not be recovered if the payment was made to an individual who was “without fault,” or if recovery would be contrary to Medicare purposes or would be against “equity and good conscience.”⁵⁸ According to CMS, a laboratory is “without fault” if it exercised reasonable care in billing and accepting payment for the test.⁵⁹

Payment Issues

The tension between the two sets of statutory provisions summarized above is obvious, particularly when the information provided to the clinical laboratory—which is generally limited to that included on the test requisition—indicated that the test was medically necessary. In recent years, the U.S. Department of Health and Human Services (HHS) and courts appear to have generally given precedence to the statutory provisions requiring documentation of medical necessity and have denied payment to the laboratory for an unnecessary test, without regard to whether the laboratory had had any reason to question its medical necessity.⁶⁰

Medicare regulations require that laboratory tests be ordered by the “physician who is treating the beneficiary, that is, the physician...who uses the results...” The regulations provide that tests that are not ordered by the treating physician “are not reasonable and necessary.”⁶¹ The OIG has stated that “Medicare may deny payment for a test that the physician believes is appropriate, but which does not meet the Medicare coverage criteria (*e.g.*, done for screening purposes)

or where documentation in the entire patient record, including that maintained in the physician’s records, does not support that the tests were reasonable and necessary for a given patient.”⁶² In the absence of a national coverage determination (NCD) or local coverage determination (LCD), the medical necessity determination is required to be determined based on whether the test is reasonable and necessary for the patient.⁶³ At least one Medicare contractor has found tests to be not medically necessary because the medical records did not provide a “nexus” between the patient’s signs and symptoms and the tests that were ordered.

Similarly, relying on the regulatory requirement that the test be ordered by the physician using the test results, Medicare contractors have found that lack of documentation related to a physician’s use of lab results causes the tests to be not medically necessary. CMS interpretations do state that clinical lab tests “must be ordered and used promptly by the physician who is treating the beneficiary or NPP...”⁶⁴ The regulatory provision, however, on which it is based does not appear to have been intended to require evidence regarding use of test results to establish medical necessity, but rather was intended to require that the test be ordered by the treating physician, not a physician whose sole involvement with the patient was to order laboratory tests.⁶⁵

Moreover, financial liability for tests that are subsequently determined to have been unnecessary is not necessarily limited to the laboratory that received the payment. The government may recover Medicare overpayments from individuals who participate in a laboratory’s submission of improper claims and benefit financially from related payments. In a recent decision, the court stated that because the laboratory’s owner-president signed payment claims as the “physician or supplier” and controlled payments received by the

laboratory, he could be required *personally* to repay the government's payments to the laboratory.⁶⁶

In sum, laboratories—and potentially their owners—will be financially responsible for medically unnecessary tests for which they submit claims for payment. If payments for medically unnecessary tests are subsequently discovered, those payments may be recouped from them. Clinical laboratories and their attorneys continue to remain hopeful that the statutory provisions protecting providers from bearing losses over which they have no control will be applied as intended.

Documentation Issues

The determination as to whether a test is medically necessary is frequently based on documentation available for review. A clinical laboratory is required to maintain documentation that it received from the ordering physician or nonphysician practitioner (NPP) requesting the test, and documentation that the information included on its payment claim accurately reflected this information.⁶⁷ The regulations require a laboratory, upon request from CMS, to provide documentation of the test order, documentation showing that the processing of the order and claim submitted were accurate, and diagnostic or other medical information that was provided by the physician or NPP.⁶⁸ The regulations also permit a laboratory to request additional information from the ordering physician or NPP to demonstrate that the tests for which it claimed payment were reasonable and necessary.⁶⁹ The regulations indicate that if the information that the laboratory provides to CMS does not demonstrate that a test was reasonable and necessary, CMS is to request the ordering physician or NPP to provide the relevant part of the Medicare beneficiary's medical record.⁷⁰ If the physician or NPP does not supply the requested information, then the claim will be denied based on lack of documentation of medical necessity.⁷¹

If the laboratory is subject to an audit, investigation, or recoupment claim, these regulations may make it difficult or impossible for a laboratory to demonstrate satisfaction of all payment requirements. The laboratory will likely be required to obtain documentation from the ordering physician to establish medical necessity, and if the laboratory performed testing upon receipt of an unsigned test requisition, it may be required to request documentation of the test order from the physician.

The regulations, however, do not require the physician to provide the documentation requested. In fact, while the regulations require CMS to request relevant documentation from the ordering physician, there do not appear to be any consequences if it fails to do so.⁷² Given this, laboratories may wish to attempt to obtain a contractual commitment from physicians to provide documentation related to the medical necessity of tests that they order, upon request from the laboratory. Unfortunately, even if the ordering physician does provide the relevant medical records at the laboratory's or CMS' request, the records may not be sufficient to establish the laboratory's right to payment for the test, particularly if the Medicare contractor requires documentation regarding an explanation of the basis for the test request or use of the test results.

PROTECTIVE ACTIONS

There are some steps that a clinical laboratory can take to reduce the likelihood that it will suffer financial or legal consequences from submission of claims for tests that are not medically necessary. The OIG compliance guidance includes several, including those discussed previously. The OIG has stated that requisitions should be designed so that the physician will have to make an independent decision regarding the medical necessity of each test ordered.⁷³ Consistent with the OIG statement, when a laboratory requisition includes panels or profiles, the components of each should be

specified on the requisition. Additionally, generally the requisition should permit physicians to select individual tests that the physician believes are necessary to diagnose or treat his or her patient without being required to order or accept additional tests.

Clinical laboratories should attempt to educate physicians and their office staff regarding Medicare medical necessity requirements as applicable to laboratory services, the medical record documentation required to establish medical necessity and the use of advance beneficiary notices of non-coverage (ABNs) when the physician has reason to believe that Medicare will not find a particular test medically necessary. As previously noted, a policy requiring signed requisitions may be helpful, as would the physician's contractual liability to provide medical records upon the laboratory's request, as necessary to establish medical necessity. One Medicare contractor has suggested encouraging physicians to include additional information supporting medical necessity in the remarks section of the requisition.

Arrangements under which physicians maintain medical documentation using an electronic health record (EHR) system and order clinical laboratory tests electronically may reduce laboratory risk based on the lack of a valid test order and may facilitate the process of providing clinical laboratories with documentation that they require to establish medical necessity. The OIG compliance guidance includes a description of auditing and monitoring techniques to identify potentially improper payment claims.⁷⁴ While these techniques should continue to be helpful, there may now be better ways to identify physicians who may be ordering unnecessary tests or particular tests that may be being "over utilized." Clinical laboratories want to avoid submission of claims for unnecessary services. Failing that, it is in their interest to identify such

claims as soon as possible to minimize related damages.

OVERPAYMENT ISSUES

Medicare regulations require a clinical laboratory that has received an overpayment to report and return the overpayment within 60 days of the date on which the overpayment was "identified."⁷⁵ Failure to do so can result in an FCA violation and can serve as grounds for civil monetary penalties.⁷⁶ Under Medicare regulations, an overpayment includes any payment to which the recipient was not entitled.⁷⁷ This includes payments resulting from upcoding (whether or not intentional), payments that were made without sufficient supporting documentation, and payments for services that were not medically necessary.⁷⁸

An overpayment has been identified when (1) a person determined that it received an overpayment and quantified the overpayment or (2) when the person should have determined that it has received an overpayment and quantified the overpayment using reasonable diligence.⁷⁹ CMS has stated that a person should have determined that it received an overpayment if it has in fact received an overpayment and it failed to exercise reasonable due diligence on a proactive basis.⁸⁰ According to CMS, "[t]here may be situations where a significant increase in Medicare revenue should lead a laboratory to conduct reasonable diligence."⁸¹

Similarly, a person which receives information about a potential overpayment is required to use reasonable diligence to determine whether an overpayment actually exists.⁸² This duty could be triggered by advice from a governmental agency upon completion of an audit or an internal audit.⁸³ The required investigation as to whether an overpayment exists and the amount of any such overpayment should reflect relevant facts and circumstances. If, for example, a laboratory initiated the type of testing at issue only three years earlier or put in place a new billing process

at that time, then it may be reasonable to review billings for the tests during the previous three years, even though the regulations apply to any overpayment identified within six years of its receipt.⁸⁴

The obligation to report and return overpayments exists irrespective of the cause of the overpayment and whether or not the overpayment recipient was aware that it was not entitled to the payments upon their receipt.⁸⁵ Similarly, reporting and returning an overpayment does not resolve any liability for any action that resulted in the overpayment.⁸⁶ For that reason, although the overpayment regulations provide a laboratory with various alternatives to which it can report and return the overpayment, including CMS, the OIG, and the Medicare contractor, the selection of the organization requires careful analysis.

Medicare regulations permit a suspension of payments if CMS or the Medicare contractor “possesses reliable information that an overpayment exists or that the payments to be made may not be correct.”⁸⁷ The initial suspension is for up to 180 days but may continue for up to 18 months routinely.⁸⁸ There is no administrative appeal available to contest a suspension. Similarly, Medicare can recoup payments from a laboratory when the Medicare contractor’s overpayment determination has been upheld on reconsideration, notwithstanding a request for a hearing before an ALJ.⁸⁹

The government’s longstanding position is that a laboratory must proceed through the administrative appeals process, however long it may take, and that a federal court does not have “jurisdiction” over the matter until conclusion (exhaustion) of that process. This position has generally been upheld by courts. One court did so recently even when it was alleged that the Medicare contractor disregarded regulations addressing procedures for suspension of Medicare payments.⁹⁰ A Court of Appeals, however, recently rejected the government’s position in a

case challenging the Medicare Program’s right to recoup funds before ALJ review of the overpayment determination.

In *Family Rehab., Inc. v. Azar*, 886 F.3d 496, Medicare & Medicaid Guide (CCH) ¶ 306,259 (5th Cir. 2018), the Court held that a federal court could exercise limited review prior to the administrative process’ conclusion. According to the Court, the provider’s claim *was* collateral to the substantive agency decision because it sought only to prevent recoupment of Medicare payments until conclusion of the administrative process. Additionally, a court could *not* provide full relief from damages that would result from the provider’s going out of business and related disruption to Medicare patients after completion of the administrative process.

Subsequently, the district court to which the action was remanded issued a preliminary injunction preventing CMS from withholding Medicare payments to recoup the alleged overpayment, relying in part on the massive delays in processing Part B claims appeals.⁹¹ It is unclear whether other courts will reach the same conclusion and, if so, whether they will apply that conclusion in connection with claims by clinical laboratory providers. However, the fact that it is anticipated to take three years to obtain an ALJ hearing decision—contrary to statutory and regulatory requirements—appears to make courts more responsive to provider claims that if they accept the government’s position, the provider will be out of business before receipt of the administrative hearing to which they are entitled and subsequent judicial review.

Endnotes

1. Information regarding the agency’s application of the statutory provisions as well as related Medicare payment rules can be found in Medicare interpretive manuals, principally the Medicare Claims Processing Manual (MCPM), Ch. 16. A recent decision of the Departmental Appeals Board (DAB), *Maghareh v. Inspector General*, DAB, No. CR 5166 (H.H.S. Aug. 17, 2018), indicates that a laboratory is also required to

- comply with requirements included in CMS' informal pronouncements such as Medicare Learning Network (MLN) Matters articles and publications by its Medicare administrative contractor (MAC).
2. 42 U.S.C. § 1395l(h)(5).
 3. 42 C.F.R. § 414.50 (2017).
 4. In this article, we will generally address compliance issues related to claims for payment in connection with Medicare payment claims. Some third-party payers have adopted Medicare principles as their own, others have developed detailed payment rules, and still others have not established payment rules that address important issues, leaving these issues to be resolved as part of payment disputes. Similarly, while legal prohibitions under federal law will be the principal focus of this article, most states have also adopted fraud and abuse laws that apply generally without regard to the payer responsible for the service. There is no single source of compliance rules applicable to clinical laboratory services. Compliance guidance for clinical laboratory services published by the Department of Health & Human Services (HHS), Office of Inspector General (OIG) in August 1998 continues to be a useful resource. See HHS, OIG, Publication of OIG Compliance Guidance for Clinical Laboratories, 63 Fed. Reg. 45076 (Aug. 24, 1998) (OIG Compliance Guidance).
 5. *Meadowmere Emergency Physicians, PLLC v. CMS*, DAB No. CR4971, Medicare & Medicaid Guide (CCH) ¶ 123,989 (H.H.S. Nov. 20, 2017).
 6. 42 C.F.R. § 424.535(a)(1) (2017).
 7. 42 C.F.R. § 424.535(a)(8)(ii) (2017). See HHS; Medicare Program; Requirements for the Medicare Incentive Reward Program and Provider Enrollment, 79 Fed. Reg. 72,500, 72,516 (Dec. 5, 2014).
 8. 42 C.F.R. § 424.535(a)(8)(ii) (2017).
 9. 42 C.F.R. § 424.535(a)(4) (2017).
 10. *Premier Integrity Sols., Inc. v. CMS*, DAB No. CR5018, Medicare & Medicaid Guide (CCH) ¶ 124,010 (H.H.S. Feb. 1, 2018).
 11. 42 C.F.R. §§ 424.510(d)(6), .535(a)(5)(i) (2017).
 12. *Cnty. Med. Lab., LLC v. CMS*, DAB No. CR2635, Medicare & Medicaid Guide (CCH) ¶ 122,650 (H.H.S. Oct. 2, 2012).
 13. *TC Foundation, Inc. v. CMS*, DAB No. CR2834, Medicare & Medicaid Guide (CCH) ¶ 122,766 (H.H.S. June 18, 2013).
 14. 42 U.S.C. § 263a(a)-(b), 42 C.F.R. § 493.3(c) (2017).
 15. 42 U.S.C. §§ 1395x(s)(3)(15)-(17), 1396a(9)(C).
 16. 42 C.F.R. Part 493.
 17. 42 C.F.R. §§ 493.1806.1807 (2017).
 18. 42 C.F.R. § 493.1840(a)(b) (2017).
 19. 42 C.F.R. § 493.1840(a)(5) (2017).
 20. *The Malaria & Rheumatic Disease Research Inst., Inc. v. CMS*, DAB No. 2872, Medicare & Medicaid Guide (CCH) ¶ 124,029 (H.H.S. May 28, 2018).
 21. 42 C.F.R. § 493.801(b)(4), .1840(b) (2017). See generally, CMS, CLIA, Proficiency Testing and PT Referrals, Dos and Don'ts.
 22. 42 C.F.R. § 493.1840(b) (2017).
 23. CMS has specified PT referrals that would be considered "improper," but not "intentional" and would be subject to lesser penalties, including certain reflex, distributive, or confirmatory testing. 42 C.F.R. § 493.801(b)(4) (2017).
 24. HHS; Medicare Medicaid Programs: Regulatory Provisions to Promote Efficiency, Transparency and Burden Reduction, 79 Fed. Reg. 27,106, 27,140 (May 12, 2014).
 25. Medicare Program; Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral, 79 Fed. Reg. 25436, 25465 (May 21, 2014).
 26. 42 C.F.R. § 493.20 (c), .25(d) (2017).
 27. 42 C.F.R. § 493.801(b)(3) (2017).
 28. 42 C.F.R. § 493.801(b)(4) (2017).
 29. 31 U.S.C. § 3729.
 30. In the case of tests for a hospital patient, including individuals being treated in an off-campus hospital provider-based facility, Medicare pays the hospital, and no other provider, for the tests which are considered to have been provided to a hospital patient. Broad, unclear, and questionable CMS interpretations add to the difficulty of compliance, particularly a provision indicating that a laboratory test is considered a hospital outpatient test if ordered during or as a result of an "encounter" while the individual was an outpatient. MCPM, Ch. 21 § 90.6. This might include an individual who elected to take such a test order to an unrelated laboratory which then collected the specimen and performed the test. Laboratories should avoid any arrangement that may be seen as an attempt to circumvent Medicare requirements related to tests for hospital patients.
 31. 42 C.F.R. § 410.32 (2017).
 32. Medicare Program; Payment Policies Under The Physician Fee Schedule, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition, and Other Revisions to Part B for CY 2012, 76 Fed. Reg. 73,026, 73,303-304 (Nov. 28, 2011).
 33. Medicare Learning Network (MLN) Fact Sheet, Provider Compliance Tips for Laboratory Tests—Other (Non-Medicare Fee Schedule), ICN 909407 (Feb. 2018) at 2. See Medicare Benefit Policy Manual (MBPM), Ch. 15, § 80.6.1.
 34. MLN, Complying With Documentation Requirements for Laboratory Services, ICN 909221 (Aug. 2016) (CMS Documentation Requirements).
 35. Noridian Healthcare Solutions, Laboratory Regulations and Billing Guidelines (Aug. 2017) at 55.
 36. *Id.*
 37. Noridian, Signature Requirement Questions and Answers at A17 (June 1, 2018).
 38. Noridian Medicare Portal, Physician Impact on Laboratory Service Providers (Nov. 2017).

39. *Nephropathology Assocs., PLC v. Sebelius*, 2013 WL 3285685, Medicare & Medicaid Guide (CCH) ¶ 304,509 (E.D. Ark. June 27, 2013).
40. *Doctors Testing Ctr., LLC II v. U.S. Dept. of Health & Human Servs.*, 2014 WL 112119, Medicare & Medicaid Guide (CCH) ¶ 304,750 (E.D. Ark., Jan. 10, 2014), *aff'd sub nom, Doctors Testing Ctr., LLC II v. Dep't. of Health & Human Servs.*, 588 Fed. Appx. 517 (8th Cir. 2015).
41. *U.S. ex rel. Daugherty v. Bostwick Labs*, 2012 WL 6593804, Medicare & Medicaid Guide (CCH) ¶ 304,509 (S.D. Ohio Dec. 18, 2012).
42. OIG Compliance Guidance, 63 Fed. Reg. at 45,081.
43. See *generally*, Recognizing the Meaning of Standing Orders, Wisconsin Physician Services (July 27, 2018) (WPS, Standing Orders).
44. *Id.*
45. OIG Compliance Guidance, 63 Fed. Reg. at 45,081.
46. *Id.*
47. See WPS, Standing Orders.
48. See *Meridian Laboratory Corp. v. Advance Med. Corp.*, DAB, Decision of Medicare Appeals Council, Doc. No. M-11-568, Medicare & Medicaid Guide (CCH) ¶ 122,892 (H.H.S. June 24, 2011), *remanded, Meridan Laboratory Corp. v. Sebelius*, 2012 WL 3112066 (W.D. N.C., July 31, 2012) (remanded for consideration of limitation of liability principles).
49. See WPS, Standing Orders.
50. See OIG Compliance Guidance, 63 Fed. Reg. at 45,079-80.
51. *United States v. Family Med. Ctrs. of S.C., LLC*, 2016 WL 6601017, Medicare & Medicaid Guide (CCH) ¶ 305,791 (D.S.C. Nov. 8, 2016).
52. OIG Compliance Guidance, 63 Fed. Reg. at 45,081.
53. See *Family Med. Ctrs.*, 2016 WL 6601017, (CCH) ¶ 305,791.
54. MCPM, Ch. 16 § 100.5.1.
55. 42 U.S.C. § 1395y(a)(1)(A).
56. 42 U.S.C. § 1395l(e).
57. 42 U.S.C. § 1395pp(a)(2).
58. 42 U.S.C. § 1395gg(c).
59. Medicare Financial Management Manual, Ch. 3, § 90.
60. See *Meridian Laboratory Corp. v. Advance Med. Corp.*, DAB, Decision of Medicare Appeals Council, Doc. No. M-11-568, Medicare & Medicaid Guide (CCH) ¶ 122,892 (H.H.S. June 24, 2011), *remanded, Meridan Laboratory Corp. v. Sebelius*, 2012 WL 3112066 (W.D. N.C., July 31, 2012) (remanded for consideration of limitation of liability principles). See *generally, Maximum Comfort Inc. v. Sec'y of Health & Human Servs.*, 512 F.3d 1081, 1088-89, Medicare & Medicaid Guide (CCH) ¶ 302,260 (9th Cir. 2007); Mazer, Robert E., Medicare Medical Necessity Requirements Continue to Vex Clinical Laboratories, G2 Compliance Advisor (Sept. 2014).
61. 42 C.F.R. § 410.32(a) (2017).
62. OIG Compliance Guidance, 63 Fed. Reg. at 45,079.
63. Medicare Program Integrity Manual, Ch. 3, § 3.6.2.2.
64. MBPM, Ch. 15 § 80.1.
65. Health Care Financing Administration, Final Rule with comment period, Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustment to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1997, 61 Fed. Reg. 59,490, 59,497 (Nov. 22, 1996).
66. *U.S. ex rel. Drummond v. BestCare Lab. Servs.*, 2017 U.S. Dist. LEXIS 212729 (S.D. Tex. Dec. 28, 2017).
67. 42 C.F.R. § 410.32(d)(2) (2017).
68. *Id.*
69. 42 C.F.R. § 410.32(d)(3) (2017).
70. *Id.*
71. *Id.*
72. See *Nephropathology Assocs., PLC v. Sebelius*, 2013 WL 3285685, Medicare & Medicaid Guide (CCH) ¶ 304,509 (E.D. Ark. June 27, 2013).
73. OIG Compliance Guidance, 63 Fed. Reg. at 45,079.
74. OIG Compliance Guidance, 63 Fed. Reg. at 45,084-85.
75. 42 C.F.R. § 401.305(a), (b) (2017).
76. See 42 C.F.R. §§ 401.305(e), 1003.200(b)(8)(2017).
77. 42 C.F.R. § 401.303 (2017).
78. Medicare Program; Reporting and Returning of Overpayments, 81 Fed. Reg. 7654, 7657-58 (Feb. 12, 2016).
79. 42 C.F.R. § 401.305(2) (2017).
80. 81 Fed. Reg. at 7661.
81. *Id.* at 7665.
82. *Id.* at 7659.
83. *Id.* at 7659.
84. 42 C.F.R. § 401.305(f) (2017).
85. *Id.* at 7666.
86. See Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Civil Monetary Penalty Rules, 81 Fed. Reg. 88,334, 88,339 (Dec. 7, 2016).
87. 42 C.F.R. § 405.371(a) (2017).
88. 42 C.F.R. § 405.371(b)(2) (2017).
89. 42 C.F.R. § 405.379(d)(4)(f) (2017).
90. *MedPro Health Providers, LLC v. Hargan*, 2017 WL 4699239, Medicare & Medicaid Guide (CCH) ¶ 306,138 (N.D. Ill. Oct. 19, 2017).
91. *Family Rehab., Inc. v. Secretary*, 2018 WL 3155911, Medicare & Medicaid Guide (CCH) ¶ 306.325. (N.D. Tex. June 28, 2018).