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CMS Proposes to Divide Proficiency Testing Sanctions Into Three Categories

The Centers for Medicare and Medicaid Services (CMS) is proposing additional changes to policies under which certain proficiency testing (PT) referrals by laboratories would generally not be subject to revocation of their Clinical Laboratory Improvement Amendments (CLIA) certificate or a two-year prohibition on laboratory ownership or operations.

In a final rule issued Sept. 23, CMS proposes to divide the sanctions for PT referral into three categories based on severity and extent of the referrals. The rule also includes proposals to fully implement the Taking Essential Steps for Testing Act of 2012, enacted Dec. 4, 2012. That law gives CMS discretion to substitute intermediate or alternative sanctions in cases of intentional PT referral.

Category 1

The first category is for the most serious, egregious violations, encompassing cases of repeat PT referral or cases where a laboratory reports another laboratory's test results as its own. In this case, CMS

Continued on p. 2

ACLA Questions CMS Policies on Lab Tests Included in ESRD Bundle

A recent transmittal issued by the Centers for Medicare and Medicaid Services (CMS) related to the end-stage renal disease (ESRD) prospective payment bundle has generated concern from the lab industry over lab tests that are being included in the bundle.

Several provisions in CMS Transmittal 171 (CR 8261, issued June 7, 2013) appear to constitute new or significantly revised CMS policy with regard to laboratory tests included in the ESRD prospective payment system (PPS), says the American Clinical Laboratory Association (ACLA) in a letter to Laurence Wilson, director of the Chronic Care Policy Group at CMS.

When the ESRD PPS was implemented, CMS properly included diagnostic laboratory services that are furnished for the treatment of ESRD, notes ACLA. In fact, the ESRD PPS final rule, issued in 2010, contained a table (Table F) that listed the lab tests that were purported to be included in the ESRD bundle. ACLA strongly supported the establishment of a clearly defined list of lab tests to be included in the bundle since the "absence of such specificity would create uncertainty and chaos."

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CMS Proposes to Divide Proficiency Testing Sanctions, from p. 1

does not believe alternative sanctions would be appropriate and thus is proposing to revoke the lab's CLIA certificate for at least one year and ban the owner and operator from owning or operating a CLIA-certified laboratory for at least one year. CMS may also impose a civil monetary penalty (CMP).

CMS is proposing to define "a repeat proficiency testing referral" as "a second instance in which a proficiency testing sample, or portion of a sample, is referred, for any reason, to another laboratory for analysis prior to the laboratory's proficiency testing program event cut-off date within the period of time encompassing the two prior survey cycles (including initial certification, recertification, or the equivalent for laboratories surveyed by an approved accreditation organization)."

For example, a laboratory may have two distinct sites, Laboratory A and Laboratory B, that operate under different CLIA numbers, where Lab A has received PT samples to be tested as part of its enrollment in PT. If Lab A were to refer PT samples to Lab B, receive test results back at Lab A from Lab B prior to the event cutoff date, and report to the PT program those results obtained from Lab B, the scores for the PT event would not reflect the performance of Lab A but rather the performance of Lab B. This would undermine the purpose of PT testing, says CMS in its proposal.

Category 2

A second category of sanctions would be applied to certain PT referral situations in which the CLIA certificate would be suspended or limited (rather than revoked), in combination with alternative sanctions. CMS proposes to use this approach in those instances in

In contrast to revocation of the CLIA certificate and its accompanying ban on the owner and operator, suspension usually applies only to the individual laboratory in question rather than all laboratories that are under the control of the owner or operator.

which a laboratory refers PT samples to a laboratory that operates under a different CLIA number before the PT event close date and, while the laboratory reports its own results to the PT program, it receives results from the second lab prior to the event close date.

Such a referral situation would allow the referring laboratory an opportunity to confirm, check, or change its results prior to reporting its results to the PT program. If, upon investigation, surveyors determine that the referral does not constitute

a repeat PT referral, CMS proposes to suspend or limit the CLIA certificate for less than one year rather than revoke the CLIA certificate and to impose alternative sanctions, which would always include required training of staff.

A suspension of the CLIA certificate means that no testing of human specimens for health care purposes may be performed by that laboratory during the period of suspension. In such cases, the owner or operator typically contracts out for laboratory services or contracts with another operator to operate the lab under the contracted lab's CLIA certificate.

In contrast to revocation of the CLIA certificate and its accompanying ban on the owner and operator, suspension usually applies only to the individual laboratory in question rather than all laboratories that are under the control of the owner or operator.

A limitation of the CLIA certificate means the laboratory is not permitted to perform testing or to bill Medicare or Medicaid for laboratory work in the specialty or subspecialty that has been limited but may continue to conduct all other testing under its own CLIA certificate.

For cases in the second category, alternative sanctions would be applied in addition to suspension or limitation and would include a CMP, as well as a directed plan of correction. CMS also would impose state on-site monitoring of the laboratory.

Category 3

A third category of sanctions would be applied to those PT referral scenarios in which the referring laboratory does not receive test results prior to the event cutoff date from another laboratory as a result of the PT referral. CMS proposes that in such scenarios, at a minimum, the lab will always be required to pay a CMP as well as comply with a directed plan of correction (which would include training of staff).

For example, a lab may place PT samples in an area where other patient specimens are picked up by courier to take to a reference laboratory. The reference laboratory courier

may take the PT samples along with the patients' specimens. The laboratory personnel notice that the PT samples are missing and contact the reference laboratory to inquire if they have received the PT samples along with the patients' specimens. The reference lab is instructed to discard the PT samples and not test them since they were picked up in error. In this case, the "referring" laboratory realized the error, contacted the receiving laboratory, and did

not receive results back for any of the PT samples. In this scenario, CMS proposes to impose only alternative sanctions.

Comments on CMS's proposal are due by 5 p.m. on Nov. 18, 2013. The proposal is contained in a proposed rule published in the Sept. 23 Federal Register, available at www.federalregister.com.

Takeaway: CMS's proposals to divide PT sanctions into three categories gives the agency flexibility in determining how to respond when a lab refers a PT sample to another lab. G2

HHS Delays HIPAA Requirement That Labs Update Privacy Notices

The Department of Health and Human Services (HHS) has delayed indefinitely enforcing provisions in the Health Insurance Portability and Accountability Act (HIPAA) privacy rule requiring medical labs to revise their notices of privacy practices that routinely are given to patients to make them aware of HIPAA privacy protections and rights.

The HHS Office for Civil Rights (OCR) announced Sept. 19 that HIPAA-covered medical labs certified under the Clinical Laboratory Improvement Amendments rules would not be required to update their notices of privacy practices (NPPs) as directed in the HIPAA omnibus rule published in January (78 Fed. Reg. 5566, Jan. 25, 2013). The OCR was scheduled to begin enforcing much of the HIPAA omnibus rule Sept. 23.

The enforcement delay does not apply to labs that are part of larger entities, such as hospitals, and do not have their own lab-specific NPPs, the OCR said.

Pending CLIA, HIPAA Rule

The reason for the delay, the OCR explained, is because the OCR, along with the Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services will, "in the coming months," publish a final rule amending the HIPAA privacy rule and CLIA rules to give patients the ability to request test results directly from labs.

"Consequently, the affected laboratories would need to ensure that their NPPs inform individuals of this new right and include a brief description of how to exercise the right," the OCR said in announcing the delay.

The HHS agencies proposed the modifications to the CLIA and HIPAA rules in 2011, and the White House Office of Management and Budget (OMB) posted on its *reginfo.gov* Web site Sept. 19 that it had received the final regulation for review. Review by the OMB is a final step in completing the rulemaking process.

Takeaway: Labs will have more time to comply with the HIPAA privacy rule requiring them to revise their notice of privacy practices. G2

focus on: Medicare Lab Payment

Medicare Payment Proposals Portend Implementation Problems

Three new lab payment proposals from the Centers for Medicare and Medicaid Services (CMS) represent major changes in Medicare policy, and the implementation of each of them raises substantial problems, concludes Bruce Quinn, a senior health care policy adviser for the law firm of Foley Hoag and a former regional Medicare medical director for the California Part B program.

In a new white paper, “Is Medicare Zero for Three? Diagnostic Policy Proposals for CY2014,” Quinn analyzes Medicare’s latest proposals and explores their potential impact on clinical and anatomic pathology laboratories.

All three proposals were issued July 8, 2013—two in the Physician Fee Schedule (PFS) proposed rule and one in the Hospital Outpatient Prospective Payment System (OPPS) proposed rule. Final rules are due out around Nov. 1.

“Taken as a group, the three policy proposals show remarkable ingenuity and reflect a deep-seated agency desire to policymakers to pull their weight in finding creative ways to reduce costs and prices in the U.S. health care system,” write Quinn. “While granting ‘A for effort’ or ‘I for ingenuity,’ all of the three proposals portend major implementation problems and none should be finalized as proposed.”

CLFS Technological Revaluation

While Quinn notes that CMS has statutory authority to revalue the prices of the Clinical Laboratory Fee Schedule (CLFS) based on changes in technology, CMS has never used this authority. CMS is proposing to review all CLFS prices over the next five years, assess-

ing “technological change” by comparing technology in place at the time each code was priced with current technology and repricing each test accordingly.

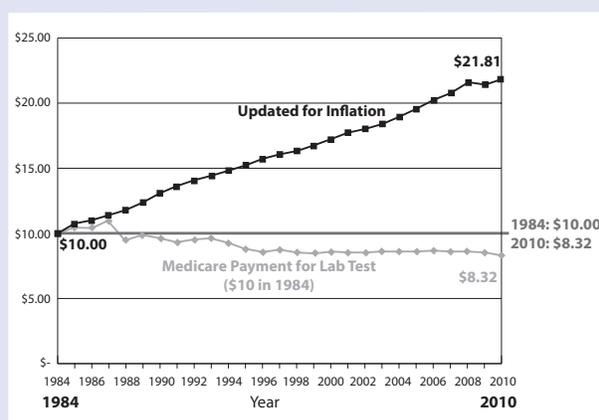
Most prices on the CLFS were set in 1984 and in real dollars they have eroded over time due to inflation. A test priced at \$10 in 1984 was paid at \$8.32 in 2010. If updated for inflation, this test should currently be paid at \$21.81 (see chart).

Under the proposed policy, CMS defines “technological changes” as “changes to the tools, machines, supplies, labor, instruments, skills, techniques, and devices by which laboratory tests are produced and used.” However, Quinn notes that in defining technological changes, CMS makes no acknowledgement that, like drugs, some particular

advanced lab-developed tests (LDTs) are developed with large research trials by one manufacturer or provider; therefore the invested costs are vastly higher than the marginal costs of delivering one more test.

In addition, CMS provides no information on how it would crosswalk from technology costs to total costs, says Quinn. “CMS must produce a more granular and

CLFS Payment Since 1984



Source: American Clinical Laboratory Association

explicit statement of the process it will go through to suggest (to extrapolate) new prices for comment from its proposed ‘technology review,’” concludes Quinn. “Otherwise, stakeholders may be subject to an arbitrary and inaccurate process in July 2014, with no time to provide appropriate data and corrections.”

Cap PFS Tests at APC Rates

In its second proposal, CMS would cap prices paid to independent labs for certain pathology tests at the payment rate for hospital outpatient services. CMS proposes that when the PFS price for a pathology test Current Procedural Terminology (CPT) code is higher than the ambulatory payment category (APC) price for the group of tests it is aggregated to, CMS will override the relative value unit (RVU) pricing system and use the lower APC price. For some pathology tests, this would cut 2014 payment by more than 70 percent.

Quinn notes that there is little relationship between APC classification and the RVU prices of many CPT codes. In addition, the charge and cost-to-charge data from which CMS calculates APCs is “extremely noisy,” he says. For APCs 342, 343, and 661, costs for tests by hospitals in each APC ranged from \$1 to \$3,095, \$4 to \$7,685, and \$10 to \$24,986. For a single CPT code cost (which may include multiples), submitted hospital costs (calculated from charges) ranged from \$6 to \$2,708 for immunohistochemistry, 88342.

“On a CPT code line item basis, in this summer’s OPFS amended data, Pathology II (APC 433) contains codes with median charges ranging from \$40 to \$349, almost a factor of 10, in an APC that would be priced at calculated APC median of \$57 next year,” writes Quinn. “It is no wonder that the costs or prices of some CPT codes are cut off when an APC rate is used as a cap.”

Quinn says that it is unclear that CMS has the authority to do what it has proposed, noting that it is under statutory guidance to use practice expenses alone to set RVUs.

Bundling Diagnostic Tests

Quinn notes that in some ways this is the simplest, and in others the most complicated, CMS proposal. The hospital outpatient prospective payment system is based on packaging services; there are only several hundred ambulatory payment categories into which many thousand CPT codes are aggregated. Some APCs contain only one major service; others contain over 200 CPT codes.

CMS proposes to move seven types of service from line item payment to bundled or packaged payment: (1) drugs used as a supply for a diagnostic test, (2) drugs used as supplies during surgical procedures, (3) clinical diagnostic laboratory tests, (4) procedures described by add-on codes, (5) ancillary services (including pathology tests), (6) bypass list diagnostic tests, and (7) device removal procedures.

According to the proposal, CLFS tests will be bundled when they are provided on the same date of service as a primary service and ordered by the same practitioner who ordered the primary service. The new rule appears to apply if the specimen is drawn at the hospital or elsewhere on the same day as the “primary service.”

Quinn notes that the impact of this proposal would fall much more on some specialties, such as oncology and endocrinology outpatient clinics, than others. The proposal also would discourage lab-intensive visits from occurring in the OPFS setting and would encourage them to occur in the freestanding Part B setting where the laboratories would be paid as fee-for-service line items.

Takeaway: Medicare’s proposed payment policies are ill-conceived and should not be implemented as proposed. 

ACLA Questions CMS Policies on Lab Tests Included in ESRD Bundle, from p. 1

Recent guidance from CMS, including the June 7 transmittal, “deviates from the clearly defined ESRD PPS lab list in a way that makes unclear whether the lab list remains the definitive guidance on which laboratory tests are included in, and excluded from, the ESRD PPS.”

This statement implies that for every laboratory test ordered for an ESRD beneficiary, the ordering practitioner is required to determine on an individual test-by-test basis whether the test is ESRD-related.

Specifically, the June 7 transmittal contains the following provision:

“The distinction of what is considered to be an ESRD-related laboratory test is a clinical decision determined by the ESRD patient’s ordering practitioner. If a laboratory test is ordered for an ESRD-related condition, then the laboratory test is considered

to be renal dialysis services and is not paid separately.”

This statement implies that for every laboratory test ordered for an ESRD beneficiary, the ordering practitioner is required to determine on an individual test-by-test basis whether the test is ESRD-related. “Leaving such determinations to the discretion of individual practitioners will have the effect of causing a great deal of confusion, inconsistent billing practices, and potential overuse of the AY modifier,” says ACLA.

Other Issues

ACLA also notes that CMS added the lipid panel (CPT code 80061) to the ESRD PPS through a change request and without proper notice and opportunity for comment. However, none of the three components of the lipid panel were determined to be “furnished for the treatment of ESRD” by the deliberative group that developed the original list of lab tests, and these lipid tests were not included in Table F of the 2010 ESRD PPS final rule.

As a result, the dialysis facility (and the contracted laboratory) are put in the position of using the AY modifier for the vast majority of lipid tests to justify payment as they are not furnished for the treatment of ESRD.

“Had the renal community been given the opportunity to articulate its position and concerns about adding lipid testing prior to the inclusion of these tests in the ESRD PPS through appropriate notice and comment rulemaking, this situation could have been avoided,” says ACLA.

ACLA also raises concerns about terminology used to describe services included in the ESRD PPS, as well as concerns about post-payment audit liability and additional revisions to lab tests in the PPS.

ACLA is urging CMS to take the following actions:

- Clarify that the only clinical laboratory tests included in the ESRD PPS are those CPT codes on the list of “Labs Subject to ESRD Consolidated Billing”;
- Implement a periodic review process that includes various stakeholders to evaluate current standards of clinical care for ESRD beneficiaries, including new lab tests that may be determined to be furnished for the treatment of ESRD;
- Consistent with the requirements under the Administrative Procedure Act, follow notice and comment rulemaking procedures when seeking to issue changes or additions to items and services in the ESRD PPS;
- Remove uncertainty and requirements for ordering practitioners to determine on a test-by-test basis what is considered to be furnished for the treatment of ESRD and revise guidance documents accordingly; and

- ❑ Revise manual guidance to be consistent with the statutory requirement that clinical laboratory tests in the ESRD PPS are “furnished for the treatment of ESRD” and eliminate terms such as “ESRD-related” and “renal related.”

Takeaway: CMS has created confusion regarding which lab tests are included in the ESRD bundle. ACLA is requesting that the agency use its original list of tests published with the ESRD PPS final rule. 

LabMD Challenges FTC Authority Over Data Breaches

LabMD, an Atlanta-based laboratory that allegedly exposed the personal information of almost 10,000 consumers, is challenging the Federal Trade Commission’s (FTC’s) authority to bring an enforcement action against the lab.

The FTC lacks the authority to bring an enforcement action under Section 5 of the FTC Act against LabMD Inc. for lax data security practices following several data breaches, the medical testing laboratory said in a Sept. 17 answer to an FTC administrative complaint (*In re LabMD, Inc., FTC, No. 9357*).

The case comes as the FTC’s authority to regulate the data security practices of companies under Section 5’s unfairness prong is pending in a federal district court case involving hotelier Wyndham Worldwide Corp.

Atlanta-based LabMD analyzes blood, urine, and tissue specimens for cancer, according to a Sept. 19 statement by the nonprofit government accountability organization Cause of Action, which filed the answer on LabMD’s behalf.

In an Aug. 28 administrative complaint, the FTC alleged that LabMD’s billing department manager made an insurance aging report available through a peer-to-peer file-sharing network. The report contained the names, dates of birth, Social Security numbers, medical treatment codes, and health insurance information of approximately 9,300 consumers, the FTC said.

A second incident allegedly occurred when the Sacramento, Calif., police department found LabMD documents in the possession of identity thieves, according to the FTC. The documents contained the personal information, including Social Security numbers, of several hundred consumers, the FTC alleged.

The commission said LabMD’s “failure to employ reasonable and appropriate measures to prevent unauthorized access to personal information” was an unfair act or practice under Section 5(a) of the FTC Act, 15 U.S.C. § 45(a). The commission said that the company “could have corrected its security failures at relatively low cost using readily available security measures.”

“The FTC admitted in 2000 that it ‘lacks the authority to require firms to adopt information practice policies,’ and while they have wanted Congressional approval for that authority, Congress has said no,” Reed Rubinstein, senior vice president of litigation at Cause of Action, partner at Dinsmore & Shohl LLP in Washington, and counsel for LabMD, said in the Cause of Action statement. “This is why we are asking the Administrative Law Judge to deny the Commission’s requested relief and dismiss the Complaint in its entirety.”

According to the FTC’s complaint, a hearing on the case is scheduled for April 28, 2014.

Takeaway: LabMD’s challenge to the FTC could set a precedent for whether the agency has authority over information practice policies. 

DLR Agrees to \$19.4 Million Settlement Over Kickback Charges

Diagnostic Laboratories and Radiology (DLR) in Burbank, Calif., has agreed to pay \$19.4 million to the state and federal governments to settle a lawsuit that alleged the company provided kickbacks to skilled nursing facilities (SNFs).

The qui tam lawsuit was brought by two former employees of DLR who claim the company was charging SNFs as much as 80 percent below market value for lab testing in order to receive referrals for Medi-Cal and Medicare patients, according to the Pathology Blawg (www.pathologyblawg.com). In some cases, the SNFs would pay only \$1 per patient for some services, the lawsuit alleged. When DLR received Medi-Cal and Medicare referrals, it would then bill the government the maximum amount allowed.

Although DLR believes it would have been acquitted at trial (scheduled for next week), it chose to settle so as to avoid further litigation expense, company officials said.

The settlement will be divided as follows: \$12.95 million to the federal government, \$4.55 million to California; and \$1.9 million to the plaintiff attorneys. The two former employees will split at least \$3.5 million between the two of them.

As the Pathology Blawg notes and G2 Intelligence has reported, the billing practices alleged in this lawsuit are not new. Quest and LabCorp paid a total of \$290.5 million in 2011 to settle similar charges in California. Two other lawsuits against Quest and LabCorp containing the same allegations were unsealed earlier this month in Virginia and Georgia.

DLR, which is owned by Trident USA, is the largest clinical laboratory and radiology company operating in Southern California. The company does business with approximately 80 percent of all nursing homes in Southern California.

It's interesting to note that lawsuits involving health care fraud are on the rise, and labs appear to be an easy target. Laboratories must ensure that their fee schedules for services provided comply with all state and federal requirements and must not provide discounts in exchange for referral of federal health care business. When considering whether to offer discounts, be sure to consult with inside or outside counsel to ensure you are on the right side of the law. 

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