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CMS Proposes Changes to CLIA Proficiency Testing Rules

Of the current 229,815 CLIA-certified laboratories, 35,084 labs would be affected by the proficiency testing (PT) changes. These labs perform moderate- or high-complexity testing, are required to enroll in a CLIA-approved PT program, and are subject to all PT regulations.

The Centers for Medicare and Medicaid Services (CMS) has proposed important changes and clarifications to the regulations governing proficiency testing (PT) samples under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

The proposals, CMS said, would "prevent confusion on the part of laboratories, reduce the risk of noncompliance, and establish policies under which certain PT referrals by labs would not generally be subject to revocation of a CLIA certificate or a two-year prohibition on laboratory ownership or operation that may be applied to an owner and an operator when a CLIA certificate is revoked."

They were published in the Feb. 7 *Federal Register*, "Medicare and Medicaid Programs; Part II—Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction." Comments are due April 8.

Treatment of PT Samples

Under CLIA rules, for each PT event, labs are required to attest that PT samples are tested in the same manner as patient specimens

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Sequestration Cuts Just Days Away

When Congress returns from its weeklong recess for the Presidents Day holiday, there will be only a few days left to decide what to do about the governmentwide sequestration cuts scheduled for March 1: come up with a compromise to block them, delay them, or let them kick in.

Under the sequestration agreed to in July 2011, federal budget cuts would total $1.2 trillion over 10 years, with the ax falling equally on defense and most nondefense spending. The draconian cuts, agreed to in a deal to increase the federal debt ceiling limit, were intended to force lawmakers and the White House to reach an accord that would begin to reduce the deficit.

Medicare is slated for a cut up to a maximum of 2 percent, including payment reductions for clinical laboratories, physicians, and hospitals. If that takes effect, the program would be cut by $11 billion in 2013 or $100 billion over 10 years, according to the Office of Management and Budget. While beneficiaries are spared, they could feel the effects if the cuts lead physicians to stop treating Medicare patients, notes the College of American Pathologists.

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are tested, that is, by integrating them into the lab's routine patient workload, with the testing performed by the personnel who routinely perform such testing, using the laboratory's routine methods. Some have interpreted this to mean they can send out PT samples for reflex or confirmatory testing if this is their standard operating procedure.

To clarify this point, CMS would add a statement to the rules that would "explicitly note that the requirement to treat PT samples in the same manner as patient specimens does not mean it is acceptable to refer PT samples to another laboratory for testing even if that is the standard operating procedure for patient specimens. . . . A PT sample must never be sent to another laboratory under any circumstances."

Narrow Exception for Intentional Referrals

The CLIA rules prohibit a lab from intentionally referring a PT sample to another lab for analysis of a test that the lab is certified to perform. Violating this ban results in a one-year revocation of the lab's CLIA certificate and triggers a two-year ban on the lab's owner or operator from owning or operating another lab.

The term "intentional referral" has not been defined by the statute or regulations, CMS noted, "but we have consistently interpreted it from the onset of the program to mean general intent, as in intention to act. Whether or not acts are authorized or even known by the lab's management, a lab is responsible for the acts of its employees." Expansive case law has supported this interpretation, the agency pointed out.

Exception for Intentional Referrals: Terms and Definitions

CMS would amend Section 493.2 of the CLIA rules to add the following:

- *Confirmatory testing*: Testing performed by a second analytical procedure that could be used to substantiate or bring into question the result of an initial laboratory test.
- *Reflex testing*: Confirmatory or additional laboratory testing that is automatically requested by a laboratory under its standard operating procedures for patient specimens when the laboratory's findings indicate test results that are abnormal, are outside a predetermined range, or meet other pre-established criteria for additional testing.
- *Repeat proficiency testing referral*: A second instance in which a PT sample, or a portion of a sample, is referred, for any reason, to another laboratory for analysis prior to the lab's PT program event cutoff 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).

Now, CMS is proposing to carve out a narrow exception to its policy on intentional referrals. If a CMS investigation reveals that PT samples were sent to another lab for reflex or confirmatory testing, it is not a repeat PT referral, and it occurred "in full conformance with the lab's written, legally accurate, and adequate standard operating procedure," the referral would be deemed improper, but not intentional, and would be subject to intermediate sanctions. These may include any combination of civil money penalties, a directed plan of correction (such as required remedial training of staff), temporary suspension of Medicare or Medicaid payments, or other sanctions specified in the rules.

There are caveats attached to the exception, however. The carve-out, CMS said, "is meant to be a one-time exception to a finding of an intentional referral by virtue

of a general intent to forward a PT sample to another lab." The agency expects labs to eliminate any improper referrals "or we will find that future referrals are intentional."

Also, any lab that receives a PT sample from another lab for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing or for any other reason.

Change in Statutory Language

CMS is proposing to amend the regulations to implement the Taking Essential Steps for Testing (TEST) Act, signed into law last December, which gives the agency express authority to impose alternative sanctions in the event of an intentional PT referral. Specifically, the word "will" would be replaced with "may" in the regulation that currently requires revocation of a lab's CLIA certificate if it refers a PT sample to another lab and bars the lab's owner or operator from owning or operating another lab for two years from the effective date of the certificate revocation. CMS said it plans further rulemaking to implement provisions of the new law.

Perspectives on the Proposals

In comments to *NIR*, attorney Robert E. Mazer, with Ober/Kaler in Baltimore, noted, "Most of the discussion in the proposed rule does not relate to the recent legislation that gives CMS enforcement discretion in handling intentional PT referrals.

"CMS would first bolster its authority to find that there's been an unlawful referral of PT samples when the referral is for confirmatory or reflex testing by specifying that the requirement that the lab treat PT samples like patient specimens applies *only until the lab would refer a sample to another laboratory* [emphasis added]. This will make it even more difficult for a lab to defend a charge of an improper PT referral by saying that it followed regulations requiring that it test PT samples just as it tests patient specimens. CMS then specifies narrow circumstances where such referrals would not be considered intentional. In those circumstances, CMS cannot revoke the lab's CLIA certificate.

"CMS proposes to only partially implement the recently enacted TEST Act. The proposed regulations state that a lab that CMS has determined to have intentionally referred its PT samples to another lab for analysis may have its CLIA certificate revoked. The regulations currently say that such a lab *will* have its certificate revoked. This change reflects the discretion provided to the agency by the TEST Act.

"CMS states that it will 'undertake further rule-making' to implement the legislation. Accordingly, the proposed rule does not provide any insights as to how CMS will exercise its new discretion to impose penalties other than revocation—and the related two-year ban on the lab's owner or operator from owning or operating another lab—in the case of PT referrals which the agency continues to consider 'intentional.'"

"CMS did not propose any change to the provision within the enforcement procedures section of the CLIA regulations that states that CMS revokes the lab's CLIA certificate if it determines that it has intentionally referred a PT sample to another laboratory for analysis. 42 CFR 493.1840 (b). Therefore, if the proposed regulatory changes were adopted, there would be a potential inconsistency between these two provisions."

SGR Repeal Efforts Stirring in the House

With an eye toward formulating a legislative proposal, key House health committees have asked physician groups for feedback by Feb. 25 on how to create a new Medicare physician payment system to replace the sustainable growth rate (SGR) system that over the past decade has triggered negative fee updates which Congress has blocked with a series of short-term fixes.

A one-page questionnaire, circulated by the committees on Ways and Means and Energy and Commerce, asks how different medical specialties should be rewarded financially under a performance-based system and how a quality reporting system should be crafted to replace the one now used by the Centers for Medicare and Medicaid Services (CMS).

Rep. Fred Upton (R-Mich.), chairman of the House Energy and Commerce Committee, predicted Feb. 13 that legislation repealing Medicare's current physician payment system would be on the House floor before the August congressional recess. "Fixing this issue is one of our No. 1 priorities in this Congress, and our goal is to get it done this year," he told an American Medical Association conference.

The questionnaire is in follow-up to a three-phase reform outline released earlier that would repeal the SGR and freeze physician fees for an unspecified period during the transition to a payment system based on physician-endorsed quality measures and efficiencies achieved in providing care.

Separately, a bipartisan bill (H.R. 574) has been introduced in the House by Reps. Allyson Schwartz (D-Pa.) and Joseph Heck (R-Nev.) that would replace the SGR. It would keep current physician payment levels through 2014 while CMS tests new coordinated care models for reimbursement over the next five years as an alternative to traditional fee-for-service Medicare. From 2015 to 2018 physician payments would increase annually by 2.5 percent for primary care doctors and 0.5 percent for all other doctors. Afterward, physicians would have to adopt a replacement model approved by CMS.

Schwartz and Heck proposed similar legislation in the last Congress (H.R. 5707), but unlike that measure, their new bill would not offset the cost of SGR repeal by tapping unused war expenditures from the Overseas Contingency Fund, instead leaving open the question of how to pay for such reform.

The cost of SGR repeal has been a major obstacle to physician payment reform in the past, but a new estimate from the Congressional Budget Office (CBO) has raised hopes that this could be overcome. On Feb. 5, CBO said that freezing physician fees over the 2014-2023 period would cost $138 billion versus its previous estimate of $245 billion. Where the money would come from, however, is an issue that SGR repeal proponents have yet to address.

The SGR was enacted in the 1997 Balanced Budget Act as a mechanism to control the rate of growth in Medicare spending for physician services. It limits the yearly increase in costs per beneficiary to the growth rate in the nation's gross domestic product. If the target is exceeded, this triggers a reduction in the physician fee update formula.

It is also unclear whether any effort to change the Medicare physician payment system would advance as stand-alone legislation or as part of a larger legislative vehicle.

House Bill Would Repeal Independent Pay Advisory Board

A bill has been reintroduced in the House to repeal the Independent Payment Advisory Board (IPAB) created by the health care reform law and scheduled to begin operating by April 30. Similar legislation passed the House in 2012 but was not taken up by the Senate.

The new bill is H.R. 351, the Protecting Seniors' Access to Medicare Act, a bipartisan measure introduced by Reps. David P. Roe (R-Tenn.) and Allyson Schwartz (D-Pa.) with 100 co-sponsors.

It got quick support from the American Medical Association. Its president, Jeremy Lazarus, said, "IPAB is a panel that would have too little accountability and the power to make indiscriminate cuts that adversely affect access to health care for patients. Patients and physicians are still struggling with the frequent threat of drastic cuts from the broken SGR [sustainable growth rate] Medicare physician payment update formula. IPAB would be another arbitrary system that relies solely on payment cuts."

IPAB supporters say it is a fail-safe mechanism to control Medicare spending growth when Congress fails to act and it removes politics from decisions affecting Medicare providers. Opponents, including pathology and clinical laboratory groups, say the board's unelected officials would have power over spending that historically has been reserved to Congress.

The Board's Mission

Under current law, the IPAB, whose members have yet to be appointed by the president and confirmed by the Senate, is required to make recommendations to Congress on reductions in Medicare spending, beginning in 2014, in any year when the per capita growth rate exceeds a target growth rate. The recommendations would be put on the legislative fast track and take effect unless Congress approved, within the statutory time frame, an alternative with the requisite savings.

The law also limits the IPAB, barring it from making any proposals that would ration care, increase beneficiary cost sharing, or otherwise restrict benefits or modify eligibility criteria.

Hospital payments are exempt from the board's purview until 2020, so before then any required savings would have to come from cuts to clinical labs, pathologists, and other health care providers. However, the Congressional Budget Office has said the spending targets are unlikely to be triggered until at least 2022, so the board might not make recommendations before then.

In Memoriam

David Mongillo, a well-known and respected member of the clinical laboratory and pathology community, passed away on Feb. 18. He had been seriously ill for the past year and a half and late last year had suffered a stroke. He was vice president for policy and medical affairs at the American Clinical Laboratory Association for six and a half years before having to retire about a year ago. Prior to that he was director of economic affairs for the College of American Pathologists. His memorial service will be March 23 at 11:30 a.m. in Ruckersville, Va. His wife, MaryAnn, requests no flowers, but donations can be made to the ALS Foundation (*www.alsa.org*) and/or the Hospice of Piedmont, 675 Peter Jefferson Parkway, Charlottesville, VA 22911 in his memory.

Sequestration Cuts Just Days Away, *from p. 1*

At press time, the outlook for avoiding the sequestration deadline is anyone's guess, with some lawmakers saying a deal could be reached prior to March 1 and others saying it is not likely.

A Democratic proposal would block sequestration through Dec. 31 and pay for it with a mix of targeted spending cuts and new tax revenue by closing loopholes in the tax code.

Republicans have countered with a proposal to block defense spending cuts and institute reforms to entitlement programs. But the president in his State of the Union address objected to increasing cuts to these programs without new revenue. The GOP, however, having given in to a tax hike on the wealthiest Americans starting Jan. 1, have said they are in no mood to agree to more taxes and have insisted that entitlements must be pruned.

Settlement Reached Over Alleged Pathology Kickback Scheme

A Florida dermatologist has agreed to pay $26.1 million to resolve allegations that he violated the False Claims Act by accepting illegal kickbacks from a pathology laboratory and by billing the Medicare program for medically unnecessary services.

He also is excluded from treating patients and being paid under Medicare, Medicaid, and all other federal health care programs.

The settlement, announced Feb. 11, is the largest ever with an individual under the False Claims Act in the Middle District of Florida and one of the largest with an individual under the act in U.S. history, the Justice Department said.

Kickbacks and Medically Unnecessary Services

The government alleged that in or around 1997, Steven J. Wasserman, M.D., practicing in Venice, Fla., entered into an illegal kickback arrangement with Tampa Pathology Laboratory (TPL) and Dr. José SuarezHoyos, a pathologist and the owner of TPL, in an effort to increase the lab's referral business.

Under that agreement, Wasserman allegedly sent biopsy specimens for Medicare beneficiaries to TPL for testing and diagnosis. In return, TPL allegedly provided him a diagnosis on a pathology report that included a signature line to make it appear to Medicare that he had performed the diagnostic work that TPL had performed. The government alleged that Wasserman then billed Medicare for TPL's work, passing it off as his own, for which he received more than $6 million in payments. In addition, the government asserted that in furtherance of his agreement with TPL, Wasserman substantially increased the number of skin biopsies on Medicare patients, thus increasing the referral business for TPL.

The government further alleged that in addition to his involvement in the alleged kickback scheme, Wasserman also performed thousands of unnecessary skin surgeries known as adjacent tissue transfers on Medicare beneficiaries in order to obtain reimbursement for them and not because they were medically necessary.

Settlement Brings Whistleblower Lawsuit to a Close

The allegations resolved by the settlement were initiated by a lawsuit originally filed in the District Court for the Middle District of Florida by Alan Freedman, M.D., a

pathologist who formerly worked at TPL. He filed the suit under the whistleblower provisions of the False Claims Act. The government took up his case, filing its own complaint in October 2010. Freedman will receive $4,046,000 of the settlement.

The United States previously settled with TPL and SuarezHoyos for $950,000 to resolve the allegations asserted against them in the same lawsuit.

The lawsuit is captioned *U.S. ex rel. Freedman v. SuarezHoyos et al.*, No. 04-933 (M.D. Fla.).

Tavenner Renominated to Lead CMS

For the second time, President Obama has nominated Marilyn Tavenner to be administrator of the Centers for Medicare and Medicaid Services (CMS), an $820 billion federal agency that ensures health care coverage for 100 million Americans, with 10 regional offices and more than 4,000 employees nationwide.

The post requires Senate confirmation. If confirmed, she will be the first permanent CMS administrator in seven years. Finance Committee Chairman Max Baucus (D-Mont.) said Feb. 12 that the panel will hold a hearing on the nomination soon and he expects it to clear the full Senate.

Tavenner has served as the agency's principal deputy administrator under former chief Donald Berwick and has been acting CMS administrator since December 2011 when she was first nominated to fill the position on a permanent basis, following Berwick's departure. The Senate, however, did not hold a hearing on the nomination.

A nurse and former hospital executive, she served as Virginia's secretary of health and human resources under former Gov. Timothy M. Kaine (D) and before that was a member of the board of the American Hospital Association (AHA).

The president's Feb. 7 announcement was greeted by strong support from health care provider and industry groups who urged the Senate to confirm her quickly.

"Simply stated, she is the best-qualified person in the country to serve as CMS administrator based upon her outstanding leadership skills, exceptional knowledge of health policy and the health care industry, experience as a caregiver, and the qualities she already has demonstrated running CMS," said the Federation of American Hospitals.

"As the acting administrator for CMS, she has proven to be an effective, thoughtful leader," said the American Medical Association. "She actively seeks input and considers various sides of an issue, making sure all stakeholders have an opportunity to be heard during decisionmaking processes."

The AHA said her "varied and rich background as a nurse, health care executive, and government official at the state and national levels gives her a unique perspective and demonstrates that she is a very capable leader of the Medicare and Medicaid programs."

Former CMS Administrator Thomas A. Scully also weighed in with his support, telling BNA that Tavenner is well regarded by Democrats and Republicans and "there's no conceivable reason she should not be confirmed." He said it is crucial that CMS have a Senate-confirmed administrator because it allows that person to act more boldly in setting policy. "It's very important top-to-bottom. It's not a good idea to have an agency that big rudderless."

ASCP Survey Shows Overall Decline in Vacancy Rates

Overall vacancy rates for clinical laboratory personnel appear to be declining, according to the American Society for Clinical Pathology's 2012 Vacancy Survey of Clinical Laboratories.

Across the nation, the vacancy rate was highest for phlebotomy departments (8 percent) and lowest for cytogenetics, histology, and immunology departments, as well as laboratory safety personnel (4 percent each). Specimen processing (14 percent) had the highest overall supervisory vacancy rate.

The total vacancy rate for anatomic pathology is 7 percent, with the nonsupervisory vacancy rate at 7 percent, and the supervisory vacancy rate at 2 percent. Compared with other departments in the survey, AP has a low percentage (2 percent) of positions anticipated to become open within six months of when the survey was performed.

According to survey findings, immunology and chemistry/toxicology departments have the highest overall percentage (10 percent) of employees expected to retire in the next 24 months. Cytogenetics and phlebotomy have the lowest rate of employees expected to retire in the next 24 months (4 percent).

The staff retirement rate is highest in the immunology department (10 percent) and lowest in the phlebotomy department (3 percent). The supervisor retirement rate is highest in the hematology/coagulation department (24 percent) and lowest in the histology and molecular biology/diagnostics departments (4 percent).

Results of the survey are available at *www.ascp.org*.

Upcoming G2 Events

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March 20, 2013

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Barry Portugal, President, Health Care Development Services Inc.
Dan Angress, Chief Commercial Officer, PathCentral
www.G2Intelligence.com/88305SurvivalGuide

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