G2 INTELLIGENCE

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## Provider Cuts Looming Under Medicare Sequestration

*The sequestration comes on top of other reimbursement cuts scheduled for pathologists and clinical laboratories in 2013.*

Nearly $11.1 billion would be cut from Medicare payments to health care providers and health plans in 2013 under sequestration rules, the Office of Management and Budget (OMB) said in a report to Congress released Sept. 14.

Physicians, clinical laboratories, hospitals, and other providers would be hit with an across-the-board cut of 2 percent, OMB noted. The portion of Medicare subject to the 2 percent cut totals $554.265 billion.

The automatic cut is part of the deficit reduction deal reached in July 2011 to raise the federal debt ceiling. Unless Congress intervenes, the deal (or sequestration) requires that beginning in 2013 at least $1.2 trillion in federal spending must be cut over 10 years, split equally between defense and nondefense accounts. The deal limits the Medicare cut to a maximum of 2 percent.

Medicare benefits to enrollees are not affected by the sequestration. Nor are Medicare inventive payments to physicians and hospitals for meaningful use of certified electronic health records. Also spared are Medicaid and the state Children's Health Insurance Program.

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## CLIA PT Referral Bills Advance in Congress

Legislation giving the Centers for Medicare and Medicaid Services (CMS) leeway in enforcing sanctions on clinical laboratories for violating proficiency testing (PT) referral rules has moved forward in the House and the Senate.

The House passed H.R. 6118, the TEST Act, by unanimous voice vote on Sept. 19. That same day the Senate Health, Education, Labor, and Pensions Committee reported out a companion bill, S. 3391, for floor consideration.

"The hope among Senate staff working on this is that it will be passed before the Senate recesses for the November elections," said Jason DuBois, vice president for government affairs at the American Clinical Laboratory Association, in an update to the Clinical Laboratory Coalition. The goal is to have the legislation on the president's desk to be signed before year's end.

Currently, CMS takes a strict interpretation that the Clinical Laboratory Improvement Amendments (CLIA) require the agency to revoke a

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Sequestration will also force major cuts in programs created by the health care reform law and not subject to the 2 percent cap: $66 billion from grants to states to create health insurance exchanges and $76 billion from the prevention and public health fund.

In releasing the OMB report, the Obama administration said sequestration is a "blunt and indiscriminate instrument" for deficit reduction that would devastate many valuable programs, and it called on Congress to put forward a new proposal that the president can sign to avoid sequestration.

The American Medical Association, pathology and lab groups, and other health care providers are lobbying Congress to repeal the 2 percent Medicare cut.

### Sequestration an Added Blow

The 2 percent cut only adds to the pain of pathologists and clinical labs already facing major reductions in Medicare payments next year under separate statutes.

Physician fees under Part B are scheduled for a 27 percent cut, effective Jan. 1, 2013, in accord with the sustainable growth rate formula. Pathologists are slated to absorb an additional 1 percent cut to offset primary care fee increases and another 1 percent cut due to a change in the practice expense methodology. They also could see a cut in payment for the technical component of the most commonly ordered pathology code, CPT 88305.

Clinical labs are due for a cut of 2.75 percent under the Part B lab fee schedule for 2013, according to current projections. The additional 2 percent sequestration would slash 2013 lab fees by a total of 4.75 percent. Labs also had to absorb a 2 percent fee cut this year (or a savings of $2.7 billion over 10 years) to help pay for a physician fee fix and remain wary of being tapped again to help pay for blocking the 27 percent cut in store for physicians in 2013.

# Prostate Biopsy Limits Under Fire From Providers

Palmetto GBA, the nation's largest Medicare contractor, jolted the pathology and laboratory community when it announced Aug. 7 that it was implementing a policy limiting the number of prostate biopsy specimens reported using Current Procedural Terminology (CPT) code 88305.

The policy cuts pathology reimbursement roughly in half. Previously, pathologists and labs could bill up to $1,270 for a 12-core prostate biopsy. Now, the global fee (unadjusted for geographic practice cost variations) will be limited to $671 whenever five or more specimens are billed.

The prospect is that with the profit incentive slashed, urology groups will likely close their in-office pathology labs, a goal long sought by the College of American Pathologists (CAP) and the American Clinical Laboratory Association (ACLA), Joe Plandowski, a founder of In-Office Pathology (Lake Forest, Ill.), told *NIR*. But their member labs as well as all pathologists will also see their prostate biopsy revenue drop, he pointed out, even though they will be doing the same amount of work for less pay.

CAP, ACLA, and the American Urological Association are urging Palmetto and officials at the Centers for Medicare and Medicaid Services (CMS) to scrap the policy.

  

## Controversial Change

Based on an edit under the National Correct Coding Initiative (NCCI), Palmetto said that effective Jan. 1, 2012, Medicare has limited the number of prostate biopsies that may be reported for 88305, Level IV- Surgical pathology gross and microscopic examination, prostate, needle biopsy, to four services.

To report five or more prostate biopsies, providers must use G0416, Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling (1-20 specimens), but limited to one unit of service.

Providers who have submitted claims for more than four 88305 services for dates of service on and after Jan. 1, 2012, may be at risk for overpayment collection.

## Impact on Reimbursement

CPT 88305 is the most commonly used pathology procedure code, accounting for almost $1.3 billion in allowed charges in 2010. More than one million prostate biopsies are performed annually in the United States, each containing an average of 10 cores, according to the September issue of *Laboratory Economics*.

Prior to the NCCI edit, Medicare had the "G" code only for saturation biopsies of the prostate and allowed the standard 12-core biopsy to be billed as 12 x 88305. Critics of the new policy say it mistakenly applies an edit intended for post-diagnosis saturation biopsies and applies it to prediagnosis conventional techniques with no regard for the manner in which the samples were collected.

The current global fee for 88305 is $105.86 (professional component, $36.08; technical component, $69.78) while the national fee for G0416 is $670.88. It is not uncommon for pathologists to take 10 or more specimens, but they will be paid less, a difference of $387.72. In a case where there are 20 specimens, the difference would be $1,446.32.

The Palmetto policy also conflicts with the voluntary guidelines for standard of care issued by the National Comprehensive Cancer Network that call for collection of 12 cores, Plandowski said. This has prompted other critics to contend that the limits are based not on medical necessity or benefit to patients but on a decision to cap reimbursement rates.

### Controversial NCCI Edit

HCPCS codes G0416-G0419 describe surgical pathology, including gross and microscopic examination, of prostate needle biopsies from a saturation biopsy sampling procedure. CMS requires that these codes rather than CPT code 88305 be utilized to report surgical pathology on prostate needle biopsy specimens only if the number of separately identified needle biopsy specimens is five or more. Surgical pathology on four or fewer prostate needle biopsy specimens should be reported with CPT code 88305 with the unit of service corresponding to the number of separately identified biopsy specimens.

*Source: National Correct Coding Initiative, Policy Manual Chapter 10, effective Jan. 1, 2012.*

## More to Come From CMS?

As of Sept. 14, Palmetto was the first Medicare contractor to officially implement the prostate biopsy limitations. They apply to its Jurisdiction 1 (including California, Nevada, and Hawaii) and Jurisdiction 11 (West Virginia, Virginia, North Carolina, and South Carolina). In these states Palmetto handles claims and payment for approximately 13.6 million Medicare beneficiaries.

Other Medicare Administrative Contractors are likely to follow suit if CMS insists. "If CMS were leading the pack, all Medicare carriers would have announced the new policy," said Plandowski. "However, if the Medicare edict is truly out to all carriers, I expect to see it soon."

  

# Pathologists Get Reprieve From Meaningful Use Penalties

Pathologists won't be punished with a cut in Medicare payments, beginning in 2015, for failing to demonstrate meaningful use (MU) of certified electronic health record technology (CEHRT) and other requirements under the government's electronic health record (EHR) incentive programs.

Under the Medicare EHR program, the penalties for not meeting MU requirements take the form of reduced reimbursement rates for eligible professionals (EPs, including pathologists), hospitals, and critical access hospitals (CAHs). For physicians, the penalty is a 1 percent cut in Medicare payments in 2015 and as much as 5 percent in 2017 and beyond.

Now, however, the Centers for Medicare and Medicaid Services (CMS) has created a "significant hardship" exception for four categories, including one for pathologists, radiologists, and anesthesiologists in nonhospital settings, allowing them to escape the pay cut, at least in the short term.

The exception is subject to annual review, CMS noted. "As such, physicians in these three specialties should not expect that this exception will continue indefinitely, nor should they expect that we will grant the exception for the full five-year period permitted by statute."

The exception is set forth in the final MU Stage 2 rule issued Sept. 4 and effective Nov. 5. The rule specifies the criteria that eligible providers must meet to participate in Medicare and Medicaid EHR incentive programs. It also delays Stage 2 implementation from 2013 to 2014 to give providers and vendors more time to comply.

### Hardship Exception for Specialists

This applies to all EPs who are registered in the Provider Enrollment, Chain, or Ownership System (PECOS) with a primary specialty of pathology, radiology, or anesthesiology six months prior to the first day of the payment adjustment year (for calendar year 2015, July 1, 2014).

In granting the exception, CMS agreed with comments from various provider groups that "these specialties lack face-to-face interactions and need to follow up with patients with sufficient frequency to warrant granting an exception to each EP with one of these specialties. We note that anesthesiologists do interact with patients, but not in a manner that is conducive to collecting the information needed for many aspects of meaningful use."

CMS encouraged all in these specialties "to build out their ability to participate in health information exchange, adopt CEHRT, and apply for the Medicare or Medicaid EHR incentives. Those seeking Medicare EHR incentives can start through 2014; those seeking Medicaid EHR incentives can start through 2016."

The College of American Pathologists (CAP) had urged CMS to grant this exception, pointing out that "the program's EP requirements have focused on office-based physicians, not reflecting pathologists' scope of practice, usual interaction with patients, and type of information technology system used in laboratories and practices (an APIS/LIS rather than EHR)."

  

To make this exception permanent, CAP is lobbying lawmakers to back H.R. 4066, the Health Information Technology Reform Act, introduced by Rep. Tom Price, M.D. (R-Ga.). The bill exempts pathologists from eligibility for both MU penalties and incentives and has secured 43 co-sponsors to date.

### Lab Test Orders and Reporting of Results

On this subject the MU Stage 2 final rule contains specific objectives for EPs, eligible hospitals, and CAHs to meet in order to receive an incentive payment:

- ❑ They must enter 30 percent of laboratory orders through computerized provider order entry.
- ❑ They must incorporate more than 55 percent of all laboratory test results into CEHRT as structured data. Results must be in either a positive or negative affirmation or numerical format.
- ❑ Eligible hospitals and CAHs must provide structured electronic lab results to ambulatory ordering providers for more than 20 percent of electronic lab orders received.
- ❑ A new menu objective for cancer reporting requires EPs to report case information from CEHRT to a public health cancer registry for the entire EHR reporting period in accordance with applicable law and practice.
- ❑ Outpatient lab reporting is added as a menu objective, giving hospitals the flexibility to mix and match this with other objectives to meet MU requirements for an incentive payment.

### Definition Modified for Hospital-Based EPs

CMS has modified the regulations so that pathologists and other EPs who can demonstrate that they fund the acquisitions, implementation, and maintenance of CEHRT, including supporting hardware and interfaces needed for meaningful use without reimbursement from an eligible hospital or CAH—and use such CEHRT at a hospital, in lieu of using the hospital's CEHRT—can be determined "nonhospital-based" and receive an incentive payment. Determination will be made through an application process.

### Medicare Incentive Payments for Meaningful Use

EPs who successfully demonstrate meaningful use of CEHRT during the relevant EHR reporting period may be eligible for a Medicare incentive payment, subject to an annual limit, equal to 75 percent of the EP's Medicare-allowed charges submitted not later than two months after the end of the calendar year.

The total amount of incentive payments that an EP can receive depends in part on the year in which meaningful use is successfully demonstrated. Maximum incentive payments over the five years of the program total $44,000. It is less for those entering the program later: the maximum for 2013 is $39,000 and for 2014 when the program ends, $24,000.

More than 120,000 eligible health care professionals and more than 3,300 hospitals have qualified for EHR incentive payments since the program began in January 2011, according to the U.S. Department of Health and Human Services. That exceeds a 100,000 goal the department set earlier this year. The total includes more than half of all eligible hospitals and CAHs and 1 of every 5 eligible health care professionals.

  

**CLIA PT Referral Bills Advance,** *from p. 1*

lab's certificate for one year and bar its owner and operator from running another lab for two years for intentional PT referrals for a test that the lab is certified to perform.

H.R. 6118 and S. 3391 would allow CMS to substitute intermediate sanctions for PT referral violations instead of the two-year prohibition against ownership or operation that would otherwise apply and would make the one-year certificate revocation for the lab optional rather than mandatory.

At the markup of H.R. 6118, its lead sponsor, Rep. Michael Grimm (R-N.Y.), chairman of the Energy and Commerce health subcommittee, said, "Congress properly wanted the CLIA statute to hold labs to a high standard. However, we don't want to unduly punish labs that are doing their best to comply and even self-reporting mistakes. CMS should have more leeway to consider sanctions on a case-by-case basis and make sure that we keep quality labs up and running."

This legislative relief is especially needed, say pathology and clinical lab groups, noting that a growing number of labs across the country have been sanctioned for inadvertent PT referrals.

The latest high-profile case involves Ohio State University's Wexner Medical Center. CMS proposed to revoke its CLIA certificate for prohibited PT referrals, though Wexner self-reported six incidents, saying these were accidental and corrective action has been taken. The center is appealing, putting the proposed sanctions on hold (*NIR 12, 16/Sept. 6, pp. 4-5*).

The Ohio congressional delegation has weighed in on the case, asking CMS "to thoroughly review the facts and consider the impact the proposed sanctions would have on patients in Ohio. Ensuring that the lab can continue to operate under the ownership and control of OSU and the Wexner Medical Center is essential" and "revocation of CLIA certification, followed by a full shutdown of the lab and its affiliated network of labs, would be devastating to the care of patients."

In a letter to Health and Human Services Secretary Kathleen Sebelius, the delegation noted that the lab unintentionally referred the specimens and did not intend to circumvent CLIA's PT requirements. Patient safety and the high caliber of care delivered were never in jeopardy. "Revocation of the lab's CLIA certificate is an extreme interpretation of the applicable statutory provision. It is a punishment that exceeds the nature of the offense."

# CMS Adopts Unique Health Plan Identifier

The Centers for Medicare and Medicaid Services (CMS) has adopted a national 10-digit unique identifier for health plans (HPIDs) to replace the multiple plan identifiers now in use that differ in length and format and can cause claims processing problems. CMS also adopted an "other entity" identifier (OEID) for those that are not health plans, providers, or individuals but need to be identified in electronic transactions under the Health Insurance Portability and Accountability Act (HIPAA).

The changes were announced in a final rule in the Sept. 5 *Federal Register* and are effective Nov. 5, 2012. Health plans must obtain an HPID by Nov. 5, 2014 (small health plans have an extra year). HIPAA-covered entities must use HPIDs in standard e-health transactions on or after Nov. 7, 2016.

  

# CAP Submits New Quality Reporting Measures

The College of American Pathologists (CAP) has submitted three new measures to qualify for incentive payments under Medicare's Physician Quality Reporting System (PQRS) for 2014.

The new measures, recently sent to the Centers for Medicare and Medicaid Services (CMS), are:

- *Lung cancer reporting (biopsy/cytology specimens):* Pathology reports based on biopsy and/or cytology specimens with a diagnosis of non-small cell lung cancer classified into specific histologic type or classified as NSCLC-NOS with an explanation included in the pathology report.
- *Lung cancer reporting (resection specimens):* Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category, and, for non-small cell lung cancer, histologic type.
- *Melanoma reporting:* Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness and ulceration and for pT1, mitotic rate.

For the 2013 PQRS, there are five currently approved CAP-developed pathology measures that CMS says it will retain (these do not, however, cover all pathologists, noted CAP's *Statline*):

- *Barrett's Esophagus:* Esophageal biopsies with a diagnosis of Barrett's esophagus that also include a statement on dysplasia.
- *Radical Prostatectomy Pathology Reporting:* Reports include the pT category (primary tumor), the pN category (regional lymph nodes), the Gleason score, and a statement about margin status.
- *Immunohistochemical (IHC) Evaluation of HER2 for Breast Cancer Patients:* Quantitative HER2 evaluation by IHC using the system recommended by the American Society of Clinical Oncology-CAP guidelines.
- *Breast cancer resection pathology reporting:* pT category and pN category with histologic grade.
- *Colorectal cancer resection pathology reporting:* pT category and pN category with histologic grade.

The PQRS also contains measures, developed by other professional societies, which impact pathologists. They include preoperative diagnosis of breast cancer; sentinel lymph node biopsy for invasive breast cancer; and biopsy follow-up

### PQRS Financial Rewards at a Glance

Incentive payments for satisfactorily reporting data on CMS-approved quality measures for covered professional services to Medicare beneficiaries were authorized by the 2006 Tax Relief and Health Care Act (P.L. 109-432) and are available through 2014. Eligible professionals (EPs) include pathologists; other physicians; nonphysician practitioners; and physical, occupational, and speech-language therapists.

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**CAP Submits New Quality Reporting Measures,** *from p. 7*

- ❑ Incentive payments are based on a percentage of an EP's total estimated Medicare physician fee schedule allowed charges processed not later than two months after the end of the reporting period.

- ❑ For reporting years 2012 through 2014, EPs who satisfactorily report will earn an incentive payment equal to 0.5 percent of allowed charges. Additionally, for reporting years 2011 through 2014, EPs who satisfactorily report can qualify to earn an additional 0.5 percent incentive payment by, more frequently than is required to qualify for or maintain board certification status, participating in a maintenance of certification (MOC) program and successfully completing a qualified MOC practice assessment.

- ❑ Beginning in 2015, EPs who do not satisfactorily report under the PQRS will be subject to a Medicare fee-for-service payment reduction of 1.5 percent of their allowed charges, rising to 2 percent in 2016 and beyond.

More information on the PQRS program can be found at *www.cms.gov/PQRI/01_Overview.asp*.



  

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