G2 INTELLIGENCE

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Mixed Bag for Pathology in Final 2012 Medicare Fee Rule

The final rule with comment period is scheduled to be published in the Nov. 28 Federal Register. *CMS will accept comments on provisions subject to comment until Jan. 3, 2012, and will respond in the Medicare physician fee schedule for 2013.*

The final Medicare physician fee schedule rule for calendar year 2012, released Nov. 1 by the Centers for Medicare and Medicaid Services (CMS), contains a steep cut in pathology and other physician Part B reimbursement, scraps the pathology grandfather protection, adds new pathology measures for quality reporting, and includes a series of pathology codes in the agency's review of potentially misvalued codes.

Pathology and other physician fees are scheduled for a cut of 27.5 percent under the sustainable growth rate (SGR) formula required by current law. This is less than the 29.5 percent cut that CMS estimated earlier this year. The lesser cut is due to lower cost growth in Medicare, the agency explained.

The 27.5 percent cut would result in the conversion factor used to set payment rates, based on relative value units (RVUs), falling to $24.6712 for 2012 vs. $33.9764 this year. This would cut the global fee for the most frequently ordered pathology code—CPT 88305, Gross and microscopic tissue exam Level 4—to $74.01 in 2012 compared with $101.93 if the current conversion factor were retained.

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Labs Face Big Cuts in California Medicaid Payments

Clinical laboratories and most other outpatient providers in California stand to see their Medicaid reimbursement cut by 10 percent, following approval by the Centers for Medicare and Medicaid Services (CMS) of spending cuts that the state had sought for the Medi-Cal program.

In addition to clinical labs, the payment cut affects physicians, pharmacists, clinics, optometrists, therapists, dentists, and durable medical equipment suppliers.

Norman Williams, a spokesperson for the state Department of Health Care Services, has said the statute calling for the 10 percent reduction allows the state to make the cuts retroactive to services provided on or after June 1, 2011, though the department does have flexibility in how it implements the cuts.

CMS officials on Oct. 27 gave California the green light to move ahead on the cuts, which state officials say will save Medi-Cal $632 million.

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Mixed Bag for Pathology, *from p. 1*

This is the 11th time that the SGR formula has triggered a negative annual update to Medicare physician fees, though Congress has blocked the cuts in all but 2002, CMS noted. "The Obama administration is committed to fixing the SGR and ensuring these payment cuts do not take effect."

Congress is expected to block the looming 2012 cut and at least approve another short-term fix of one or two years, though pathology and other medical groups are pushing hard for repeal of the SGR. Though most lawmakers agree that the SGR is broken, the cost of its repeal, an estimated $300 billion over 10 years, has been a stumbling block. The president's budget request called for a two-year freeze on the physician fee update, from Jan. 1, 2012, to Jan. 1, 2014.

Pathology Grandfather Protection

The pathology grandfather protection is yet again targeted by CMS for elimination. "Absent additional legislation, for services furnished after Dec. 31, 2011, an independent laboratory may not bill a Medicare contractor for the technical component (TC) of physician pathology services for fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital."

CMS has sought to eliminate such billings since 1999, but Congress has repeatedly thwarted this by approving a series of extensions. The current extension ends Dec. 31, 2011, and pathology and lab groups are lobbying to have the grandfather protection made permanent or at least be further extended.

Bipartisan bills supporting the grandfather protection have been introduced in the Senate and in the House. The Senate bill (S. 1680) would extend the protection for another year, through Dec. 31, 2012. The House bill (H.R. 2461) would make it permanent.

CMS estimates that the savings from ending the protection would be approximately $80 million for 2012. The agency contends that payment for the TC (the preparation of the slide involving tissue or cells that a pathologist interprets) is included in the hospital's prospective payment, and labs should seek reimbursement from the hospital, not the Part B program.

The grandfather provision applies to hospital-lab arrangements in effect as of July 22, 1999, when the Medicare program first proposed to end such billings. The protection applies to the hospital, not the lab, CMS has ruled. Hospitals may switch labs without forfeiting the protection; however, independent labs cannot switch hospitals and still be protected. The TC of pathology services includes anatomic services, cytopathology, and surgical pathology.

More Measures for Quality Reporting

The final rule adds three new measures for which pathologists participating in the Physician Quality Reporting System (PQRS) are eligible for incentive payments, bringing the total to five.

The three new measures for 2012, all developed by the College of American Pathologists (CAP), are:

- ❑ *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.

The two current measures for quality reporting for pathology, also developed by CAP, are:

- ❏ 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.

Also added are measures, developed by other societies, that would impact pathologists:

- ❏ Preoperative diagnosis of breast cancer.

- ❏ Sentinel lymph node biopsy for invasive breast cancer.

- ❏ Biopsy follow-up.

Payments for Quality Reporting

In 2012, pathologists and other eligible Part B providers will be entitled to an incentive payment of 0.5 percent of total allowed charges, down from 1 percent this year, for successfully reporting on quality measures. The health care reform law authorized the incentive payment program through 2014 and established a penalty for providers who do not report quality measures beginning in 2015.

Potentially Misvalued Coding Initiative

CMS is expanding its effort to identify potentially misvalued codes for physician fee schedule services by looking at all specialties. In the final rule, the agency opted not to review all evaluation and management (E/M or office visit) codes pending further research, but it did adopt without modification its target list of the highest non-E/M expenditure codes for each specialty.

The target list includes three CPT pathology codes: 88342, Immunohistochemistry; 88112, Cytopath, cell enhance tech; and 88312, Special stains group. CMS said it will send these to the American Medical Association's Relative Value Scale Update Committee (RUC) for review and possible revisions in the 2013 fee schedule.

In addition, the agency says that despite provider objections it will ask the RUC to review the direct practice expense (PE) inputs for CPT 88305, which have not been reviewed since 1999. It also will seek review of the direct PE inputs and work values for in situ hybridization codes 88365, 88376, and 88368, all using specimen media other than urine. For two cytopathology codes, 88120 and 88121, new in 2011, that use urine samples for such testing, the agency is retaining the current direct PE inputs on an interim basis subject to public comment.

CMS Aims to Make ACOs More Appealing

In a bid to make the new Medicare shared savings program more attractive to health care providers, the Centers for Medicare and Medicaid Services (CMS) has issued a final rule easing the formation and operation of accountable care organizations (ACOs) that voluntarily participate.

The program, created by the health care reform law, is to be established as of Jan. 1, 2012. Under the ACO model for coordinated care, providers and suppliers furnish or arrange for all the treatment that Medicare patients need across all care settings, including physician offices, hospitals, and long-term care facilities.

Will the changes be enough to propel ACO momentum? Hospitals and physician groups have responded favorably, but interested participants could face major startup and operating costs. Integrated delivery systems are among those well positioned to make a transition to the ACO model in the Medicare shared savings initiative. In the end, it will be up to the entity forming an ACO to determine if such an arrangement can be financially viable.

Participants continue to receive Medicare fee-for-service payments under Parts A and B and are eligible for additional payments if they meet specified quality and savings goals.

In the final rule, published in the Nov. 2 *Federal Register*, CMS has reworked the ACO program to address provider concerns that the requirements in the proposed rule, issued earlier this year (*NIR 11, 7/April 8, p. 1*), were too burdensome and costly.

Specifically, CMS has:

- ❏ Made the one-sided model risk-free for the entire length of the agreement. This bonus-only approach is intended to help ACOs that need a longer time to ramp up and assume financial risk. Under the previous proposal, they would have shared savings for the first two years and in the third year shared savings and losses. ACOs continue to have the option of a two-sided risk model, sharing savings and losses over three years, for higher rewards. The savings rate for the one-sided risk model is 50 percent, for the two-sided risk model 60 percent.

- ❏ Increased the amount of potential bonuses—before CMS shared savings after the first 2 percent in cost reductions; now savings are shared from the outset, based on first dollar saved after meeting a minimum savings benchmark.

- ❏ Reduced the number of quality measures that providers must report from 65 to 33. These include measures to assess diabetes management (HbA1c control and low-density lipoprotein) and ischemic vascular disease management (complete lipid profile and LDL control).

- ❏ Provided a longer phase-in period for reporting and performance measures. In the first year, pay for reporting; in the second and third years, pay for reporting and performance.

- ❏ Established a "rolling admissions" process. The first round of applications will be due in early 2012 and the first ACO agreements will begin April 1, 2012, and July 1, 2012. ACOs also will have agreements with a first performance "year" of 18 months or 21 months, depending on the start date.

- ❏ Changed the beneficiary assignment process from retrospective (based on use of primary care services) to prospective, which allows ACOs to be told up front which beneficiaries are likely to be included. Assignment will be every three months prospectively. Under the shared savings program an ACO must serve at least 5,000 Medicare beneficiaries.
- ❏ Allowed rural health providers and federally qualified health centers to become their own ACOs or join an ACO as a participant with other organizations. They had been excluded from the proposed rule.

Speakers at the G2 Lab Institute, held Oct. 19-21, emphasized that laboratorians need to lobby local ACO leaders to ensure they are not left out of what appears to be an important new delivery model, especially given that the default mode seems to be laboratories as service contractors rather than value-added providers.

Even without the Medicare ACO program, private payers are driving ACO adoption in some parts of the country at unprecedented rates. James Crawford, M.D., Ph.D., from North Shore LIJ Laboratories (Lake Success, N.Y.), told the Lab Institute audience that he is seeing new ACOs in his region on a monthly basis, representing a growth curve he has never witnessed before.

- ❏ Introduced an advanced payment program for smaller, physician-owned practices and rural hospitals. This provides up-front capital to fund an ACO to be paid back with ACO savings.
- ❏ Dropped as a condition of participation a provision that would have required half of primary care doctors in an ACO to be defined as meaningful users of electronic health records by the start of the second performance year. While no longer a condition of participation, it is retained as a quality performance measure and counts for double the points in terms of quality scoring.
- ❏ Removes a provision that would have required all ACO marketing materials to be approved by CMS prior to distribution.

CMS estimates that 50 to 270 organizations will take part in the shared savings program in its initial three-year phase.

The advance payment ACO model, developed by the CMS Innovation Center, is open only to two types of organizations participating in the Medicare shared savings program:

- ❏ ACOs that do not include any inpatient facilities and have less than $50 million in total annual revenue.
- ❏ ACOs in which the only inpatient facilities are critical access hospitals and/or Medicare low-volume rural hospitals and have less than $80 million in total annual revenue.

Only ACOs that enter the shared savings program in April 2012 or July 2012 will be eligible for advance payments. ACOs that are co-owned with a health plan will be ineligible, regardless of whether they fall into one of the above categories.

For more on ACOs and other coordinated care initiatives sponsored by CMS, go to *http://innovations.cms.gov.*

In conjunction with the final ACO rule, CMS and the Department of Health and Human Services Office of Inspector General released an interim final rule with comment period establishing fraud-and-abuse waivers for ACOs in the Medicare Shared Savings Program. The Department of Justice and the Federal Trade Commission also issued a statement on antitrust enforcement policy regarding ACOs.

Labs Face Big Cuts, *from p. 1*

In a conference call, Cindy Mann, director of the CMS Center for Medicaid and State Operations, said the decisions were difficult, but "we are providing California with the flexibility they have sought to address their difficult budget circumstances."

Some cuts were not approved, she noted, including reductions in payment for home health services and in payments to doctors treating children. It was agreed that cuts in these areas would impede patients' access to care, and state officials withdrew them.

CMS also decided to start a monitoring program in the state to check that the cuts do not affect access, Mann said. The program will follow 23 measures, such as whether the number of doctors in a given area who accept Medi-Cal patients declines. This is the first such program in the nation, she noted.

Labs would be hard hit if the cuts go through, says the California Clinical Laboratory Association (CCLA). Medi-Cal payments are capped at 80 percent of Medicare lab fee schedule rates but can be lower. CCLA says it will continue to work with the Alliance for Patient Care, a statewide coalition formed to protect the Medi-Cal program from cuts, to determine future actions. Physician, pharmacy, and consumer groups have also weighed in against the 10 percent reduction.

Meantime, the U.S. Supreme Court has taken up a case stemming from California Medi-Cal cuts. Physicians, hospitals, and pharmacists in Medi-Cal sued to stop reductions of up to 10 percent imposed by the state legislature in 2008 and 2009 to help resolve the state's budget crisis but without federal approval.

At issue is the broad question of whether courts can stop states from cutting Medicaid payments that allegedly violate federal law, which requires that Medicaid rates be set high enough to get health care providers to participate and serve low-income patients. Before a state can cut the rates, it must study the potential consequences and get federal approval.

While the case involves more than $1 billion in contested reimbursement, the lawsuits against the state of California seek only to affirm the right of providers in the state to sue in federal court. The Supreme Court heard oral arguments in the case, *Douglas v. Independent Living Center of Southern California*, Oct. 3 (*NIR 11, 18/Oct. 6, p. 1*).

G2's 2011 Lab Public Service National Leadership Award

Award recipient Thomas O. Tiffany (center) with Dennis Weissman, founder of Washington G2 Reports (left), and Kevin Ellison, president and CEO of Kellison & Co., which sponsors the annual award.

The recipient of this year's award honoring significant contributions to laboratory medicine and pathology is Thomas O. Tiffany, Ph.D., the CEO of Pathology Associates Medical Laboratories (PAML), based in Spokane, Wash. He received the award, presented by G2 Intelligence and sponsored by Kellison and Co., at a special ceremony held during Lab Institute 2011, Oct. 19-21, in Arlington, Va.

Tiffany has had a distinguished 40-year career in the biomedical industry. He began as a senior research scientist at Oak Ridge National Laboratory in Oak Ridge,

Tenn. For the past 23 years he has served as chief operating officer of PAML, which has grown from 125 employees when he first joined in 1987 as general manager to become today one of the 10 largest reference laboratories in the country with more than 1,600 employees across seven partnerships.

The award recognizes singular accomplishments that directly enhance patient care and the laboratory profession in one or more specific areas: basic and applied research, business creativity and innovations, public policy, and lifetime achievement.

Prior to joining PAML, he held the position of research and development director and subsequently general manager of the MicroChemical Division at Instrumentation Laboratories. He received his doctorate in biochemistry/biophysics from Oregon State University, is board-certified in clinical chemistry, and is a fellow of the National Academy of Clinical Biochemists. He has been published 49 times and holds 15 U.S. patents.

Presentation remarks for this 16th annual award noted, "Tiffany is a true business visionary who developed and successfully implemented an innovative joint venture partnership model with health systems in multiple states that provides laboratory services to more than 100 hospitals nationwide. Having announced his retirement effective the end of this year, our recipient's legacy is certain to live on both within the various organizations he has nurtured and grown over the years as well as in the larger industry in light of his groundbreaking work in partnering with health systems to leverage their outreach testing to achieve a wider strategic purpose."

Dennis Weissman Scholarship Award Presented at Lab Institute 2011

Recipient Scottia Miller and Bob Weathers, vice president of pathology and laboratory medicine for McKesson Revenue Management Solutions. McKesson is a co-sponsor of the scholarship.

The eighth annual Dennis Weissman Scholarship Award for Excellence in Clinical Laboratory Sciences, sponsored by McKesson and G2 Intelligence, was presented to Scottia Miller during G2's Lab Institute held Oct. 19-21, 2011, in Arlington, Va.

The $5,000 scholarship is intended to help develop future leaders and qualified medical laboratory scientists.

Miller, a citizen of the Bahamas, came to the United States three years ago to enter the medical profession, selecting medical laboratory science as her field, and has recently been accepted for the prestigious MLS program at the University of Kentucky in Lexington.

While maintaining a 3.5 grade point average, she has worked in a number of university-related lab positions to help finance her education. Recently, she was an assistant in the department of molecular and cellular biochemistry, and her work in gene isolation related to aging and iron deficiency is soon to be published in conjunction with the senior researcher. She also served as a resident assistant to help pay for room and board.

Advisory on Use of Medicare's Advance Beneficiary Notice

Starting Jan. 1, 2012, providers and suppliers must use the 2011 version of Advance Beneficiary Notice of Noncoverage (ABN) (form CMS-R-131), the Centers for Medicare and Medicaid Services (CMS) has announced.

They may use either the 2008 or 2011 version of the ABN through the end of this year, CMS says, which extended the deadline for mandatory use of the 2011 version to give providers and suppliers with preprinted stockpiles of ABNs enough time to exhaust their supplies. The 2008 and 2011 notices are identical except that the release date of "3/11" appears in the lower left-hand corner of the 2011 version.

Information and a copy of the 2011 version of the ABN (form CMS-R-131) can be found online at http://www.CMS.gov/BNI, *under the "FFS Revised ABN" link.*

However, ABNs issued after Jan. 1, 2012, that are prepared using the 2008 version will be considered invalid by Medicare contractors. 2008 versions issued prior to Jan. 1, 2012, as long-term notification for repetitive services delivered for up to one year will remain effective for the length of time specified on the notice.

The ABN is used by all providers, practitioners, and suppliers paid under Medicare Part B, as well as hospice providers and religious nonmedical health care institutions paid exclusively under Part A.

Upcoming G2 Events

Webinar *(2 p.m. – 3:30 p.m. Eastern)*

Nov. 10

What's New for 2012: The Latest in Lab and Pathology Coding and Reimbursement

Featured speaker:
Diana Voorhees, M.A., CLS, MT, president of DV & *Associates*
G2Intelligence.com/Events/Webinars/detail/1107

Conferences

Dec. 12-14

LabCompete: Laboratory Sales & Marketing

Sheraton Wild Horse Pass Resort
Chandler, Ariz.
www.labcompete.com

Feb. 9-10

Pathology Institute 2012

Program partner: Laboratory Economics
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