G2 INTELLIGENCE

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Congress Heading Toward an Economic 'Fiscal Cliff'

The looming budget crisis includes automatic cuts to Medicare providers and finding offsets to pay for another Medicare physician fee fix and avert a 27 percent cut in these fees on Jan. 1.

Congress returns next month from its August recess facing what Ben S. Bernanke, chairman of the Federal Reserve, has called an economic "fiscal cliff" at the end of this year, but lawmakers aren't expected to decide how to avoid falling off the edge until a lame-duck session after the November elections.

The term refers to the combination of tax increases and spending cuts mandated under current law and set to take effect in January 2013 as well as the need to increase the federal debt ceiling. Lawmakers will have to decide whether to let them stand or cancel some or all of them, thus adding to the federal deficit.

Deep spending cuts (or sequestrations) totaling $1.2 trillion over 10 years, split equally between defense and nondefense spending, are scheduled to kick in under the Budget Control Act of 2011 unless Congress waives this requirement. Under sequestration, Medicare providers, including clinical laboratories and pathologists, are scheduled for a 2 percent cut next year.

Calls have been made in Congress, echoed by the Defense Department, to undo drastic military budget cuts, ratcheting up the pressure to slash nondefense programs, including Medicare.

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Closing the Stark 'Loophole' for In-Office Ancillary Services

Two new articles add more fuel to the drive to remove anatomic pathology from the in-office ancillary services (IOAS) exception in the Stark physician self-referral law. One is published in an online journal from the Center for Strategic Planning at the Centers for Medicare and Medicaid Services (CMS), the other in the Aug. 1 *New England Journal of Medicine*.

The CMS article, "Linkages Between Utilization of Prostate Surgical Pathology Services and Physician Self-Referral," presents a trends analysis based on research published in the April issue of *Health Affairs* that compared Medicare billings and prostate cancer detection rates by self-referring urology groups with those that did not self-refer.

That research, commissioned by the College of American Pathologists and the American Clinical Laboratory Association, suggested that financial incentives prompt self-referring urologists to perform prostate biopsies on men who are unlikely to have prostate cancer.

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Closing the Stark 'Loophole,' *from p. 1*

The results, researchers concluded, support closing the loophole that permits self-referral to in-office pathology laboratories (*NIR, 12, 7/April 12, p. 2*).

The findings in the article in CMS's *Medicare and Medicaid Research Review*, using regression analysis, show that the self-referral share (percentage) of total utilization was associated with significant increases in the use rate of surgical pathology specimens (jars). That rate would be 41.5 units higher in a county where the self-referral share of total utilization was 50 percent compared with a county with no self-referral share.

The conclusion: "Urologist self-referral of prostate surgical pathology services results in increased utilization and higher Medicare spending," suggesting that "exceptions in federal and state self-referral prohibitions need to be reevaluated."

The *New England Journal* article, "A Systemic Approach to Containing Medicare Spending," presents a range of options by experts on how to "bend the health care cost curve," including closing the IOAS loophole and expanding the Stark ban on physician self-referrals to services reimbursed by private insurers. Physicians who use alternatives to fee-for-service payment should be exempt, the authors said, because these methods reduce incentives to increase volume.

How widespread is the trend of tapping the IOAS exception to insource pathology work? According to Laboratory Economics*, an estimated 300 urology groups, 250 gastroenterology groups, and more than 500 dermatology groups operate in-office histology labs. While these arrangements are spread throughout the country, Florida, Ohio, New Jersey, and Arizona are among the states with the most of these labs.*

The recommendations were applauded in an Aug. 2 joint statement from the Alliance for Integrity in Medicare (AIM)—a coalition of pathology, laboratory, radiology, radiation oncology, and physical therapy groups—which urged Congress to pass legislation to remove anatomic pathology, advanced diagnostic imaging, radiation therapy, and physical therapy from the IOAS exception.

"Reforming this policy," AIM stated, "will ensure that patients receive the highest quality and safest health care most appropriate to their needs, rather than care that enriches the revenue streams of referring physicians . . . and also is likely to produce substantial savings to Medicare."

CMS is silent on the IOAS controversy in its proposed Part B physician fee schedule rule for 2013, prompting critics to charge that this leaves the door open for urology, gastroenterology, and dermatology groups to continue to insource pathology work and increase their Medicare revenue stream.

With no regulatory relief in sight, AIM continues to press its case in meetings with members of the House and the Senate. While no specific legislation is yet in the works, key health leaders want to investigate the issue further. Senate Finance Committee Chairman Max Baucus (D-Mont.) and the author of the self-referral ban, Rep. Pete Stark (D-Calif.), the ranking minority member on the House Ways and Means health subcommittee, have asked the Congressional Budget Office to "score" closing the loophole. Scoring is a means of calculating the amount that a proposed measure will either increase or decrease federal spending and tax revenues.

AIM last year submitted to the congressional Joint Select Committee on Deficit Reduction draft legislative language that would exclude anatomic pathology, radiation therapy and supplies, advanced diagnostic imaging, and physical therapy from Stark exceptions for IOAS and physician services (*NIR 11, 10/Oct. 6, p. 3*). In other provisions, the draft would:

- ❑ Create a new exception to permit multispecialty group practices, as defined in the law, to bill and be paid for excluded services without violating the self-referral law.
- ❑ Change regulations to make the technical component of physician pathology services subject to the same supervision requirements as the professional component. They are currently exempt from physician supervision requirements. AIM said this "virtually exempts them from Medicare's anti-markup rules."

However, the select committee adjourned in December after members failed to corral a majority for any deficit-reduction plan.

IOAS Changes: Pro and Con

The Stark physician self-referral law prohibits Medicare and Medicaid referrals of beneficiaries for designated health services to entities with which the physician (or an immediate family member) have a financial relationship (either by ownership interest or compensation arrangements or both) unless it fits within an exception.

Medical specialty practices defend their use of the IOAS exception, saying it enables them to make rapid diagnoses and initiate treatment during a patient's office visit, improves care coordination, and encourages patients to comply with diagnostic and treatment recommendations.

AIM argues that these arrangements flout the rationale behind the exception, namely, "to allow physicians to offer services integral to a single visit to the physician office." A common feature of anatomic pathology, advanced diagnostic imaging, physical therapy, and radiation therapy is "that each requires time to complete outside of an office visit, specialized training, and independent professional judgment to perform."

UnitedHealthcare Backtracks on Pathology TC Payment

Private insurers generally try to align their medical coverage and payment policy with Medicare's. That's what industry analysts expected would happen after Congress eliminated the Medicare pathology technical component (TC) protection as of July 1, 2012. This protection, in place since 1999, allowed certain independent clinical laboratories to bill Part B for the TC. It was long challenged by the Centers for Medicare and Medicaid Services as duplicative payment, arguing that the TC reimbursement is included in the hospital's prospective payment and thus labs should seek TC payment from the hospital.

Reportedly following Medicare's lead, UnitedHealthcare, one of the country's largest insurers, announced earlier this year that beginning July 15, 2012, ambulatory service centers (ASCs) would be treated as a facility place of service (POS 24) when reported on the CMS 1500 claim form and that TC claims for pathology services at ASCs would not be reimbursed.

The College of American Pathologists (CAP) pounced and United reversed course based on additional information, according to CAP's *Statline*. The college pointed out that federal regulations and Medicare claims processing guidelines stipulate that services furnished by an independent lab are not included in the ASC payment.

United has indicated it will make claims processing changes to allow TC payment of pathology lab services when reported with an ASC POS (24) and will announce the policy on its Network Bulletin when the changes are completed. CAP requested that the fix be applied retroactive to July 15.

Legislative Update on Lab, Pathology Priorities

With only a few months remaining before the 112th Congress comes to an end, Medicare reimbursement cuts looming in January 2013 top the legislative agenda for clinical laboratory and pathology advocacy organizations:

- ❑ For labs, it's a projected 4.95 percent cut under sequestration and the lab fee schedule update formula.
- ❑ For pathologists, it's an estimated 27 percent cut under the sustainable growth rate (SGR) formula used to update the physician fee schedule.

But these organizations are pursuing additional priorities reflected in a host of bills awaiting action on Capitol Hill. Below is a look at where they stand as of the start of the August congressional recess.

Only two measures have passed the House and been sent to the Senate (repeal of the medical device excise tax and the Independent Payment Advisory Board (IPAB)); the others are pending at the committee or subcommittee level in either the House or the Senate or both.

CLIA Proficiency Testing Referrals

❑ ***Bill Number/Latest Title: H.R. 6118, Taking Essential Steps for Testing Act of 2012***

Summary: Gives the Centers for Medicare and Medicaid Services (CMS) enforcement discretion to take steps other than revoking a lab's certificate under the Clinical Laboratory Improvement Amendments (CLIA) for violating the prohibition against referral of proficiency testing samples from one clinical laboratory to another for analysis of a test that it is certified to perform in its own facility. Strikes the CLIA statutory language that a lab's certification "*shall* be suspended" and inserts the term "*may* be suspended." Allows CMS to substitute intermediate sanctions where warranted, including a directed plan of correction, civil money penalties, and costs for on-site monitoring or any combination of these.
Sponsor: Rep. Michael Grimm (R-N.Y.). Co-sponsors: 3
Introduced: July 12, 2012
Latest Major Action: Referred to the Committee on Energy and Commerce

❑ ***Bill Number/Latest Title: S. 3391, Taking Essential Steps for Testing Act***

Summary: Same as H.R. 6118 above.
Sponsor: Sen. Amy Klobuchar (D-Minn.). Co-sponsors: 2
Introduced: July 17, 2012
Latest Major Action: Referred to the Committee on Health, Education, Labor, and Pensions

Regulation of Lab-Developed Tests

❑ ***Bill Number/Latest Title: H.R. 3207, Modernizing Laboratory Test Standards for Patients Act of 2011***

Summary: Gives CMS the lead authority over regulating laboratory-developed tests (LDTs), not the Food and Drug Administration, which has asserted its en-

forcement authority over them and is preparing draft guidance for a risk-based regulatory framework. Requires CMS to establish a single publicly accessible test registry data bank of LDTs and direct-to-consumer DNA tests, which shall include information on the purpose of each test, the claimed use or uses of each test, and information regarding the analytical validity of each test. Requires that CMS be notified before marketing such a test, after any significant modification to it, and if evidence of clinical validity is adequate to support one or more of the claimed uses.
Sponsor: Rep. Michael C. Burgess (R-Texas). Co-sponsors: 17
Introduced: Oct. 14, 2011
Latest Major Action: Referred to the Energy and Commerce Subcommittee on Health

Medical Device Excise Tax

❑ ***Bill Number/Latest Title: H.R. 436, Health Care Cost Reduction Act of 2012***

Summary: Includes provision to amend the Internal Revenue Code to repeal the 2.3 percent excise tax on medical devices.
Sponsor: Rep. Erik Paulsen (R-Minn.). Co-sponsors: 240
Introduced: Jan. 25, 2011
Latest Major Action: Passed the House amended June 7, 2012, read the second time June 12, 2012, and placed on Senate Legislative Calendar under General Orders, Calendar No. 427

❑ ***Bill Number/Latest Title: S. 17, Medical Device Access and Innovation Protection Act***

Summary: Same provision as in H.R. 436 above.
Sponsor: Sen. Orrin G. Hatch (R-Utah). Co-sponsors: 33
Introduced: Jan. 25, 2011
Latest Major Action*:* Referred to the Committee on Finance

❑ ***Bill Number/Latest Title: S. 262, A Bill to Repeal the Excise Tax on Medical Device Manufacturers***

Summary: Same provision as in S. 17 above.
Sponsor: Sen. Scott P. Brown (R-Mass.). Co-sponsors: 3
Introduced: Feb. 3, 2011
Latest Major Action: Referred to the Committee on Finance

Pathology E-Health Record Penalties

❑ ***Bill Number/Latest Title: H.R. 4066, Health Information Technology Reform Act***

Summary: Amends Titles XVIII (Medicare) and XIX (Medicaid) of the Social Security Act to exclude pathologists from Medicare and Medicaid incentive payments and, in particular, penalties relating to the meaningful use of electronic health records.
Sponsor: Rep. Tom Price (R-Ga.). Co-sponsors: 33
Introduced: Feb. 16, 2012
Latest Major Action: Referred to Committees on Energy and Commerce and on Ways and Means

(*Note:* at press time, a Senate version of the bill is to be introduced by Johnny Isakson (R-Ga.), the College of American Pathologists reports, adding that he is also seeking a Democratic co-sponsor.)

Independent Payment Advisory Board

❑ ***Bill Number/Latest Title: H.R. 5, Protecting Access to Healthcare Act***

Summary: Repeal of the IPAB included in this bill that puts major limits on medical malpractice lawsuits brought in state court, including a cap of $250,000 for noneconomic damages, and also preempts existing state laws. The IPAB, created by

the health care reform law, is a 15-member board, appointed by the president and subject to Senate confirmation. Beginning in 2014, in any year in which the Medicare per capita growth rate exceeds a target growth rate, the IPAB must recommend program spending reductions that would become law unless Congress passes an alternative. The IPAB cannot make recommendations that would ration care, increase Medicare beneficiary cost sharing, or otherwise restrict benefits or modify eligibility criteria.

Sponsor: Rep. Phil Gingrey (R-Ga.). Co-sponsors: 134
Introduced: Jan. 24, 2011
Latest Major Action: Passed the House amended on March 22, 2012. Read the second time on April 16, 2012, and placed on Senate Legislative Calendar under General Orders, Calendar No. 353

Medicare Physician Payment Fix

❑ ***Bill Number/Latest Title: H.R. 5707, Medicare Physician Payment Innovation Act of 2012***

Summary: Amends Title XVIII (Medicare) of the Social Security Act to eliminate the sustainable growth rate (SGR) system from the formula for determination of the fee schedules for such services. Pays for SGR repeal by using unspent funds from the wars in Afghanistan and Iraq. Keeps physician fees in 2013 at their 2012 levels. Increases fees, beginning in 2014, with an annual 0.5 percent update for four years (2.5 percent for primary care). During this four-year period, directs CMS to expand various coordinated care delivery and payment models that reward quality outcomes and cost efficiencies as alternatives to traditional fee-for-service payment based on volume. Freezes the fee schedule update for 2018 at 0 percent. Prescribes updates of -2 percent in 2019, -3 percent in 2020, -4 percent in 2021, and -5 percent in 2022. Freezes update again, beginning in 2023.

Sponsors: Reps. Allyson Y. Schwartz (D-Pa.) and Joseph J. Heck (R-Nev.). Co-sponsors: 28
Introduced: May 9, 2012
Latest Major Action: Referred to the Committees on Energy and Commerce and on Ways and Means

❑ ***Bill Number/Latest Title: H.R. 6142, Assuring Medicare Stability and Access for Seniors Act of 2012***

Summary: Provides a one-year extension of physician payment rates, setting the single conversion factor at 0 percent for 2013.
Sponsor: Rep. Michael C. Burgess (R-Texas). Co-sponsors: 4
Introduced: July 18, 2012
Latest Major Action: Referred to House Committees on Energy and Commerce and on Ways and Means

❑ ***Bill Number/Latest Title: S. 3337, Access to Physicians in Medicare Act of 2012***

Summary: Includes provisions to eliminate the SGR formula and to set the update for physician services for 2013 and each subsequent year at the lesser of the annual percentage increase in the consumer price index for urban wage earners and clerical workers for the year or 3 percent. Also repeals health care coverage expansion in Medicaid and state-based exchanges enacted in the health care reform law.

Sponsor: Sen. Rand Paul (R-Ky.). Co-sponsors: 0
Introduced: June 25, 2012
Latest Major Action: Referred to the Committee on Finance G2

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To address such concerns, Congress, in sending H.R. 5872 to the president on July 27, directed the administration to present, within 30 days of enactment, a detailed report on how all spending categories will be affected by sequestration.

Adding to the sequestration threat to the health care industry is the 27 percent cut in Part B physician fee schedule payments on Jan. 1. While industry sources think only another short-term fix is in the cards, it will be costly—a one-year reprieve would cost $18.5 billion, according to the Congressional Budget Office—and paying for it could mean savings offsets elsewhere in the Medicare budget.

"Labs face our own fiscal cliff," Jason DuBois, vice president of government relations at the American Clinical Laboratory Association (ACLA), tells *NIR*. In 2013, Medicare Part B lab fee schedule rates are due to be cut by 4.95 percent—a combination of the sequestration, the revised fee schedule update formula, and a 2 percent cut to help pay for this year's physician fee fix. Over the next 10 years cumulative reductions are slated to total some 23 percent, according to ACLA.

ACLA has urged Congress to spare labs from more cuts "in light of the stark differences between historical updates to payments for clinical labs compared to other providers." In a letter sent earlier this year, ACLA noted, "The cumulative growth in Medicare provider updates from 1995 to 2011 was 51.4 percent for inpatient hospital care, 35.6 percent for outpatient care, and 27.9 percent for physician services, but only 7.7 percent for clinical labs." The fallout of fee cuts would be "most devastating," ACLA warned, on thousands of smaller labs across the country that are often the sole provider of lab services to Medicare's most vulnerable beneficiaries in nursing homes and other similar settings.

To emphasize that point to policymakers, the National Independent Laboratory Association (NILA) has commissioned George Washington University to conduct an independent survey of the community laboratory industry. The timing is critical, NILA said. "For independent community labs, the accumulation of reduced payments from health care reform, the 2012 physician pay cut delay, and anticipated cuts from sequestration cannot be absorbed. The threat of additional cuts from another physician pay fix by the end of 2012, and offsets Congress must find for other Medicare extenders, threatens the continued existence of these labs."

Mayo Clinic Settles Surgical Pathology Fraud Allegations

The Mayo Clinic and three related entities Aug. 2 agreed to a $1.26 million settlement in a federal government lawsuit alleging that Mayo submitted false claims for payment to Medicare and Medicaid for surgical pathology services that were not provided.

The suit, brought in 2007 by whistleblowers under the False Claims Act, targeted Mayo pathology labs in Rochester, Minn., alleging that Mayo knowingly billed for the preparation and examination of permanent human tissue slides it never made or examined.

After receiving a subpoena over such billings, Mayo paid approximately $263,000 to the government. The settlement reflects this payment and an additional $1 million. The whistleblowers in the case, *United States ex rel. Ketroser, et al. v. Mayo Foundation, Case No. 07-cv-4676 (D. Minn.)*, will get $229,822 from the monetary recovery. Mayo will pay their attorneys' fees and legal expenses.

Medicare *Claims Advisory*

Interest Rate on Overpayments, Underpayments Rises to 11%

The rate of interest that Medicare will pay you for claims that were underpaid, or collect from you for claims that were overpaid, has increased to 11 percent as of July 18, up from 10.875 percent in effect since April 18.

The latest quarterly rate update was announced by the Centers for Medicare and Medicaid Services in Transmittal 211, Change Request 7572.

Medicare Regulation 42 CFR §405.378 provides for the assessment of interest at the higher of the current value of funds rate (1 percent for calendar year 2012) or the private consumer rate as fixed by the Department of the Treasury. The Treasury has notified the U.S. Department of Health and Human Services that the private consumer rate has been changed to 11 percent.

The highest interest rate in the past decade was in early 2001, 14.125 percent, but for most of the years since, the rate has hovered between 10.50 percent and 12 percent.

Reminder: August is a one-issue month for *NIR*.

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Aug. 21

Beyond Meaningful Use: How to Improve Reliability and Save Time through Automated Electronic Results Reporting

Featured Speaker:
Sherri Huber, Laboratory Quality and Informatics Coordinator, HealthPartners Central Laboratory

Conferences

Sept. 13-14

MDx *NEXT*: Reimbursement Realities, Payment Priorities, and the Future of Genomic Medicine

University Club of Chicago
Chicago
www.mdxconference.com

Oct. 10-12

30th Anniversary Lab Institute *Separating the Best From the Rest*

Crystal Gateway Marriott
Arlington, Va.
www.labinstitute.com

Nov. 14

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