G2 INTELLIGENCE

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Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 33rd Year of Publication

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Finding a Way Forward on Medicare Physician Payment Reform

Under the current fee update formula, Medicare physician payments are to be cut by nearly 31 percent in 2013. Congress is expected to block the cut but sentiment is growing to end the cycle of short-term fee fixes to which lawmakers have resorted since 2003 in favor of a complete payment system overhaul.

Bipartisan unhappiness with the current Medicare physician fee-for-service payment system has made news on Capitol Hill over the past several weeks. Legislation has been introduced in the House to scrap the system, while in both the House and the Senate key committees with jurisdiction over Medicare have asked for outside help in coming up with an alternative as well as short-term improvements until an alternative is approved.

The cause of the discontent is the system's reliance on the sustainable growth rate (SGR) formula used to update physician fees annually. Enacted in the 1997 Balanced Budget Act, the aim of the SGR is to limit growth in Medicare spending for physician services to a target spending level roughly tied to the nation's economic growth. By 2002 actual cumulative spending for physician services exceeded the target levels, and further growth in the volume and intensity of physician services subsequently widened the gap between actual and target spending, triggering yearly negative updates.

In 2002 a fee cut of 4.8 percent was allowed but from 2003 to 2012 Congress has stepped in with 14 short-term patches to override the scheduled SGR reductions. This year it blocked a 27.4 percent cut and froze the fee update at 0 percent. In cancelling the cut for 2012, lawmakers required the Department of Health and Human Services and the Government Accountability Office to submit reports on a long-term replacement for the SGR system.

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New Start Date for MolDx Program

Since our last issue went to press, the Medicare contractor, Palmetto GBA, announced a new start date for its controversial program, called MolDx, to determine coverage and payment for molecular diagnostic tests performed and billed in Medicare's Jurisdiction 1 Part B.

For claims received on or after June 1, 2012, Palmetto will reject all claims for tests submitted without either an assigned McKesson Z-Code or a Palmetto Test Identifier (PTI) that has been entered into the comment/narrative field of the claim form. The contractor had previously set May 7 as the start date for adjudicating MolDx claims.

If a PTI or Z-Code is pending or the laboratory provider is unable to update internal systems for claims submission, Palmetto will accept a fax and a completed Palmetto GBA Test Identifier Application Form with each claim.

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Medicare Physician Payment Reform, *from p. 1*

However, "to address the accumulated difference between actual and allowed spending levels, the current SGR mechanism will require a fee schedule reduction in 2013 of an estimated 30.9 percent," according to the 2012 Medicare Trustees Report.

While Congress is not expected to allow such a steep cut to take effect, lawmakers face two big obstacles to an overhaul of the SGR system: the cost of SGR repeal (an estimated $300 billion over 10 years, a figure that will only increase the longer Congress delays) and agreement on the reimbursement mechanisms that should take its place.

House Bill Seeks SGR Repeal

Reps. Allyson Y. Schwartz (D-Pa.) and Joseph J. Heck (R-Nev.) on May 9 introduced the Medicare Physician Payment Innovation Act, which would repeal the SGR formula and maintain 2012 physician payment levels through 2013, followed by a four-year transition to a system in which pay levels would be raised 0.5 percent annually before a new system is implemented in 2018. The bill would require the Centers for Medicare and Medicaid Services (CMS) to test and evaluate possible new payment systems.

But the bipartisan measure would pay for SGR repeal by using unspent funds from the wars in Afghanistan and Iraq, an idea that has already been considered in Congress this year only to run into opposition from numerous lawmakers.

"Don't succumb to issue fatigue. It's critically important that physicians continue to be engaged with the SGR issue."

—Cecil B. Wilson, immediate past president of the American Medical Association, speaking at the College of American Pathologists 2012 Policy Meeting, held May 7-9 in Washington, D.C.

Nonetheless, the other provisions of the bill offer a legislative framework to replace the status quo. Schwartz said in a statement, "Now is the time to fix the broken system once and for all by moving forward with a payment system that rewards quality and value, saves lives, and assures seniors' access to the care they need." Heck echoed this in his statement, "The current SGR formula has consistently produced unrealistic spending targets, which have threatened access to care for our seniors. This bill provides long-overdue certainty for physicians, and Medicare beneficiaries."

House Panel Invites Input on Payment Reform

Providing certainty to the Medicare patient-physician relationship is a key point in the April 27 letter sent to some 70 physician groups by the House Ways and Means Committee's 22 Republican members. Responses are requested by no later than May 25.

"This committee recognizes the urgent need to transform Medicare's physician payment system to one that rewards physicians for high-quality and efficient care," the letter notes. "Experts agree that there is no 'one size fits all' solution and that a reformed payment system will require some flexibility to account for the diverse needs of both beneficiaries and physicians."

The letter invites comments on value-based measures and practice arrangements in the following areas:

- ❑ Incorporating rewards for quality and efficiency in the Medicare program, including experiences with non-Medicare payers, in such areas as outcome measures, evidence-based guidelines, patient registries, and electronic health records.
- ❑ Having alternatives to fee-for-service, such as shared savings models and bundled payments, which physicians have experience with or are developing with private payers.

- ❑ Removing regulatory and administrative barriers that obstruct fundamental delivery system reform or that take time away from seeing patients and increase costs to Medicare.

Last year the bipartisan leadership of the House Energy and Commerce Committee and its health subcommittee also sent a letter to 51 physician organizations inviting proposals for a permanent, sustainable Medicare physician fee fix and followed up with a hearing on the issue (*NIR 11, 9/May 12, p. 1*). The consensus that emerged was that a permanent fix would require repeal of the SGR; replacing fee-for-service with a menu of reimbursement options tailored to the medical specialty, its capabilities, and the patient population served; and stable annual fee increases to ensure a smooth transition to a new payment system beginning in 2017. The fee updates should be in line with the growth in medical practice costs, said the American Medical Association (AMA). The American College of Surgeons proposed separate service category growth rates for like services with increased payments for primary care.

Medicare expenditures for physician services totaled $67.6 billion in 2011, according to the latest official data in the 2012 Medicare Trustees Report. For hospitals, the total was $167.8 billion; for private health plans (Part C), $123.7 billion; for prescription drugs (Part D), $66.7 billion; for skilled nursing facilities, $32.9 billion; for home health services, $19.6 billion; and for the "other services" category, $62.9 billion.

In commenting on payment models, physician groups and health policy experts advised Energy and Commerce members to consider some that are being tested in the private sector or in Medicare, such as accountable care organizations, bundled payments (per episode of care or a global payment covering all services a patient needs for a given period of time), a team-based primary care medical home model, and private contracting. The AMA cautioned, however, that in many cases major investments are required to retrieve and analyze data, spot inappropriate utilization, and coordinate patient care. "With the vast majority of medical practices qualifying as small businesses, it is important to put in place transitional models that will help small and solo practices develop these capabilities."

What to Do While Waiting for a Fix

The Senate Finance Committee on May 10 held the first of a series of planned roundtables on physician payment reform and got an earful from four former CMS administrators who served under Republican and Democratic presidents.

No alternative to the current SGR system is ready to be launched, they pointed out, but until one is developed Congress could direct CMS to do more to align Medicare payments with physician treatment patterns, especially those in small-group practices, and reward physicians for providing better, not more, care. They also advised against repealing the SGR without having some mechanism in place to control Medicare spending growth for physician services.

The former administrators included Gail Wilensky, who served under president George H.W. Bush; Bruce Vladeck, who served under president Bill Clinton; and Thomas Scully and Mark McClellan, who served under president George W. Bush.

Among the suggestions they offered to bolster coordinated care:

Scully: Capitation is the way Medicare and other payers are trending.

Vladeck: Replace the SGR with a system that updates payments to physicians in a way similar to other Medicare providers. Develop separate payment conversion factors to reward primary care and office visits. Bundle different services into code

groups and pay doctors 95 percent of what they would have been paid separately for each code. Allow physicians a choice of being paid under a bundled payment system or fee-for service.

Wilensky: Short-term improvement options include setting the SGR at the level of physician practices to link payment to physician practice behavior. Develop aggregate payment systems, beginning with payments that cover all of the services that physicians provide for chronic diseases as well as bundled payments for high-cost, high-volume interventions.

McClellan: Adopt bundled payment models under Medicare. Physicians are already working on these in the private sector and CMS should tap their experience.

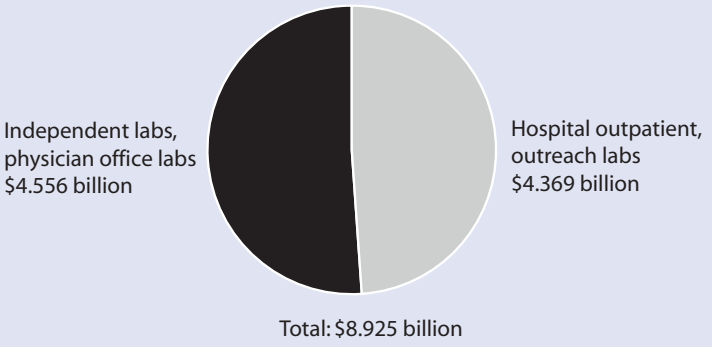
Looking down the road, the four former CMS administrators foresaw a new Medicare physician payment system that, if current trends in coordinated care payment and delivery models pan out, will incorporate capitation, bundled payments, and performance measures that hopefully will improve outcomes for beneficiaries and control program costs.

Part B Lab Spending Totaled $8.9 Billion in 2011

Medicare spending on Part B clinical laboratory services totaled $8.925 billion in calendar year 2011, essentially flat from the previous year, according to data from the 2012 Medicare Trustees Report, prepared by actuaries at the Centers for Medicare and Medicaid Services.

Intermediary labs (hospital lab outpatient and outreach) accounted for $4.369 billion of Part B lab spending in 2011, up from $4.131 billion in 2010 and $3.999 billion in 2009.

Part B Lab Outlays, 2011



Source: 2012 Medicare Trustees Report, Table IV.B6

Carrier labs (independent labs and physician office labs) accounted for $4.556 billion in 2011, down from $4.808 billion in 2010 and $4.671 billion in 2009.

Part B lab services represented 1.6 percent of overall Medicare expenditures in 2011. Between 2006 and 2011 lab expenditures rose an average 4.3 percent per year, compared with an average growth of 6.1 percent per year for total Medicare spending over that same period.

Total Medicare spending in 2011 reached $549.1 billion, up 5 percent from $522.9 billion in the previous year. The total expenditures for 2012 are projected to reach $586.1 billion.

In 2011 the number of beneficiaries increased to 48.7 million compared with 47.6 million in 2010 and 46.3 million in 2009. In 2012 the total is projected to rise to 50.7 million.

Over the next 10 years , 2011-2021, the annual growth in total Medicare spending will slow from an average 8.1 percent to an average 6.2 percent, the trustees' report projects. However, this is based in part on scheduled physician payment reductions, which Congress is not likely to allow (including a cut of 30.9 percent in 2013).

The report is available at *https://www.cms.gov/ReportsTrustFund/downloads/tr2012.pdf.*

New Start Date for Molecular Diagnostics Program, *from p. 1*
However, as currently planned, for claims received on or after Sept. 1, 2012, the Test Identifier Application Form will no longer be available and providers must submit the required information in its entirety attached to each submitted MolDx service.

Under MolDX, all labs that perform molecular diagnostic testing and bill in the Medicare Jurisdiction 1 Part B region (encompassing California, Nevada, Hawaii, and the Pacific territories of American Samoa, Guam, and the Northern Marianas) must register each assay and, if applicable, be assigned either a McKesson Z-Code or a Palmetto Test Identifier and submit test information and supporting evidence (though certain tests are exempt—see below).

MolDx Program: Types of Testing Affected

Exempt (no unique identifier or technical assessment required)	*Unique identifier required (Z-Code or PTI), but no technical assessment*	*Unique identifier (Z-Code or PTI), technical assessment required**
• Tests described by a single Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code and submitted with one unit of service • Infectious disease testing (CPT codes 87001-87905) • Cytogenetics (CPT 88230-88291) • Surgical pathology (CPT 88300-88372) • Flow cytometry (CPT 88182-88189) • Immunochemistry (CPT 88342) • In situ hybridization (CPT 88365) • Analyte-specific reagents • Research use only reagents	• 101 new CPT molecular diagnostic codes • FDA-cleared or -approved tests (unmodified) • Current New York state (NYS) approved tests • Grandfathered NYS tests developed prior to 2003 • National Institutes of Health Genetic Testing Registry • Tests assessed by an independent review entity, such as United States Diagnostic Standards • Tier 2 molecular pathology procedures (American Medical Association) • Local coverage determination by Palmetto GBA or article. For example, tumor of origin assays, Oncotype DX Breast™, Oncotype DX Colon™, Allomap™, HERmark™	• A laboratory-developed test (LDT) producing a single result and billed with multiple CPT codes, including any combination of the following: – Methodology-based stacking codes (CPT 83890-83914) – Microarray codes (CPT 88384-88386) – Microdissection codes (CPT 88380-88381) – Other pathology or laboratory codes not otherwise specified (CPT 84999, 85999, 86849, 87999) • Molecular diagnostic test or LDT that provides: – Diagnostic determination – Prognostic or predictive determination – Risk assessment – Screening • Pathology/laboratory CPT codes not otherwise classified (NOC codes) • FDA-cleared or -approved tests (modified)

** Technical assessments of test information and supporting evidence will be provided by subject matter experts in academia and industry, Palmetto said. They will sign confidentiality agreements and can access only the data that Palmetto gives them.*

Source: Palmetto GBA. CPT codes © American Medical Association

Per Capita Health Spending Rose 3.3 Percent In 2010 Due to Provider Price Increases

Per capita health spending among those younger than 65 grew 3.3 percent in 2010, mostly as a result of provider price increases and not more utilization of services by patients, according to a report released May 21.

The report by the Health Care Cost Institute (HCCI) found that per capita health spending grew at nearly three times the rate of inflation from 2009 to 2010. The rise in costs followed spending increases of 6 percent in 2008 and 5.8 percent in 2009, HCCI said in *Health Care Cost and Utilization Report: 2010.*

HCCI was founded in September 2011 as a nonprofit organization tasked with making health care data available for research. This is its first report.

The report found that hospital and ambulatory care facility prices rose by 5.1 and 10.1 percent, respectively, in 2010. Increases in facility prices were offset by decreases in the number of inpatient admissions (minus 3.3 percent) and use of outpatient facilities (minus 3.1 percent), it said.

During the same period, the use of laboratory and pathology services increased by 2.4 percent.

The use of health care services declined in 2010, according to the report. Usage fell by more than 5 percent for medical inpatient admissions, emergency room visits, primary care provider office visits, and radiology procedures, it said. However, during the same period, the use of laboratory and pathology services increased by 2.4 percent.

Each insured person on average filled more than nine prescriptions in 2010, the report said. The number of brand-name prescriptions dropped by nearly 4 percent, while the number of generic prescriptions increased by 2.5 percent, it added.

The institute found that per capita spending on health care services averaged $4,255 in 2010, up 3.3 percent from 2009. Per capita expenditures varied, with people ages 55 to 64 paying $8,327 and people younger than 18 paying $2,123.

Youth Spending

Per capita spending among those 18 and younger grew faster than any group younger than 65, the report found. Overall health spending in 2010 among the estimated 156.5 million people with employer-sponsored group insurance increased, rising 2.5 percent to about $666 billion, the report said.

The report found that patient cost sharing rose 7.1 percent in 2010, to $689. The average price for a hospital stay was $14,662 in 2010, 5.1 percent more than the previous year, and the average cost for an emergency room visit rose to $1,327, an 11 percent increase from 2009. The average out-of-pocket price of a hospital stay rose 10.7 percent from $632 in 2009 to $700 in 2010, the report found.

The institute reported that prescription drug prices increased from $80 per prescription in 2009 to $82 in 2010. Brand-name drug prices increased 13 percent from 2009 to 2010, while generic drug prices decreased 6.3 percent, it added.

The price of professional procedures that include physician visits, laboratory tests, and diagnostic imaging increased 2.6 percent in 2010, while the cost of a physician office visit rose more than 5 percent.

The report is available online at *www.healthcostinstitute.org/report*.

CMS Announces New Waived Tests, Billing Codes

The July 1, 2012, update to the list of tests waived under the Clinical Laboratory Improvement Amendments (CLIA) includes 11 more devices, the latest approved by the Food and Drug Administration (FDA) for this category. New waived tests are approved on a flow basis and are valid as soon as approved.

The Centers for Medicare and Medicaid Services cautions that when billing for the tests below, you must use the QW modifier so your local Medicare contractor can recognize the code as waived under CLIA. Prior to payment approval, claims are checked for waived testing certification.

Below are the latest tests approved by the FDA as waived under CLIA.

CPT CODE	EFFECTIVE DATE	DESCRIPTION
G0434QW	April 22, 2011	Diagnostic Test Group Clarity Multiple Drug Screen Cups
87804QW	Dec. 9, 2011	BD Veritor System for Rapid Detection of Flu A+B (for use with nasal and nasopharyngeal swabs) {includes a Reader}
G0434QW	Dec. 14, 2011	Alere Toxicology Services Alere iCassette DX Drug Screen
82055QW	Jan. 6, 2012	Jant Pharmacal Corp. Accustrip Saliva Alcohol Test Strip
82055QW	Jan. 6, 2012	Alfa Scientific Designs Inc. Oral-View Saliva Alcohol Test Strip
83861QW	Jan. 23, 2012	TearLab Corp. TearLab Osmolarity System
G0434QW	Jan. 26, 2012	Alere iCassette Drug Screen
87804QW	Jan. 27, 2012	Alere Influenza A & B Test (for use with nasal Swabs only)
87808QW	Feb. 3, 2012	Sekisui Diagnostics LLC, OSOM Trichomonas Rapid Test
87880QW	Feb. 3, 2012	Sekisui Diagnostics LLC, OSOM Ultra Strep A Test
87880QW	March 1, 2012	Sekisui Diagnostics LLC, OSOM Strep A Test {direct from throat swab}

Your carrier or Medicare Administrative Contractor is not required to search its files to either retract payment or retroactively pay claims; however, it should adjust claims you bring to their attention.

White House Urges Vote on CMS Nominee

The White House May 22 urged the Senate to act on the nomination of Marilyn Tavenner, President Obama's choice to head the Centers for Medicare and Medicaid Services (CMS), despite reports that Senate Democrats have decided to forgo a confirmation hearing because of Republican opposition.

Senate Finance Committee Chairman Max Baucus (D-Mont.) said he will not schedule a confirmation hearing for Tavenner. He expressed doubt that she could win the 60 votes needed in the Senate to overcome a likely GOP filibuster against her confirmation, according to reports published May 21.

Obama nominated Tavenner, CMS's acting administrator, in November 2011 to replace Donald Berwick, who had held the position through a recess appointment. Berwick, who left the post in December, also failed to receive a confirmation vote in the Senate, with GOP opposition centered on remarks he made praising the British health care system.

Tavenner, prior to becoming acting administrator in late 2011, was CMS's principal deputy administrator, the agency's second-ranking official. She oversaw CMS policy development and implementation, as well as management and operations.

NILA to Survey Labs About Cuts, Business Practices

The National Independent Laboratory Association (NILA) is preparing to launch a survey of small and midsized clinical laboratories that is designed to provide insight into a number of areas, including the impact of Medicare payment cuts, business practices, and profit margins. Results of the survey, expected in September, will be shared with congressional lawmakers in an effort to stave off further reductions in Medicare payment for laboratory services, according to a spokesperson for NILA and the American Association of Bioanalysts.

Currently labs face cuts in Medicare payments approaching 23 percent over the next 10 years. The reductions come from a combination of three things: the revised annual update formula for the Part B lab fee schedule, enacted as part of the Patient Protection and Affordable Care Act of 2010 and effective in 2011; the 2 percent cut in 2013 to help pay for a physician fee fix enacted as part of the Middle Class Tax Relief and Job Creation Act of 2012; and the 2 percent automatic cut (or sequestration) over the next 10 years required by the Budget Control Act of 2011. Congress will be looking for additional Medicare savings later this year as it faces the expiration of the Bush tax cuts and expiration of the debt ceiling expansion.

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