G2 INTELLIGENCE

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

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Vol. 13, Iss. 9, May 9, 2013

CMS Publishes Interim Molecular Pathology Pricing

For more on pricing of molecular pathology codes, see G2 Intelligence's newest report: Medicare's New Payment System for Molecular Tests: Coding Methodology, Reimbursement Strategies, Rate Updates. *Purchase of the report, available at* www.G2Intelligence.com/MDxPayment Guide.com, *includes two updates with interim MAC pricing and final pricing for 2014.*

The Centers for Medicare and Medicaid Services (CMS) on May 9 published interim pricing for 114 new molecular pathology CPT codes developed by its Medicare administrative contractors (MACs). Industry groups hope the release will trigger MAC payment to labs that have not been paid for molecular testing performed since Jan. 1.

While many of the interim prices had been released previously by individual MACs, CMS's publication of all the prices officially launches a 60-day comment period. CMS is expected to release final pricing in September.

The pricing release also includes "gapfill rationale methodology" from five contractors—CGS, WPS, Noridian, First Coast, and Palmetto. While CMS had promised that all contractors would provide rationale methodology that would explain how they arrived at their prices, many provided no rationale whatsoever. In three of the five instances, rationale is only given for why a particular code is not covered (i.e., not medically necessary, investigational, or screening).

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CAP Seeks Carve Out From EHR Safe Harbor

The College of American Pathologists (CAP) is urging the Department of Health and Human Services (HHS) to carve out laboratories and pathologists from a proposed extension of the safe harbor exception for donations of electronic health records (EHRs).

In an April 22 letter to HHS, the college urged caution in using the exception to incentivize further interoperability "as the laboratory and pathology communities have seen significant abuses of these exceptions."

The letter was sent in response to proposed rules published in the April 10 *Federal Register* that would extend the sunset date for EHR exceptions under the Stark law and the anti-kickback safe harbor. The Centers for Medicare and Medicaid Services and the HHS Office of Inspector General have proposed extending the safe harbor until Dec. 31, 2016. It currently is scheduled to expire at the end of 2013.

"The divergence between current laboratory EHR donation practices and those originally contemplated and intended under the safe harbor when established in 2006 is significant," writes CAP. "It results

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First Coast, one of the most recent MACs to announce pricing, is the only contractor that actually explained how it determined pricing. First Coast serves Florida, Puerto Rico, and the U.S. Virgin Islands. First Coast established six payment rules (a-f), many of which deferred to the Palmetto GBA rate or the rate suggested by the American Medical Association (AMA).

For example, First Coast's payment rule C states, "Single source test: allow at the AMA suggested rate if available, if not allow at Palmetto rate, if there is not an established rate then allow at the 2012 stacking code rate."

MOPATH PRICING (selected codes)		
CPT CODE, TEST	***PALMETTO REVISED***	***FIRST COAST***
81210, BRAF	$97.45	$60.12
81226, CYP2D6	$426.43	$505.76
81227, CYP2C9	$169.50	$73.79
81235, EGFR	$225.00	$108.19
81241, F5	$78.39	$41.79
81270, JAK2	$82.88	$78.44
81275, KRAS	$246.00	$156.71
Sources: G2 from XIFIN and First Coast. CPT codes © American Medical Association.		

In many cases, First Coast's pricing is below the revised prices published by Palmetto GBA in April (*NIR*, 13,8/April 25, p. 1), although in a few instances it is higher.

For example, First Coast priced CPT code 81235 (EGFR) at $108.19 while Palmetto's revised price is $225. However, First Coast priced CPT code 81226 (CYP2D6) at $505.76 compared to Palmetto's revised price of $426.43.

Many other MACs also did not price certain CPT codes but did not provide rationale as to why they did not assign a price. In some cases, such as for the BRCA 1 and 2 tests, testing is performed by only one company and claims filed in only one jurisdiction.

Palmetto GBA, which serves California, Nevada, Hawaii, and the U.S. Pacific territories, noted in its rationale that it "applied multiple methodologies appropriate to the specific test to determine an equitable value for each submitted test." It referred those wanting more details to its molecular diagnostic service program, which it launched last year.

Payment rates for specific codes vary widely by MACs, which had led many industry groups to question the methodologies the contractors used to arrive at prices. For example, CPT 81226 (CYP2D6) ranges in price from $50 to $505.76. CPT 81265 (STR markers specimen analysis) ranges from $123 to $470.24.

Labs and industry groups have criticized the gap-fill process for molecular pathology codes since CMS announced it late last year. Many have complained that the gap-filling process has turned into a repricing exercise when it was supposed to be a coding initiative. The groups have been lobbying lawmakers to intervene on the behalf of labs, many of which have not been paid for molecular testing since the new codes went into effect. One group reportedly is looking into legal action against CMS for failing to meet its statutory obligations.

White House 'Doc Fix' Language Mirrors House Proposal, Raising Hopes for Action

Language in President Obama's fiscal year 2014 budget proposal on fixing Medicare's physician payment system is strikingly similar to that being used by House Republicans, which could add further momentum to the drive to adopt a permanent fix this year, according to physician and stakeholder groups.

Stakeholders say language in the White House plan, released April 10, in many ways mirrors that being used by House Republicans on such subjects as allowing for a period of stable payments while new payment models are developed and implemented, and linking payments to the delivery of quality care.

"The administration supports a period of payment stability lasting several years to allow time for the continued development of scalable accountable payment models," the White House budget plan says. "Such models can take different forms, but all will have several common attributes such as encouraging care coordination, rewarding practitioners who provide high-quality, efficient care, and holding practitioners accountable through the application of financial risk for consistently providing low quality care at excessive costs."

Despite similarities between the permanent physician pay fix proposals by the White House and House Republicans, stakeholders say significant hurdles to creating a new system remain, including how it will be paid for. The Department of Health and Human Services has not yet devised a way to pay for a "doc fix."

The House Energy and Commerce and Ways and Means committees have released the second draft of a permanent physician payment fix plan and say they hope to have legislation on the House floor by the August congressional recess. Their draft contains language on implementing quality-of-care reimbursement measures that also reward providers for delivering high-quality care.

Significant Similarities

The language similarities between the White House and congressional proposals "is significant because it means, conceptually, the administration accepts the same path towards a permanent fix as do the House committees of jurisdiction," said Julius Hobson, a policy adviser at Polsinelli Shughart PC in Washington, D.C.

The White House language "is also significant because its timing comes early enough in the year to provide momentum towards a final solution," Hobson added. He noted, however, that "as always . . . much will depend on the budget offsets proposed to pay for a permanent fix."

Dan Boston, executive vice president of consultant Health Policy Source Inc., said, "The administration's reinforcing the House Ways and Means and Energy and Commerce efforts on [the sustainable growth rate formula] can only further reinforce the momentum that can—and should—build behind congressional reform efforts."

Medicare's sustainable growth rate (SGR) formula is designed to ensure that yearly increases in costs per Medicare beneficiary do not exceed the growth in gross domestic product.

Despite similarities between the permanent physician pay fix proposals by the White House and House Republicans, stakeholders say significant hurdles to creating a

new system remain, including how it will be paid for. The Department of Health and Human Services has not yet devised a way to pay for a "doc fix."

But stakeholders and lawmakers say a new lower-cost estimate for a fix provides the best opportunity in years for action. The Congressional Budget Office has lowered by more than $100 billion the price tag for freezing physicians' pay to $138 billion over 10 years, due to lower-than-expected Medicare spending.

House Republicans have said they are focusing on developing the right doc fix policy before trying to find ways to pay for it, although some lawmakers have suggested that Medicare reforms included in a doc fix bill could save enough money to pay for it.

Funding Needed

House Republicans also are wary that including funding provisions opposed by Democrats, such as from the Affordable Care Act, could doom passage of a doc fix bill in the Senate.

Physicians' Medicare reimbursement will be reduced about 25 percent in 2014 unless Congress acts. The physician payment system has produced pay cuts for doctors for about a decade, but Congress has overridden them. A permanent fix repealing the SGR has not been approved by lawmakers in the past because of cost.

The American Medical Association in a statement praised the White House doc fix language, saying it "aligns with many of the principles developed by the AMA and 110 other physician organizations on transitioning Medicare [from the current payment system] to include an array of accountable payment models."

"It is critical for physicians to have a period of stability and the flexibility to choose options that will help them lower costs and improve the quality of care for their patients," AMA said. "We are encouraged that the president and members of Congress are focused this year on eliminating this failed formula and strengthening Medicare for patients now and in the future."

Combining Medicare, Medigap Coverage Could Save $180 Billion Over 10 Years

Combining hospital, physician, prescription drug, and Medigap coverage into a "Medicare Essential" plan could save $180 billion in health spending over the next 10 years while also improving care, according to a report released May 6 by the Commonwealth Fund.

Under the proposal, Medicare beneficiaries could save $63 billion between 2014 and 2023, with total premium and out-of-pocket costs for beneficiaries estimated to be 17 percent to 40 percent lower than current costs.

Private employers enrolled in retiree plans could save about $90 billion, and savings for state and local governments could total $27 billion over 10 years, the report said. The savings would come from simplifying administrative costs and rewarding delivery of high-quality, high-value care, according to the report, *Medicare Essential: An Option to Promote Better Care and Curb Spending Growth*.

Medicare Essential would not add to the federal budget deficit because its enhanced benefits are financed by premiums, which would be substantially lower than current premiums for Medigap and drug coverage, the report said.

Lower Administrative Costs

The savings come partly from lower administrative costs, compared with supplemental coverage purchased in the private insurance market, where administrative costs range from 10 percent to 20 percent, compared with 2 percent for traditional Medicare, according to the report.

It said Medicare fails to protect beneficiaries from high out-of-pocket costs unless they purchase a Medigap plan to cover expenses such as copayments and deductibles and also buy a Medicare Part D plan for prescription drug coverage.

The combined coverage "would offer better financial protection than traditional Medicare does, including a limit on out-of-pocket spending," the report said. "Beneficiaries could see additional cost savings by selecting medical providers that deliver high-value care."

"This plan builds on traditional Medicare, which beneficiaries are more satisfied with than private coverage," Karen Davis, director of the Roger C. Lipitz Center for Integrated Health Care at the Bloomberg School of Public Health, and one of the report's authors, said in a press release.

Overly Complex System

"But Medicare is overly complex, and it fails to protect beneficiaries against high costs unless they buy supplemental coverage," Davis said. "Medicare Essential would simplify and modernize Medicare for beneficiaries and help keep premiums and out-of-pocket costs reasonable."

Physicians and hospitals that agree to be reimbursed through innovative payment methods designed to foster the delivery of high-quality, efficient care would be designated as "high-value providers," and beneficiaries choosing such providers would save money through reduced cost sharing, the report said.

The report is the latest in a series to be released by researchers and policymakers on health care reform, including ways to improve Medicare.

Under the Commonwealth proposal, a single $250 deductible would replace deductibles of $1,156 for each hospital episode and $140 annually for Part B services that were in effect in 2012. Prescription medications would be covered with no deductible, as would preventive care.

The plan would establish an out-of-pocket maximum of $3,400 a year to protect against catastrophic costs.

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Under Medicare Essential, a beneficiary would spend an average of $354 monthly on premiums and out-of-pocket costs, including prescription drugs. This represents a savings of 17 percent, compared with a person who currently has traditional Medicare plus Part D and Medigap Part F supplemental plans.

Medicare Essential enrollees who use high-value providers would save even more: They would spend an estimated $254 a month, for a savings of 40 percent, the report said.

A summary of the report is at *www.commonwealthfund.org/Publications/In-the-Literature/2013/May/Medicare-Essential.aspx*.

CAP Seeks Carve Out, *from p. 1*

in negative effects on access to health care services, quality, competition, cost to the federal health care programs and overutilization."

Donated software typically contains several modules that may be customized for the physician practice or specialty and provide for other capabilities outside of those protected under the safe harbor. The EHR software may also include a proprietary interface between the modules and EHRs to automatically populate the patient's EHR with the data from the modules, including the results of all laboratory tests, among other features, says CAP.

> *"Electronic exchange of laboratory test orders and results represents an incremental requirement on laboratories for which there is no incremental reimbursement or compensation."*
> *— The College of American Pathologists*

The EHR safe harbor requires that the software donated be interoperable to protect against donors who improperly attempt to create closed or limited EHR systems by offering technology that functionally or practically locks in business for the donor, notes CAP. In this situation, the EHR software package donated appears to be theoretically interoperable but does not function with the software packages and EHR systems of other providers who need to access clinical information contained in the records of the donated software.

"The interface component is specific for the donor and functions only if specimens are referred to the donor's laboratory rendering them inaccessible to other health care providers within patients' continuum of care," writes CAP. "The creation of these 'walled gardens' is completely at odds with the goals of the [proposal]."

Other Concerns

CAP also commented on the ways pathologists can improve coordinate patient-centered care with increased access to EHRs and the need for pathologists to have input into sharing and storing laboratory data in interoperable and multidirection EHRs, and verifying such systems.

In addition, the college also discussed the extraordinary expenses laboratories face managing and sharing patient data electronically with each client's individual EHR system interfaces and urged HHS to identify funding streams to cover the costs of multiclient laboratory interfaces and maintenance.

"Electronic exchange of laboratory test orders and results represents an incremental requirement on laboratories for which there is no incremental reimbursement or compensation," the college writes. "Laboratories must pay to establish electronic connections with EHRs. In addition, there are disparities among laboratories in their ability to pay for and to support interfaces. Creating some type of incentive or reimbursement model that [incentivizes] (or reduces the burden to) laboratories could foster the implementation of electronic exchange."

Washington State Upholds Ban on EHRs by Labs

The Washington State Legislature has passed legislation upholding an attorney general opinion that labs cannot donate electronic health record (EHR) software to physicians.

The state attorney general in late 2012 ruled that a donation by a laboratory to a referring physician of 85 percent of the software cost of the physician's EHR system, when the physician either has a continued referral arrangement with the laboratory or subsequently initiates a referral relationship with the laboratory, violates the Washington anti-rebate statute.

The Washington State Hospital Association attempted to void the opinion by deferring state law to federal but subsequently agreed to legislation (SB 5601) that expressly ensures that all provisions of the Washington state anti-kickback law, including those forbidding such donations, continue to apply to clinical laboratories.

ACMG Clarifies Statements on Return of Incidental Findings

The American College of Medical Genetics and Genomics (ACMG) has issued a clarification of its recent practice release on recommendations for reporting of incidental findings in clinical exome and genome sequencing.

The March 22 recommendations stressed that there is a subset of conditions, genes, and variants for which there is the significant potential for preventing disease morbidity and mortality if identified in the presymptomatic period. Thus, the college recommended that certain genetic findings uncovered by a lab during sequencing be reported back to the physician and patient, even if those findings were unrelated to why the patient was undergoing testing.

Commentaries about the ACMG recommendations have raised a number of points and discussion both in favor of and against the recommendations. According to the association, because there is some misinformation and misinterpretation about the recommendations, ACMG has prepared the clarification document to address five issues raised: patient autonomy, incidental findings in children, clinical laboratory considerations, result communication, and prediction of disease likelihood.

For example, ACMG notes that it has previously articulated the position that a laboratory should have a clear policy on whether it reports incidental findings resulting from genomic sequencing.

"The current recommendation defines a minimal set of incidental findings that we believe should be sought and reported by the laboratory," says the group in its clarification. "Indeed, given the low probability of an individual having such an incidental finding, it is imperative that a very high bar be set with return of only those variants with a very high probability of being deleterious. Otherwise, the risk of false positives will be significant.

"We recognize that some genome or genome sequencing tests may not be optimized for coverage of variants associated with these incidental findings. We do not recommend that laboratories modify these tests if they are otherwise suitable to achieve their clinical objectives; in such cases, however, laboratories should specify that the test was not optimized to detect incidental findings."

The clarification is available online at *www.acmg.net*.

Survey Finds Americans Would Pay for Testing

A new study conducted by Siemens Healthcare finds that the majority of Americans would want to know if they have a serious illness or injury, even if there is no cure, and that they are willing to pay out of pocket for medical tests that aren't covered by their insurance in order to get a clear diagnosis.

According to Siemens, 92 percent of Americans agree that "the value of knowing exactly what is wrong with their health is as important as having access to a doctor in the first place," and 78 percent would want to have a test done to diagnose a disease, even if there is no treatment or cure available. Two-thirds (66 percent) of Americans would even be willing to pay out of their own pocket for tests to diagnose serious illness if there were such a test but it was not covered by their own insurance.

Diagnostic testing has come under increased scrutiny as the nation examines health care expenditures. However, the survey results show that--despite the belt-tightening times for many American families--the majority of U.S. adults see real value in such tests.

The survey was conducted online within the United States by Harris Interactive on behalf of Siemens Healthcare from April 9-11, 2013, among 2,222 adults.

Upcoming G2 Events

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

May 30

Blood Management for the Lab: Collaboration for Better Patient Outcomes and Fewer Transfusions

www.G2Intelligence/BloodManagement

June 19

Keeping Ahead of the Curve: CLIA Compliance 2013

www.G2Intelligence/CLIACompliance

Conferences

May 16

Lab Contracting Workshop: How to Master Changing Market Realities in Dealing with Payers

Westin Atlanta Airport
www.G2Intelligence.com/ContractingWorkshop

June 12-14

MDx Next 2013 Gaining Ground in Molecular Testing and Genomic Medicine

Westin Las Vegas Hotel Casino and Spa
www.mdxconference.com

Oct. 16-18

Lab Institute 2013

Hyatt Regency Crystal City
Arlington, Va.
www.labinstitute.com

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NIR 5/13A

 National Intelligence Report (ISSN 0270-6768) is published by G2 Intelligence, 24 Railroad Street, Keene NH 03431-3744 USA. Tel: 800-531-1026 or +1 603-357-8101. Fax: +1 603-357-8111. Web site: www.G2Intelligence.com.

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