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INSIDE *NIR*

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Upcoming G2 Events

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

Sept. 26

Managing Lab Test Utilization: How to Avoid Overuse and Make Better Decisions

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Conferences

Oct. 16-18

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

Dec. 9

Lab Leaders' Summit 2013

Union League Club of New York
New York City
www.lableaderssummit.com

Dec. 10

Laboratory and Diagnostic Investment Forum

Union League Club of New York
New York City
www.labinvestmentforum.com

Moran Co. Finds CMS Payment Proposals Flawed; Industry Groups Call for Withdrawal

A new report from the Moran Co. provides support to industry arguments that the Centers for Medicare and Medicaid Services' (CMS's) proposal to cap payment for anatomic pathology (AP) services paid under the Medicare Physician Fee Schedule (PFS) at Outpatient Payment System (OPPS) rates is flawed.

The report, contracted by the American Clinical Laboratory Association (ACLA), concludes that CMS's rationale for using OPPS values to cap PFS payment "explicitly contradicts a variety of prior announcements regarding the comparative accuracy of OPPS valuations at the level of individual codes, and the utility of cross-system comparisons of absolute payment amounts.

"OPPS rate-setting allows for meaningful comparison of resource-intensiveness and costs of services within the OPPS system," continues the report. "But the methodology is not designed to allow for comparisons to services outside the OPPS."

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MolDx to Continue in Medicare JE; Palmetto Will Administer

As Noridian Administrative Services takes over Medicare Jurisdiction E from Palmetto GBA, many in the laboratory industry wondered what would happen to the molecular diagnostic service (MolDx) program that Palmetto had implemented in that region last year.

Now, we know: Palmetto will continue to administer the MolDx program in JE (formerly J1). In addition, Palmetto is deploying the MolDx program in J11, which is being renamed Jurisdiction M.

J1/JE covers California, Nevada, and Hawaii, as well as the U.S. territories of American Samoa, Guam, and the Northern Mariana Islands. J11/JM covers North Carolina, South Carolina, Virginia, and West Virginia.

In an e-mail to *National Intelligence Report*, Mike Barlow, vice president, Palmetto GBA, confirms that the MolDx program will remain intact in JE.

"Noridian has republished the Molecular Diagnostic Testing (MDT) policy and the requirement to register and submit new testing for

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Moran Co. Finds CMS Payment Proposals Flawed, *from p. 1*

CMS proposed to cap payment for 211 codes as part of its proposed PFS rule for 2014, announced July 8 and published in the July 19 *Federal Register*. Of those 211 codes, 38 are for AP services. The final rule is expected out around Nov. 1.

If finalized as proposed, Medicare payment for pathology services billed for non-hospital patients could be cut by as little as 4 percent to as much as 80 percent, depending on the service.

According to an analysis by the Moran Co., the cost-accounting information CMS is explicitly relying on in making these cost comparisons is insufficiently granular to be reliable at the level of individual codes. The cost findings are based on averages across data submitted by thousands of hospitals.

"When the distribution of actual hospital cost findings for these 38 codes is compared to the distribution of procedure-level costs from our survey findings, there is substantial overlap in the range of cost findings, calling into question whether costs are, in fact, sufficiently different in both settings to justify capping one set of payment rates with another," says the report.

If finalized as proposed, Medicare payment for pathology services billed for nonhospital patients could be cut by as little as 4 percent to as much as 80 percent, depending on the service.

In comments submitted to CMS, ACLA is urging the agency to withdraw its proposal to cap payments for certain services at the OPPS rates, noting that the "proposed policy is built upon the faulty assumption that facility cost reports yield more accurate data about the actual cost of providing a service and that the cost to perform a service in a physician's office must always be lower."

The OPPS and the PFS systems are hardly comparable, being derived through entirely different methodologies and for different purposes, and individual codes on the PFS cannot and should not be compared to Ambulatory Payment Classification rates in the facility context, the group says in its comments.

Violation of Statute

Not only does the CMS proposal fail to take into consideration the distinct costs associated with specific individual codes, but it also fails to recognize the distinct costs of physician services, which are required by law to be based on the resources required to perform the service, notes the College of American Pathologists (CAP) in its comments on the proposal. In addition, an analysis by CAP's legal counsel, Sidley Austin LLP, concludes that CMS's proposal "violates the statutory Medicare requirement that PE RVUs be resource-based for the particular practice setting."

According to Sidley Austin, CMS has previously observed that taking facility costs into account in determining the PFS in the nonfacility setting would be inconsistent with a resource-based methodology. The agency also has previously stated that comparisons between the PFS and the OPPS payments for services are not appropriate because of the different nature of the cost inputs and has explicitly refused to impose one payment system on the other in rulemakings.

The American Society for Clinical Pathology (ASCP) also opposes CMS's proposals and has launched a grassroots effort to get its members to contact members of Congress and CMS. According to ASCP, more than 7,000 messages had been sent to officials on Capitol Hill by early September, and almost 3,000 messages had been sent to CMS. ASCP, along with ACLA, CAP, and the American Medical Association, has also signed on to a number of letters sent to CMS raising concern about the OPPS cap.

PROPOSED MEDICARE PAYMENT REDUCTIONS FOR PATHOLOGY SERVICES *(selected codes)*					
CODE	***MOD***	***DESCRIPTION***	***2014 PFS PROPOSED PAYMENT***	***2013 PAYMENT***	***PERCENT CHANGE***
88108	TC	Cytopath, concentration technique	23.82	56.82	-58%
88112	TC	Cytopath, cell enhance technique	23.82	51.37	-54%
88173	TC	FNA interp	38.45	79.95	-52%
88184	TC	Flow cytometry, 1st marker	23.82	88.80	-73%
88185	TC	Flow cytometry, additional marker	12.93	54.10	-76%
88304	TC	Level III path exam	23.82	33.34	-29%
88307	TC	Level V path exam	60.90	215.37	-72%
88312	TC	Special stain, Grp 1	23.82	71.11	-67%
88313	TC	Special stain, Grp 2	23.82	55.80	-57%
88331	TC	Path consult, during surgery	23.82	38.45	-38%
88342	TC	Immunohistochemistry	38.45	73.15	-47%
88360	TC	Immunohistochemistry	38.45	74.85	-49%
88361	TC	Immunohistochemistry	38.45	99.35	-61%
88365	TC	In situ hybridization	38.45	120.44	-68%
88367	TC	In situ hybridization	38.45	198.35	-81%
88368	TC	In situ hybridization	60.90	170.46	-64%
Source: American Clinical Laboratory Association. All CPT codes copyright American Medical Association.					

Review of Technology Changes

ACLA also commented on CMS's proposed review of technological changes that may affect the cost of performing some laboratory tests, urging CMS to proceed with "great caution" to ensure that it does not impose unreasonable cuts to laboratory reimbursement.

"While we take issue with premise that payment amounts for test codes on the [Clinical Laboratory Fee Schedule] have remained unchanged for years, we do agree that the technological changes can affect the cost of performing laboratory tests, both increasing the costs and decreasing the costs," says ACLA. "In reviewing these technological changes, it is essential that all parties—CMS, laboratories, and other interested members of the public—be involved in the development and refinement of the review process."

ACLA recommends that CMS start with a pilot project in which it reviews a limited number of test codes. CMS also should spread its review over a greater number of years than currently proposed, balance its review of high-volume and low-volume codes, and cap and phase in fee adjustments.

Takeway: Lab and pathology groups oppose CMS's proposal to cap payment for AP services at hospital outpatient rates, and a new report provides further evidence that the proposal is flawed. G2

Bundling Proposals Come Under Fire

A separate Medicare proposal to package more than 280 physician services, including more than 80 pathology physician services, under the Hospital Outpatient Prospective Payment System (OPPS) has also come under fire from industry groups.

CMS proposed the new bundling policies as part of changes to the OPPS for 2014. The proposal was announced July 8 and published in the July 19 *Federal Register*.

Essentially, CMS is proposing three packaging policies: packaging physician pathology services into "primary procedures," packaging certain "add-on" codes, and packaging nearly all clinical diagnostic laboratory tests (except molecular pathology).

In comments submitted to CMS, the College of American Pathologists (CAP) notes that CMS has proposed this untested expansion of the OPPS packages without taking necessary steps to define the proposal in detail, engage with stakeholders to understand the impact of the proposal on affected groups, and anticipate possible consequences that could adversely affect the quality of care.

"Instead of devoting limited resources to implement untested bundling proposals on a national level, CMS should focus more attention on the Innovation Center's efforts to test bundled payment and other new models of payment."
—College of American Pathologists

"Further, CMS's justification for the proposal—that additional packaging will reduce incentives to overutilize services or provide services that are not medically necessary—carries an equal risk of creating incentives to reduce use of medically necessary services in ways that are detrimental to the quality of care," says CAP. "As pathology practices may receive referrals of specimens from multiple hospitals and physician practices, keeping track of when tests should be paid separately vs. packaged into a hospital service will create enormous administrative burdens."

CAP also notes that CMS plans to package nearly all clinical diagnostic laboratory tests (with the exception of molecular pathology) unconditionally into a "wide array of primary services provided in the hospital outpatient setting" include limited information on the primary services that would be subject to the packaging rule.

"The proposal is remarkably broad, and therefore has a very substantial potential to impact the reimbursement of laboratory tests, since it involves 1,096 laboratory tests," says CAP. "This proposal encompasses the entire clinical laboratory fee schedule, and therefore there must be an impact upon providers of these services, namely pathologists and the clinical laboratory industry. CMS provides no such impact analysis in this proposal, and CAP questions exactly how these codes will be packaged under the proposal."

Even with a more transparent process for OPPS packaging and grouping proposals, bundling services remains a relatively new concept for most providers, particularly pathologists, notes CAP. Evidence supporting these types of arrangements has been narrowly focused on a limited number of procedural episodes of specific types of integrated care arrangements.

"Instead of devoting limited resources to implement untested bundling proposals on a national level, CMS should focus more attention on the Innovation Center's efforts to test bundled payment and other new models of payment," urges CAP in its comments.

Takeaway: Industry groups are urging CMS to scrap a recent proposal to package certain pathology services and laboratory tests under the Hospital Outpatient Prospective Payment System. G2

September Update of CLIA-Waived Tests, Billing Codes

The Sept. 6, 2013, update to the list of tests waived under the Clinical Laboratory Improvement Amendments (CLIA) includes 14 tests approved by the Food and Drug Administration.

When billing for the tests below, you must use the QW modifier. This enables your local Medicare contractor to recognize the code as waived.

CPT CODE	EFFECTIVE DATE	DESCRIPTION
G0434QW	Jan. 23, 2008	Phamatech At Home 12 Drug Test (Model 9308T)
G0434QW	Jan. 23, 2008	Phamatech At Home 12 Drug Test (Model 9308Z)
81003QW	Jan. 29, 2013	Henry Schein Urispec Plus Urine Analyzer
G0434QW	Feb. 27, 2013	CLIAwaived Inc. Rapid Test Cup
G0434QW	Feb. 27, 2013	Clinical Reference Laboratory Inc. Intelligent Transport Cup
G0434QW	Feb. 27, 2013	Noble Medical Inc. Noble 1 Step Cup
G0434QW	Feb. 27, 2013	Premier Integrity Solutions P/Tox Drug Screen Cup
G0434QW	Feb. 27, 2013	US Diagnostics ProScreen Drugs of Abuse Cup
84443QW	March 5, 2013	BTNX Rapid Response TSH Test Cassette (Whole Blood)
86308QW	March 11, 2013	Henry Schein OneStep Pro+Mono (Whole Blood)
G0434QW	May 15, 2013	UCP Biosciences Inc. UCP Home Drug Screening Test Cups
G0434QW	May 17, 2013	Alere Toxicology Services Inc. Tox Screen Drugs of Abuse Test Cups
G0434QW	June 24, 2013	Advin Multi-Drug Screen Test
87880QW	July 3, 2013	Henry Schein OneStep Pro+ Strep A Cassette

The September update, plus a complete list of CLIA-waived devices, can be found in Change Request 8439 (Transmittal 2779), at *www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2779CP.pdf*. The transmittal has an implementation date of Jan. 6, 2014.

Medicare Revises CMS-1500 Claim Form

The Centers for Medicare and Medicaid Services (CMS) has revised the CMS-1500 claim form to more adequately support the use of the ICD-10 diagnosis code set.

The revised form, version 02/12, will replace version 08/05. The new form will give providers the ability to indicate whether they are using ICD-9 or ICD-10 diagnosis codes, which is important as the Oct. 1, 2014, transition approaches. The revised form also allows for additional diagnosis codes, expanding from four possible codes to 12.

Medicare will begin accepting the revised form on Jan. 6, 2014. Starting April 1, 2014, Medicare will accept only the revised version of the form.

More information is available at *www.cms.gov*.

MolDx to Continue in Medicare JE, *from p. 1*

technical assessment of clinical utility and refers test producers to the MolDx website for detailed program information (*www.palmettogba.com/MolDx*)," writes Barlow. "We (Palmetto GBA as MolDx) will continue to use the test submitted dossier information to determine clinical utility and reimbursement for those tests reviewed.

"We are deploying the program in J11 and will be developing a master edit file," Barlow continues. "Once that tool is in place, we will begin working with the other MACs to deploy the key elements of MolDx (test registration, new test evaluation, inclusion of the test ID on the claim)."

The MolDx program took effect June 1, 2012, in J1, when Palmetto still held the Part B contract. Palmetto lost the contract early in 2013 and began the transition to Noridian during the summer. Effective Sept. 11, 2013, all Part B claims for J1/JE must now be submitted to Noridian.

COVERAGE DETERMINATIONS UNDER MOLDX

COVERED TESTS	*NONCOVERED TESTS*	
Vectra DA	PTCH1 Dup/Del	HEXA Gene Analysis
BCR/ABL	BLM Gene Analysis	IKBKAP
CYP2C9 and VKORC1 (CED/one per lifetime)	GBA (Gaucher) Testing	SMPD1
Oncotype DX	ATP7B	FANCC
Therascreen KRAS PCR kit	know error DNA Specimen Provenance	HAX1
Veridex CellSearch	CYP2B6	MCOLN1
bioTheranostic Cancer TYPE ID	MMACHC	CFTR
Abbot Vysis ALK Break-Apart FISH	VEGFR2	Fragile X
Progensa PCA3	PIK3CA	L1CAM
Cobas 4800 BRAF V600	STAT3	Mitochondrial Nuclear Gene Tests
Corus CAD Gene Expression	CHD7	PAX6
Oncotype DX	HTTLPR	4q25-AF
Avise PG	MPL	9p21
Pathwork Tissue of Origin	NSD1	APoE
Monogram HERmark	RPS19	BluePrint
MammaPrint	TERC	KIF6
AlloMap	HBB	LPA-Aspirin
Veracyte Affirma	TP53	LPA-Intron 25
	Specimen Validity Testing	Pervenio Lung RS
	UGT1A1	PreDx
	MECP2	Prostate Markers (HOXD3, PTEN, ERG)
	ARVD/C	SLCO1B1
	Aspartoacyclase 2 Deficiency	Cytogenomic Constitutional Microarray
	BCKDHB	Septin 9
	myPap	

Source: Palmetto GBA (*www.palmettogba.com/palmetto/MOLDX*)

Under the MolDx program, labs that perform molecular diagnostic testing and bill in J1/JE or J11/JM must register their tests, obtain a unique identifier, and provide additional information on the test that the Palmetto uses to determine coverage. According to Palmetto, all molecular tests are evaluated to determine analytical and clinical validity and clinical utility.

According to an analysis by G2 Intelligence, since Palmetto implemented MolDx in J1/JE, it has issued coverage decisions for 18 tests and noncoverage decisions for 49 tests. Noncovered tests are those that are used only for screening, do not provide the clinician with actionable data, confirm a diagnosis, determine a risk of developing a disease in the absence of symptoms, or are used for quality control.

Takeaway: Palmetto GBA will continue to administer the molecular diagnostic services program in Medicare Jurisdiction E even though Noridian has taken over as the Medicare administrative contractor for that region.

Medicare Doc Payment Fix Tops List Of Health Agenda Items as Congress Returns

As lawmakers return to the Capitol Sept. 9 to begin their fall legislative session, provider group lobbyists and congressional aides are optimistic that a new Medicare provider reimbursement system will be in place by year's end.

In part because of lower cost estimates for a Medicare payment fix, lawmakers and provider groups alike see this year as a "make or break" opportunity to push through a plan to repeal and replace the current system, according to stakeholders and congressional aides from both parties.

Other legislative items that could gain congressional attention over the next few months include:

- A push by a group of House and Senate Republicans to defund or trim back provisions of the Affordable Care Act, either as part of a debt limit increase or a measure to fund the government after Sept. 30;
- A legislative proposal by members of the House Republican Study Committee spelling out their ideas to replace the ACA; and
- Ongoing scrutiny by Republican-led House committees of the Obama administration's implementation of the ACA, including enrollment of the uninsured in new health insurance marketplaces beginning Oct. 1.

In late July, just before Congress adjourned for a five-week recess, the House Energy and Commerce Committee—with bipartisan support—released a 70-page draft bill that would replace Medicare's problematic physician payment system.

The Energy and Commerce proposal would eliminate Medicare's so-called sustainable growth rate (SGR) formula, which each year mandates cuts in physician payment rates that are regularly canceled by Congress with a legislative "doc fix."

The current doc fix will expire in January 2014. If it is not canceled or replaced, physicians face a Medicare payment cut of about 25 percent under the current SGR formula.

Replacing the current Medicare fee-for-service payment structure would be a new system that bases physician Medicare reimbursements on how well providers meet new quality guidelines. The guidelines would be worked out over the next several years by the Department of Health and Human Services, provider groups, and independent medical standards-setting organizations.

During a five-year phase-in period beginning in 2014, the new system would provide physicians with modest annual reimbursement rate increases of 0.5 percent before the system is fully implemented in 2019. Physicians could also opt to participate in demonstration programs featuring alternative payment models aimed at coordinating care and improving quality for patients, according to the Energy and Commerce proposal.

The progress made by the Energy and Commerce Committee, along with the fact that the effort has strong bipartisan support, has increased chances for legislative success this year.

The current doc fix will expire in January 2014. If it is not canceled or replaced, physicians face a Medicare payment cut of about 25 percent under the current SGR formula.

Takeaway: Congress has just a few months left in the year to address the issue of a flawed Medicare physician payment system, but hopes are high that real reform could be approved by the end of the year. G2

Medicare to Consider Covering Screening for HCV

The Centers for Medicare and Medicaid Services (CMS) has initiated a new national coverage analysis for screening for hepatitis C virus (HCV) in adults. CMS will accept comments until Oct. 5, 2013, and expects to make a decision by June 3, 2014.

The decision to consider coverage for HCV screening likely is the result of a June 25, 2013, statement by the U.S. Preventive Services Task Force, which recommends screening for HCV in persons at high-risk for infection and a one-time screening for adults born between 1945 and 1965.

HCV is the most common chronic bloodborne pathogen in the United States and a leading cause of complications from chronic liver disease. The prevalence of the anti-HCV antibody in the country is approximately 1.6 percent in noninstitutionalized persons. According to data from 1999 to 2008, about three-fourths of patients in the United States living with HCV infection were born between 1945 and 1965, with a peak prevalence of 4.3 percent in persons aged 40 to 49 years old from 1999 to 2002. The most important risk factor for HCV infection is past or current injection drug use.

> *"We had an epidemic of hepatitis C transmission in the '70s and '80s, and we're now seeing an epidemic of hepatitis C disease."*
>
> *—John Ward, M.D., head of CDC's viral hepatitis divison*

The National Viral Hepatitis Roundtable, a coalition of health groups and medical providers, this spring urged CMS to offer HCV screenings as part of a patients' first Medicare exam. With baby boomers representing about 75 percent of the U.S. cases of HCV, screening for the virus could save more than 100,000 lives, the coalition said.

The Centers for Disease Control and Prevention (CDC) recommended last year that every baby boomer get tested for HCV, which many people carry without knowing it. John Ward, M.D., head of CDC's viral hepatitis division, said many older people who injected drugs in their youth have unknowingly carried hepatitis C for decades.

"We had an epidemic of hepatitis C transmission in the '70s and '80s, and we're now seeing an epidemic of hepatitis C disease," he told National Public Radio last August.

There are a number of Food and Drug Administration-approved HCV tests, including the OraQuick HCV Rapid Antibody Test (OraSure Technologies), which is a rapid assay that received a Clinical Laboratory Improvement Amendments waiver in 2011. The waiver permits the use of the assay in nontraditional settings, such as physician offices, hospital emergency departments, health department clinical, and other freestanding counseling and testing sites.

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