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INSIDE *NIR*

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CMS Scraps Proposal to Cap Lab Payment At Hospital Outpatient Levels

In a pre-Thanksgiving surprise, the Centers for Medicare and Medicaid Services (CMS) announced that it would not finalize a proposal to cap reimbursement for certain pathology services furnished by independent labs and in physician offices at hospital outpatient payment rates.

Lab and pathology groups applauded the announcement, contained in the final Medicare Physician Fee Schedule (PFS) rule for 2014. The rule was issued Nov. 27, the day before Thanksgiving.

CMS elected not to finalize the proposal and instead said it will consider more fully all comments received and plans to develop an alternate proposal for using outpatient and ambulatory surgical center rates in developing relative value units. CMS's stated goal is to bring payment for lab services provided in nonfacility settings more in line with services provided in facility settings.

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Medicare Payment for Clinical Laboratory Tests Likely to Be Reduced 2.75% in 2014

Under the final Medicare Clinical Laboratory Fee Schedule (CLFS) for 2014, released just before Thanksgiving, clinical laboratory tests will get a 0.75 percent negative update. When combined with the ongoing 2 percent reduction resulting from sequestration, lab fees will be cut a total of 2.75 percent beginning Jan. 1.

This marks the fourth time in the last five years that the lab fee update has fallen into negative territory (*see table on page 2*).

The 2014 update is determined by a multipart statutory formula: the consumer price index for urban areas (1.8 percent) minus a productivity adjustment of 0.8, minus a 1.75 percentage point reduction required by the Patient Protection and Affordable Care Act. The 0.75 reduction is taken off of the 2013 CLFS rates. The 2 percent sequestration reduction is added on to this.

Under current law, Medicare payment for clinical laboratory tests is scheduled to be reduced by 23 percent between 2010 and 2022 as a result of rebasing mandated by Middle Class Tax Relief and Job

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Medicare Payment for Clinical Laboratory Tests, *from p. 1*

MEDICARE LAB FEE SCHEDULE FOR 2014: NEW CPT CODES AND FINAL PAYMENT DETERMINATIONS		
CODE/DESCRIPTOR	***FINAL FEE DETERMINATION***	***NATL FEE CAP, 2014***
80155 Drug Screen - Caffeine	Crosswalk to 80198	$19.30
80159 Drug Screen - Clozapine	Crosswalk to 80154	$25.23
80169 Drug Screen - Everolimus	Crosswalk to 80195	$18.73
80171 Drug Screen - Gabapentin	Crosswalk to 80157	$18.09
80175 Drug Screen - Lamotrigine	Crosswalk to 80157	$18.09
80177 Drug Screen - Levetiracetam	Crosswalk to 80157	$18.09
80180 Drug Screen - Mycophenolate	Crosswalk to 80158	$24.63
80183 Drug Screen - Oxcarbazepine	Crosswalk to 80157	$18.09
80199 Drug Screen - Tiagabine	Crosswalk to 82542	$24.63
80203 Drug Screen - Zonisamide	Crosswalk to 80157	$18.09
87661 Infectious agent detection by nucleic acid (DNA or RNA); Trichomonas vaginalis, amplified probe technique	Crosswalk to 87511	$47.87
81287 MGMT (O-6-methylguanine-DNA methyltransferase)	Gap-fill	
RECONSIDERATION REQUESTS		
8277 Galectin-3	Crosswalk to 84244	$30.01
81161 Duplication/Deletion Analysis	Gap-fill	
Source: CMS 2014 Clinical Laboratory Fee Schedule. CPT codes copyright American Medical Association.		

Creation Act of 2012 and the sequestration. This means that a test paid at $10 in 2010 will be paid at $9.88 in 2022, according to the American Clinical Laboratory Association. If payment for this same $10 test kept pace with inflation, it would be paid at $12.87 by 2022.

Payment for a clinical lab test is the lesser of the actual charge billed for the test, the local fee schedule payment, or the national limitation amount. Since the Medicare CLFS was created in 1984, reimbursement for lab services has been systematically reduced. The limits—or ceilings—on payments for each test, which were originally set at 115 percent of the average fee across all carriers, have been declining over the past 20 years. In 1997, limits were set at 74 percent, where they stand today.

LAB FEE SCHEDULE UPDATES, 1990-2014			
Year	***Percent***	***Year***	***Percent***
1990	4.7	2003	1.1
1991	2.0	2004-2008	0.0
1992	2.0	2009	4.5
1993	2.0	2010	-1.9
1994	0.0	2011	-1.75
1995	0.0	2012	0.65
1996	2.8	2013	-2.95
1997	2.7	2014	-0.75
1998-2002	0.0		
Source: G2 Intelligence			

The 0.75 percent negative update to the lab fee schedule also reduces the national minimum payment for Pap smears, from $14.53 this year to $14.42 in 2014. The national minimum payment for Pap smears was $14.97 in 2012, $14.87 in 2011, $15.13 in 2010, and $15.42 in 2009. From 2004 through 2008 it was frozen at $14.76.

CMS to Adjust Clinical Lab Test Payment Based on Technology

The Centers for Medicare and Medicaid Services (CMS) is moving forward with plans to begin individually reviewing all 1,250 codes on the Clinical Laboratory Fee Schedule (CLFS) and make adjustments based on "technological changes," which includes tools, machines, supplies, labor, instruments, skills, techniques, and devices by which lab tests are produced and used.

In the 2014 final Physician Fee Schedule rule, released Nov. 27, CMS said it would begin reviewing codes starting in 2015. In the proposed rule issued in July, CMS said it would start with the oldest codes and would review only tests that had been on the CLFS for at least five years.

However, in the final rule, CMS indicated that it is not bound to adjusting oldest codes first and will consider volume, increasing utilization, and high-cost tests. Each year, the agency will conduct a data analysis of codes on the CLFS to determine which codes should be proposed during the rulemaking cycle for a payment adjustment due to technological changes.

The American Clinical Laboratory Association (ACLA) believes the technology adjustment simply duplicates the current annual productivity adjustment used to modify pricing of CLFS tests. ACLA and other groups had requested a cap on any cuts and had asked for a negotiated rulemaking so they could be involved in the discussions. CMS rejected virtually all comments, or failed to respond at all. The agency says a negotiated rulemaking would be a "time-consuming and resource intensive process" and that it "can accomplish the same purpose by utilizing the rulemaking process." G2

CMS Makes Limited Changes to Final MoPath Rates for 2014; BRCA1/2 Pricing Remains a Source of Confusion

Medicare's final 2014 pricing rates for more than 100 new CPT codes for molecular pathology procedures is notable for two things: the apparent lack of any reconsideration of pricing released in September and the final pricing for Myriad Genetics' BRCA test, which is half of what it had been paid previously.

Despite receiving numerous reconsideration requests after publishing rates Sept. 30, 2013, the Centers for Medicare and Medicaid Services (CMS) did not make additional adjustments and in fact did not publicly respond to any of the requests. Given that the agency typically goes to great lengths to explain decisions made in the physician fee schedule rule, the lack of discussion or even acknowledgement of reconsideration requests is surprising.

The final MoPath pricing rates contained in the 2014 final Clinical Laboratory Fee Schedule (CLFS) do reflect the negative 0.75 percent negative update applied to the entire fee schedule. It's unclear whether the 2 percent reduction from sequestration will also apply.

The final MoPath prices are about 26 percent higher than the proposed rates released in May 2013 (*NIR, Oct. 10, 2013, p. 1*). However, CMS released final prices for only 65 of the new codes, leaving coverage and pricing for the remaining codes

up in the air. Many of the new codes are not being paid by Medicare at all, based on noncoverage decisions issued by Medicare administrative contractors (MAC).

Myriad BRCA Pricing

Final pricing for Myriad's BRCA1/2 test (CPT 81211) remains a source of confusion. When final rates were released Sept. 30, Noridian, the Medicare contractor that processes Myriad's BRCA claims, set the price at $1,449.01 while the national limit was set at $2,795.09. However, Noridian later indicated that its price was a clerical error and that the pricing was unchanged from the interim price of $2,795.

But the final pricing released by CMS in November shows a rate of $1,438.14 for the BRCA1/2 test (the same payment as for a BRCA1 test). Some industry analysts continue to believe the rate is still a mistake and that CMS will adjust payment upward. However, the fact that CMS has not addressed this issue since releasing the final CLFS could indicate that the final rate was no mistake.

Amanda Murphy, an analyst with William Blair & Co., says she continues to view this as a binary situation. "We still believe it is possible, and probably more likely, that the final rate of $2,795 established through MAC gap-fill will ultimately be the rate; however, we assigned a lower probability to that scenario than earlier in the week (i.e., if we were assigned a 80 percent likelihood to positive resolution, it is 60 percent now)," she wrote in a Dec. 6 research note.

Myriad is engaged in a number of lawsuits with competitors over BRCA testing, the latest involving Invitae Corp., which said Nov. 19 that it would begin offering genetic testing services for BRCA1 and BRCA2.

A Myriad spokesman tells *National Intelligence Report* that the company is in discussions with CMS to resolve the issue and that company officials continue to believe the $1,438 price is an error.

Further compounding the issue is the fact that a number of other lab companies now are offering BRCA testing at a lower price point than Myriad. Until June of this year, Myriad held the monopoly on BRCA testing, but a Supreme Court ruling that naturally occurring human genes cannot be patented opened the door for other companies to offer competing tests.

Just hours after the Supreme Court ruling, Ambry Genetics launched a BRCAPlus test for $2,280 and Gene by Gene began offering BRCA testing for $995. Since then, many other companies have launched BRCA tests at a much lower price point than what Myriad had been charging (more than $3,000). Quest announced in October that it would offer a BRCAvantage test, and LabCorp jumped into the fray Dec. 2 with its BRCA*ssure* test.

Myriad is engaged in a number of lawsuits with competitors over BRCA testing, the latest involving Invitae Corp., which said Nov. 19 that it would begin offering genetic testing services for BRCA1 and BRCA2.

BRCA1 and BRCA2 gene mutations account for 20 percent to 25 percent of heriditary breast and ovarian cancers, and testing for them has represented 75 percent of Myriad's sales.

Myriad stock price currently is well off its 52-week high of $38.27. As of Dec. 11, the stock was trading at around $24.

CMS Scraps Proposal to Cap Lab Payment, *from p. 1*

The proposal, which was contained in the proposed PFS rule issued in July, would have reduced reimbursement to independent laboratories by an estimated 26 percent. Some common anatomic pathology (AP) codes would have seen reimbursement cut by as much as 80 percent.

Congressional pressure to abandon the proposal likely contributed to CMS's decision. A total of 115 representatives and more than 40 senators signed on to a letter sent to CMS Administrator Marilyn Tavenner opposing the cuts.

The American Clinical Laboratory Association commended CMS for not finalizing the proposal to "slash Medicare payments for anatomic pathology services which diagnose breast, colon, prostate, skin, ovarian, leukemia, and other cancers.

The College of American Pathologists said it remains opposed to efforts to cap AP payment at facility rates and "will consult with coalition partners and Congressional supporters on both sides of the aisle on the next steps to prevent future implementation of this or similar proposals that do not accurately account for the cost of delivering laboratory services." G2

Lab Tests to Be Bundled in Outpatient Settings

In a move that could have a significant impact on hospital laboratories, the Centers for Medicare and Medicaid Services (CMS) is moving forward with plans to bundle certain clinical laboratory tests performed in hospital outpatient settings into payment for the primary service.

Beginning Jan. 1, 2014, CMS will package laboratory tests "when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting." To be packaged, the lab tests would have to be provided on the same date of service as the primary service and ordered by the same practitioner who ordered the primary service. Molecular pathology tests are exempt from this packaging policy.

A laboratory test will be separately paid when it is the only service provided to a beneficiary on that date of service or the lab test is the same date of service as the primary service but is ordered for a different purpose than the primary service by a practitioner different than the practitioner who ordered the primary service. When a lab test is the only service provided to a beneficiary at the hospital, the hospital can receive separate payment for those lab tests by billing for these services on a 14x claim. Medicare will pay hospitals for those services based on the Clinical Laboratory Fee Schedule payment rate.

CMS will move five types of services from line item payment to bundled or packaged payment: (1) drugs used as a supply for a diagnostic test, (2) drugs used as supplies during surgical procedures, (3) clinical diagnostic laboratory tests, (4) procedures described by add-on codes, and (5) device removal procedures. In a change from the proposed rule, CMS did not finalize plans to package ancillary services or diagnostic tests on the bypass list under the Hospital Outpatient Prospective Payment System (HOPPS). This is good news since ancillary services includes most anatomic pathology procedures.

CMS says it may review ancillary services and diagnostic tests on the bypass list to determine which may be appropriate for packaging as ancillary services in the HOPPS in future years.

Lab tests that are included in this packaging policy range from CPT 80047 to CPT 89332. There are seven pathology codes listed as add-on codes that are also subject

to packaging (88177, 88185, 88311, 88314, 88332, 88334, and 88388). The final rule and a full list of codes subject to the packaging policy can be found at *www.cms.gov* (click on Medicare, Hospital Outpatient PPS, 2014 final rule. A list of lab test codes and add-on codes subject to packaging is included in Addendum P).

It's unclear just how much this will affect the bottom line of hospital laboratories, say industry experts, who note that further analysis needs to be done. On the one hand, if hospitals believe their labs are not profitable because they can no longer track payment for the tests they perform, they could increase outsourcing to independent labs. However, since the packaging rule applies only to certain tests performed on certain days and only for tests paid by Medicare, it's possible the impact could be limited.

CMS Reduces Payment for 'Misvalued' Pathology Codes

Immunohistochemistry and enhanced cytology services took a big hit in the final Physician Fee Schedule rule for 2014, with the Centers for Medicare and Medicaid Services (CMS) cutting payment for both as part of its code revaluation initiative.

Under the final rule, released Nov. 27, two new G codes have been established to replace CPT 88342 (immunohistochemistry). Global payment for G0461 will be reduced by 24 percent when compared to current levels for 88342 while global payment for G0462 will be cut by 41 percent compared to current levels.

2014 MEDICARE PAYMENT FOR IMMUNOHISTOCHEMISTRY

CPT CODE	MODIFIER	88342 2013 TOTAL PAYMENT	2014 TOTAL PAYMENT	TOTAL % CHANGE FROM 2013 88342
G0461		$115.34	$88.04	-24%
G0461	TC	$73.15	$57.39	-22%
G0461	26	$42.19	$30.65	-27%
G0462		$115.34	$68.08	-41%
G0462	TC	$73.15	$55.61	-24%
G0462	26	$42.19	$12.48	-70%

Source: College of American Pathologists. CPT codes copyright American Medical Association

Enhanced cytology services (CPT 88112) also will be cut significantly in 2014, with the technical component (TC) cut by 33 percent, the professional component (PC) cut by 52 percent, and global payment cut by 43 percent.

CMS deferred action on revaluation of the PC and TC of in situ hybridization services (88365, 88367, and 88368) until 2015 and also decided to not to further reduce payment for the TC of 88305.

2014 MEDICARE PAYMENT FOR ENHANCED CYTOLOGY SERVICES

CPT CODE	MODIFIER	2013 TOTAL PAYMENT	2014 TOTAL PAYMENT	TOTAL % CHANGE FROM 2013
88112		$109.55	$62.73	-43%
88112	26	$58.18	$28.16	-52%
88112	TC	$51.37	$34.58	-33%

Source: College of American Pathologists. CPT codes copyright American Medical Association

Prostate Biopsies

CMS also imposed new restrictions on billing of 10 or more prostate biopsy specimens and will require individuals who bill more than 10 to use a G code to bill. These changes are designed to clear up confusion over what code to use for multiple

CHANGE IN MEDICARE RATES FOR OTHER TOP VOLUME CODES					
CPT CODE	MOD	DESCRIPTION	2013 TOTAL PAYMENT	2014 TOTAL PAYMENT	TOTAL % CHANGE
88305		Tissue exam by pathologist	$70.09	$70.22	0%
88305	26	Tissue exam by pathologist	$36.74	$38.14	4%
88305	TC	Tissue exam by pathologist	$33.34	$32.08	-4%
88185		Flowcytometry/tc add-on	$54.10	$53.47	-1%
88313		Special stains group 2	$67.71	$65.59	-3%
88313	26	Special stains group 2	$11.91	$12.12	2%
88313	TC	Special stains group 2	$55.80	$53.47	-4%
88312	26	Special stains group 1	$26.54	$27.45	3%
88312	TC	Special stains group 1	$71.11	$66.66	-6%
88312		Special stains group 1	$97.65	$94.10	-4%
88304	26	Tissue exam by pathologist	$11.23	$11.41	2%
88304	TC	Tissue exam by pathologist	$33.34	$31.72	-5%
88304		Tissue exam by pathologist	$44.57	$43.13	-3%
84165	26	Protein e-phoresis serum	$20.07	$19.25	-4%
88307	26	Tissue exam by pathologist	$82.00	$83.76	2%
88307		Tissue exam by pathologist	$297.36	$286.94	-4%
88307	TC	Tissue exam by pathologist	$215.37	$203.17	-6%

Source: College of American Pathologists. CPT codes copyright American Medical Association

biopsies. Effective Jan. 1, 2012, a National Correct Coding Initiative edit limited the number of prostate biopsies that could be reported using 88305 to four, which resulted in a significant cut in payment for more than four biopsies. Under this new policy, up to nine prostate biopsies can be reported using 88305.

For 10-20 prostate biopsies, providers will bill using G0416 (Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method; 10-20 specimens). G0417 is used for 21-40 specimens. G0418 is used for 41-60 specimens, and G0419 is used for more than 60 specimens.

Physician Quality Reporting System

While CMS did not accept the College of American Pathologists' (CAP's) three new pathology measures in its final rule, CMS will allow pathologists to qualify for 2014 incentives by reporting on the existing five measures proposed by CAP by either claims or registry. Until now, the measures could be reported only by claims. CAP supports this change, noting that a greater number of pathologists are able to qualify for incentives when they report using a registry.

In 2011, pathologists received on average a bonus of $856.50. By participating in the 2013 Physician Quality Reporting System (PQRS), pathologists avoided penalties that begin at 1.5 percent of their Medicare Part B billing in 2015 and rise to 2 percent in subsequent years. These measures take effect Jan. 1, 2014.

"While CAP is disappointed that its three new pathology measures were not included in the 2014 PQRS measure set, the CAP is pleased that CMS accepted the CAP's request that the registry reporting option be available to those with fewer than nine measures," said Jonathan Myles, M.D., chair of CAP's Economic Affairs Committee. "The CAP will continue to engage and educate policymakers about the difficulties pathologists have meeting current CMS requirements and will continue to seek relief from penalties in cases where pathologists have no pathway in which to meet requirements."

Study Refutes Claims That Medicare Pays More for Tests

A new study from Avalere Health refutes past claims that commercial health plans pay lower rates for lab services than Medicare.

Commissioned by the American Clinical Laboratory Association (ACLA), Avalere's study compared private data for a mix of 27 lab test codes representing low-dollar and high-dollar tests, which constituted nearly half of Medicare spending in the 2011 Clinical Laboratory Fee Schedule—including the top four codes by Medicare spending. The study included data from both hospital and independent labs.

MEDICARE VS. COMMERCIAL PAYMENT FOR SELECTED LAB TESTS

			COMMERCIAL MEAN		
CPT CODE	DESCRIPTION	MEDICARE NATIONAL LIMIT	PRICE OVERALL	HOSPITAL	NONHOSPITAL
85610	Prothombin time	$5.56	$13.18	$20.09	$6.67
85025	Complete CBC w/auto diff WBC	$11.02	$20.26	$32.61	$11.15
80053	Comprehensive metabolic panel	$14.97	$32.14	$57.91	$14.85
88237	Tissue culture bone marrow	$178.90	$278.42	$306.99	$212.67
88261	Chromosome analysis 5	$250.32	$420.40	$480.43	$235.30
87901	Genotype DNA HIV reverse t	$364.64	$301.01	$424.58	$245.06

Sources: Avalere Health analysis. CPT codes copyright American Medical Association

The study found that for every high-volume code reviewed, Medicare paid lower rates than the weighted commercial mean price. For example, commercial payers paid an average of $20.26 for a complete blood count (CBC), while Medicare's price is almost half at $11.02. For column chromatography for drug screening, commercial payers paid $69.48 and Medicare paid $25.57.

Commercial rates grew even more expensive than Medicare when services were provided in rural areas. For example, the study found that rates could more than double in low-volume areas such as Boise, Idaho, compared to high-volume areas such as New York.

For 15 common lower-priced tests, the average Medicare national limit is $11.82 while the average overall commercial mean price is $19.14, according to Avalere's analysis. For 12 high-priced tests, the Medicare national limit is $168.09 while the overall commercial mean price is $188.79.

Avalere's findings contrast with earlier studies which ACLA says failed to consider more than half of the private market. A June 2013 report by the Department of Health and Human Services Office of Inspector General (OIG) claimed that private payers receive a better deal on lab services than Medicare (*NIR, June 27, 2013, p. 1*). Based on its analysis, the OIG concluded that in 2011, Medicare paid between 18 percent and 30 percent more than other insurers for 20 high-volume or high-expenditure lab tests. Medicare could have saved $910 million on these tests if it had paid providers at the lowest established rate in each geographic area, the OIG said.

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