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INSIDE *NIR*

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FISH Payment Cut for 2015 Under Medicare; IHC Code 88342 Resurrected

The final Physician Fee Schedule (PFS) for 2015, released on Halloween, contains good news and bad news for clinical and anatomic pathologists.

First the good news: The Centers for Medicare and Medicaid Services (CMS) has resurrected CPT 88342 for immunohistochemistry (IHC) and killed the two G codes (G0461 and G0462) that it had put into place for 2014. Two new IHC codes, 88341 and 88344, have been introduced.

Now the bad news: Medicare payment for fluorescent in situ hybridization (FISH) testing in 2015 will drop significantly despite an earlier proposal by the CMS to increase FISH payment by 30 percent.

While payments for some pathology services considered overvalued are adjusted downward, some others will see payment increases. The net change, says the College of American Pathologists (CAP), is 0 percent.

Continued on p. 2

CMS Finalizes Plans to Package TC of Ancillary Services Under Hospital Outpatient Payment

The Centers for Medicare and Medicaid Services (CMS) has finalized its proposal to package the technical component of certain ancillary services, including many anatomic pathology services, into a single payment for services provided in hospital outpatient departments or freestanding surgical centers (ambulatory surgical centers).

The agency will package certain ancillary services when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service. The initial set of services to be packaged under this ancillary service policy are the services assigned to ambulatory payment classifications (APCs) having an APC geometric mean cost (prior to application of status indicator Q1) of less than or equal to $100. Services that are significant for pathologists include those assigned to APC 352 (Level 1 Pathology) and APC 433 (Level II Pathology). Services that fall under APC 0345, Transfusion Laboratory Procedures, also are subject to the packaging policy.

The packaging policy applies only to the facility payment for the technical aspect of the services and does not affect the Physician Fee Schedule payment to the pathologist for the physician work in performing pathology services.

Continued on p. 5

FISH Payment Cut for 2015 Under Medicare, *from p. 1*
Details of the final PFS rule for 2015 are detailed below:

FISH Testing

CMS has revised both codes and payments used for FISH testing. First, it revised codes 88365, 88367, and 88368 to specify "each separately identifiable probe per block." It also created six new codes, three of which apply to add-on FISH services (88364, 88373, and 88369) and three of which apply to multiplex probes (88366, 88374, and 88377).

For five of the FISH codes, CMS established relative units that were lower than what was recommended by the American Medical Association. As a result, payment for the technical component of FISH testing is slated to drop by up to 58 percent in 2015.

Immunohistochemistry

In recent years, CMS targeted IHC as overvalued and created G codes in 2014 to reduce Medicare spending in this area. For 2015, CMS has eliminated the G codes and 88343 and has reinstated 88342, immunohistochemistry or immunocytochemistry, per specimen, initial single antibody stain procedure ($90.58). In addition, CMS has introduced two new IHC codes:

- 88341, immunohistochemistry or immunocytochemistry, per specimen, each additional single antibody stain procedure (list separately in addition to code for primary procedure); and
- 88344, immunohistochemistry or immunocytochemistry, per specimen, each multiplex antibody stain procedure.

Prostate G Codes

CMS is finalizing its proposal to use a single code, G0416, to cover all prostate needle biopsies regardless of the number of biopsies submitted and to delete three other recently introduced G codes for prostate biopsies. According to the rule, CMS believes that using G0416 to report all prostate biopsy pathology services, regardless of the number of specimens, would simplify the coding and mitigate overutilization incentives.

"Given the infrequency with which G0417, G0418, and G0419 are used, we did not believe this was a significant change," it said. "Based on our review of medical literature and examination of Medicare claims data, we indicated that we believe that the typical number of specimens evaluated for prostate biopsies is between 10 and 12."

For 2015, there will be one payment for prostate biopsy services on Medicare patients using G0416. Medicare will pay $467 for the technical component (TC), $183 for the professional component, and $649 for global payment.

CAP opposes this change and plans to work with CMS on its review of payment for this code in 2016.

Other Code-Level Changes

CMS accepted CAP's argument to pay for CPT code 88375, which was new in 2014. This code is for endomicroscopy interpretation and represents a reversed decision not to pay separately on the PFS last year.

The agency also accepted Relative Value Update Committee-approved values developed by CAP for microdissection (88380 and 88381), which was also targeted.

The agency also made cuts to the direct costs used to determine payment for microdissection services. Although payment for the service decreased, there was significant concern that Medicare would take actions to not pay for pathologists' work associated with the services, as well as the technical costs.

LCD Changes

CMS had sought to expand the Palmetto Molecular Diagnostic Service program (MolDx) for all local coverage determinations (LCDs) for clinical diagnostic laboratory tests. The new process would have shortened the public comment period from 45 days to 30 and limited the opportunities for stakeholders to suggest improvements to draft LCDs based upon their knowledge of the medical literature and local practice patterns. The number of Medicare contractors also would have been reduced as required by the Protecting Access to Medicare Act of 2014.

The 2015 Physician Fee Schedule and supporting documents are available at www.cms.gov. *Click on Medicare, and then click on Physician Fee Schedule.*

CMS says it will not move forward with the LCD proposal through this rulemaking and will explore the possibility of future notice and comment on this issue.

New PQRS Measures

CMS added three new pathology measures under its Physician Quality Reporting System:

- *Lung Cancer Reporting (Biopsy/Cytology Specimens)*: Pathology reports based on biopsy or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type or classified as NSCLC-NOS with an explanation included in the pathology report.
- *Lung Cancer Reporting (Resection Specimens)*: Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category, and for non-small cell lung cancer, histologic type.
- *Melanoma Reporting*: Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness and ulceration and for pT1, mitotic rate.

Targeted Codes for Revaluation in 2016 Fee Schedule

The 2015 final rule requested that several pathology services may be overvalued and need additional review next year. These include cytopathology interpretation services, the TC payment for flow cytometry, and the Medicare G code for reporting all prostate biopsy specimens.

Physician Payment

Under the final PFS, Medicare payment for physicians is slated to be reduced by 21.2 percent after March 2015, but the chances that such a cut will actually take effect are slim. The cut is required under the Sustainable Growth Rate (SGR) formula but has been overturned repeatedly by Congress in short-term "doc fixes." The Protecting Access to Medicare Act of 2014, signed into law in April, provides for no reduction in physician pay furnished through March 2015.

Pay for physician services is multiplied by the fixed-dollar conversion factor. The conversion factor for Jan. 1, 2015, through March 31, 2015, will be $35.8013. Absent intervention by Congress, the conversion factor will drop to $28.2239 for the remainder of 2015.

Takeaway: The final Physician Fee Schedule for 2015 is a mixed bag for pathologists, though the net effect of payment changes is negligible.

MEDICARE PAYMENT FOR PATHOLOGY SERVICES, 2015

(PARTIAL LISTING OF PATHOLOGY CODES)

**Please note that there is not a direct crosswalk between payment for in situ hybridization and immunohistochemisty services as the codes and reporting have changed for 2015. The College of American Pathologists worked for these changes in 2015 to address payment and reporting limitations sought from the Centers for Medicare and Medicaid Services as both code families were targeted by the agency as overvalued. For example, in 2014 CMS payment policies reduced the reporting of CPT code 88368 to one unit of service. In 2015 one unit of the new multiplex code (88377) would be reported.*

HCPCS	DESCRIPTION[1]	2014 TOTAL PAYMENT[2]	2015 TOTAL PAYMENT[3]	TOTAL PAYMENT PERCENT CHANGE
80500	Lab pathology consultation	$21.14	$23.27	10.1%
80502	Lab pathology consultation	$68.42	$73.39	7.3%
88120	Cytp urine 3-5 probes ea spec	$618.66	$625.09	1.0%
88121	Cytp urine 3-5 probes cmptr	$535.19	$555.64	3.8%
88125	Forensic cytopathology	$22.21	$26.49	19.3%
88184	Flowcytometry/tc 1 marker	$87.77	$93.80	6.9%
88185	Flowcytometry/tc add-on	$53.73	$56.92	5.9%
88187	Flowcytometry/read 2-8	$71.65	$72.32	0.9%
88188	Flowcytometry/read 9-15	$90.27	$91.65	1.5%
88189	Flowcytometry/read 16 or more	$110.69	$113.13	2.2%
88291	Cyto/molecular report	$31.17	$31.86	2.2%
88300	Surgical path gross	$14.69	$15.39	4.8%
88302	Tissue exam by pathologist	$30.09	$32.22	7.1%
88304	Tissue exam by pathologist	$43.35	$45.83	5.7%
88305	Tissue exam by pathologist	$70.57	$73.03	3.5%
88307	Tissue exam by pathologist	$288.37	$307.18	6.5%
88309	Tissue exam by pathologist	$438.83	$465.06	6.0%
88312	Special stains group 1	$94.57	$97.74	3.3%
88313	Special stains group 2	$65.91	$68.02	3.2%
88314	Histochemical stains add-on	$78.09	$74.82	-4.2%
88329	Path consult intraop	$57.32	$59.07	3.1%
88331	Path consult intraop 1 bloc	$98.87	$103.11	4.3%
88332	Path consult intraop addl	$43.70	$45.47	4.0%
88333	Intraop cyto path consult 1	$104.60	$109.55	4.7%
88334	Intraop cyto path consult 2	$65.20	$66.95	2.7%
88341*	Immunohisto antibody slide	$0.00	$67.31	N/A
88342*	Immunohisto antibody stain	$0.00	$90.58	N/A
88344*	Immunohisto antibody slide	N/A	$117.07	N/A
88346	Immunofluorescent study	$106.39	$110.27	3.6%
88347	Immunofluorescent study	$88.84	$93.08	4.8%
88348	Electron microscopy	$702.49	$210.51	-70.0%
88356	Analysis nerve	$279.78	$205.86	-26.4%
88365*	In situ hybridization (FISH)	$177.32	$157.17	-11.4%
88367*	In situ hybridization auto	$255.77	$107.40	-58.0%
88368*	In situ hybridization manual	$232.49	$108.84	-53.2%
88377	M/phmtrc analysis quant/semiq	N/A	$214.45	N/A
88380	Microdissection laser	$190.58	$132.82	-30.3%
88381	Microdissection manual	$160.84	$124.59	-22.5%
88387	Tiss exam molecular study	$35.82	$42.96	19.9%
G0416	Prostate biopsy, any mthd	$651.26	$648.72	-0.4%

1. CPT codes and descriptions are copyright 2014 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.
2. Payments based on the 2014 conversion factor of 35.8228.
3. Payments based on the 2014 conversion factor of 35.8228, adjusted to 35.8013 to include the budget neutrality adjustment.
Source: College of American Pathologists

CMS Finalizes Plans to Package TC of Ancillary Services, *from p. 1*

The $100 geometric mean cost limit for the APC is part of the methodology of establishing an initial set of conditionally packaged ancillary service APCs and is not meant to represent a threshold above which a given ancillary service would not be packaged but as a basis for selecting an initial set of APCs that would likely be updated and expanded in future years.

The final HOPPS rule is available at www.cms.gov. *Click on Medicare, and then click on Hospital Outpatient PPS.*

According to CMS, the ancillary services that will be packaged are primarily minor diagnostic tests and procedures that are often performed with primary services, although there are instances where hospitals provide such services alone and without another primary service during the same encounter.

The College of American Pathologists opposed the packaging policy, saying it would increase administrative burdens, provide disincentives for medically necessary services, and lead to disruptions in patient care.

PATHOLOGY SERVICES SUBJECT TO PACKAGING UNDER HOPPS (PARTIAL LISTING)		
LEVEL I PATHOLOGY (APC 0342)		
CODE	**DESCRIPTOR**	**GEOMETRIC MEAN**
88304	Tissue exam by pathologist	$41.07
88112	Cytopath cell enhance tech	$42.94
88305	Tissue exam by pathology	$59.71
88173	Cytopath eval fna report	$60.82
88312	Special stains group 1	$63.13
88313	Special stains group 2	$74.82
88365	In situ hybridization (FISH)	$124.88
LEVEL II PATHOLOGY (APC 0433)		
88307	Tissue exam by pathology	$175.74
88331	Path consult, frozen section one block	$98.82
88342	Immunohistochemistry antibody stain	$128.92
88120	Cytp, urine 3-5 probes, manual	$137.91
88121	Cytp, urine 3-5 probes, computer-assisted	$162.53
88360	Tumor immunohistochemistry, manual	$144.39
88361	Tumor immunohistochemistry, computed assisted	$143.42
88184	Flow cytometry, technical component only, first marker	$316.97
Source: Centers for Medicare and Medicaid Services		

Payment Update

CMS will update the Hospital Outpatient Prospective Payment System (HOPPS) market basket by 2.2 percent for calendar year 2015. The increase is based on the projected hospital market basket increase of 2.9 percent minus both a 0.5 percentage point adjustment for multifactor productivity and a 0.2 percent adjustment required by the Affordable Care Act.

CMS will continue to implement the statutory two percentage point reduction in payment for hospitals failing to meet the hospital outpatient quality reporting requirement by applying a reporting factor of 0.980 to the HOPPS payments and all applicable services.

Takeaway: Pathologists who provide services in hospital outpatient settings may need to adjust their provider agreements to ensure they receive payment from the hospital for some services that now will be packaged into a single payment.

Labs Urged to Coordinate With CDC on Ebola Testing

The Centers for Medicare and Medicaid Services (CMS) is urging clinical laboratories to coordinate with the Centers for Disease Control and Prevention (CDC) and state public health laboratories before handling Ebola specimens. In a Nov. 7 memo sent to state survey directors, CMS notes that CDC has issued interim guidance for "specimen collection, transport, testing, and submission for persons under investigation for Ebola virus disease in the United States."

Among the key points in the CDC specimen guidance:

- ❑ Clinical laboratories can safely handle specimens from potential patients by taking all required precautions and practices in the laboratory specifically designed for pathogens spread in the blood;
- ❑ Risk assessments should be conducted by each laboratory director, biosafety officer, or other responsible person to determine the potential for sprays, splashes, or aerosol generated during laboratory procedures;
- ❑ Any person collecting specimens from a patient with suspected Ebola virus disease should wear appropriate personal protective equipment; and
- ❑ Anyone collecting specimens from a patient should follow the procedures listed in the guidance for transporting them through the health care facility, clean-up of spills, storing, packaging, and shipping to CDC for testing.

If surveyors determine that a survey must be conducted, surveyors are expected to assess compliance with only the Clinical Laboratory Improvement Amendments, the memo instructs. "The laboratory director is ultimately responsible for the physical plant and environmental conditions under which testing is performed," it says. "All CLIA regulations remain in effect and all individual state protocols must be met. Specific questions about device decontamination should be directed to specific manufacturers and CDC."

Takeaway: Laboratories should work closely with the CDC and state public health laboratories as they prepare for the possibility of handling Ebola specimens.

Ebola Resources

- CDC guidance for specimens and personal protective equipment is available at *http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html*.
- CDC Ebola virus disease information and updates are available at *http://www.cdc.gov/vhf/ebola/index.html*.
- Occupational Safety and Health Administration Ebola guidelines are available at *https://www.osha.gov/SLTC/ebola/*.
- FDA test system information is available at *http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/UCM410308.htm*.

HIPAA Privacy Rule Allows Disclosure Of Some Patient Information in Emergencies

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule allows for the disclosure of protected health information (PHI) without patient permission in public health emergency situations, such as the ongoing Ebola outbreak, according to a bulletin from the Department of Health and Human Services (HHS) Office for Civil Rights, released Nov. 10.

The bulletin said the Privacy Rule "protects the privacy of patients' health information (protected health information) but is balanced to ensure that appropriate uses and disclosures of the information still may be made when necessary to treat a patient, to protect the nation's public health, and for other critical purposes."

For example, covered entities may share PHI with public health authorities "for the purpose of preventing or controlling disease, injury or disability," the HHS bulletin said. PHI also can be shared with foreign governments, as well as with individuals who might be at risk of infection or disease, all without patient permission.

Allowable Disclosures

The HHS bulletin outlines several other instances where PHI disclosures are allowed without patient permission, including when patients are undergoing treatment and the information is needed to improve coordination of care and when patients represent an imminent danger to public health.

Disclosures also are allowed to a patient's family or friends who are involved in the provision of care. In lieu of disclosing PHI directly to family and friends, the information can be shared with disaster relief organizations, such as the Red Cross, which may use the PHI to coordinate care with a patient's family or friends or inform them of a patient's death, the HHS said.

In public health emergencies, PHI can be disclosed to media organizations, albeit in a limited fashion, such as "facility directory information to acknowledge an individual is a patient at the facility and provide basic information about the patient's condition in general terms (e.g., critical or stable, deceased, or treated and released) if the patient has not objected to or restricted the release of such information or, if the patient is incapacitated, if the disclosure is believed to be in the best interest of the patient and is consistent with any prior expressed preferences of the patient."

'Minimum Necessary' Limits

Although acknowledging that PHI can be shared without patient permission, the HHS bulletin said covered entities disclosing PHI, even in emergency situations, must do all they can to make sure they are sharing only the "minimum necessary" information.

Covered entities can rely on reassurances from public health authorities that the information being requested is the minimum necessary for the particular public health emergency, the HHS said.

"For example, a covered entity may rely on representations from the CDC that the protected health information requested by the CDC about all patients exposed to or suspected or confirmed to have Ebola virus disease is the minimum necessary for the public health purpose," the bulletin said.

Takeaway: PHI can be disclosed without patient permission during public health emergencies.

Wall Street Journal Highlights Self-Referral

A recent article in the *Wall Street Journal* (*WSJ*) is calling attention to the topic of self-referral, an issue that has irked laboratories for years.

The article, published Oct. 22, 2014, highlights a program used at 21st Century Oncology Holdings Inc.—a national chain of cancer practices—that gives its urologist a financial incentive to order fluorescence in situ hybridization (FISH) tests for bladder cancer from a central in-house lab. The Health and Human Services Office of Inspector General subpoenaed 21st Century Oncology in February requesting records, according to a company filing with the Securities and Exchange Commission (SEC).

While the SEC filings didn't mention self-referral, the *WSJ* article says ordering treatments and tests in-house is a pillar of the company's business model.

"By grouping several medical specialties under the same corporate roof, it captures revenues generated when one group of doctors refers patients to another," the article states. "Its 95 urologists can get a cut of the revenues generated by the Fort Myers lab to which they refer tests."

Medicare billing records released earlier this year show that 21st Century Oncology is an outlier in billing for computer-assisted FISH testing. According to the *WSJ*, its two current pathologists in 2012 each billed Medicare more for that version of the test than any other pathologist or lab in the country.

Lab groups, including the American Clinical Laboratory Association and the College of American Pathologists, have long advocated for Congress to close the exception to the Stark law, which prohibits self-referrals. When it was passed, the Stark law included an exception for "in-office ancillary services," which was designed to allow simple lab tests, such as glucose and urinalysis, to be done at the time of the patient's doctor visit. Anatomic pathology (AP) services typically are not done at the time of the office visit.

Opponents of the exception say some physicians have exploited the exception to refer AP services to laboratories in which they have a financial interest, thus creating incentives for those physicians to bill Medicare for more tests than necessary and increasing costs with no benefits to patient care.

A 2014 report from the Government Accountability Office found that physicians who self-refer AP services cost Medicare about $69 million in 2010.

While the White House has recommended narrowing the scope of the Stark law's in-office ancillary services exception, saying it would save Medicare $6 billion over 10 years by eliminating medical overutilization, Congress has refused to touch the exception, presumably because of intense lobbying by physician groups.

Takeaway: At a time when lawmakers are looking for a way to reduce medical spending and control health care costs, the WSJ article highlights one area where cost savings can be found.

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