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Medicare Physician Fees On Track for Cuts in 2008

For a quick guide to the final 2008 physician fee schedule rule and the key changes impacting pathologists and independent clinical laboratories, see the Focus, *pp. 3-6.*

Unless Congress dictates otherwise, all physicians will see their Medicare fees cut 10.1% on average next year under the statutory SGR formula, the Centers for Medicare & Medicaid Services announced in the final 2008 Part B physician fee schedule rule, released November 1.

For pathologists, the cut will be deeper, -12%, when the negative update is combined with reductions in work and practice expense relative value units. For the professional component of CPT 88305, the combined impact will be -15%. In one bright spot, fees will continue to increase significantly for technical component codes in flow cytometry and in situ hybridization.

Meantime, the Senate Finance Committee is working on a physician fee fix, but one sticking point at press time was whether to go for one or two years. GOP members reportedly favored one year because this would cost less and require less of a cut in Medicare managed care payments. The House has approved a two-year fix, increasing fees by 0.5% in 2008 and 2009 and paying for the increase in part by a major cut in Medicare Advantage payments, currently 12% higher than traditional fee-for-service (*NIR, 28, 20/Aug 13 '07, p. 1*).

CMS Willing to Rethink Final Lab Fee Decisions

If you disagree with how Medicare has established a final fee for a new test on the Part B lab fee schedule, you will have one more chance to ask the Centers for Medicare & Medicaid Services to change its mind.

CMS has adopted new procedures to allow clinical labs, other providers in the industry, and the public to request a reconsideration of the final fee determination for a new test, including the method used to derive the fee and the payment amount set. The agency approved the new policy as part of the final 2008 physician fee schedule rule, with an effective date of January 1. It had called for a reconsideration process in the proposed physician fee schedule issued earlier this year (*NIR, 28, 18/Jul 16 '07, p. 8*).

The reconsideration process applies to "new tests," defined by CMS as "any new test for which a new or substantially revised HCPCS code is assigned on or after January 1, 2008." It is an addition to the procedures CMS now follows annually in determining payment rates for new tests on the lab fee schedule. Currently, the agency holds two rounds of public comment on whether to use *Continued on p. 2*

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Final Lab Fee Decisions, *from p. 1*

gap-fill or crosswalk methods to set the rates before publishing the final fee decisions (*NIR, 28, 17/Jun 25 '07, p. 1*).

Now following the release of the final fee rates, typically in November, providers and the public have 60 days to request a reconsideration of any fee for a new test. Those who submit written comments within that period will have the opportunity to present at the next public meeting on lab fee-setting (typically held in July each year). In addition, all those at the meeting will be allowed to comment as well.

Attorney Peter Kazon, with Alston & Bird in Washington, DC and also outside counsel for the American Clinical Laboratory Association, told *NIR* that "in the big picture, the reconsideration process reflects CMS's continuing effort to hone the way it sets fees for new lab tests," providing more transparency and time to get input on particulars that are sensitive to the lab industry.

It is up to CMS to decide whether to reconsider and, if so, whether to change the prior final fee determination. Either way, the agency's decision is final. There are no further rights to appeal, Kazon said. CMS's ultimate determination is effective in January of the following year.

Do Gene Patents Stifle or Stimulate Research, Genetic Testing?

This question was aired at an October 30 hearing before the House Subcommittee on Courts, the Internet & Intellectual Property. At issue is whether patents and exclusive licensing of genomic discoveries encourage research by protecting investment or hinder patient access to genetic testing as well as the public's access to relevant information.

Marc Grodman, MD, CEO of Bio-Reference Laboratories, told the panel that patents and exclusive licensing severely restrict the ability of clinical labs to offer new genetic tests, and this raises "potential concerns about the public's health." Examples of diseases where testing has been halted due to patent enforcement include breast cancer, Alzheimer disease, Canavan disease, and Charcot-Marie-Tooth disease, according to the College of American Pathologists.

In its testimony at the hearing, CAP stressed that given the advances clinical medicine has made from the genetic revolution, "Pathologists have a keen interest in ensuring that gene patents do not restrict the ability of physicians to provide quality diagnostic services to the patients they serve."

When patents are granted, CAP said, "subsequent exclusive license agreements, excessive licensing fees, and other restrictive licensing conditions prevent physicians and labs from providing genetic-based clinical testing services. As a consequence, patient access to care is limited, the quality of patient care is jeopardized, clinical observations as the basis for new discoveries are compromised, and the training of healthcare providers is restricted."

CAP said "the Frist-Ganske law should be amended to protect clinical lab medical practitioners from patent infringement, just as other medical providers are protected." The College also supports H.R. 977, the Genomic Research & Accessibility Act, that would prohibit patents from being obtained for a nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies.

focus on: *Medicare Payment Policy*

CMS Releases Final 2008 Medicare Physician Fee Schedule: *A Quick Guide to Key Pathology, Lab Changes*

In 2008, Medicare will pay approximately $58.9 billion to about 900,000 physicians and other healthcare professionals for covered services, CMS estimates.

For pathologists and independent clinical laboratories, the final 2008 Medicare physician fee schedule rule, released November 1 by the Centers for Medicare & Medicaid Services, ushers in a host of changes, good and bad.

On the upside, it imposes anti-markup provisions aimed at ending pod lab arrangements, a move supported by pathology and lab lobbies. On the downside, pathologists along with other physicians are scheduled for a double-digit cut in their Part B fees, plus pathology payments will be reduced even more due to changes in work and practice expense relative value units (RVUs). Some pathology technical component fees, however, will continue to increase due to higher overhead RVUs.

The final rule with comment period is on display at the *Federal Register* and will be published in the November 27 issue, CMS said. Provisions affecting pathologists and clinical laboratories, effective January 1, are discussed below.

Physician Payments

Q What is the scheduled cut in Medicare physician fees under the SGR formula?

A The cut is 10.1%. The impact will vary by individual physicians, according to speciality, mix, and volume of the covered services they provide. The Sustainable Growth Rate (SGR) formula is used to calculate annual physician fee updates, positive or negative. The SGR ties the rate of spending growth for Medicare physician services to a target rate, based on spending growth in the total economy, among other factors. If the actual rate of spending growth exceeds the target, the update is decreased; if it is less, the update is increased.

Since 2002, the SGR has triggered fee cuts, but Congress has stepped in repeatedly to block the reductions and is expected to do so again for 2008. The House has already passed a Medicare bill that repeals the SGR, replaces it with expenditure targets for six categories of physician services, and grants a 0.5% fee increase for 2008 and 2009.

In 2007, Congress approved a zero update, in effect freezing physician fees at 2005 levels. But lawmakers also approved a 1.5% bonus payment to physicians who voluntarily report specified quality performance measures on their fee-for-service claims.

Q Can pathologists expect more of a cut?

A Yes, because on top of the negative update, CMS has decreased work and practice expense relative value units (RVUs), resulting in an additional 2% reduction in pathology fees. The combined impact for pathology and independent labs is as follows:

	Allowed Charges ($M)	Combined Impact
Pathology	$948	-12%
Independent lab	$1,087	-10%

Q What is the 2008 conversion factor that will translate a physician service's RVUs (work, practice, and malpractice expense) into a dollar amount?
A The 2008 conversion factor is $34.0682, down from $37.8975 in 2007.

Q Which high-volume pathology code is cut significantly?
A The professional component non-facility fee for CPT 88305, Tissue exam by pathologist, will fall from $37.90 in 2007 to $32.36 in 2008, a drop of 15%.

Q Which pathology codes continue to show major fee increases?
A Technical component fees for flow cytometry and most in situ hybridization (fish) services remain on the rise, benefiting from higher transitional practice expense RVUs (*see table below*). Flow cytometry TC fees started to climb in 2006 after being slashed in 2005—sometimes by as much as 50%—when CMS first priced the new CPT flow cytometry codes that were introduced that year (*NIR 28, 6/Jan 15 '07, p. 3*). The interpretation fee for these codes, however, continues to decline due to reduced work and practice expense RVUs.

Anti-Markup Provisions for Diagnostic Tests

Q What test fees are affected?
A CMS is imposing anti-markup provisions on diagnostic tests (other than clinical lab tests), based on where the service is performed and not on the employment status of the individual performing the service.

The provisions apply to the technical component (TC) and the professional component (PC) of purchased diagnostic services and to the TC and the PC of a service subject to reassignment, ordered by the billing physician or other supplier (or

Selected Pathology Codes:
Final Non-Facility RVUs, Fees for 2008

CPT Code	Work RVUs	PE RVUs (07/08)	Malpractice RVUs	Total RVUs (07/08)	Fee (07/08)*
Flow Cytometry					
88184, 1st marker	0.00	1.60/1.89	0.02	1.62/1.91	$61.39/$65.07
88185, add'l marker	0.00	0.85/1.07	0.02	0.87/1.09	$32.97/$37.13
88187, read 2-8 markers	1.36	0.44/0.42	0.01	1.81/1.79	$68.59/$60.98
88188, read 9-15	1.69	0.54/0.50	0.01	2.24/2.20	$84.89/$74.95
88189, read 16 & more	2.23	0.68/0.61	0.01	2.92/2.85	$110.66/$97.09
In Situ Hybridization (fish)					
88365-TC	0.00	1.88/2.33	0.02	1.90/2.35	$72/$80.06
88367-TC	0.00	3.85/4.21	0.06	3.91/4.27	$148.18/$145.47
88368-TC	0.00	2.46/3.20	0.06	2.52/3.26	$95.50/$111.06

Source: Final rule, Medicare physician fee schedule, 2008. CPT codes © American Medical Assn. *"Pure" fee, rounded up, not adjusted for geographic cost differences, using conversion factor of $37.8975 for 2007 and $34.0682 for 2008.

ordered by a party related by common ownership or control to the biller) if the TC or the PC is purchased outright or performed by another physician or supplier at a site other than the office of the billing physician or other supplier.

The anti-markup rules do not apply to independent labs that have not ordered the TC, CMS notes.

For purposes of the anti-markup provisions, CMS says, the "office of the billing physician or other supplier" means "the space where the physician or other supplier regularly furnishes patient care. With respect to a billing … physician organization, it is defined as the space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally."

The definition of the group's office does not include, CMS notes, "space utilized by the group as a 'centralized building' (or other space) where only (or primarily) diagnostic testing is performed by radiologists and pathologists."

Q What effect will the anti-markup provisions have on pod labs?

A The final rule differs in details from the proposed rule in this regard, but the effect is the same, according to industry sources (*NIR, 28/20/Aug 13 '07, p. 3*). It will put an end to such arrangements by drying up their profitability.

Under typical pod lab arrangements, physician specialty groups tap pathology referrals to increase revenue in a shrinking reimbursement environment. The group typically rents or leases space off-site, often in a site remote from the group, and "outsources" the referrals to "pod labs" that operate under contract with a pathologist. Groups often have labs in a common location and the pathologist rotates from lab to lab, rendering interpretations for a number of referring specialists.

The anti-markup provisions, however, do not cover contractual arrangements between pathologists and the billing physician or other supplier when the work is performed in the office of the billing physician or group. This appears to not implicate a practice known as "insourcing," whereby specialty physicians bring the lab in-house and the work is done there under contract with a pathologist.

CMS cautions that it will monitor contractual joint ventures to see if "arrangements that are currently taking place at a site other than the office of the billing physician or group simply migrate to the 'office of the billing physician or other supplier' to escape the anti-markup provisions," adding "we may revisit the idea of imposing an anti-markup provision for services performed by a technician or physician who works for more than a certain number of physician practices."

Q Is there a "net charge" limit under the anti-markup provisions?

A Yes. If the provisions apply, payment to the billing physician or group, including applicable deductibles and co-insurance paid by or on behalf of the beneficiary may

Modification to Archived Specimen Rule

In the 2007 final rule, CMS stated that for a laboratory test that uses a stored specimen, the date of service (DOS) is the date the specimen was obtained from storage when it's more than 30 days before testing. Specimens stored 30 days or less have a DOS of the date the test was performed only if:

- ❑ The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital
- ❑ The specimen was collected while the patient was undergoing a hospital surgical procedure
- ❑ It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted
- ❑ The results of the test do not guide treatment provided during the hospital stay
- ❑ The test was reasonable and medically necessary for the treatment of an illness

In the final rule, CMS is applying the above policy to the technical component of physician pathology services, commenting that the collection date for these services and clinical lab services is similar.

not exceed the lowest of: the supplier's net charge to the physician, the physician's actual charge, or the fee schedule amount for the test that would be allowed if the supplier billed directly.

CMS declined, however, to specify a methodology to calculate the "net charge," saying it is up to billing physicians and other suppliers to determine the method they use, and urged them to retain documentation on how they derived the charge. The burden of proof is on those who bill, the agency cautioned.

'Grandfather' Protection for Independent Labs

Q Does CMS plans to eliminate this protection for certain pathology technical component billings?

A Yes. The "grandfather" protection allows qualified independent clinical laboratories to bill Part B for the TC of anatomic pathology services to hospital patients. It is set to expire at the end of this year. The protection applies to hospital-lab arrangements in effect as of July 22, 1999, the date when CMS first proposed to end such billings. CMS contends that the TC is reimbursed as part of Medicare's payment to the hospital and that labs should seek payment from the hospital, not Part B.

Q What are the prospects for legislation to continue the protection?

A Despite repeated attempts by CMS to end the protection, Congress has intervened to stay the agency's hand. The Medicare bill that passed the House earlier this year approved a two-year extension of the "grandfather" provision, through 2009. Pathology and laboratory groups are lobbying to get the extension included in a broader Medicare bill the Senate Finance Committee is developing. The groups, however, continue to support making the protection permanent.

Physician Quality Reporting Initiative

Q Are pathology measures included in the 2008 PQRI program?

A Yes. Two performance measures based on breast and colon cancer protocols are included in the final 2008 Medicare physician fee schedule rule, making pathologists eligible to participate in the PQRI next year. The measures are:

- ❑ #1: Breast cancer resection pathology reporting: pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade.
- ❑ #2: Colorectal cancer reaction pathology reporting: pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade.

The measures were developed by the College of American Pathologists and the AMA's Physician Consortium for Performance Improvement (*NIR, 29, 3/Nov 5 '07, p. 1*). CAP has been picked by the AMA to spearhead the effort to develop pathology pay-for-performance measures. The College is already working to add more measures to the PQRI list for 2009.

Under the PQRI, eligible physicians who voluntarily report CMS-specified performance measures qualify to receive a bonus payment on their Medicare fee-for-service claims. CMS has identified 119 measures for reporting next year. For a summary, *http://www.cms.hhs.gov/PQRI/downloads/2008PQRIMPFSSummary.pdf*.

The bonus for 2008 will be paid in mid-2009 on all claims identified with the NPI and reported correctly. Specifications for the 2008 PQRI, including the pathology measures, will be available in December, CMS says.

♦ CLIA *Advisory*

CMS Announces New Waived Tests & Billing Codes

The Centers for Medicare & Medicaid Services has recently updated its list of clinical laboratory tests approved by the Food & Drug Administration as waived under CLIA (the Clinical Laboratory Improvement Amendments). The following tests have been added, as of October 1, and must be billed with the QW modifier in order to be recognized by local Medicare contractors as a waived test. The list of CLIA waived tests and billing codes is typically updated quarterly. The full list is presented in CMS Change Request 5715, posted at *www.cms.hhs.gov/transmittals*.

CPT Code/Modifier	*Description*
83001QW	Genosis Fertell Female Fertility Test
84443QW	Jant Pharmacal Accutest TSH (Whole Blood)
86308QW	Signify Mono Whole Blood
86308QW	Clearview MONO Whole Blood
82465QW, 83718QW, 84460QW, 80061QW, 84478QW	Cholestech LDX (Lipid Profile – ALT (GPT) {Whole Blood}
86318QW	Immunostics Detector H. Pylori WB (H. pylori Antibody Test) {Whole Blood}
86308QW	Immuno Detector Mono {Whole Blood}
80101QW	Innovacon Multi-Clin Drug Screen Test Device
80101QW	Jant Pharmacal Accutest MultiDrug ER11 Drug Screen Test Device
87880QW	Cardinal Health SP Brand Rapid Test Strep A Dipstick (K010582/A028)
83618QW	Cardinal Health SP Brand Rapid Test H. pylori {Whole Blood} (K024350/A15)
82042QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84520QW	Arkay SPOTCHEM EZ Chemistry Analyzer (Spotchem II Basicpanel 1) {Whole Blood}
86308QW	Cardinal Health SP Brand Rapid Test Mono {Whole Blood}
82247QW, 84075QW, 84157QW, 84450QW, 84460QW	Arkay SPOTCHEM EZ Chemistry Analyzer (Spotchem II Basicpanel 2) {Whole Blood}
86318QW	Fisher Healthcare Sure-Vue H. pylori Test {Whole Blood}
89321QW	Fertell Male Fertility Test

NPI Update ★

Medicare Sets a New Key Date for Using National Provider Identifier

The recently announced NPI deadline, March 1, 2008, will affect you if you are a physician, other practitioner, provider, or supplier who bills Medicare carriers, Medicare Administrative Contractors (MACs), and DME MACs using an electronic claim form ASC X12 837P or the paper claim form CMS-1500.

As of that date, the Centers for Medicare & Medicaid Services says, your Medicare fee-for-service claims must include a National Provider Identifier (NPI) in the primary fields on the claim (that is, the billing, pay-to, and rendering fields). You may continue to submit NPI/legacy pairs in these fields or submit only your NPI on the claim. You may not submit claims containing only a legacy identifier in the primary fields. Failure to submit an NPI in the primary fields will result in your claim being rejected or returned as "unprocessable," beginning March 1, 2008. Until further notice, you may continue to include legacy identifiers only for the secondary fields.

CMS previously announced that it will apply similar requirements to 837I electronic claims and UB04 paper claims as of January 1, 2008 (*NIR, 29, 3/Nov 5 '07, p. 7*). Effective May 23, 2008, Medicare will accept only NPIs on all HIPAA electronic transactions, paper claims, and SPR remittance advice. Reporting of legacy identifiers will result in rejection of the transaction.

Lab Bidding Demo Update

In our November 5 issue (p. 5), we erroneously reported that CMS plans to conduct the Medicare lab competitive bidding demonstration in two sites within a single state. The demo design calls for each site to be located in a Metropolitan Statistical Area (MSA) within a single state.

The first site selected is the San Diego-Carlsbad-San Marcos MSA. The second site could be in California as well or in another state, CMS project officials have confirmed.

The San Diego site has 223,000 Medicare fee-for-service beneficiaries, and total Part B spending for the 303 demo tests up for bid was $21.1 million in 2006, CMS project head Linda Lebovic told *Laboratory Economics*.

Meantime, bipartisan House legislation to repeal the demo (H.R. 3453) has gained more co-sponsors—a total of 20 at press time, seven more since our last report in the November 5 issue. Five Senators have signed on to a companion bill (S. 2099). Lab lobbyists are pushing to get the repeal included in a broader Medicare bill now working its way through Congress.

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