G2 INTELLIGENCE

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Labs Fight Back Over Proposed Medicare Cuts

Medicare paid approximately $8.2 billion for lab tests in 2010, which accounted for about 3 percent of all Medicare Part B payments.

After seeing Medicare payment for lab services cut by more than 11 percent since 2010, clinical laboratories are bristling over recommendations from the Health and Human Services Office of Inspector General (OIG) that Medicare lower payment rates and establish deductibles and coinsurance for lab tests.

Since 2011, the year that data was analyzed for the OIG report, clinical laboratories have received significant cuts in reimbursement, including a cut to pay for a short-term fix in Medicare physician payments and another cut through sequestration, notes Mark Birenbaum, administrator of the National Independent Laboratory Association (NILA), which represents community and regional labs. These cuts are on top of a cumulative 20 percent cut implemented through health care reform—five direct fee cuts and a permanent provider productivity adjustment.

"This is death by a thousand cuts for the nation's community laboratories," said Birenbaum. "NILA is very concerned that OIG would make such drastic and baseless recommendations without considering the impact such changes would have on access to community-based laboratory services."

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Federal Court Upholds Stark Ban On Physician Self-Referral

In a ruling that many pathologists are sure to applaud, a group of urologists recently lost their bid to overturn regulations that prohibit inappropriate physician self-referral and "per-click" leases.

The District of Columbia on May 24 rejected an appeal brought by the Council for Urological Interests (CUI) challenging a 2008 regulatory change that characterized urologists' arrangement with hospitals as impermissible, whereas under prior interpretation by the Centers for Medicare and Medicaid Services (CMS), such arrangements were allowed under compensation exceptions.

Under the Stark law, physicians may not refer Medicare patients to entities "furnishing" designated health services (DHS) with which they have a financial relationship unless an exception applies. A financial relationship may be either an ownership interest or a compensation arrangement.

In the past, under these arrangements, Medicare would pay the hospital a technical fee for nonprofessional personnel, space, and

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Labs Fight Back Over Proposed Medicare Cuts, *from p. 1*

Alan Mertz, executive director of the American Clinical Laboratory Association (ACLA), concurred. "Despite clinical labs only accounting for 1.6 percent of annual Medicare spending, payment for lab services have been cut by over 11 percent since 2010 and face double the amount of cuts already scheduled for the next nine years," he said. "The OIG used Medicare payment data from 2011. In 2013 alone, Medicare payment was cut by 5 percent."

OIG Findings

The OIG recommendations are contained in a report issued in June, "Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings" (OEI-07-11-00010). The OIG collected payment data from 50 state Medicaid programs and three federal employee health benefits (FEHB) plans that pay for lab tests on a fee-for-service basis. The office requested payment rates in effect from Jan. 1-March 31, 2011, for 20 lab tests. The OIG then compared Medicare-paid claims with the state Medicaid program fee schedule amount and FEHB plan median claim payment amounts. Investigators also surveyed Medicaid programs and FEHB plans to determine how the payment rates were formulated, whether a copayment was charged to the patient, and whether lab test charges counted toward a member's deductible.

The report, "Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings" (OEI-07-11-00010) is available at www.oig.hhs.gov.

The OIG found 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, or 38 percent, on these lab tests if it had paid providers at the lowest established rate in each geographic area, the OIG said.

According to the OIG, Medicare paid 29 percent more than Medicaid for CPT 81002 (urinalysis, nonautomated, without microscopy) and 30 percent more for CPT 83550 (iron binding test). The report recommends that the Centers for Medicare and Medicaid Services seek legislation that would allow it to establish lower payment rates for lab tests and consider seeking legislation to institute copayments and deductibles for lab tests.

Flawed Conclusions

While Medicare may pay more than Medicaid for some tests, the report examines only 20 of more than 1,000 laboratory test codes. By comparing Medicare clinical laboratory fee schedule payment rate for these codes to Medicaid and three FEHB plans in 56 areas, there appear to be more than 4,000 comparisons in the report, notes Mertz of ACLA.

"As we examine all of the comparisons . . . we find that Medicare is sometimes the lowest payer in comparison to Medicaid and/or some or all FEHB plans," he says.

Mertz also noted that there is extremely wide variation in prices in the FEHB plans. For instance, FEHB payment for CPT 81003 (urinalysis, automated) ranges from $2.85 to $29 in one state. For CPT 80061 (lipid panel), FEHB prices ranged from $8.20-$52.50.

"These variations raise questions about what these prices represent and how they were determined," says Mertz.

Birenbaum adds that the Medicare payment rates were compared to Medicaid at a time when many state Medicaid budgets are strained and reimbursement levels for health care services across the board are very low. What's more, the report only includes data from independent and physician office-based laboratories, ignoring hospital laboratories, which make up the rest of the clinical laboratory market.

"There are clear oversights and omissions in the approach taken by the OIG to examine the laboratory market," says Birenbaum. "But what's most concerning are the recommendations that the OIG makes from this limited review, which would devastate the small and midsize laboratory market today."

COMPARISON OF MEDICARE PAYMENT WITH MEDICAID PAYMENT

CPT CODE	DESCRIPTION	2011 NUMBER OF ALLOWED TESTS	2011 MEDICARE-ALLOWED AMOUNT	NUMBER OF TESTS WITH POTENTIAL FOR SAVINGS	ALLOWED AMOUNT IF MEDICAID LOWEST RATE USED	PERCENTAGE MEDICARE PAID MORE THAN MEDICAID
80048	Metabolic panel, total calcium	8,622,383	$85,612,322	5,668,213	$75,265,426	14%
80053	Comprehensive metabolic panel	26,667,106	$308,060,147	13,365,771	$279,044,002	10%
80061	Lipid panel	20,096,974	$293,294,006	9,799,707	$254,514,132	15%
81001	Urinalysis, automated, with microscopy	6,636,868	$29,518,138	6,307,849	$25,392,723	16%
81002	Urinalysis, nonautomated, without microscopy	4,153,597	$14,808,195	3,980,171	$11,481,389	29%
81003	Urinalysis, automated, without microscopy	4,808,096	$15,157,960	4,530,759	$12,590,841	20%
82306	Vitamin D, 25 hydroxy	5,308,512	$218,018,917	5,200,763	$173,834,730	25%
82570	Assay of urine creatinine	4,432,117	$31,958,084	4,274,416	$26,437,934	21%
82607	Vitamin B-12	3,283,484	$69,600,580	3,208,218	$54,998,544	27%
82728	Assay of ferritin	2,343,336	$44,791,773	2,285,840	$36,235,474	24%
83036	Glycosylated hemoglobin test	12,374,324	$168,495,108	11,889,154	$139,534,720	21%
83540	Assay of iron	2,573,826	$22,783,202	2,416,826	$17,777,978	28%
83550	Iron binding test	2,001,213	$24,090,743	1,952,675	$18,554,959	30%
83880	Natriuretic peptide	982,145	$46,274,487	947,719	$38,836,439	19%
83970	Assay of parathormone	1,131,955	$65,699,438	1,103,363	$54,696,192	20%
84153	Assay of prostate-specific antigen, total	3,530,885	$91,280,209	3,415,111	$78,423,161	16%
84443	Thyroid stimulating hormone	14,431,323	$340,218,728	13,470,738	$278,608,047	22%
85025	Complete blood count with automated differential white blood cell count	29,982,902	$324,139,981	28,708,580	$256,024,097	27%
85610	Prothrombin time	19,778,756	$109,118,351	18,595,275	$90,002,308	21%
87086	Urine culture colony count	4,622,255	$52,313,325	4,523,417	$43,254,698	21%

Source: OIG Report; CMS, National Claims History Part B Carrier File, 2012. CPT codes © American Medical Association.

focus on: Clinical Lab Regulation

CLIA Update: What's on the Agenda for 2013?

Almost two years after first being proposed, a rule allowing patients to have direct access to their laboratory test results is expected to be finalized by late summer or early fall, according to Judy Yost, director of the Division of Laboratory Services at the Centers for Medicare and Medicaid Services (CMS).

The rule currently is being reviewed by the secretary of Health and Human Services and will then go to the Office of Management and Budget for final review before publication. Yost discussed the rule June 19 during a G2 Intelligence webinar, "Keeping Ahead of the Curve: CLIA Compliance 2013."

The proposed rule, published Sept. 14, 2011, would modify regulations under both the Clinical Laboratory Improvement Amendments (CLIA) and the Health Insurance Portability and Accountability Act. Currently, under CLIA regulations, patients in states that do not provide individual access to test results must request and receive results through their health care provider. At the time the proposal was published, 39 states prohibited a laboratory from releasing a test report directly to a patient without the consent of the health care provider.

CLIA Enrollment

Total Laboratories	235,828
Total Nonexempt	222,899
• Compliance	19,235
• Accredited	15,760
• Waived	156,653
• Provider Performed Microscopy	36,887
Total Exempt	7,293
• New York	3,583
• Washington	3,447

Source: CMS Database, January 2013

While many larger labs that operate in multiple states already have processes in place for release of test results directly to patients, smaller laboratories may face significant costs in adapting their processes and systems to accommodate such changes. Yost says the final rule will specifically address the burden on laboratories.

Once the rule is published, CLIA Interpretive Guidelines for Laboratories will be revisited to ensure laboratories and stakeholders have clear guidance on best practices and resources to implement the technology that will be required to comply with the rule.

PT Regulations

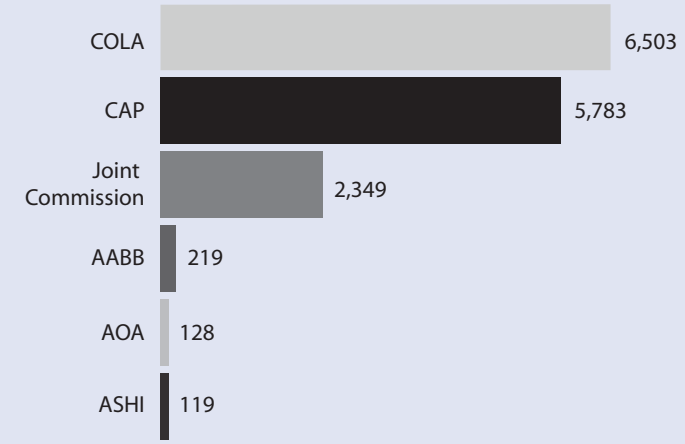
CMS is continuing work on updating proficiency testing (PT) regulations in collaboration with the Centers for Disease Control and Prevention (CDC). The agencies currently are gathering and analyzing data and reviewing analyte lists, grading criteria, and target values.

CMS also is finalizing proposals that would modify CLIA rules that govern the referral of PT samples. Previously, CLIA had adopted a strict interpretation of the term *intentional referrals*, stating that when a lab for any reason referred a PT sample

to another lab for analysis, it had no choice but to impose the harshest sanctions: revocation of the lab's CLIA certification and its approval to receive Medicare and Medicaid payment for one year, as well as barring the lab's owner and operator from owning or operating another lab for two years from the date of revocation.

However, Congress last year passed the Taking Essential Steps in Testing (TEST) Act, which gave CMS discretion in using its enforcement authority to consider penalties on a case-by-case basis for breaches of the PT referral rules.

Accredited Labs by Organization



Source: CMS Database, January 2013

Subsequently, CMS on Feb. 7, 2013, published a proposed rule that would carve out a one-time exception for confirmatory and reflex testing if the PT sample goes to another lab for testing. Described by CMS as "an infrequent and narrowly crafted carve-out from the long-standing interpretation of 'intentional,'" the exception would apply only to a laboratory that refers a PT sample to another laboratory for confirmatory or reflex testing in accordance with the laboratory's standard operating procedures for patient testing.

As long as the PT referral is not a repeat referral (i.e., no other PT referral occurred during the two survey cycles prior to the time of the PT referral at issue), CMS would consider the referral to be "improper" rather than "intentional" and would impose alternative sanctions rather than revoke a laboratory's CLIA certificate. The final rule should be out late this year.

The next step in implementing the TEST Act, says Yost, is a rulemaking to detail adverse actions for PT referrals—defining when the discretion will be applied and when revocation will be imposed.

Individualized Quality Control

CMS has revised quality control (QC) guidelines to incorporate risk-management principles used in manufacturing and other industries contained in Clinical Laboratory Standards Institute guidance, called EP-23, which was published in October 2011. Under EP-23, labs should consider what could go wrong in their operations and take into account a host of factors, such as specific device capabilities, package-insert recommendations, literature about the test, the laboratory setting, operator experience, how the test will be used in medical care, and local quality regulations. CMS has incorporated key EP-23 concepts into its guidelines, and it is now called individualized quality control plan (IQCP).

IQCP applies to CMS-certified nonwaived labs and covers all phases of the testing process. The plan is optional and may or may not reduce the QC amount or frequency, notes Yost. IQCP covers existing and new analytes, test systems, and specialties, except cytology and histopathology.

According to Yost, the IQCP can be customized based on patient population, environment, test system, personnel, and test uses. It also offers flexibility to achieve

QC compliance for each test and is adaptable to future technology advancements. In addition, IQCP permits labs to develop a QC plan using their existing quality practices and information, considers known risks mitigated by manufacturers, and formalizes laboratories' risk-management decisions.

Once effective, IQCP will supersede CLIA's current equivalent quality control policy, says Yost. However, existing regulations will not change, nor will existing QC concepts change. National surveyors will be trained on IQCP, and there will be an education and transition period for labs before IQCP is fully effective, she adds.

Recordings of the June 19 CLIA webinar may be purchased at www.G2Intelligence.com *or by calling 800-531-1026.*

Meantime, CMS-certified labs should continue to follow existing QC protocols, learn about EP-23 and IQCP, and plan and complete their transition by phasing out existing QC and deciding to implement either default QC or IQCP, advises Yost. CMS will notify labs of when the transition and education period begins and ends. At the end, labs must be in compliance with the QC program of their choice or deficiencies will be cited.

CMS will solicit accrediting organizations (AOs) to determine their interest in IQCP, says Yost. Accredited labs should continue to meet their AO's QC standards until they hear otherwise from their AO. More information on IQCP is available at *www.cms.gov/clia*. Questions about the alternate QC option may be sent to *IQCP@cms.hhs.gov*.

Competency Assessment

Laboratories should be assessing the competency of lab personnel on an annual basis (all technical, supervisory, and testing personnel). New guidance from CMS defines *competency* as the ability of laboratory personnel to apply their skill, knowledge, and experience to perform their duties correctly. "Competency is not the same thing as proficiency testing," explains Yost. "PT can be used to meet some elements of competency, but not all."

The individual conducting the competency assessment must be qualified to do so. Depending on the complexity of the testing involved, the individual must be qualified as a technical supervisor, general supervisor, or technical consultant.

The six elements of competency assessment must be completed for each person, each test, each year:

1. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing.
2. Monitoring the recording and reporting of test results.
3. Review of intermediate test results or worksheets, QC records, PT results, and preventive maintenance records.
4. Direct observation of performance of instrument maintenance and function checks.
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external PT samples.
6. Assessment of problem-solving skills.

Competency records should match the laboratory's actual procedures as performed by its personnel, advises Yost. When observing test performance, use the procedure

manual package insert to ensure the information is current and is being followed. Competency for clinical and technical consultants and supervisors is based on their regulatory responsibilities.

Labs don't have to do competency assessment all at one time; it can be spread out through the year, notes Yost. Elements such as preanalytic, analytic, and post-analytic can be combined. Assessors can also combine analytes tested on the same platform but not test systems with different platforms, methods, or manufacturers.

Ultimately, the lab director is accountable for all competency assessments, and the director must also demonstrate proficiency. Yost advises building competency assessment into existing quality practices and procedures as part of the lab's QC system.

Good Practices for Waived Testing

CLIA officials, in conjunction with CDC, have developed education material designed to assist labs that perform waived testing. "Ready? Set? Test!" comes in a poster and booklet format. The poster reminds testers of 10 important practices to follow for accurate and reliable testing, while the booklet describes recommended practices for physicians, nurses, medical assistant, pharmacists, and others who perform patient testing under a CLIA certificate of waiver. CLIA and CDC also have developed an online course for health care professionals performing testing in waived testing sites.

To see how effective the materials are, CMS conducted a pilot study involving two states in each region. Selected waived labs received a copy of the "Ready? Set? Test!" booklet prior to their certificate-of-waiver survey. Post-survey information was collected regarding lab use of the booklet to improve lab practices. In 2010, the baseline year, only 18 percent of surveyed waived labs received letters of congratulations from surveyors. This figure increased to 32 percent in 2011 and 44 percent in 2012.

The conclusion of the study, says Yost, is that educational materials do actually help improve the quality of laboratory testing. The materials are available on both the CLIA Web site and on the CDC Web site at *www.cdc.gov* (search for "waived tests").

Federal Court Upholds Stark Ban on Physician Self-Referral, *from p. 1*

equipment, and the hospital would in turn pay the urologist's company for the personnel and equipment (per-click fee), notes the Pathology Blawg (*www.pathologyblawg.com*). Since the urologist's company was not billing Medicare directly, the joint ventures were technically permitted under the Stark law.

In 2008 CMS changed its regulations to not allow joint ventures to provide services for patients referred to it by urologist owners even if the joint venture was not billing Medicare directly. The new regulations also prohibited per-click payment to hospitals if the patient was referred to a joint venture by one of its owners.

CUI filed a motion with the U.S. District Court in D.C. to prevent the Department of Health and Human Services (HHS) from enforcing the 2008 regulations. HHS then filed a countermotion saying that it felt per-click arrangements were susceptible to abuse.

In its ruling, the court said it believed CMS was entitled to take prophylactic regulatory action without waiting for "extensive evidence of program or patient abuse." According to Thomas Crane, an attorney with Mintz Levin (Washington, D.C.), the

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court was sufficiently satisfied with the small number of comments to the 2008 regulations that pointed to abuse with per-service leases to uphold CMS's rulemaking.

"Without question, prior to the enactment of the Stark law, there were abusive joint ventures, primarily with laboratories, the Congress chose to stop," writes Crane in a recent health law alert. "At the same time, there was a long history of physician-owned service, primarily where the physician-owners provided clinical services, which were free of abuse, that Congress chose to permit under the Stark law [under earlier interpretations].

"Few would argue that CMS had some evidence that some providers were taking advantage of these Phase I decisions to allow these physician-owned services to flourish in ways not intended—particularly with imaging services," Crane continues. "In deciding how to address these problems, CMS had options to take a more surgical approach, for example to continue to permit physician-owned under-arrangement services where physician owners performed clinical services, thereby relying on what has come to be known as the 'extension of practice' exception."

The argument, notes Crane, may come down to how CMS defines the term *furnishing* when it comes to DHS. He believes that CUI has several arguments to appeal in the hopes of finding a court that would be willing to overturn the 2008 regulations.

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