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Proposed Rule Implementing PAMA Causes Concern About Sufficiency of Data to Be Collected

After much waiting, laboratories finally have a proposed rule from the Centers for Medicare & Medicaid Services (CMS) officially setting a framework for implementing the Protecting Access to Medicare Act of 2014 (PAMA), which requires Applicable Laboratories to report private payer reimbursement data regarding laboratory testing. CMS intends to collect such data in order to set new benchmark reimbursement rates modeled after what private insurers pay for laboratory services. The Office of Management and Budget has concluded that making such an adjustment would save the Medicare program as much as $360 million for fiscal 2017 and as much as $5 billion over the next decade, although the laboratory sector has argued that Medicare is acting on less than comprehensive information.

Continued on page 2

Latest IOM *Quality Chasm* Series Report Targets Diagnostic Errors

What the Institute of Medicine (IOM) did for the discussion of medical errors in its *To Err is Human* report, it now seeks to do for diagnostic errors with the latest installment of its *Quality Chasm* Series titled *Improving Diagnosis in Health Care*. Estimating that most individuals experience at least one diagnostic error at some point in life, and 5 percent of adults experience an error each year, the report asserts that "[i]mproving the diagnostic process is not only possible, but also represents a moral, professional, and public health imperative."

"Diagnostic errors are a significant contributor to patient harm that has received far too little attention until now. I am confident that *Improving Diagnosis in Health Care*, like the earlier reports in the IOM series, will have a profound effect not only on the way our health care system operates but also on the lives of patients," said Victor J. Dzau, president of the National Academy of Medicine, in a statement announcing the release of the report. The Institute of Medicine is a unit of the newly formed National Academies of Sciences, Engineering, and Medicine.

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Proposed Rule Implementing PAMA Causes Concern, *from page 1*

Lack of Hospital Data Raises Claims Data Will be Skewed

Applicable Laboratories required to report would be those receiving at least $50,000 under the Clinical Laboratory Fee Schedule and "more than 50% of Medicare revenues from laboratory and physician services." Such laboratories would need to report private payer payment rates and volume of services. If an organization includes multiple facilities, not just laboratories, that 50% threshold is calculated based on the Medicare revenue for the entire organization—so the organization must receive more than 50% of its entire revenue for all components, not just its laboratories, from payments under the Clinical Laboratory Fee Schedule and Physician Fee Schedule.

> *"We do not expect hospital laboratories to meet the definition of applicable laboratory, and we estimate that more than 50 percent of independent laboratories and more than 90 percent of physician offices will be precluded from reporting private payer data under the low expenditure criterion."*
>
> — Centers for Medicare & Medicaid Services

In a Fact Sheet, CMS reports: "We do not expect hospital laboratories to meet the definition of applicable laboratory, and we estimate that more than 50 percent of independent laboratories and more than 90 percent of physician offices will be precluded from reporting private payer data under the low expenditure criterion." However, CMS still predicts that "physicians and laboratories that would be required to report account for 96 percent of CLFS spending on physician office laboratories and more than 99 percent of CLFS spending on independent laboratories."

The omission of hospital laboratories has many concerned about the resulting data that will be used to set Medicare payment rates. *NIR*'s sister publication *Laboratory Industry Report* (*LIR*) reported this month that Alan Mertz, president of the American Clinical Laboratory Association expressed concern that "[i]f you take the hospitals out and they don't report their pricing, we are concerned that the pricing would not reflect the true marketplace." Mertz pointed to a 2013 study performed on behalf of ACLA by Avalere Health that concluded commercial payments for tests were significantly higher than in the hospital setting. Francisco Velázquez, M.D., chief executive officer of PAML in Spokane, Wash., also expressed concern to *LIR*: "When you exempt hospital-based laboratories and physician office-based laboratories which provide a significant percentage of the testing in this country, an uneven burden is placed on independent laboratories," said Velázquez, who heads the largest independent lab in the Pacific Northwest. "For the most part independent laboratories are small to medium-sized, most often regional or extended regional facilities which provide a community focused high quality service with value added offerings such as home draws which benefit the Medicare population significantly. There seems to be a somewhat narrow focus on pricing which for the most part will not allow for value-added services, community impact and local continuity of services to be factored in as a value."

Not every laboratory, however, was concerned regarding the proposed PAMA rules. "While details on the proposed PAMA rule still need to be evaluated, we believe it provides a pathway to market-based pricing for the Afirma GEC and we continue to support PAMA's goal of bringing transparency and a market-based approach to how CMS sets Medicare rates for personalized medicine diagnostic tests," said Bonnie Anderson, chief executive officer of molecular lab Veracyte, in a statement. The

South San Francisco, Calif.-based Veracyte specializes in molecular-based tests for thyroid cancer, which includes the Afirma assay.

Reporting Obligations

Reported data will be from the period July 1, 2015 through Dec. 31, 2015. Reports are due by March 31, 2016 and CMS promises new Medicare rates based on that reporting will be released Nov. 1, 2016 to be effective Jan. 1, 2017. There is some cushion built in to prevent payment from dropping too dramatically in the initial period of implementation. Payment can't drop more than 10 percent from the prior year's amount during the first three years of implementation (through 2019) and not more than 15 percent in the three years following (through 2022).

Every year, payment rates for Advanced Diagnostic Laboratory Tests (ADLTs) will be adjusted based on market rates and every three years for Clinical Diagnostic Laboratory Tests (CDLTs). ADLTs are tests provided by a single laboratory and that analyze multiple biomarkers of RNA, DNA or proteins, including a unique algorithm, for a specific patient or are FDA cleared or approved tests.

The proposed rule indicates comments must be received by 5 p.m. on Nov. 24, 2015.

Takeaway: Private payer reimbursement reporting obligations will finally become a reality and the industry is most concerned about who won't be reporting and how that will affect the data.

OIG Analyzes 2014's Top 25 Laboratory Tests

While laboratories gear up to report payment data now that the Centers for Medicare & Medicaid Services has issued a proposed rule implementing the Protecting Access to Medicare Act (PAMA), the Office of Inspector General (OIG) is fulfilling its oversight role by issuing its annual analysis of the top 25 lab tests based on Medicare payments for 2014. The OIG analyzed claims under the Clinical Laboratory Fee Schedule from independent labs, physician-based labs and outpatient facilities and looked at the claims based on procedure code, beneficiary, lab, setting and test category.

Some highlights from the data OIG reported:

- $7 billion was paid to 63,000 labs under Medicare Part B in 2014 for 451 million lab tests performed for 27 million Medicare beneficiaries.
- Medicare paid $4.2 billion in payments for the top 25 lab tests. Most of the top 25 tests were in chemistry and the most expensive tests molecular pathology tests.
- Over half of Medicare beneficiaries receive at least one lab test in 2014; the average was 17 tests per beneficiary. One percent of beneficiaries received 95 or more tests.
- Lab tests generated approximately 3 percent of total Medicare Part B payments.
- The majority of Medicare payments for the top 25 laboratory tests went to independent labs.
- 63,730 labs received an average of $109,898 in Medicare payments.
- The top three laboratories based on volume performed an aggregate total of 69 million tests billed under Medicare Part B.
- 80 million venipunctures led to $239 million in Medicare payments.
- The top three lab tests according to payment were: Blood test for thyroid-stimulating hormone, Blood test for a group of blood chemicals, and Complete blood cell count automated test.
- 13 of the top 25 lab tests by payment totals were chemistry tests which yielded $2 billion in 2014.

The OIG's report, "Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data" is available on the OIG website.

Latest IOM *Quality Chasm* Series Report Targets Diagnostic Errors, *Continued from bottom of p.1*

Analysis reveals causes for diagnostic errors

The report defines diagnostic errors, focusing on the patient's perspective, as either the failure to establish an "accurate and timely explanation" of the patient's health issue or failure to "communicate that explanation to the patient." Predicting that diagnostic errors "will likely worsen as the delivery of health care and the diagnostic process continue to increase in complexity," the expert committee convened for the report concluded the following causes contribute to diagnostic errors:

- insufficient communication between providers, patients and families,
- lack of support for the diagnostic process within the health care system, and
- "a culture that discourages transparency and disclosure of diagnostic errors."

"Diagnosis is a collective effort that often involves a team of health care professionals—from primary care physicians, to nurses, to pathologists and radiologists."

— John R. Ball, EVP, American College of Physicians

Recommendations emphasize collaboration, communication

The report sets eight goals for improving diagnostic processes and reducing errors. Overall, those goals focus on themes such as teamwork and collaboration, integrating the patient into the process and providing a forum for identifying, discussing and learning from errors.

"Diagnosis is a collective effort that often involves a team of health care professionals—from primary care physicians, to nurses, to pathologists and radiologists," said the committee's chair, John R. Ball, executive vice president emeritus of the American College of Physicians in a statement. Explaining that diagnostic decisions can't always be made by one lone provider and human error isn't always the source of diagnostic errors, Ball asserted "[t]o make the changes necessary to reduce diagnostic errors in our health care system, we have to look more broadly at improving the entire process of how a diagnosis [is] made."

Thus, the committee's recommendations promote collaboration among providers in the diagnostic process and more emphasis on patient involvement. To support this process, the committee calls for payment models that move away from fee-for-service and provide payment to pathologists for consultation with treating physicians about diagnostic testing for patients.

As with the *To Err is Human* report, this latest report in the Chasm series also promotes a "non-punitive culture" where performance issues and disclosure of errors can be openly discussed. The committee noted that to support this level of transparency, changes are needed in the liability system. Finally, the committee challenged federal agencies to set a research agenda regarding the diagnostic process and diagnostic errors by the end of 2016.

The report was sponsored by the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, College of American Pathologists, American Society for Clinical Pathology and several other organizations and foundations.

Industry reacts positively to recommendations

Reaction in the industry to the report has been positive—particularly with regard to the need for collaboration among professionals. An AACC statement identifies the report's call for collaboration among health care professionals as "one of the report's most powerful recommendations" and "one that deserves more prominence." "The field of diagnostic testing is growing at an incredible rate, with recent ad-

vances in DNA, RNA, and protein testing adding more complexity to an already enormous catalogue of available tests." Thus, AACC says laboratory professionals are "critical" to helping determine the right tests for patients and interpreting and using the results "appropriately."

The College of American Pathologists, which also sponsored the report, similarly issued a statement emphasizing its support for the need for "collaboration among pathologists, other diagnosticians, and treating health care professionals" and new payment methodologies that support such collaboration. "Beyond regulation, clinical quality and the avoidance of error requires a team based approach to diagnosis that the report encourages and that we wholeheartedly support."

A Perspective published in the *New England Journal of Medicine*, says now is the time to be focusing on the diagnostic process and effecting change: "we would argue diagnostic errors are clinically and financially more costly today than every before" and "[a]dvances in HIT and big data offer new instruments for measuring and reducing diagnostic errors" while the shift in payment methodologies mean "accurate, timely diagnosis can be rewarded." The authors call for development of "validated metrics" that define how often certain errors occur, quantify their ramifications and identify factors that can reduce those errors.

Takeaway: IOM Report emphasizes need for teamwork and collaboration in the diagnostic process and communication about errors and near misses. G2

8 Goals for Improving Diagnosis in Health Care

1. **Effective teamwork.** The report emphasizes the need for teamwork in the diagnostic process among providers, patients and their families, including collaboration between pathologists and treating providers in the diagnostic process. It recommends engaging patients in the diagnostic process by ensuring access to health records and test results and promoting discussion of patient needs and preferences, involving patients in review of records for accuracy, and welcoming discussion with patients about near misses and errors.
2. **Education and training.** The report recommends that providers be educated about appropriate testing and use of test results in decision making, and that certification and accreditation should require competency in diagnostic processes.
3. **IT support for the diagnostic process.** The committee suggested the Office of the National Coordinator for Health Information Technology (ONC) should work with vendors "to ensure that health IT used in the diagnostic process demonstrates usability, incorporates human factors knowledge, integrates measurement capability, fits well within clinical workflow, provides clinical decision support, and facilitates the timely flow of information among patients and health care professionals involved in the diagnostic process." ONC should, by 2018, impose interoperability standards that allow for sharing information across health care settings. Finally, IT vendors should have to submit their products for review and notify users of potential adverse effects on diagnostic processes.
4. **Learn from errors and near misses.** The report recommends four pronged strategy including: mandatory programs to identify and learn from diagnostic errors; inclusion of diagnostic process in quality improvement and safety programs; HHS funding to support routine review of "a representative sample of" patient deaths within specific health systems; and professional societies addressing ways to improve the diagnostic process and reduce errors.
5. **Foster a supportive culture.** Policies and procedures and practice should encourage discussion, feedback and communication about errors and diagnostic performance in a non-punitive way; work systems should be designed to facilitate the diagnostic process; and communication between diagnostic and treating professionals should be facilitated.
6. **Voluntary reporting and liability reforms.** The Agency for Healthcare Research and Quality and other agencies should encourage voluntary reporting of errors and evaluate patient safety organizations' effectiveness in facilitating this reporting; state laws should provide protection for error disclosures and apologies and explore alternative resolution mechanisms including safe harbors based on compliance with evidence-based guidelines; and liability insurers should collaborate on education, training and practice improvement opportunities.
7. **Payment supporting diagnostic processes.** CMS and payers should create codes for evaluation and management activities for interaction of pathologists and other diagnosticians with clinicians on "selection, use and interpretation of diagnostic testing"; fees should value time spent with patients; and documentation guidelines should support diagnostic process and decision making.
8. **Research funding.** HHS and other agencies should develop by end of 2016 an agenda for and provide funding to support research of diagnostic processes and errors. Government should encourage public and private partnerships to support such research.

Expect More Concerted HIPAA Enforcement Due to OIG Reports

The protection of individuals' private health information isn't being adequately enforced, according to the Health and Human Services Office of Inspector General (OIG). The OIG issued two reports criticizing the Office for Civil Rights (OCR) for failing to proactively enforce privacy rules under the Health Insurance Portability and Accountability Act (HIPAA) and follow through fully on the enforcement action it does take.

While 61 percent of staff "at least sometimes" checked for prior reports of large breaches by a covered entity, 39 "rarely or never" checked and the case tracking system's limited functionality was again blamed for failing to facilitate such searches.

In the first report, focused on privacy rule enforcement, the OIG reviewed enforcement cases from 2009-2011, and found that the OCR was more reactive than proactive in investigating noncompliance and failed to fully implement its required audit program. While OCR requested corrective action in most cases of noncompliance with HIPAA privacy rules, the OIG said it failed to follow up on those corrective action requirements—lacking documentation of corrective actions in 26 percent of closed privacy cases. OCR staff also failed to check for prior history of noncompliance but even if they did, the OIG found that such review would be hampered by "limited search functionality" of its case-tracking system. Therefore, the OIG called for full implementation of OCR's audit program, improved documentation, and better case-tracking systems which staff should be required to check. It also recommended that OCR continue to expand outreach and education efforts to prevent noncompliance.

A second OIG Report criticized OCR for failing to adequately follow up on breaches of protected health information privacy. The OIG reviewed a statistical sampling of breach cases (both large and small) and found that while corrective action was documented in most large-breach cases, there was incomplete documentation of corrective actions in 23 percent of cases. Once again OCR staff were criticized for failure to check for prior history of noncompliance. While 61 percent of staff "at least sometimes" checked for prior reports of large breaches by a covered entity, 39 "rarely or never" checked and the case tracking system's limited functionality was again blamed for failing to facilitate such searches. Thus, the OIG recommended improvements to case-tracking systems that include tracking small-breach information, requiring staff check for prior breaches, and improved documentation of corrective action in breach notification cases. The OIG also again emphasized the need for the OCR to provide outreach and education to covered entities.

Takeaway: Laboratories and other covered entities may benefit from additional education and assistance from OCR but should also expect increased oversight and enforcement of HIPAA's privacy and breach notification rules. G2

$685 Million Awarded to Promote "Quality, Patient-Centered Care"

As part of the Transforming Clinical Practice Initiative, the Health and Human Services' Center for Medicare & Medicaid Services is awarding $685 million to 39 national and regional health care networks and supporting organizations to "improve quality of care, increase patients' access to information and reduce costs." Many of the programs benefitting are targeting unnecessary diagnostic tests as part of their efforts to improve care.

"Supporting doctors and other health care professionals change the way they work is critical to improving quality and spending our health care dollars more wisely," said HHS Secretary Sylvia M. Burwell in a statement. "These awards will give patients more of the information they need to make informed decisions about their care and give clinicians access to information and support to improve care coordination and quality outcomes."

The awards fund two different types of initiatives: 1) efforts by medical groups and regional health care systems to improve communication between clinicians and patients, better manage chronic disease, and centralize data reporting and 2) activities of national organizations and health care professional associations aimed at aligning clinical practice guidelines across specialties, sharing best practices and promoting education about and access to registry data.

The Transforming Clinical Practice Initiative consists of 29 Practice Transformation Networks and 10 Support and Alignment Networks. Practice Transformation Networks are learning networks that provide support for clinicians to develop core competencies, help improve chronic disease management and increase patient access. Support and Alignment Networks promote practice transformation through continuing education, generating evidence-based guidelines and formation of collaboratives to address, among other things, unnecessary testing.

Takeaway: Funding aims to improve quality and reduce costs but targets diagnostic test utilization in the process. G2

CMS Releases New CLIA-Waived Tests, Billing Codes

CMS notified contractors of new CLIA-waived tests effective Oct 1, 2015. There are 36 newly waived complexity tests, the latest approved by the FDA. Once again, the list is dominated by drug-related tests. The tests listed in the table below all require the QW modifier be attached to the CPT code for recognition as a waived test.

The following table provides a listing of the new CLIA-waived tests with their CPT Code, effective date and description.

CPT CODE	EFFECTIVE DATE	DESCRIPTION
G0434QW	Jan. 28, 2015	Healgen Amphetamine Test Cassette
G0434QW	Jan. 28, 2015	Healgen Amphetamine Test Cup
G0434QW	Jan. 28, 2015	Healgen Amphetamine Test Dip Card
G0434QW	Jan. 28, 2015	Healgen Amphetamine Test Strip
G0434QW	Jan. 28, 2015	Healgen Oxycodone Test Cassette
G0434QW	Jan. 28, 2015	Healgen Oxycodone Test Cup
G0434QW	Jan. 28, 2015	Healgen Oxycodone Test Dip Card
G0434QW	Jan. 28, 2015	Healgen Oxycodone Test Strip
G0434QW	Mar. 4, 2015	Healgen Scientific LLC Healgen MDMA (Ecstasy) Test Cassette
G0434QW	Mar. 4, 2015	Healgen Scientific LLC Healgen MDMA (Ecstasy) Test Cup
G0434QW	Mar. 4, 2015	Healgen Scientific LLC Healgen MDMA (Ecstasy) Test Dip Card

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CPT CODE	EFFECTIVE DATE	DESCRIPTION
G0434QW	Mar. 4, 2015	Healgen Scientific LLC Healgen MDMA (Ecstasy) Test Strip
G0434QW	Mar. 4, 2015	Healgen Scientific LLC Healgen Phencyclidine Test Cassette
G0434QW	Mar. 4, 2015	Healgen Scientific LLC Healgen Phencyclidine Test Cup
G0434QW	Mar. 4, 2015	Healgen Scientific LLC Healgen Phencyclidine Test Dip Card
G0434QW	Mar. 4, 2015	Healgen Scientific LLC Healgen Phencyclidine Test Strip
G0434QW	Mar. 31, 2015	Medical Distribution Group Inc., Identify Home Drug Testing Device Test Cards
G0434QW	Mar. 31, 2015	Medical Distribution Group Inc., Identify Home Drug Testing Device Test Cups
G0434QW	April 20, 2015	Chemtron Biotech, Inc. Chemtrue Drug Screen Cup Tests
G0434QW	April 20, 2015	Chemtron Biotech, Inc. Chemtrue Drug Screen Cup Tests with OPI 2000
G0434QW	April 29, 2015	Quest Products, Inc. DrugHAWK MDMA and OPI Drug Test Cup (Urine)
G0434QW	April 30, 2015	Quest Products, Inc. DrugHAWK Drug Test Cup
G0434QW	May 6, 2015	Quest Products, Inc. DrugHAWK Buprenorphine Drug Test Cup
87651QW	May 15, 2015	Roche Molecular, cobas Liat System
87880QW	May 26, 2015	Medline Strep A Test Strip (Throat Swab)
80061QW, 82465QW, 83718QW, 84478QW	May 28, 2015	Polymer Technology Systems, Inc., CardioCheck Plus Test Systems (PTS Panels Lipid Panel test strips)
80061QW, 82465QW, 83718QW, 84478QW	May 28, 2015	Polymer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home Lipid Panel test strips)
82947QW	May 28, 2015	Polymer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels eGLU test strips)
82947QW	May 28, 2015	Polymer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels Glucose test strips)
82947QW	May 28, 2015	Polymer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home eGLU test strips)
82947QW	May 28, 2015	Polymer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home Glucose test strips)
G0434QW	June 3, 2015	Native Diagnostics International DrugSmart Drug Screen Cup Tests with OPI 2000
G0434QW	June 3, 2015	Onsite Testing Specialists, Inc. On-Site Testing Specialists Drug Screen Cup Tests
G0434QW	June 3, 2015	Onsite Testing Specialists, Inc. On-Site Testing Specialists Drug Screen Cup Tests with OPI 2000
G0434QW	June 4, 2015	Transmetron, Inc. Invitro Pro Drug Test Cards
87651QW	July 15, 2015	Alere i Instrument

Source: CPT Codes are Copyright American Medical Association

The CMS Transmittal announcing the latest FDA approved waived tests also notes that the new CPT code 87651QW has been assigned to the "Streptococcus group A test performed on the Roche Molecular cobas Liat System and the Alere i Instrument" which use nucleic acid amplification technology. That Transmittal 3327, Change Request 9261, Pub. 100-04, dated Aug. 14, 2015, and a complete list of CLIA waived devices is available on the CMS website in the Regulations & Guidance Tab, under Transmittals. Note that Contractors won't look for claims affected but are required adjust claims that are brought to their attention.

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