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Lab Institute 2016
Oct. 26-28, Hyatt Regency
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Happy Birthday HIPAA!

In another Olympic year, 20 years ago, HIPAA was born this month. On Aug. 21, 1996, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) was enacted.

CMS Proposes Pathology, Cytology Cuts for 2017 Physician Fee Schedule

CPT Code 88305 is headed to the chopping block again. The Centers for Medicare & Medicaid Services (CMS) has suggested cutting the technical component of 88305—a tissue examination and a primary component within the practice of pathology—by 15 percent for calendar year 2017 as part of its proposed changes to the Medicare Physician Fee Schedule.

The pathology world was shaken three years ago when the technical component of 88305 was cut by 57 percent. The decision by CMS to dramatically ratchet down reimbursement then led to the devaluation of many pathology practices. There have been other cuts since then, but they have remained below double digits percentagewise.

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The PAMA Snag: Many Hospital Labs May Not Be Able to Participate in Reporting

When the Centers for Medicare & Medicaid Services (CMS) announced in mid-June the final rules governing the Protecting the Access to Medicare Act (PAMA), it drew praise from several groups that had lobbied for major changes. PAMA is essentially serving as a reset for the reimbursement formula the federal government uses to make payments under the Clinical Laboratory Fee Schedule.

The feds believe the Medicare program may be overpaying laboratories for services compared to commercial insurers, which have ratcheted down their rates through hard bargaining in recent years. As a result, PAMA requires labs to gather their commercial billing data and submit it to CMS for review and as the basis for future rate-setting. All labs that billed Medicare for $12,500 or more during the first half of this year would be affected.

Under the rules, labs have to submit payer data for the first half of this year to CMS by the end of the first quarter of 2017. CMS's payment recalculations would then begin in 2018, a year later than originally proposed.

Labs are obviously not paid at uniform rates, but the differences can be significant. Hospital-based laboratories, for example, can be paid at much higher rates than standalone labs. Their inclusion on a large scale would therefore be economically advantageous for the sector as a whole.

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CMS Proposes Pathology, Cytology Cuts for 2017 Physician Fee Schedule, *from page 1*

The proposed cut to 88305 would bring the technical portion of 88305 below $30, to $29.34. The proposed rate for professional interpretation remains essentially unchanged at $39.71.

The Physician Fee Schedule is a delicate ballet wherein CMS tries to reconcile the intellectual challenge of performing each task with how much time it takes to complete in order to compute how much Medicare will pay for each procedure. The agency tries to assign specific values to the work through what is known as relative value scale. The higher the value, the more laborious or complicated the task.

"For the second time in four years, another reduction on primary Pathology codes is being proposed. The first reduction was dramatic, this second would be catastrophic."

— Ana L. Viciana, M.D.

For this latest round of proposed cuts, the CMS said prices have dropped for some disposables to perform pathology services, particularly eosin stain supplies. That has also led to other smaller cuts to 14 other pathology-related CPT codes and G-code G0416, which pertains to prostate needle biopsies.

Another significant change is proposed reductions in payments around CPT code 88184, which pertains to flow cytometry/tc1 markers. The proposed cuts range from 3 cents to more than $5, depending on the work task related to the use of the assay. Each antibody flow cytometry test would be cut by $5.10 (input code SL186). But the dye sublimation printing attached to the task (input code ED031) would see just the smallest cut.

According to CMS, that is due to refinements connected to the amount of time such equipment is being used. However, the reductions total about a 20 percent cut in reimbursement around a significant amount of flow cytometry work.

The College of American Pathology and American Clinical Laboratory Association have yet to submit formal comments on the proposed rule, which impacts virtually every medical practice that accepts Medicare patients. CMS is accepting input through much of the next month.

The "proposals are intended to give a significant lift to the practice of primary care and to boost the time a physician can spend with their patients listening, advising and coordinating their care—both for physical and mental health," said CMS Acting Administrator Andy Slavitt in a statement.

Some pathologists have expressed displeasure in early comments submitted to the agency.

"For the second time in four years, another reduction on primary Pathology codes is being proposed. The first reduction was dramatic, this second would be catastrophic," remarked Ana L. Viciana, M.D., a pathologist in Miami, Fla. "Pathology services simply can barely afford to be provided adequately. The continued reduction in reimbursement results in an inability to maintain the level of professional services required to reduce medical errors!"

Megan Kressin, M.D., a pathologist in Austin, Texas, also expressed concern.

"These proposed fee reductions are extreme, and will challenge the ability of the pathology laboratory to accurately and quickly diagnose a patient's tumor. Histology is a delicate and time consuming art that can result in suboptimal tissue for diagnosis if rushed. Under the proposed fee codes, labs will be forced to reduce their histology workforce and overly burden an already stressed histology workforce,"

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Kressin remarked. "Similarly, flow cytometry is the cornerstone of diagnosis for many leukemia and lymphoma cancers. A 20 percent reduction will challenge many labs to be able to continue to offer this vital and time-sensitive testing. My hospital must perform flow cytometry within an hour of sample collection in order to determine if there are enough cells for a bone marrow transplant; this is not a test that can be outsourced and it requires significant time, expertise, and equipment. This fee reduction would be devastating for the patients who depend on an accurate and timely pathology diagnosis for their treatment."

Takeaway: The CMS is proposing more significant cuts to the practice of pathology in its 2017 Physician Fee Schedule.

As Congress Asks Theranos for Documentation, Its CEO Zigs to A Whole New Platform

Its business plan and technology under fire, Theranos appears to be playing metaphorical three-card monte with federal lawmakers and the laboratory community curious as to whether it will become a more transparent enterprise.

Members of the U.S. House of Representatives' Committee on Energy and Commerce have been pressing the California-based laboratory to produce a variety of answers regarding how it plans to correct a multitude of defects in testing platforms and associated medical devices.

Theranos has been under fire for the better part of a year, as *The Wall Street Journal* began reporting serious issues with the company's Edison testing platform, which it had claimed could perform hundreds of tests with just a few drops of blood. It has since spiraled into federal investigations, fines, and a potential barring of Chief Executive Officer Elizabeth Holmes from operating a laboratory for two years.

In a July 26 letter to the U.S. Food and Drug Administration (FDA), three ranking members of the Energy and Commerce Committee—Frank Pallone Jr, Gene Green and Diana DeGette—said they were concerned about the number of tests Theranos had invalidated that had been performed on its platform. Theranos had said in June approximately 70,000 tests—slightly less than 1 percent of 7 million performed—had been invalidated.

But the letter quoted a statement issued by Theranos saying that at least 57 percent of patients using its test services had undergone finger-stick testing and by December of 2014, "'more than 80 tests on Theranos' online test menu were offered via finger-stick and performed using proprietary technologies.'" The committee also questioned an internal investigation undertaken by the company that concluded that no patients had been harmed by the inaccurate tests.

This follows a letter sent to the company directly in June that requested a briefing to inform the committee about Theranos' efforts to comply with CMS inspection letters and FDA 483 inspection reports. See "Democratic Committee Leaders and CMS Present Latest Challenges to Theranos," *National Intelligence Report*, 7/14/16, p. 4.

A lawsuit filed in Arizona last month by a Theranos patient claimed he suffered a heart attack less than a month after undergoing routine lipid and A1C testing that

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showed no abnormalities, leading his doctor to make no changes to his medication or lifestyle. The test results were later invalidated by the company.

"It is unclear whether the corrected blood-test reports Theranos has issued thus far capture the universe of inaccurate blood test results that the company has provided patients," the House letter to the FDA said.

"The architecture of Theranos' technologies, and the associated science and technology are sound, as was demonstrated ... at the AACC Scientific Meeting."

— Susan A. Evans

Meanwhile, after Theranos founder and Chief Executive Officer Elizabeth Holmes promised for months she would provide data detailing the practicality of her company's testing platform at the American Association of Clinical Chemistry's annual meeting earlier this month, she chose to provide another platform instead.

That would be a food processor-sized device called a miniLab that would theoretically be able to perform hundreds of tests. It contains a miniaturized luminometer and fluorometer, spectrophotometer and cytometer. The movement of fluids is performed by a miniaturized robotic arm. All analytes and reagents are stored within disposable cartridges that are inserted into a slot in the front of the platform.

Data can be transmitted remotely to full clinical labs for further analysis. Holmes suggested that a remote site—say in a developing country—would use many such devices for test processing, with full-scale labs in the U.S. and elsewhere drilling down to provide deeper analysis.

Holmes said trials have shown that tests can be performed accurately with as little as two microliters of blood. Testing for potassium, lipids and the Zika virus have shown to be within national standards, according to Holmes. However, she conceded that the figures presented were not assay validation data—the kind that would allow the FDA to eventually approve the platform for full-scale use. "What we wanted to do today is introduce the invention and multiple methods of testing," Holmes told the audience.

There was no lack of skepticism from conference attendees. One was curious that the potassium testing was through normal venous samples and not through Theranos' nanotainer collection device, which was touted as a primary component of both Theranos' faulty Edison platform and the miniLab. Holmes said the sample collection occurred in a regular hospital setting, and that the acuity of the patients had to be taken under consideration when gathering samples.

"The architecture of Theranos' technologies, and the associated science and technology are sound, as was demonstrated ... at the AACC Scientific Meeting," said Susan A. Evans, a member of Theranos' Scientific and Medical Advisory Board, in a statement released not long after Holmes presentation concluded. "Innovations like this are very exciting. The Theranos miniLab ... has the potential to increase access and bring laboratory testing to the patient, whether close to home or in remote locations that are currently underserved."

At the conference, Holmes very briefly acknowledged her company's difficulties at the start of her remarks: "We take full responsibility for our lab operations and we're working diligently to rectify all outstanding issues and to realize the highest standards of excellence in lab operations," she said.

Takeaway: Theranos continues to face skepticism despite initial efforts to be more transparent about its technology.

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Senate Hearing Addresses Potential Stark Law Change

In Mid-July, the Senate Finance Committee heard testimony from stakeholders arguing for changes to the Stark Law that could make compliance easier and facilitate new business models that promote value-based, coordinated health care services. The hearing followed a round table held last year and a recent Senate Finance Committee white paper on the self-referral law.

> *"This paper reflects critical feedback from the stakeholder community on the law's ambiguities, its unintended consequences and the need for reform, and I am hopeful it jumpstarts the discussion on how Congress can modernize the law to make it work for patients, providers, and taxpayers."*
>
> — Orrin Hatch, Senate Finance Committee Chairman

In December 2015, the Senate Committee on Finance and the House Committee on Ways and Means convened a group of experts to discuss the Stark Law, which prohibits physicians from referring Medicare patients for "designated health services (DHS)" to entities with which the physician has a financial relationship. The group considered changes that might be needed to facilitate implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and keep up to date with an industry shifting to alternative payment models.

At the end of June 2016, the Senate Finance Committee released a white paper, "Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models," addressing potential revisions to the law that could make it easier for health care providers to collaborate and pursue alternative payment models that promote the government's Triple Aim. Senate Finance Committee Chairman, Orrin Hatch (R-Utah), explained in a statement: "This paper reflects critical feedback from the stakeholder community on the law's ambiguities, its unintended consequences and the need for reform, and I am hopeful it jumpstarts the discussion on how Congress can modernize the law to make it work for patients, providers, and taxpayers."

At the July hearing, health care executives Ronald A. Paulus, MD, President and CEO of Mission Health System, and Peter B. Mancino, Deputy General Counsel of The Johns Hopkins Health System Corporation explained how the Stark Law generates significant compliance costs because of its complexity and vagueness and complicates efforts to adapt to a changing health care environment. Paulus argued the law had "outlived its usefulness" and suggested the law's repeal would allow providers to do what the government has asked the industry to do—focus on patients and transform the fee-for-service reimbursement system. Mancino advocated revisions that would eliminate ambiguities, make penalties more reasonable and reform the law to allow innovative arrangements. Health care lawyer Troy A. Barsky, Esq. a partner at Crowell & Moring, LLP provided his perspective as counsel to health care providers, explaining the difficulty in complying with the Stark Law, grave consequences for even inadvertent technical violations, and how it is "diametrically opposed" to goals of new payment systems. He argued Congress should consider repealing the law and if not, make "common sense" reforms such as removing technical requirements or limiting the consequences of technical violations and "removing barriers" to health care reform.

Takeaway: As the health care industry seeks to implement alternative payment models to improve quality and reduce costs, regulators are considering how current regulatory requirements could put up barriers to reform.

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FDA Holds Exploratory Meeting on Liquid Biopsies

So-called "liquid biopsies" are increasingly becoming the future for precision medicine, often allowing deep analysis of a patient's medical condition without an invasive and uncomfortable medical procedure.

However, the regulation of liquid biopsies is also becoming an inevitability, particularly as the U.S. Food and Drug Administration (FDA) has been taking aggressive actions toward the regulation of laboratory-developed tests.

And while the FDA has been on the receiving end of criticism from the laboratory community as being heavy-handed and potentially stifling regulation, the agency did hold a joint meeting in Washington, D.C., last month with the American Association of Cancer Research to discuss the future of liquid biopsies.

The meeting was co-chaired by Gideon Blumenthal, M.D., clinical team leader, for thoracic and head/neck oncology at the FDA's Center for Drug Evaluation and Research.

Although Blumenthal suggested that there may be room for some generalized public-private partnerships to develop liquid biopsies and protocols in the future, the daylong session was heavily weighted with discussion and debate over clinical issues. The presentations included 355 slides, most of which focused on how liquid biopsies are performed. FDA officials mostly gave the floor over to other presenters from institutions such as the Dana Farber Cancer Institute, the Memorial Sloan-Kettering Cancer Center and Johns Hopkins University.

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For the most part, the FDA officials present at the session appeared to be in the exploratory phase as to how liquid biopsies and next-generation sequencing for such diagnostics are developing. The agency recently issued draft guidelines for some next-generation sequencing tests that are currently in the public comment phase.

"We've heard there are some concerns or doubts, some uncertainties about whether different ways of evaluating liquid biopsy results agree," said Abraham Tzou, M.D., an FDA medical officer and a pathologist by training. "Are they telling you the same thing, are they telling you different things? Obviously the best [outcome] would be to just have clinical outcomes based on liquid biopsies. I think most people would agree that is the ultimate answer. We've heard about different trials or proposals that are in progress where that is primarily the design. The question of course is … [what to do] in the interim."

Takeaway: The Food and Drug Administration and various research institutions convened to discuss the emerging role of liquid biopsies, but the agency appears mostly in a preliminary examination stage for the new form of tests.

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The PAMA Snag, *Continued from bottom of p.1*

One of the biggest of those changes CMS made to the final PAMA rule was the relaxing of reporting guidelines as they relate to hospital-based laboratories. Under the proposed rule, CMS had said a qualifying hospital laboratory would not only be an independent Medicare entity, but have a taxpayer identification number (TIN) and a national provider identifier number (NPI).

Instead, CMS relented, dropping the TIN requirement but keeping the NPI prerequisite. It also moved back the reimbursement changes from 2017 to 2018.

"It's great CMS made the change because that will open it up for hospital lab outreach programs," said Jane Pine Wood, a Massachusetts-based member of the health care law practice of McDonald Hopkins, although she wished the participation would have included all hospitals that performed any lab work.

> *"The way (the PAMA rules) have been engineered, most big hospital labs are going to be excluded."*
>
> — Stan Schofield, president, NorDx

"We are pleased that CMS will delay the program start date and include data from hospital-based labs in setting payment rates," said American Hospital Association Executive Vice President Tom Nickels in a statement. "Including hospital-based labs will better reflect market trends and lead to more appropriate reimbursement."

But whether or not many hospital labs actually have their own NPIs is a matter of speculation. In perhaps what is a reflection of the data gap the CMS is seeking to close through PAMA, no one appears to know how many hospital labs actually have their own NPI.

"We know there are more hospital labs that have their own NPI than TIN," said Alan Mertz, president of the American Clinical Laboratory Association, which had supported the change in the PAMA final rules to help include hospital laboratories. "We don't know how many hospital labs have their own NPI, but we also know a lot of them don't. It's not as easily discoverable."

Mertz noted that ACLA's own membership includes only a handful of significant hospital-based labs.

Wood also was uncertain of how many hospital labs have NPIs. "There are some hospitals with separate NPIs for their outreach programs, but many do not have one," she said.

Stan Schofield, president of NorDx, the laboratory network for MaineHealth and vice president and managing principal for the Compass Group, a trade federation that represents hospital-based labs, actually believes few hospital labs will participate in reporting data.

"The way (the PAMA rules) have been engineered, most big hospital labs are going to be excluded," he said.

Barry Portugal, president of Health Care Development Services, a Florida-based consulting firm, said he has contacted operators of many hospital-based labs. Most are not participating in PAMA, he noted.

"Everyone with whom I have spoken has said they do not plan to participate in the PAMA data collection process because their hospital laboratory does not meet the definition of an applicable lab," Portugal said.

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Portugal added that there are exceptions. Those are primarily hospital-owned labs located outside of the hospital, and where the lab performs inpatient, outpatient, and outreach testing. But he believes there are no more than 100 in operation nationwide.

Schofield concurred. "The criteria for reporting does not loop them in unless there is a really sizable number to loop them in," he observed.

> *"It's my view that the impact of a very few hospital-affiliated labs participating in PAMA data collection will be minuscule at the end of the day."*
>
> — Barry Portugal, president, Health Care Development Services

Wood and Mertz noted that this may spur a surge of NPI-seeking.

"There may be more and more of them to decide and quickly get an NPI number so they can report, because generally everyone is going to be better off with more hospitals reporting," she said.

While Mertz agreed that hospital labs could obtain their own NPI to participate in reporting, he said it was too late to do so for the 2016 reporting period. The next reporting period is in 2019, he added.

Another issue raised by Portugal is more esoteric. For those off-premise labs that do qualify, he said the average pricing for PAMA purposes "would be far less than typical outpatient pricing because a large portion of the lab testing performed at these facilities is billed back to their hospital parents at 'intra-hospital' prices which are a fraction of a hospital's typical outpatient fees."

Mertz did not believe such situations would be widespread, while Wood said she was unaware of the issue.

But with many hospital labs seemingly cut out of the loop, Schofield believes it will present a "worse-case scenario" for reimbursement cuts.

"If a hospital lab is billing at $10 a test and they're facing a 10 percent cut, that's $9. But if the actual base under PAMA is going to $7, then it's going to be cut to $6.30. The point is, they'll be looking at 30 percent-plus cuts."

Schofield pointed to aggressive cuts by Anthem and other big payers in recent years as the likeliest influencers of rates set under PAMA. In New Hampshire, for example, Anthem cut reimbursement to 66 percent below Medicare rates, he added.

Portugal believes that while on the face of it the changes to the PAMA final rules seemed beneficial to labs, he's skeptical for now.

"It's my view that the impact of a very few hospital-affiliated labs participating in PAMA data collection will be minuscule at the end of the day," he said. "CMS will get what they originally wanted—to pay out far less money for Medicare Clinical Laboratory Fee Schedule testing."

Takeaway: Although CMS has relaxed its PAMA reporting rules to include more hospital-based laboratories, it remains to be seen just what percentage will be able to participate in that first reporting period.

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