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Lab Payment Issues Lead CMS to Propose Some Outpatient Cuts

If cash flow from outpatient business at hospitals and ambulatory surgical centers suffers in 2016, laboratories will be among the culprits.

That's because the Centers for Medicare & Medicaid Services (CMS) has proposed a 2 percent cut to the Hospital Outpatient Prospective Payment System (HOPPS) and Ambulatory Surgical Center Payment System (ASC) to address perceived inflation in the HOPPS payment rates. That inflation is linked to what the feds believe are excess payments for laboratory tests that are currently paid separate from the overall HOPPS and shifted last year from the Clinical Laboratory Fee Schedule. According to the CMS, excess payments to labs may have exceeded $1 billion last year.

That cut would be mitigated by an overall market basket increase for HOPPS of 2.7 percent, minus a 0.6 percentage point adjustment for multi-factor productivity and a legally mandated 0.2 percentage point cut. Altogether, the HOPPS would experience a 0.1 percent payment cut next year.

In addition to those changes, CMS has proposed a 2 percent payment reduction to providers that don't meet the requirements of the Hospital Outpatient Quality Reporting Program.

CMS is soliciting comments on its HOPPS proposal through August, and will likely make some changes accordingly.

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Federal Court Defines "Identified" for Purposes of 60-Day Overpayment Deadline

A federal district court has weighed in on the meaning of "identified" for purposes of determining when Medicare and Medicaid overpayments must be returned to avoid violating the False Claims Act (FCA). In *Kane v. Healthfirst, Inc.* and *U.S. v. Continuum Health Partners, Inc.*, a New York federal court resolved the debate about when the Affordable Care Act's 60-day deadline for returning overpayments begins to run, explaining the deadline is triggered when providers are on notice that they may have received overpayments—not after they've determined with certainty the precise amount.

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Lab Payment Issues Lead CMS to Propose Some Outpatient Cuts, *from page 1*

Hospitals will receive a very modest inpatient payment increase from the CMS for calendar year 2016 as a result of the Inpatient Prospective Payment System final rule that it issued in mid-August that is slated to go into effect in October.

Altogether, the payment increase is expected to total 0.9 percent. That includes an overall 2.4 percent market basket increase for all hospitals that can demonstrate the meaningful use of electronic health records, mitigated by cuts stemming from increased productivity (0.5 percent), a cut mandated by the Affordable Care Act (ACA) (0.2 percent) and another reduction as a result of the American Taxpayer Relief Act of 2012 (0.8 percent). The cost of and work required to deliver laboratory services was included in the decisionmaking process.

CMS is collecting comments on the IPPS through the end of September.

However, hospitals participating in the Disproportionate Share Hospital (DSH) program for safety net providers will also receive cuts totaling $1.2 billion in 2016. That's also related to the ACA—the DSH was expected to be supplanted by the nationwide expansion of the Medicaid program. However, since the U.S. Supreme Court ruled in 2012 that participation in expansion by states is optional, only 30 states have participated to date, damaging cash flow to DSH hospitals that are operating in non-expansion states.

CMS is collecting comments on the IPPS through the end of September. It is unclear if CMS would make any more changes. Although it had proposed doing away with the partial suspension of the so-called two-midnight rule for hospitals later this year, it recently agreed to extend the suspension through at least the end of this calendar year after coming under intense pressure from the American Hospital Association and other lobbying groups. That rule provides guidance to hospitals regarding how long they have to keep a short-stay inpatient before Medicare will cover costs beyond observation care.

Takeaway: Laboratories may be the linchpin for cuts in inpatient rates for the Medicare program. G2

Two Lab Cases Lead U.S. Patent Office to Update Interim Guidance on Natural Phenomena

The United States Patent and Trademark Office (USPTO) has updated interim guidance regarding the interpretation of patents based on natural phenomena. The guidance stems from significant U.S. Supreme Court rulings issued in 2012 and 2013 regarding patent battles over laboratory tests.

The update responds to more than 60 public comments received concerning initial interim patent eligibility guidance issued in 2014. Those comments address six themes including a request for additional examples addressing abstract ideas and laws of nature, how examiners identify abstract ideas, and an explanation of "the markedly different characteristics analysis." Public comments on this update must be submitted by October 28, 2015.

Three years ago, the high court ruled in favor of the Rochester, Minn.-based Mayo Clinic in a patent dispute with Prometheus Laboratories over an esoteric blood test. Prometheus had sued regarding Mayo's development of a similar test. Prometheus had claimed that the observation of natural phenomena—such as the results of the test—could be patented. The Supreme Court said that natural phenomena could not be patented.

Earlier this year, Sequenom, Inc. lost a patent case in a federal circuit court regarding its amplification and detection of paternally inherited cell-free fetal DNA in order to perform non-invasive prenatal genetic testing. The court in that case ruled that the testing method, although considered a scientific breakthrough, did not meet the Mayo test because the activity behind obtaining test results "is purely conventional or obvious."

The high court took a similar tack the following year, when it ruled that a patent Myriad Genetics held on BRCA testing was invalid, concluding that a single human gene could not be protected under patent law.

The loss of Myriad's patent on the BRCA gene led to a variety of other laboratories offering the tests at a much lower price than what Myriad charged, cutting into the Utah-based lab's revenues and bottom line. Myriad has since been engaged in other lawsuits regarding how BRCA testing is conducted or combined with other assays.

The legal wrangling in the former case led to what is known as the "Mayo exception," or "Mayo test," wherein the USPTO subjects patents to a two-part examination: Is the claim directed to a law of nature, a natural phenomenon, or an abstract idea? If so, does the claim contain additional elements that amount to "significantly more" than the Mayo exception?

For the purposes of illustration, the USPTO noted that gunpowder, although comprised of ingredients that occur in nature, could be patented because the ingredients do not occur in nature in the combination required to create an explosion—a function significantly more than what the ingredients do in their normal, natural state. And if the gunpowder is packaged with other substances to create a specific device, such as a firework, that is also patentable.

The Mayo test has had implications in other legal cases over patents. Earlier this year, Sequenom, Inc. lost a patent case in a federal circuit court regarding its amplification and detection of paternally inherited cell-free fetal DNA in order to perform non-invasive prenatal genetic testing. The court in that case ruled that the testing method, although considered a scientific breakthrough, did not meet the Mayo test because the activity behind obtaining test results "is purely conventional or obvious." (See *NIR*, June 25, 2015, p. 7)

According to a recently published article by Irena Royzman and Andrew D. Cohen, attorneys in the law firm Patterson Belknap Webb & Tyler LLP, "the federal circuit's application of Mayo puts in stark relief the limitations of Mayo's reductionist approach. A ground-breaking invention somehow became patent-ineligible subject matter because the genetic information being detected exists in nature and that information was not altered in amplifying and detecting it by known techniques. The decision reflects the need for a legislative solution…."

Takeaway: Changes to patent law as the result of litigation in the laboratory sector will likely impact the patenting of lab tests for the foreseeable future.

Senior Medicare Patrol Had Significant Drop in Fraud Recoveries Last Year

The Senior Medicare Patrol (SMP) has been an initiative of the Centers for Medicare & Medicaid Services (CMS) since the late 1990s, initially as a pilot project, and now operates initiatives in every state and territory, staffed by more than 5,000 volunteers.

Despite the fairly dramatic notion behind the SMP—enlisting Medicare enrollees to be on the lookout for and report what they believe might be fraud—it has had modest results in recent years, according to a new report from the Office of the Inspector General for the U.S. Department of Health and Human Services.

In calendar 2014, recoveries from Medicare and Medicaid fraud inquiries led to expected recoveries of ill-gotten payments totaling $661,333—a 93 percent decrease from 2013. But in 2013, much of the $9.1 million of expected recoveries were tied to what the agency called "a single event."

The OIG also noted that "we continue to emphasize that the projects may not be receiving full credit for savings attributable to their work. It is not always possible to track referrals to Medicare contractors or law enforcement from beneficiaries who have learned to detect fraud, waste, and abuse from the projects. In addition, the projects are unable to track the substantial savings derived from a sentinel effect whereby fraud and errors are reduced by Medicare beneficiaries' scrutiny of their bills."

A survey determined that more than 1,000 labs had exceeded five or more thresholds for what is considered to be questionable billing. They included claims that are ordered by a physician located more than 150 miles away from the beneficiary; duplicate tests; and claims submitted with compromised lab provider or ordering physician numbers.

Since the program was launched in 1997, SMP has led to $115.1 million worth of recoveries, with $20.3 million pegged to the Medicare program and the large bulk of it connected to Medicaid.

The OIG has not provided any specifics about recoveries, and little has been published over the past 20 years about how the SMP has been connected to specific Medicare or Medicaid fraud allegations and investigations.

However, laboratories are suspected to contribute to excessive billing in the Medicare program. According to an OIG report issued last year, Medicare Part B enrollment increased 10 percent from 2005 to 2010, but spending on lab services increased by 29 percent during that same period.

A survey determined that more than 1,000 labs had exceeded five or more thresholds for what is considered to be questionable billing. They included claims that are ordered by a physician located more than 150 miles away from the beneficiary (the average distance for each claim was actually 851 miles); duplicate tests (nearly 1 million in total); and claims submitted with compromised lab provider or ordering physician numbers.

Altogether, the OIG concluded that Medicare allowed $1.5 billion in questionable laboratory claims in 2010. It recommended that CMS review those labs it had concluded had engaged in submitting a significant number of questionable claims.

Takeaway: The Senior Medicare Patrol has had significant but uneven success over the years in leading to recoveries from Medicare and Medicaid fraud. G2

Federal Court Defines "Identified", *Continued from bottom of p.1*

After a software glitch led to filing of improper Medicaid claims, a health system investigated and developed a list of 900 potential overpayments which required further investigation to confirm they were improperly paid and determine the amount of overpayment to be returned. While a few overpayments were returned shortly after that list was created, the health system didn't repay hundreds of overpayments until two years after receiving the list and after the government filed a Civil Investigative Demand inquiring about the potential overpayments. Because further investigation was needed, the health system argued the list didn't "identify" overpayments triggering the 60-day deadline.

"The court specifically acknowledged that investigating large numbers of claims within a 60-day timeline could be difficult and said prosecutors should "avoid enforcement actions aimed at well-intentioned healthcare providers working with reasonable haste to address erroneous overpayments."

The court disagreed, explaining that triggering the 60-day deadline only after providers did all they needed to "determine conclusively the precise amount owed to the Government" created "a perverse incentive to delay learning the amount due and relegat[ed] the sixty-day period to merely the time within which they would have to cut the check." "[W]hile the Government's interpretation would impose a stringent—and, in certain cases, potentially unworkable—burden on providers, Defendants' interpretation would produce absurd results," the court decided.

Health care attorney Robert E. Mazer of Ober Kaler in Maryland explains there are two issues—when an overpayment was identified and whether the failure to report and return the overpayment violated the FCA. In interpreting the statutory language regarding the identification of an overpayment, he says the court was "really very harsh and very strict."

But it's not all bad news, advises Mazer. While it would have been better if the court said "an overpayment is not 'identified' until known with certainty and quantified," he explains, the court's ruling referenced prosecutorial discretion and suggested the government may not prevail on its FCA claim if it pursued a provider who was trying hard to return the overpayment but was beyond the 60 days. The court specifically acknowledged that investigating large numbers of claims within a 60-day timeline could be difficult and said prosecutors should "avoid enforcement actions aimed at well-intentioned healthcare providers working with reasonable haste to address erroneous overpayments." Thus, Mazer indicates the court "may look at whether [a provider] acted with reasonable diligence, which is a somewhat subjective standard, in determining whether an obligation is knowingly concealed or knowingly and improperly avoided or decreased in violation of the FCA."

Mazer notes that the defendants "made it a little bit easier for the judge" with a two-year delay and repayment occurring after the government's CID. Finally, it's important to note that this ruling responded to the defendant health system's request that the court dismiss the lawsuit before trial. The court refused to dismiss the lawsuit so this is not the final ruling in the matter. It means the defendant hasn't successfully argued that the government has no valid claim. In making such a decision, a court has to accept all the factual allegations made in the complaint as if they are true and make reasonable inferences in favor of the government plaintiffs, explains Mazer. To keep its claim alive and defeat such a motion, the government plaintiff has to show its claims are plausible—that there are enough facts to support more than a mere possibility the defendant violated the law. The court noted this in stating that "at a

later stage in the proceedings" the defendants would have the opportunity to show they did investigate the potential overpayments but, so far, the government had sufficiently shown the health system "avoided returning the overpayments."

(*Kane v. Healthfirst, Inc.* and *U.S. v. Continuum Health Partners, Inc.*, No. 11 Civ. 2325(ER), S.D.N.Y. Aug. 3, 2015)

Takeaway: Federal court defines identified overpayments stringently but also raises potential for leniency for providers acting with "reasonable haste" to report and return overpayments.

AMP Offers Proposal for Regulation of Laboratory-Developed Tests

While the Food and Drug Administration's proposed framework for regulating laboratory developed tests (LDTs) remains to be finalized, other stakeholders are proposing alternative oversight models. On August 4, the Association for Molecular Pathology (AMP; Bethesda, Md.) issued a proposal for modernizing CLIA regulations. The proposal reiterates AMP's position that FDA regulations are not appropriate for professional services and refers to the testing as laboratory developed testing *procedures* or LDPs. Representatives from AMP presented the recommendations to the Senate Health, Education, Labor, and Pensions (HELP) Committee, which is now drafting legislation that would provide opportunities for enhanced support for medical innovation and patient access to new medicines and technologies.

> *"Our proposal is a streamlined, cost-effective approach that enhances transparency, ensures quality, and preserves innovation."*
>
> — Roger D. Klein, M.D., J.D.

The proposal's stated objectives include ensuring "[r]egulatory oversight does not slow innovation, constrain flexibility and adaptability, or limit a test's sustainability as a result of being unduly burdensome and beyond the fiscal capacity for the laboratory to reasonably perform or the health care system to financially support."

Explaining the need to update the CLIA regulations, the proposal highlights the growth and evolution of molecular diagnostics and distinguishes LDPs from medical devices asserting that one set of regulations "can never address both adequately." "While we maintain that there is no evidence of systemic problems with laboratory testing or LDPs that would necessitate an increase in what is already rigorous oversight, the CLIA statute and regulations are over twenty years old. Given the advances in technology and laboratory science, these regulations can be modernized to better fit with contemporary practice," says AMP Professional Relations Chair Roger D. Klein, M.D., J.D., in a press release announcing the proposal. "Our proposal is a streamlined, cost-effective approach that enhances transparency, ensures quality, and preserves innovation."

Identifying specific sections of CLIA regulations for updating, the proposal describes a tiered, risk-based model, that defines each risk level based on the purpose for the test, associated morbidity or mortality or threat to public health of the disease for which the LDP is used or the consequences of incorrect results, the test methodology employed, and the ability to perform inter-laboratory comparisons or proficiency testing. The review process for each risk category is as follows:

- **Low-risk:** validated by the laboratory, put into service, and subject to inspection in the normal course of laboratory inspection.

- **Moderate-risk:** information submitted for third party review at least 30 days before the test is offered to the public with a time limit on the review process and grandfathering provision for previously introduced LDPs.
- **High-risk:** information submitted for third party review at least 90 days before the test is offered to the public, with a time limit on the review process.

While the AMP's proposal seeks to avoid duplicative regulation it does include a role for the FDA, requiring that multianalyte assays with algorithmic analyses (MAAAs) with proprietary algorithms be submitted to FDA unless the laboratory reveals its proprietary algorithm to third party review and inspection.

The proposal defines an LDP as a "testing procedure or service that encompasses and integrates, in a single CLIA-certified laboratory, the design, development, validation, verification, and quality systems used in laboratory testing and interpretative reporting in the context of clinical care or public health services." It also includes publication requirements geared to providing transparency for providers, patients and regulatory agencies, and allowing comparisons between LDPs by giving access to information about "accuracy, precision, and known clinical significance of an LDP." Addressing concerns raised by many in the debate about FDA regulation in this area, the proposal also: 1) calls for development of a minimum level of standards and time frames for submitting information about a new laboratory developed procedure prior to offering the test to the public and imposes presumptive approval if the reviewing party doesn't make a determination in the required time period; 2) addresses types of evidence for demonstrating clinical validity; and 3) discusses when modifications to an LDP or to an FDA cleared or approved IVD require notice or a new review.

Finally, to fund the oversight functions, the proposal allows for an annual fee linked to a laboratory's number of LDPs and "limited to cost recovery."

Takeaway: The debate concerning oversight of laboratory developed testing continues with detailed alternatives to the FDA framework being recommended to legislators. G2

CDC Investing $110 Million in Disease Surveillance and Detection

Public health laboratories could get a boost from a large infusion of federal funds for testing. That would come from $110 million being provided by the Centers for Disease Control and Prevention (CDC) to help states and communities track and respond to infectious diseases. The funding is intended primarily to increase surveillance of vaccine-preventable-diseases, foodborne-disease prevention and the use of advanced molecular testing for disease detection. Of that total sum, $51 million is being provided through the mandate of the Affordable Care Act.

"In the last year alone, states were hit with emerging diseases, like chikungunya and respiratory infections from enterovirus D-68, while also responding to outbreaks of measles, foodborne illness, and other threats. These awards lay the foundation for those on the front lines—state and local health departments—to act quickly to prevent illness and deaths," said Beth P. Bell, M.D., director of the CDC's national center for emerging and zoonotic infectious diseases, in a statement.

The funding breaks down along these lines:

- $6 million to establish local, state, and territorial health coordinators to track vaccine-preventable diseases like measles and pertussis, the rates of which have been increasing in recent years due to a growing resistance by some parents to vaccinate their children
- $17.4 million for foodborne disease prevention and tracking—up $4 million from fiscal 2014. This will include support for the existing CDC surveillance system called PulseNet, and to establish a new regional center in the Northeast for the CDC's Food Safety Centers of Excellence
- More than $2 million to help states build their capacity for advanced molecular detection
- About $1.5 million to better monitor and prevent the spread of Lyme and other diseases spread by ticks. Lyme disease has been spreading in recent years, according to the agency
- $9.2 million to state and local health departments to build and maintain disease detection, surveillance, and prevention programs to reduce infections of West Nile virus and other mosquito- and tick-borne viruses.
- More funding to help U.S. States on the Mexico border prepare for and respond to potential outbreaks of the mosquito-borne chikungunya virus, which infected more than 1.5 million people throughout the Caribbean, Mexico and Central America last year.

67 percent of the 20 million or so reportable conditions submitted by laboratories were sent electronically last year.

The money comes at a time when many labs—particularly those based in hospitals—are struggling to convert from paper-based information gathering that would speed up identification of potential serious outbreaks.

According to data released earlier this year by the CDC, 67 percent of the 20 million or so reportable conditions submitted by laboratories were sent electronically last year. That compares to 62 percent in 2013. But only 20 percent of hospital-based labs are reporting electronically—a significant leap in recent years, but still far behind the rates of commercial labs. And smaller rural labs are also far less likely to report data electronically, officials said.

Moreover, changing technologies are also creating issues. The use of pulsed-field gel electrophoresis to test certain bacterias can help spot outbreaks of serious diseases such as cryptosporidiosis more rapidly. But it also means slides and stool samples that can be sent to public health agencies for inspection are vanishing.

Takeaway: The Affordable Care Act and Medicaid expanded eligibility have increased the number of insured but overall the rate of growth in health care cost remains slower than historical averages. G2

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