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Covering Government Policy For Diagnostic Testing & Related Medical Services

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INSIDE THIS ISSUE

Medicare Reimbursement: CMS Proposes 2019 Physician Fee Schedule

On July 12, CMS issued its proposed Medicare physician fee schedule (PFS) rule for calendar year 2019. Although not yet finalized, the proposed Part B policy changes are sweeping and worth reviewing even at this early stage. Here are 5 of the key changes labs need to be aware of. Note that public comments are due on Sept. 10.

1. Physician Payment Rates

CMS is proposing a 0.25% increase in physician payment rates. Using a 0.12% budget-neutrality adjustment required by law, CMS calculates the 2019 physician fee schedule conversion factor at $36.05, up from $35.99 in 2018.

2. Diagnostic Imaging Tests

Of immediate impact to labs is CMS's proposal to allow diagnostic imaging tests to be furnished under a physician's direct supervision (instead of personal/in-the-room supervision) when performed by a radiologist assistant in accordance with state law and state scope of practice rules. Radiologist assistants would be required to personally perform the test and not supervise a technologist.

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OIG Backs CMS on PAMA Market Rate Setting—and the Lab Industry Is None Too Pleased

CMS did it right and saved Medicare a boatload of money in the process, concludes a new OIG report examining the agency's work in carrying out its PAMA mandate of establishing market-based Medicare Part B rates for lab tests. But to the extent it was designed to quell the controversy over the new PAMA rates, the OIG report is likely to prove a dismal failure.

The Context

At heart of the controversy is CMS's decision not include hospital outreach labs as "applicable labs" when calculating market rates. Since these and other excluded labs generally command higher rates than freestanding labs, their exclusion from the calculation artificially

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3. Changes to Evaluation/Management Coding and Payment

CMS is proposing several coding and payment changes designed to reduce administrative burdens and improving payment accuracy for E/M visits. Examples:

- Allow practitioners to review and verify certain information in a patient's medical record that's been entered by ancillary staff or the patient himself rather than having to re-enter the information themselves; and
- A new multiple-procedure payment adjustment that would apply when E/M visits are provided in conjunction with other procedures.

4. New Telehealth Payment Policies

Besides paying physicians for their time when they check in with beneficiaries via telephone or other telecommunications device, CMS proposes paying physicians for the time it takes to review a video or image sent by a patient to assess whether a visit is needed.

5. Reduced "Add-On" Payments for New Part B Drugs

CMS proposes to reduce from 6% to 3% the "add-on" payment for new, separately-payable Part B drugs and biologicals that are paid based on wholesale acquisition cost when average sales price during first quarter of sales is unavailable.

OTHER PROPOSED CHANGES

Some of the other proposed changes in the new CFS potentially affecting labs include:

- Implementation of a *Bipartisan Budget Act of 2018* provision pertaining to writing and signature requirements in certain compensation arrangement for purposes of Stark Law exceptions;
- Addition of mobile stroke units, renal dialysis facilities and the homes of ESRD beneficiaries as Medicare telehealth originating sites;
- Payment for new communication technology-based service codes; and
- Discontinuation of certain functional reporting requirements for outpatient therapy services and creation of payment modifiers for services furnished by therapy assistants, which will be paid at 85% of the applicable Part B payment.
- Changes to the definition of "applicable laboratory" for clinical laboratory fee schedule purposes.

No Changes to OPPS Site-Neutral Payment Policies

One of the key takeaways from the CMS proposal is what is *not changing*, namely, the site-neutral payment policies under Section 603 of the **Bipartisan Budget Act**. Much to the consternation of hospital groups, the agency is proposing to continue allowing nonexcepted provider-based departments to bill for nonexcepted services on the institutional claim and maintain payment for nonexcepted services at 40% of the OPPS amount for calendar year 2019. Section 603 requires, with the exception of dedicated emergency departments, services furnished in off-campus provider-based departments that began billing under OPPS on or after Nov. 2, 2015 no longer be paid under OPPS, but under another applicable Part B payment system.

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Proposed 2019 OPPS Rule Includes Site-Neutral Payment, Other Changes

On July 25, CMS released its proposed Medicare Outpatient Prospective Payment System (OPPS) proposed rule for calendar year 2019. Here are the four takeaways for labs.

1. 1.25% Rate Increase

CMS proposes increasing 2019 OPPS rates by 1.25%, based on a:

- 2.8% market basket update;
- -0.8% productivity adjustment update; and
- -0.75-percentage point adjustment for cuts under the *Affordable Care Act* (ACA).

2. 40% Site-Neutral Payment

Under the proposed rule, CMS would make payments for clinic visits site-neutral by reducing the payment rate for hospital outpatient clinic visits provided at off-campus provider-based departments to 40% of the OPPS rate. The clinic visit is currently the most common service billed under the OPPS. The proposed rule would also cut payments to currently grandfathered sites for certain clinic visit services to address concerns about the trend where more services are shifting away from doctor offices and into hospital outpatient departments.

3. Hospital Outpatient Quality Reporting Program

CMS is proposing to remove one measure from the Hospital Quality Reporting Program beginning with the 2020 payment determination and remove nine other measures beginning with the 2021 payment determination. "The proposals to remove these measures are consistent with the CMS's commitment to using a smaller set of more meaningful measures and focusing on patient-centered outcomes measures, while taking into account opportunities to reduce paperwork and reporting burden on providers," the agency noted in the fact sheet for the proposed rule.

4. Opioid-Related Policies

CMS wants to modify the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience of care survey measure by removing three recently revised pain communication questions. The change stems from concerns that providers may feel unduly pressured by patients seeking opioid-based therapies who can, in turn, report the physician neglected their preferences, as well as an intent to avoid any potential unintended consequences of possible opioid overprescribing. In addition, the *President's Commission on Combating Drug Addiction and the Opioid Crisis* has recommended that CMS review its payment policies for certain drugs that function as a supply: specifically, non-opioid pain management treatments.

CMS will accept public comments on the proposed rule through Sept. 24, 2018.

HHS Calls for Cutting Back Patient Privacy Protections to Fight Opioid Abuse

Political reaction to the opioid crisis may soon bring about changes to HIPAA and other medical privacy laws. Patient privacy is all well and good—except when that protected patient is a substance abuser. At least that's the tenor of HHS Secretary Alex Azar's recent speech proclaiming the agency's determination to review "regulations that impede the ability of doctors, hospitals and payors to coordinate."

Scope of Review

It's not just HIPAA. HHS is also planning to hold hearings on Title 42 CFR Part 2. The Confidentiality of Substance Use Disorder Patient Records was established in 1975 to prevent misuse of a patient's confidential Substance Use Disorder (SUD) information in criminal cases, administrative proceedings and other non-treatment settings involving the patient. The idea is to make sure that SUD-related records generated by federally-assisted Part 2 programs don't become Exhibit A in a prosecution against the patient. Part 2 program rules supplement standard HIPAA privacy protections by requiring the use of consent forms and imposing strict limits on provider collection, use and disclosure of personal information that can be used to identify the patient.

Fighting Opioid Abuse Trumps Privacy Rights

Secretary Azar suggests that once comments conclude, HHS will take "regulatory action to reform these rules." HIPAA and Part 2 privacy protections "get in the way of communities and families working together to combat our country's crisis of opioid addiction, another top priority for President Trump."

Of course, changing privacy regulations will be neither simple nor swift, requiring a lengthy rulemaking process. It remains to be seen whether Congressional elections and the simple passage of time dulls the ardor of the anti-opiate crusade and/or fuels the determination of patient privacy rights advocates.

FDA Says LOINC Coding of IVD Tests Is Voluntary, Not Mandatory

On June 15, the FDA issued a new guidance document clarifying the rules for laboratory coding of *in vitro* diagnostic tests. There are four key takeaways for IVD test makers and labs:

1. No Mandatory Lab Coding of Tests

Laboratory coding is voluntary, not mandatory. However, the FDA recommends that test makers use the Observation Identifiers Names and Codes (LOINC) for coding IVD tests.

2. No Mandatory Lab Coding of Devices

Similarly, the FDA is recommending but not requiring inclusion of LOINC codes for IVD tests in labeling of medical devices. The agency does not in-

tend to perform premarket review of the LOINC codes that manufacturers provide to labs or other users.

3. LOINC Codes Must Be for Test's Approved Indications

According to the guidance document, the LOINC codes the device manufacturer provides should be consistent with the particular IVD test's FDA-cleared or approved indications for use. Dissemination of LOINC codes suggesting an unapproved or uncleared indication may be evidence that the device is adulterated and/or misbranded.

4. LOINC Code Distribution Format Neither Required nor Recommended

While declining to recommend a specific format for distribution, the agency "acknowledges" that LOINC codes may be displayed as simple text in a table format, or in structured formats such as Java Script Object Notification (JSON) or Extensible Markup Language (XML). However, the FDA "strongly encourages" use of an FDA-recognized consensus standard, e.g., the LOINC transmission document for IVDs (LIVD) standard, for communicating or disseminating the LOINC codes provided by manufacturers or others *to labs or other end users.*

Case of the Month: Alabama Hospital Lab Settles Data Breach Class Action Suit

Class action lawsuits by patients victimized by data breaches have become increasingly common. And, more often than not, they prove unsuccessful. But a recent case involving Flowers Hospital in Alabama is something of an outlier.

The Case

This long running case began in 2013 when a Flowers Hospital lab employee stole confidential patient information and used the data to file fraudulent tax returns in the victims' names. The hospital discovered the breach, notified the roughly 1,200 patients potentially affected and fired the employee who was later arrested and sent to jail.

But the response wasn't enough to keep a group of patients from filing a data breach lawsuit against the hospital's parent company. The turning point came in March 2017 when the federal district court judge allowed the case to proceed as a class action. That decision completely altered the balance of leverage. Faced with potential liability to an entire class, as opposed to an individual, the parent company had greater incentive to settle.

And that is apparently what has happened. Under the $150,000 settlement agreement, which the judge still needs to approve, each patient filing a claim would get up to $5,000 covering reimbursement for their out-of-pocket crediting costs, four hours of lost wages and interest on delayed tax refunds. Dec. 13 is the deadline for claims filing.

Why the Patients Won

Suing hospitals, labs and other providers for data breaches has not proven a successful litigation strategy. But the claims in this case were different and more compelling:

- Rather than the usual claim of facing increased risks of financial harm, the patients contended they suffered "concrete economic" damages, namely the loss of their tax refunds; and
- The fact that the lab employee confessed also bolstered the patients' case by enabling them to trace the harms directly back to the hospital lab.

New Zika Blood Testing Guidance Effective Immediately

On July 6, the FDA issued revised guidance for testing of donated blood for Zika virus.

Summary

After initially recommending universal nucleic acid testing of individual blood donation units, the agency indicates that it will now allow pooled testing which the guidance describes as more cost effective and "less burdensome" for blood establishments. However, according to the guidance, the need for individual testing may be triggered "when certain threshold conditions are present," such as an increased risk of local mosquito-borne transmission of Zika virus in a specific geographic area.

The final guidance still requires blood establishments to test all donated whole blood and blood components for Zika virus using a nucleic acid test. Since 2016, two assays have been approved under investigational new drug applications: the Cobas Zika (Roche Molecular Systems, Inc.) and the Procleix Zika Virus Assay (Grifols Diagnostic Solutions, Inc.). In May of this year, the FDA approved an additional claim for Roche's Cobas Zika test for pooled testing of blood or plasma donations.

Additional Recommendations

All FDA recommendations in the new guidance are classified as nonbinding.

Nevertheless, the agency recommends communication between blood establishments, and communication with state or local health departments or other public authorities, if Zika virus is detected—and that blood establishments remain up to date on any announcements related to Zika.

FDA Watch: With New FDA Input, Momentum for LDT Regulation Accelerating

In what has been called a "critical milestone" towards enacting a comprehensive new oversight framework for diagnostic tests, the U.S. Food and Drug Administration (FDA) released its comments on the draft bipartisan bill crafted last year by Representatives Larry Bucshon (R-IN) and Diana DeGette (D-CO) on the House Energy and Commerce Committee.

While the Diagnostic Accuracy and Innovation Act (DAIA) was introduced back in March 2017, momentum seems to be building towards enactment of a new diagnostic oversight framework, possibly by the end of the year.

The draft bill, which was created with industry representation on the Diagnostic Test Working Group, established a new category of in vitro clinical tests (IVCTs) that includes both finished products (such as test kits), and lab test protocols (known as laboratory developed tests [LDTs]). In what can be seen as a compromise, the draft legislation included the creation of a new FDA center that would regulate test development and manufacturing, while lab operations would be overseen by the Centers for Medicare and Medicaid Services (CMS), which currently oversees CLIA-certified laboratories.

In early August, the FDA submitted 59 pages of comments on the DAIA. Reaction to the FDA's Technical Assistance (TA) document was strong and swift. The clinical laboratory industry renounced the agency's extensive comments as a dramatic departure from DAIA, with some calling it a rewrite of the bill, rather than a redlining. Representatives of the in vitro diagnostics industry, on the other hand, were pleased with the FDA's direction.

Takeaway: With lawmakers and some industry groups pushing for resolution by the end of the year, comprehensive diagnostic reform may soon become a reality. However, stakeholders and lawmakers must reconcile the notable differences between the FDA's comments and the existing draft legislation.

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

HDL's Former CEO Pays $10 Million to Settle Bankruptcy Claims

Case: Health Diagnostic Laboratory co-founder and former CEO Tonya Mallory has agreed to pay $10 million to settle claims brought by the bankruptcy trustee responsible for liquidating HDL's assets. The trustee's case against Mallory is part of its larger $600 million suit targeting more than 100 HDL executives, directors, contractors and other defendants associated with the testing firm driven to bankruptcy by a massive kickback scheme involving bribes to physicians in exchange for orders of blood tests.

Significance: The newly approved bankruptcy settlement, which also covers Ms. Mallory's husband and former HDL shareholder, Scott, is far from the end of her legal problems. Last May, a federal court in South Carolina ordered Mallory and two principals of HDL's former contract sales organization, BlueWave Healthcare Consultants, to shell out $114.1 million after a jury found the three defendants liable for Medicare fraud for their part in the HDL scam. (See *GCA*, June 21, 2018, Case of the Month.) The defendants are appealing the verdict.

Michigan Hospital System Pays $84.5 Million for Alleged Billing of Kickback-Induced Services

Case: William Beaumont Hospital has agreed to cough up $84.5 million to settle False Claims Act charges. The case, which began as a qui tam whistleblower lawsuit, contends that the Detroit-based regional hospital system provided free or below-market office and employment assistance to eight physicians in exchange for referrals of lab and other services between 2004 and 2012.

Significance: Paying kickbacks to referring physicians was the primary offense (although the feds also claim that Beaumont misrepresented that its CT radiology center qualified as an outpatient department in its billings). So, it may seem odd that was this an FCA rather than an Anti-Kickback case. The explanation is simple: Beaumont brought the FCA—and its more punitive provisions—into play by subsequently billing the services generated by the allegedly ill-gotten referrals to Medicare, Medicaid and TRICARE.

Genomics Giants Accused of Misappropriating Sequencing Technology

Case: A trio of medical researchers are accusing Illumina, Thermo Fisher Scientific and Affymetrix of stealing the zip code sequencing technology they developed. The trade secret theft and fraud lawsuit claims, among other things, that the peer reviewer of the grant proposal the researchers submitted to the National Cancer Institute for their technology obstructed the grant and tried to get Affymetrix, the firm for which he was chief technology officer, to re-patent the idea. The suit also contends that the founders of Illumina misappropriated and submitted patent claims for the technology and incorporated it into the firm's own SNP genotyping array and AmpliSeq reagents.

Significance: This story has a lot of tentacles. Many of the same zip code sequencing technology patents at the center of this case were also involved in the recently settled infringement lawsuit brought by Thermo Fisher Scientific against Illumina. So, stay tuned...

Former Patients Sue Theranos Over Faulty Test Diagnoses

Case: Nine ex-patients filed a class-action lawsuit against Theranos and its erstwhile retail partner Walgreens seeking damages for the harms they allegedly suffered as a result of inaccurate tests performed using Theranos diagnostic technology. The Arizona federal court dismissed seven of the claims but allowed the remaining 13 to proceed in a class action, which is currently in the evidence discovery phase.

Significance: Up to now, the Theranos case has been mostly about money and the financial losses suffered by consumers, investors and business associates as a result of the firm's overhyped bloodless finger prick technology. But the patient class action is a poignant reminder of the human and patient safety dimensions of the story. The alleged victims' accounts set out in the court papers document harrowing tales of mental suffering and unnecessary testing and treatment as a result of false positives for disorders like the autoimmune disease, Sjörgen's syndrome and the thyroid condition known as Hashimoto's disease, not to mention the patient removed from blood thinner medication warfarin on the base of flawed Theranos test results. At its peak, Theranos operated 40 consumer test centers within Walgreen's in the metro Phoenix area, performing over 1.5 million blood tests for nearly 176,000 consumers.

Florida Lab Settles Claims of Bioterrorism Law Violation for $100K

Case: The OIG accused a Florida lab of violating Federal Select Agent regulations by transferring a select toxin to an entity not registered to possess, use or transfer it and failing to get Centers for Disease Control and Prevention (CDCP) for the transfer. Staring down the barrel of an administrative proceeding, the lab has decided to pay $100,000 settle the case.

Significance: Jointly comprised of the CDCP/Division of Select Agents and Toxins and the Animal and Plant Health Inspection Service/Agriculture Select Agent Services, the Federal Select Agent Program regulates possession, use and transfer of biological select agents and toxins that pose a threat to public, animal or plant health and products established in the aftermath of the 9/11 terrorist attacks to head off threats of bioterrorism. Charges against labs under the law have been relatively rare.

Cybersecurity: LabCorp Reports What Could Be a Major Data Breach

Cyberattacks and data breaches against health providers are a daily occurrence. But when the breach takes place at a firm as big and powerful as LabCorp and potentially affects the health records of millions of patients, it's major news. And according to a recent Fortune report, such a breach might have affected at least some of LabCorp's systems over the July 14 weekend.

What We Know So Far

In its filing with the Securities and Exchange Commission, the Burlington, N.C.-based company reports that it detected what it describes as "suspicious activities" during that weekend. In response, it "immediately took certain systems offline" in an effort to contain the activity. As of now, the company hasn't reported uncovering any evidence that the data was transferred or misused, but the investigation is ongoing.

The other bit of good news is that the incident seems to have been confined to LabCorp Diagnostics systems and didn't affect the systems used by newly acquired CRO Covance Drug Development.

The Threat from Within

In most industries, hackers from outside the organization pose the primary threat to cybersecurity. But in health care, it's just the opposite. "Health care is the only industry in which internal actors are the biggest threat," according to a recent Verizon cybersecurity report. What drives them to do it:

- Financial gain, e.g., using misappropriated personal information to commit tax fraud or open lines of credit: 48%;
- Personal curiosity in looking up personal records of celebrities or family members: 31%;
- Simple convenience: 10%.

Of course, many internally caused breaches are inadvertent, e.g., when an employee falls for a phishing scheme. LabCorp still hasn't said how this breach happened, e.g., whether ransomware was involved or who was behind it.

OIG Backs CMS on PAMA Market Rate Setting, *from page 1*

skewed lab prices downward. CMS brushed industry objections aside, leading to a lawsuit that's still pending in federal court.

> *"Today's OIG report skirts the central issue: that HHS deliberately chose to ignore Congressional intent in its implementation of PAMA – cherry-picking data from fewer than 1% of labs."*
>
> – Julie Khan, President, ACLA

The OIG's role is to review how CMS implemented the new PAMA system. The new OIG report is not only lacking in criticism but highly commendatory of CMS's efforts. They were able to cut rates for 75% of tests and save Medicare $670 million in 2018, the OIG gushes.

The concern that CMS didn't play fair in achieving this result gets glossed over. Sure, the new pricing data sample size was smaller than it should have been, the report acknowledges. "Some labs reported difficulty in interpreting the reporting requirements," it blithely explains. But it was the next sentence that really ticked off the industry. "CMS modeling demonstrated that increased reporting from more labs would not have had a meaningful effect on 2018 payment rates."

Industry Reaction

Needless to say, the industry wasn't impressed. The American Clinical Laboratory Association (ACLA), which is plaintiff in the federal lawsuit challenging CMS's implementation of PAMA, took the lead in criticizing the report. "Today's OIG report skirts the central issue: that HHS deliberately chose to ignore Congressional intent in its implementation of PAMA – cherry-picking data from fewer than 1% of labs," according to ACLA President Julie Khan. "Any analysis by OIG that fails to recognize that fact does a disservice to Congress and to the millions of seniors who depend on access to lab testing through Medicare."

Signs of Hope?

Although the sides are likely to remain firmly entrenched until the federal court weighs in, there are also subtle signs of accommodation from CMS. In its proposed 2019 Part B Physician Fee Schedule of July 12 (see related story on page 1), CMS calls for public comments on "alternative approaches for defining an applicable laboratory, for example, using the Form CMS 1450 14x bill type or CLIA certificate number." While not the paradigm shift demanded by CLIA—the request suggests that CMS is interested not in expanding the applicable lab tent so much as modifying the low expenditure threshold for labs already included—this is the first sign of any kind from CMS indicating flexibility on the PAMA formula.

Industry Report: Venture Capitalists Remain High on Health Care

Health care startups remain highly attractive to venture capitalists drawing $10.6 billion in investments in the first half of 2018, the most of any industry sector other than internet companies and well ahead of #3 on the list, mobile and telecommunications, according to a new MoneyTree report from PricewaterhouseCoopers and CB Insights. At this rate, health care will easily surpass the record of $15 billion in total sector investment posted in 2017.

While the report does not break down the sector data, it does note that two of the biggest U.S. venture deals in the second half of 2018 were in the healthcare sector (See *NIR*, Feb. 2018, for analysis of health care sector venture investment flows):

Rank	Company	Industry	Deal Value	Funding Stage
4	Allogene Therapeutics	Biotechnology	$300 million	Early stage
4	Grail Inc.	Disease DX	$300 million	Expansion stage

Both companies are based in California and dedicated to cancer diagnostics and treatment. Grail's experimental blood screening test has showed early promise in detecting in detecting early-stage lung cancers based on free-floating DNA released by tumors. Allogene produces "off the shelf" enabling the engineering of cell therapies to kill cancer cells.