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## IN THIS ISSUE





## Billing and Coding: OIG Calls on CMS to Crack Down on Improper Payment of Definitive Drug and LDL Cholesterol Tests

History tells us that whenever OIG issues a report pointing out a pattern of Medicare Part B overpayments for lab tests, labs and physicians that provide those tests should be concerned. In recent weeks, the agency published not one but a pair of such reports. Here are the details labs need to know about.

### 1. Improper Payment for Drug Testing Services

**Payment Rules:** Medicare Part B pays for reasonable and necessary drug testing services as part of active treatment for substance use disorders. To code for such services, labs are supposed to use the following procedure codes:

- **Presumptive drug testing:** CPT code 80305, 80306, or 80307, depending on the complexity level of the test; and
- **Definitive drug testing:** HCPCS G0480, G0481, G0482, G0483, or G0659, based on the number of drug classes, including metabolites, tested.

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## Compliance: Ensure Proper Billing of New FDA-Approved CLIA-Waived Tests

**Reminder:** Effective July 1, labs can bill Medicare for a number of new CLIA-waived tests approved by the FDA. Here are the key details you need to know to ensure maximum reimbursement and proper billing.

### Billing of New CLIA-Waived Tests

CLIA regulations require labs to be appropriately certified for each test they perform. CMS edits lab claims at the CLIA certificate level to ensure that Medicare pays only for lab tests categorized

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Billing and Coding: OIG Calls on CMS to Crack Down on Improper Payment of Definitive Drug and LDL Cholesterol Tests, *from page 1*

**Red Flag:** On June 8, OIG issued a new report indicating that in 2019, Part B paid $180 million for drug treatment testing services provided to 274,000 substance use disorders. The fee-for-service improper payment rate for the year was a relatively low 7.3 percent; however, the improper payment rate for the highest-paying drug was 58.9 percent.

**OIG Findings:** So, OIG decided to examine how effectively Medicare administrative contractors have been in rooting out improper payments for drug testing services. They cited three weaknesses in contractors' program safeguards, namely, lack of:

- Clear and consistent requirements or guidance for labs to use in determining the number of drug classes to bill for definitive drug testing services;
- Procedures for identifying or limiting the frequency of drug testing services, e.g., the number of drug tests performed per year for each beneficiary across all jurisdictions; and
- Consistent requirements in Local Coverage Determinations (LCDs) or any procedures for identifying claims for direct-to-definitive drug testing.

**OIG Recommendations:** The OIG recommended that CMS work with Medicare contractors to:

- Determine if there's clinical evidence to support a single, specific reasonable and necessary standard for drug testing services, and if so, establish a National Coverage Determination or develop LCDs with more consistent requirements for drug testing services;
- Clearly indicate in LCDs, Local Coverage Articles, and other instructions how labs should determine the number of drug classes for billing definitive drug testing services;
- Implement a system edit or procedure to identify and limit frequency of drug testing services per beneficiary across all Medicare jurisdictions;
- Consider adding a modifier to claims for definitive drug tests indicating whether a test was based on results obtained from a presumptive drug test; and
- Determine if it's necessary to conduct postpayment medical review on labs that have been paid for excessive definitive drug tests.

**Practical Impact:** The fifth recommendation, which CMS has accepted, is the one you need to be most concerned about if your lab bills Medicare for definitive drug tests. OIG didn't provide a specific definition of what it meant by "excessive" payment triggering post-payment review but did offer an example of more than one test in a one-week period for the same beneficiary. CMS also concurred with the fourth recommendation

NLR

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but not the first three. OIG stood by all three but said it had "refined" recommendations one and two in accordance with CMS's comments.

### 2. Improper Payment of LDL Cholesterol Tests and Lipid Panels

**Payment Rules:** Medicare Part B covers two basic kinds of cardiovascular-screening blood tests measuring cholesterol and triglyceride levels to detect conditions that may lead to heart attack or stroke:

- **Lipid panels** that measure the levels of four lipids in the blood, including total cholesterol, triglycerides, high-density lipoprotein (HDL) cholesterol and low-density lipoprotein (LDL) cholesterol, sometimes called "bad cholesterol"; and
- **Direct LDL tests** that measure the actual level of LDL in the blood.

**Red Flag:** The LDL cholesterol level can also be calculated from the results of the other three tests in the lipid panel. As a result, direct testing for LDL cholesterol generally isn't separately reimbursable when the lipid panel is performed for the same beneficiary on the same date of service. In 2003, CMS added the lipid panel (CPT code 80061) and direct LDL test (CPT code 83721) code pair to its National Correct Coding Initiative (NCCI) edits designed to flag codes that shouldn't be billed together for the same patient at the same time (with relatively rare exceptions flagged by addition of the -59 modifier.

**OIG Findings:** Affirming the findings of a previous audit, new OIG report published in late May concludes that the NCCI edit isn't working and that Medicare is still paying for LDL tests and lipid panels in circumstances where billing both wasn't justified. Specifically, OIG auditors found that from 2015 to 2019, Part B made $35.8 million for direct LDL tests to 11,788 providers in addition to lipid panels for the same beneficiary on the same date. OIG determined that some providers were billing LDL tests and lipid panels together on a routine basis, i.e., more than 75 percent of the time. There were 1,334 such "at-risk providers" accounting for Medicare payments of $20.4 million.

"CMS's oversight was not adequate to prevent improper payments for the direct LDL tests," the OIG concluded. "If CMS had had oversight mechanisms to prevent such payments, Medicare could have saved up to $20.4 million for our audit period."

**OIG Recommendations:** The OIG called on CMS to order Medicare contractors to:

- Develop oversight mechanisms to identify and prevent improper payments for lipid panel and direct LDL tests to at-risk providers; and
- Educate providers on the billing of direct LDL tests in addition to lipid panels.

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Billing and Coding: OIG Calls on CMS to Crack Down on Improper Payment of Definitive Drug and LDL Cholesterol Tests, *from page 3*

**Practical Impact:** CMS pushed back, indicating that it didn't agree with the first recommendation. Ordering direct LDL tests and lipid panels together is permissible under Medicare payment rules on the basis of the physician's clinical judgment, CMS insisted. The agency was only slightly less happy with recommendation two, noting that it already has issued education on correct coding requirements for the proper use of modifiers on claim lines. We maintain that our finding and recommendations are valid. But OIG held its ground, saying that current education does not address this.

### Takeaway

*The most significant impact of the new OIG reports will likely be in the form of internal action aimed at improving code edits and stepped-up outreach and education efforts from Medicare contractors. However, there's also a distinct risk of post-payment review, particularly in the case of labs that received "excessive" definitive drug testing payments. The other most likely target for audit, review and enforcement are the 1,334 "at-risk providers" accounting for Medicare $20.4 million in Medicare payments for LDL tests and lipid panels for the same patient at the same time.*

## The Biden Budget: The 9 Things Lab Managers Should Know

President Biden submitted his first budget to Congress. In case you don't have the time or stomach to read the 1,000+ page document, here's a very high-level briefing of what lab managers should know about the budget.

### The Narrative

In proposing the $6 trillion budget, the President Joe Biden called on Congress to take action this year to reduce prescription drug costs and "further expand and improve health coverage." The President supports reforms that would bring down drug prices by letting Medicare negotiate payment for certain high-cost drugs and requiring manufacturers to pay rebates when drug prices rise faster than inflation, according to the document. "These reforms would lower drug costs and save money for Medicare beneficiaries and people with job-based insurance."

Biden also urged Congress to enact some of his other healthcare initiatives outside the context of the budget. "Evidence shows that we can reform Medicare payments to insurers and certain providers to reduce overpayments and strengthen incentives to deliver value-based care." The

document also reiterates the administration's support for:

- Including a public option for health insurance in the Affordable Care Act marketplaces;
- Giving people age 60 and older the option to enroll in Medicare, with financing separate from the Medicare Trust Fund; and
- Providing premium-free, Medicaid-like coverage through a federal public option in states that haven't expanded Medicaid.
- What the budget proposal doesn't do is provide details of how the administration plans to make and pay for any of these changes.

### The Money

Of course, the heart of the budget isn't talk but money:

1. $134 billion in discretionary funding for HHS, a 23 percent increase over last year;
2. $905 billion for the Strategic National Stockpile, a $200 million increase over 2020;
3. $292 million for the Hospital Preparedness Program, an increase of $11 million;
4. $17 million to "improve operations and oversight" of the 340B program, $7 million more than last year;
5. $1.3 billion toward the National Health Service Corps, diversity training programs, and behavioral health workforce development programs and $330 million to Graduate Medical Education;
6. $6.5 billion to fund a new health research agency that would focus on cancer, diabetes, Alzheimer's and other diseases;
7. $8.7 billion for the CDC, an increase of $1.6 billion over last year, which would be the agency's biggest funding increase in nearly two decades;
8. $10.7 billion to address the opioid epidemic, $4 billion more than what Congress approved for FY 2020; and
9. $1.6 billion for the Community Mental Health Services Block Grant to address COVID-19's impact on mental health.

## OIG Enforcement: OIG Work Plan Targets Medicare Part B Billing & Payment of Lab Tests

During the Public Health Emergency (PHE), the Department of Health and Human Services (HHS) has cut labs extraordinary slack in the form of waivers that temporarily loosen Medicare test coverage rules as well as kickback restrictions for arrangements promoting COVID-19 diagnosis

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and treatment. But the détente appears to be coming to an end. In recent weeks, the OIG has quietly signalled that its historical suspicions over lab billing and payment abuses remain very much intact and that it intends to take new enforcement actions against labs that have taken advantage of the situation.

### The OIG Work Plan

The items the OIG lists in its work plan are a helpful indicator of where its enforcement focus lies at any particular time, particularly since the agency began publishing monthly updates several years ago. During the pandemic, the OIG has added three new items focusing on a specific aspect of Medicare Part B billing and payment of lab tests, including two this month.

### 1. Billing of COVID-19 Add-On Tests

The objective of COVID-19 testing is to determine whether an individual has the virus. However, labs can also perform add-on tests, e.g., to confirm or rule a diagnosis other than COVID-19. In its June 2020 work plan, the OIG added a new item targeting potential add-on test abuses. In the item, the agency expressed its "program integrity concerns" related to add-on tests in conjunction with COVID-19, particularly the potential of fraudulent billing for associated respiratory pathogen panel (RPP) tests, allergy tests or genetic tests.

Adding to the concern is that during the PHE, CMS has relaxed the rules requiring an order from the treating physician or nonphysician practitioner (NPP) for COVID-19 tests. According to the OIG, relaxation of physician ordering/NPP rules gives "unscrupulous actors more leeway for fraudulent billing of unnecessary add-on testing." To address these concerns, the OIG said it would perform a study analyzing Medicare claims data for lab testing to identify trends in the use of RPP, allergy and genetic testing and identify billing patterns indicating that labs may be committing fraud and abuse.

### 2. Medicare Payments for Clinical Diagnostic Lab Tests in 2020

The June 2021 OIG work plan includes a new item providing for annual PAMA review of Part B payments for clinical lab tests in the previous fiscal year. "Medicare is the largest payer of clinical laboratory services in the nation," the OIG notes. The agency will analyze and issue a report on the top 25 lab tests by expenditures. While this is an exercise the agency is required to perform each year under PAMA, the top 25 also represent a kind of road map the OIG relies on to prioritize its review and enforcement resources and/or confirm previous suspicions of irregularities.

### 3. Audit of CMS CLFS Rate Setting Process for PHEs

The other new item in the June 2021 work plan deals with how CMS sets the Clinical Laboratory Fee Schedule for lab tests under Part B. As required by PAMA, reimbursement rates are based on the weighted median of private payer rates as reported to CMS by "applicable laboratories." CMS sets a rate for each test's HCPCS code. The data are reported every three years—although the pandemic forced the delay of Jan. 1, 2020 reporting to Jan. 1, 2022. CMS or Medicare administrative contractors use "cross-walking" or "gap-filling" methods to set rates for new tests after considering the public comments.

Is the CLFS methodology well suited for PHEs? If not, how can it be improved? The OIG intends to carry out an audit to address these questions. While the inquiry is narrow in scope, putting PAMA rate setting methodology under a microscope is almost always a positive development.

## Global News: EU Shuffles IVDR Implementation Plan but Sticks to May 2022 D-Day

As you may know if your lab does business in Europe, the European Union (EU) has been planning to implement an ambitious new device regulation called the In Vitro Diagnostic Regulation (IVDR). Those implementation plans had to be put on hold due to the COVID-19 pandemic. But on June 7, the European Commission's (EC) Medical Device Coordination Group (MDCG) unveiled a new joint IVDR implementation and preparedness plan (Plan). Here's a compliance briefing on the Plan.

### Diagnostics Device Regulation in Europe

In April 2017, the EC and the European Parliament adopted the EU legislative framework for regulation of medical devices, comprised of two parts: i. the new medical devices regulation (MDR); and ii. the IVDR. The plan was for the MDR to apply starting in May 2020, to be replaced by the IVDR in May 2022. But things didn't go as planned. In response to the pandemic, the MDR was postponed to May 26, 2021, but the May 2022 implementation date/compliance deadline for the IVDR was not postponed.

To make the transition and prepare for compliance with the IVDR, labs, authorized representatives and other stakeholders must carry out major operational tasks such as revising documentation about their products, recruiting new staff and updating internal procedures. While achieving all of this would have been tough even in normal times, transition at a time of pandemic created extra challenges. Thus, while a few have gotten ahead of

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the compliance curve, a vast number of labs are playing a desperate game of catchup.

The IVD industry has been sounding the alarm about preparations for incoming regulation for over a year. One of the biggest concerns is the limited number and capacity of so-called Notified Bodies (NBs) who are responsible for certifying all of the diagnostics that need to be assessed for the first time by May 2022.

### What the Plan Says

Until now, the MDCG has remain unmoved and determined to stick with the May 2022 deadline. But the Plan is designed to offer some relief. The MDCG acknowledges the challenges labs and other stakeholders face in meeting the May 2022 deadline. The Plan reassesses outlines a draft joint implementation plan for IVDR based on a reassessment of the implementation priorities undertaken as of September with the objective of getting some kind of operational system in place before May 2022.

The Plan splits the listed priorities into two sets:

- Set A includes actions vital for devices to have access to the market, including those related to a framework for contingency planning, the availability of NBs and the designation of EU reference labs; and
- Set B includes legislation and guidance documents that, though not obligatory, are expected to facilitate the stakeholders' and actors' work.

The Plan lists priority actions to be carried out by the 27 member states and the EC and monitored at the MDCG level. It emphasizes the urgent need for scaling up all efforts across the board and collaborating.

### Takeaway

*While the EC has softened its position somewhat, its determination to transition to IVDR by May 2022 may not prove realistic, especially since the COVID-19 factor remains very much in play. "We may be faced with a deterioration of the COVID-19 crisis or with a new health crisis around May 2022, when the actors have relatively little experience with applying the new framework and not all guidance is fully developed," the EC acknowledges.*

## PAMA: ACLA Keeps the Pressure on CMS by Appealing Dismissal of PAMA Lawsuit

The American Clinical Laboratory Association (ACLA) is not backing down. For more than three years, the association has waged litigation warfare challenging the legality of CMS's methodology for setting PAMA

"market-based" reimbursement rates for lab tests under Medicare Part B. Twice that lawsuit has been dismissed, most recently in March 2021. But on May 28, the ACLA said that it's filed a notice of appeal.

### The ACLA's Apparent Strategy

The lawsuit, ACLA v. Azar, has ping-ponged between the US District Court for the District of Columbia and the US Court of Appeals for the DC Circuit since 2017. At issue is whether CMS went beyond its legal authority in the way it established PAMA reimbursement rates, specifically its decision to exclude hospital labs as "applicable laboratories" required to submit the private payor pricing data relied on to set the Clinical Laboratory Fee Schedule (CLFS) rates for particular tests.

The issues in the case relating to CMS's legal authority to implement PAMA are fairly technical and complex. (See, *Lab Compliance Advisor*, Feb. 26, 2018) for an analysis.) Many believe that ACLA has a solid case. But the one thing upon which most attorneys following the case agree is that it's extremely difficult to persuade a federal court to overturn the regulations authored by the executive branch agency charged with implementing a statute. The previous two dismissals are evidence of that.

The ACLA clearly understands that winning the lawsuit remains a bit of a long shot. But while victory in court would be its first choice, filing the appeal furthers the ACLA and lab industry constituents' PAMA pricing agenda by keeping up the pressure. The appeal pins down CMS on the judicial front while what's shaping up to be the real battle is waged on the legislative and regulatory fronts.

"While we continue our advocacy in the courts, it is even more critical for Congress to take legislative action on PAMA reform," noted ACLA president Julie Khani in a statement issued after the appeal was filed. "ACLA will continue to work with policymakers to establish a Medicare Clinical Laboratory Fee Schedule that is truly representative of the market and supports continued innovation and access to vital laboratory services, as Congress originally intended."

### Takeaway

*The ACLA's leadership in challenging the warped CMS PAMA pricing scheme has proven quietly effective. Significant regulatory progress was made in 2019, when CMS agreed to an ACLA proposal to revise the "applicable laboratory" qualifications to include a larger sample of hospital outreach labs. Legislative progress was also made in December of that year when Congress passed the LAB Act (Laboratory Access for Beneficiaries Act), to delay the reporting of lab payment data required by PAMA. The March 2020 CARES Act (Coronavirus Aid, Relief, and Economic Security Act) provided another one-year delay from PAMA reporting requirements as well as a one-year delay in the implementation of scheduled rate cuts.*

# In the News: CMS Proposes to Ease, but Not End Hospital Price Transparency

If you're a hospital lab administrator, you'll probably be happy to learn that the Biden administration is proposing to repeal some of the more troublesome Trump price transparency rules relating. But before you pop the champagne corks, recognize that what CMS wants to do is not completely end but just modify the price transparency rules. **Bottom Line:** Price transparency will remain a thorn in the side of hospitals, only the specific rules and protocols will be different.

## CMS Eliminates Cost Reporting Obligation

Under the Trump rule, hospitals were required to post their privately negotiated Medicare Advantage contract rates in their Medicare cost reports. On April 27, 2021, CMS issued a proposed rule eliminating this rule for the Inpatient Prospective Payment System for fiscal year 2022, which begins Oct. 1, 2021, eight months after the agency finalized the controversial rule as part of the federal push to enhance transparency in hospital pricing. CMS said it's getting rid of the requirement because it could impose an "unnecessary burden on hospitals," and estimates it could reduce the administrative burden on hospitals by approximately 64,000 hours. If this change is finalized, it would be retroactive to Jan. 1, 2021, when the hospital price transparency rule went into effect. (For an analysis of the rule, see *National Lab Report*, Jan. 29, 2021)

## Industry Reaction

Hospitals had lobbied hard for the change and are cheering the new rule. "Based on our initial review, we are very pleased CMS is proposing to repeal the requirement that hospitals and health systems disclose privately negotiated contract terms with payors on the Medicare cost report," noted American Hospital Association (AHA) Executive Vice President Tom Nickels in a statement. "We have long said that privately negotiated rates take into account any number of unique circumstances between a private payor and a hospital, and their disclosure will not further CMS's goal of paying market rates that reflect the cost of delivering care. We once again urge the agency to focus on transparency efforts that help patients access their specific financial information based on their coverage and care."

## Takeaway

*The proposed rule could signal that CMS is going to give hospitals some leeway on price transparency requirements, but experts say it's unlikely that that the government will completely back down from its goal of price transparency.*

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as waived complexity under CLIA in facilities with a CLIA certificate of waiver.

**QW Modifier Tests:** The CPT codes for the following new tests, 80305, must have the modifier QW to be recognized as a waived test:

- **80305QW**, Aug. 25, 2020, Verify Diagnostics Inc. VeriCheck Drug Test Cup
- **80305QW**, Aug. 25, 2020, Verify Diagnostics Inc. VeriCheck Drug Test Dip
- **80305QW**, Sept. 23, 2020, Axium BioResearch Inc. DrugExam Multi Drug ScreenTest
- **80305QW**, Oct. 9, 2020, American Screening LLC Discover Panel Dip Card Tests MOR 300
- **80305QW**, Oct. 9, 2020, American Screening LLC Discover Quick Cup Tests MOR 300
- **80305QW**, Oct. 9, 2020, American Screening LLC Discover Quick Cup Tests MOR 2000
- **80305QW**, Oct. 9, 2020, American Screening LLC Discover Plus Panel Dip Card Tests MOR 300
- **80305QW**, Oct. 9, 2020, American Screening LLC Discover Plus Panel Dip Card Tests MOR 2000
- **80305QW**, Oct. 9, 2020, American Screening LLC Discover Plus Quick Cup Tests MOR 300
- **80305QW**, Oct. 9, 2020, American Screening LLC Discover Plus Quick Cup Tests MOR 2000
- **80305QW**, Oct. 9, 2020, American Screening LLC OneScreen Plus Quick Cup Tests MOR300
- **80305QW**, Oct. 9, 2020, American Screening LLC OneScreen Plus Quick Cup Tests MOR2000
- **80305QW**, Oct. 9, 2020, American Screening LLC Reveal Panel Dip Card Tests MOR2000
- **80305QW**, Oct. 9, 2020, American Screening LLC Reveal Quick Cup Tests MOR300
- **80305QW**, Oct. 9, 2020, American Screening LLC Reveal Quick Cup Tests MOR2000

**Non-QW Modifier Tests:** The CPT codes for the following new tests, all of which are produced by various manufacturers, don't need a QW modifier to be recognized as a waived test:

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| CPT Code | Name | Use |
|---|---|---|
| 81002 | Dipstick or tablet reagent urinalysis—non-automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen | Screening of urine to monitor/ diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections |
| 81025 | Urine pregnancy tests by visual color comparison | Diagnosis of pregnancy |
| 82270 82272 (Contact your Medicare carrier for claims instructions) | Fecal occult blood | Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) |
| 82962 | Blood glucose by glucose monitoring devices cleared by FDA for home use | Various Monitoring of blood glucose levels |
| 83026 | Hemoglobin by copper sulfate – nonautomated | Monitor hemoglobin level in blood |
| 84830 | Ovulation tests by visual color comparison for human luteinizing hormone | Detection of ovulation (optimal for conception) |
| 85013 | Blood count; spun microhematocrit | Screen for anemia |
| 85651 | Erythrocyte sedimentation rate – nonautomated | Nonspecific screening test for inflammatory activity, increased for majority of infections, and most cases of carcinoma and leukemia |