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COVID Testing: White House Rolls Out Plan to Increase Nationwide Rapid, Point-of-Care COVID-19 Testing

Much has changed since the spring when Abbott, LabCorp, Quest and other major COVID-19 testing labs were demobilizing their coronavirus infrastructure and pivoting to normal business. The surge of new COVID-19 delta variant cases has turned back the clock to the bad old days of the early pandemic and forced the hand of not only industry but government. Thus, in early September, President Biden announced a new action plan to combat the surge. And while the mandatory vaccination initiatives have garnered most of the attention, the Biden *Path Out of the Pandemic* plan includes provisions to expand and increase COVID-19 testing, both in the lab and at home. Here's an overview of the plan and its impact on labs and the lab industry.

The 4 Key Parts of the Biden COVID-19 Testing Plan

The Biden plan is actually a combination of six comprehensive strategies for fighting the pandemic, returning the country to

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Independent Labs: CMS Clarifies IDTF Billing, Coding and Coverage Rules

In September, the Centers for Medicare & Medicaid Services (CMS) issued new guidance making some important clarifications on Independent Diagnostic Testing Facility (IDTF) billing requirements. Here's a look at the seven things lab managers need to be aware of to ensure proper billing and coding IDTF services.

Which Labs IDTF Billing Rules Affect

The new guidelines apply to you if your lab or facility is an IDTF, i.e., a facility that's independent of both an attending or consulting

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normal and providing for future public health emergencies. One of those strategies is dedicated to masking and testing. The latter proposes four sets of measures to promote widespread COVID-19 testing nationwide:

1. Expand Production of Rapid COVID-19 Tests

As he did immediately upon taking office, the President has drawn on the federal government's powers to mobilize private industry under the *Defense Production Act* (DPA) to step up production of COVID-19 tests and testing supplies. To ensure that the big test labs keep their foot on the COVID-19 production gas pedal, the administration plans to purchase nearly $2 billion worth of rapid point-of-care and over-the-counter at-home tests—280 million total tests—from multiple manufacturers. The tests will be made available to long-term care facilities, community testing sites, critical infrastructure, prisons and jails and other programs supporting vulnerable populations, as well as to create testing stockpiles for the future.

2. Make At-Home COVID-19 Tests More Affordable

The plan calls for cooperating with private business to expand test access, with major retailers Walmart, Amazon and Kroger agreeing to sell at-home rapid COVID-19 tests to consumers at cost for the next three months. The resulting price reduction of up to 35 percent, which are available in-store and online, will make tests more affordable. In addition, the government is mandating that states cover Medicaid cover at-home tests for free and not establish "arbitrary barriers" to those seeking care.

3. Ensure Access to Free COVID-19 Tests

To ensure that people with low incomes can get free tests, the administration is sending 25 million free at-home rapid COVID-19 tests to 1,400 community health centers and hundreds of food banks across the country.

4. Expand Free HHS Pharmacy Testing

The plan also calls for expanding the number of retail pharmacy sites around the country where anyone can get tested for free through the U.S. Department of Health and Human Services free testing program to 10,000 pharmacies.

Lab Industry Response to Biden COVID-19 Testing Plan

The lab industry has come out strongly in support for the Biden plan. American Clinical Lab Association (ACLA) president Julie Khani issued a statement praising the plan for taking "important steps towards boosting access to COVID-19 testing . . . to help ensure Americans have readily

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available access to COVID-19 tests as part of return to work, school and daily life."

Khani added that the ACLA "strongly supports efforts to fully leverage the broad range of high- quality molecular, antigen, serology, and T-cell tests available in laboratory, point-of-care, and over-the-counter settings."

Takeaway

The administration's recognition of the need for affordable point-of-care rapid COVID-19 testing and willingness to leverage federal government powers to serve it is certainly a welcome development. However, much more needs to be done to ensure the availability of testing in the short-, medium- and long-term. Perhaps the most immediate challenge is to resolve the supplies shortage that has bedeviled testing efforts from the beginning of the public health emergency. And while mobilizing industry capacity under the DPA is certainly necessary as a short-term response, what's really needed is for the administration to heed the industry's cry to use the powers of the federal government to support long-term planning and coordination between policy making and manufacturing for the remainder of the pandemic and beyond.

Compliance Alert: OIG Calls on CMS to Recover Phlebotomy Travel Allowance Overpayments

If your lab bills Medicare for phlebotomy travel allowances, a Medicare Administrative Contractor (MAC) claims audit may be in your future. The threat stems from a new Office of Inspector General (OIG) report citing MACs for paying travel allowances for lab test claims that didn't meet Medicare medically necessary criteria and wondering aloud whether this might not be a widespread problem that the Centers for Medicare & Medicaid Services (CMS) needs to crack down on.

Billing & Coding of Phlebotomy Travel Allowances

Medicare pays a specimen collection fee when it's medically necessary for a clinical lab technician or other trained personnel (referred to collectively as "technicians") to draw a specimen for a test. If the technician travels to a nursing home or a homebound patient's residence for phlebotomy services (or to collect a specimen via catheterization), Medicare also pays a phlebotomy travel allowance covering transportation and personnel

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expenses. Labs are supposed to use one of two Healthcare Common Procedure Coding System (HCPCS) codes for phlebotomy travel allowances:

- **HCPCS P9603**, if the average round trip to a patient's home or nursing home is farther than 20 miles, paid on a mileage per trip basis; or
- **HCPCS P9604**, if the average round trip is less than or equal to 20 miles, paid on a flat rate per trip basis.

Under either code, when one trip is made for specimen draws or pickups from multiple patients (e.g., at a nursing home), the travel payment component is prorated based on the number of Medicare and non-Medicare patients on that trip. All draws and pickups are included in the proration, and the prorated phlebotomy travel allowance is billed on behalf of each Medicare patient.

OIG Auditors Find Phlebotomy Travel Allowance Overpayments

Overpayment of phlebotomy travel allowances has become a target for OIG audit. In October 2018, the agency issued a report citing Professional Clinical Laboratory, Inc., for "generally" failing to comply with Medicare billing rules for such travel allowances. In previous audits, the agency found improper payments of phlebotomy travel allowances by two MACs for lab tests performed from Jan. 1, 2015, through Dec. 31, 2016. The auditors attributed part of the blame to CMS for its "unclear or conflicting" guidance to providers on how to bill for these allowances, particularly the prorating rules.

The new report circles back to take a closer look at the earlier audits, identify the source of overbilling and determine whether CMS and MACs had made any progress in cleaning up the problem. Those previous audits covered 753,410 paid claim lines, totaling $16.4 million, paid by the two MACs for phlebotomy travel allowances, all under HCPCS code P9603. Of the 202 sampled paid claims the OIG reviewed, only 93 complied with Medicare guidance; the other 109 did not for one or more reasons related to incorrect prorated mileage, incorrect payment rates, and inadequate documentation. On the basis of the sample results, the OIG estimated that the two MACs paid providers a combined $2.7 million in phlebotomy travel allowance payments that didn't comply with Medicare guidance.

Having accomplished part one of the mission, the auditors circled back with CMS in June 2020 to determine if they had made any progress in fixing the guidance problems that might have been behind the improper billing. The answer turned out to be no. CMS hadn't even begun the notice and comment rulemaking process necessary to clarify provider guidance related to prorating mileage on claims for phlebotomy travel allowances or issue further guidance, the auditors reported.

OIG to CMS: Collect the Overpayments & Fix the Problem

The OIG gave CMS three recommendations:

- Work with the MACs to educate providers about the documentation requirements for phlebotomy travel allowances;
- Instruct the MACs to identify and adjust any paid claims that incorrectly used the previous year's rate; and
- Issue regulations related to prorating of phlebotomy travel allowances.

CMS accepted all three recommendations, while cautioning that the new regulations the OIG wants will have to go through the notice and comment rulemaking. However, CMS did solicit comments on current specimen collection fees and travel allowance policies, including its methodology for calculating the travel allowance, as part of the calendar year 2022 Physician Fee Schedule Proposed Rule.

Takeaway

The OIG thinks that CMS and MACs have been turning a blind eye to potential overbilling of phlebotomy travel allowances. And now CMS is taking the issue seriously. The good news is that the consensus seems to be that any overbilling problems that exist are the result not of lab abuse but confusing rules and absence of guidance; the bad news is that CMS has called on the MACs to identify previous overpayments and get labs to pay them back.

Compliance Alert: OSHA Orders Inspectors to Use the Hammer to Enforce New COVID-19 Protocols

On June 21, OSHA issued a new Emergency Temporary Standard (ETS) requiring labs, hospitals and other providers to take extensive measures to protect frontline workers against risk of COVID-19 infection (for a detailed analysis of the ETS, see *Lab Compliance Advisor*, June 28, 2021). Exactly one week later, the agency issued internal Compliance Directive 2021-02 (the Directive) telling OSHA inspectors how to enforce the new ETS. The 67 pages of instructions shed light on how the agency intends to hand out penalties for violations, which, in turn, offers insights for labs on how to avoid them.

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What the ETS Covers

Responding to criticism about health care workers being left unprotected during the pandemic, the ETS lays down a laundry list of things providers must do to guard against workplace COVID-19 infections. Although most of the measures were already required under previous public health guidelines, the ETS also imposes a number of onerous new obligations, including the controversial rule that employers must provide paid leave to workers who are medically removed.

As with other OSHA standards, field inspectors will be visiting workplaces to check on compliance and issuing citations to those found in violation of the ETS. The directive makes it clear that OSHA is determined to enforce the ETS aggressively. The Directive tells inspectors to issue "Serious" citations to employers who don't pay workers at their regular rate of pay when they work remotely or in isolation as part of a medical removal. That's a big deal because if your lab gets cited, inspectors could hit you with a "Repeat" citation carrying a fine of up to $136,532 if they find similar violations during subsequent inspections.

But the Directive doesn't stop there. The Directive also gives inspectors the greenlight to bring in the really heavy artillery, namely, liability for punitive damages under the OSHA Whistleblower Protection Program. Essentially, OSHA is treating medical removal violations as potential acts of retaliation rather than run of the mill health and safety infractions.

Look at the payroll records, interview workers and consider other aspects of the situation, including the employer's size and resources, and verify that the employer is "appropriately compensating" workers that it medically removes due to COVID-19, the Directive instructs. It also tells inspectors to accrue back wages, insurance premiums and other costs in determining how much the employer owes the worker and how big a proposed fine a citation should carry.

Takeaway

OSHA's mandate is to ensure workplace health and safety. However, the ETS extends the agency's authority to matters of pay, benefits and medical leave. Ultimately, this may prove an unlawful incursion into matters beyond OSHA's jurisdiction. But the agency isn't backing down and is relying on its authority over whistleblowers as justification. Meanwhile, it's doubling down, ordering inspectors to be aggressive in enforcement, including via resort to punitive damages. Consequently, labs have no choice but to comply to avoid serious penalties.

FDA WATCH

FDA Hikes Premarket Application User Fees by 2.5 Percent

Applying for FDA premarket review of medical devices will be more expensive next year. On August 2, the agency announced that it's raising premarket approval (PMA) user fees by 2.5 percent in FY 2022.

PMA User Fees

The FDA sets the fee rate for each type of submission based on a specified percentage of the standard fee for a premarket application. The *Medical Device User Fee Amendments of 2017* (MDUFA IV) gives FDA the authority to collect user fees from the industry for certain medical device submissions to help pay for the agency's review activities. The MDUFA IV requires the FDA to meet performance goals designed to improve the efficiency, speed and transparency of the PMA and 510(k) review process. In return, the medtech industry provides the FDA $999.5 million in additional financial resources over a five-year period.

In FY 2022, the $329,000 base fee and $4,978 establishment registration fee will be adjusted "using the same methodology as that for the total revenue inflation adjustment," according to the agency. The good news is that the resulting 2.5 percent adjustment for the year, which takes effect on October 1, 2021, will be considerably less than the 7 percent increase in the user fee that the agency implemented in FY 2021.

Interoperability: CMS Delays Payer-to-Payer Data Exchange but Prior Authorization Rules Remain on Track

On Sept. 17, the Centers for Medicare & Medicaid Services (CMS) announced that it's delaying an interoperability rule governing how payors are expected to exchange with one another. However, the decision doesn't affect other parts of the interoperability rule, including provisions imposing payer prior authorization limits on certain Medicare and Medicaid health plans. Here's a quick briefing on what is and isn't changing.

The Interoperability Rule

Originally slated to take effect on Jan. 1, 2022, the payer-to-payer portions of the interoperability rule require

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insurance companies that do business with CMS, including Medicare Advantage carriers and Medicaid managed care organizations, to exchange data at the request of patients, as well as incorporate the data they receive from other payers into the health records of members.

However, insurance companies pushed back, complaining citing implementation challenges created by the rule's failure to establish an exchange mechanism or technical standard for exchanging data, leaving payers to accept data in whatever format they were sent.

CMS heard the message and announced that it is exercising "enforcement discretion" and temporarily delaying the data exchange requirement. Sticking to the Jan. 1 enforcement schedule would create the "potential for negative outcomes that [would] impede, rather than support" interoperable payer-to-payer data exchange," according to the email announcing the delay.

The agency didn't give a date, but instead said enforcement would begin once "future rulemaking is finalized." The implication is that CMS will develop the specific mechanism and exchange guidelines that payers say they need to share data more easily and effectively.

Not surprisingly, insurers expressed their approval for the delay. "Despite the continuing pandemic, health insurance providers are diligently implementing the many provisions of the interoperability rule, and we appreciate CMS recognizing the difficulty of standing up this new technology," according to an America's Health Insurance Plan spokesperson.

The data exchange enforcement delay is only the latest setback in interoperability rule implementation. The COVID-19 pandemic forced CMS and the Office of the National Coordinator for Health Information Technology (ONC) to postpone initial implementation last June. The first phase of the ONC rule did take effect in early April.

Prior Authorization Requirements Remain on Track

In the frequently asked questions document accompanying announcing the delay of the data exchange requirements, CMS clarified that the delay doesn't apply to other provisions of the interoperability final rule issued in the final months of the Trump administration. Among these, the provisions affecting payer preauthorization arguably have the greatest impact on labs.

Specifically, the final rule requires Medicaid, the Children's Health Insurance Plan (CHIP), Qualified Health Plans (QHPs) and other plans—but not Medicare Advantage plans—to build application programming interfaces (APIs) on their systems that enable electronic health records (EHR) and other information systems to talk to each other or third-party applications.

The APIs are designed to make payer authorization requirements more transparent and easy to maneuver by enabling providers to determine in advance the documentation each payer requires, streamline documentation processes and facilitate the electronic transmission prior authorization information requests and responses.

APIs are somewhat controversial due to their privacy and data security implications. Payer APIs under the final rule must meet the Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) standard. The FHIR standard is a technology solution that helps bridge the gaps between systems so that both systems can understand and use the data they exchange.

The final rule also reduces the wait time for prior authorization decisions by requiring payors (other than QHP issuers on Federally Facilitated Exchanges (FFEs)) to issue decisions on urgent requests within 72 hours, and non-urgent requests within seven calendar days. Payers must also provide a specific reason for any denial, to give providers some transparency into the process. To promote accountability for plans, the rule also requires payers to make public certain metrics that demonstrate how many procedures they're authorizing.

Reauthorization Transparency Bill for Medicare Advantage Plans

In May 2021, a bipartisan group in the House of Representatives led by Rep. Susan DelBene (D-Wash.), Mike Kelly (R-Pa.), Ami Bera (D-Calif.) and Larry Bucshon (R-Ind.) reintroduced a bill imposing similar requirements on Medicare Advantage plans. In addition to requiring Medicare Advantage plans to establish electronic prior authorization programs and provide "real-time decisions" for certain services designated by the HHS secretary, the bill would boost prior authorization transparency by obligating plans to:

- Submit annual reports to HHS listing which of their services require prior approval, as well as data on how many requests were approved, denied and overturned after initial denials in the previous plan year;
- Report the average and median amount of time between the submission of a prior authorization request and a determination from the plan; and
- Make the above information available to their contract providers along with a statement of their criteria for making prior authorization determinations.

Takeaway

Prior authorization has been a perennial source of friction between payers and physicians, labs and other providers. While payers have a legitimate need to ensure program integrity and manage utilization of

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covered health services, requiring prior authorization often imposes significant administrative burdens on providers and delays patients from receiving the care they need.

The American Medical Association (AMA) has done an effective job of keeping the issue on the agenda, including via a 2020 survey in which two of five polled physicians reporting that prior authorization delays access to necessary care, with 15 percent reporting it always happens, 39 percent saying it happens often and 40 percent saying it happens sometimes.

■ Independent Labs: CMS Clarifies IDTF Billing, Coding and Coverage Rules, *from page 1*

physician's office and of a hospital. IDTFs may be either a fixed location or a mobile entity. Other than hospital-based and mobile IDTFs, a fixed-base IDTF doesn't:

- Share a practice location with another Medicare-enrolled individual or organization;
- Lease or sublease its operations or practice location to another Medicare-enrolled individual or organization; or
- Share diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.

The IDTF Billing Clarifications

When an IDTF provides diagnostic procedures in a physician's office, IDTF general coverage and payment policy rules apply. Medicare reimburses diagnostic procedures performed by IDTFs at the Medicare Physician Fee Schedule (MPFS) rate. The IDTF billing clarifications are contained in the Medicare Learning Network (MLN) Booklet that CMS issued in September. There are seven points of clarification:

1. Reimbursement of Nurse Practitioner Supervised Tests

CMS reminded providers that it's issued waivers on certain billing rules to make it easier for Medicare patients to access lab and other diagnostic tests during the COVID-19 Public Health Emergency (PHE), including allowing nurse practitioners, clinical nurse specialists, physician assistants and certified nurse-midwives to provide the required level of supervision for reimbursement under the MPFS.

2. Billing & Coding of Transtelephonic & Electronic Monitoring Services

The Booklet lists important coding clarification you need to be aware of if your IDTF provides 24-hour EKG monitoring or other transtelephonic and electronic monitoring services without actually seeing a patient. Most, but not all of the current billing codes for these services are 93040, 93224, 93225, 93226, 93270 and 93271. CMS doesn't currently have specific certification standards for IDTF technicians.

If an entity lists and bills codes 93268, 93270, 93271, or 93272, the Booklet explains, the Medicare Administrative Contractor (MAC) must make a written determination that the entity has a person available on a 24-hour basis to answer telephone inquiries. Use of an answering service instead of the actual person isn't acceptable.

Billing Instruction: List the person performing the attended monitoring in Section D of Attachment 2 of Form CMS-855B

3. Global Billing

According to the Booklet, global billing is acceptable when the same entity performs both the TC and Modifier 26 and that entity provides both the TC and Modifier 26 within the same MPFS payment locality. It's okay to provide the TC and Modifier 26 in different locations as long as you furnish them within the same MPFS payment locality.

Note: As with all services payable under the MPFS, CMS uses ZIP Code to determine the appropriate payment locality and corresponding fee used to price the service that's subject to the anti-markup payment limitation. When a ZIP Code crosses county lines, agency uses the dominant locality to determine the corresponding fee.

Billing Instruction: If you bill with the global diagnostic test code, report the name, address, and National Provider Identifier (NPI) of the location where you provided the TC in Items 32 and 32a (or the 837P electronic claim equivalent).

4. Separate TC & PC Billing—Non-Global Billing

Billing Instruction: When you bill the TC and Modifier 26 separately (not billed globally), report the name, address and NPI of the location where you performed each component. If the billing provider has an enrolled practice location at the address where the service took place, the billing provider or supplier may report their own name, address and NPI in Items 32 and 32a (or the 837P electronic claim equivalent).

The NPI in Item 32a must correspond to the entity identified in Item 32 (no matter if it's the group, hospital, IDTF, or individual physician), the Booklet explains. The only exception for Medicare claims is when a provider performs a service out of jurisdiction and is subject to the anti-markup or a reference lab service.

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5. IDTFs & Opioid Treatment Programs (OTPs)

CMS clarifies that for an IDTF to be eligible to enroll as an OTP service provider with Medicare, its program must have current, valid, and full certification by the Substance Abuse and Mental Health Services Administration (SAMHSA), and meet all of SAMHSA's criteria, including but not limited to:

- Drug Enforcement Administration (DEA) registration;
- State licensure; and
- Accreditation.

6. Coverage of SNF Residents Requiring Transportation for IDTF Service

In 2018, CMS revised both the Medicare Benefit Policy Manual and Medicare Claims Processing Manual to clarify that Part B may cover a medically necessary ambulance transport from an SNF to the nearest supplier of medically necessary services not available at the SNF where the patient is the resident, including the return trip (including an IDTF). In the Booklet, CMS clarifies that this applies to patients in an SNF stay uncovered by Part A, but who have Part B benefits.

For SNF residents receiving Part A benefits, such ambulance trips to IDTFs for medically necessary services are subject to SNF consolidated billing.

7. Billing of IDTF Mammography Services

Under (Chapter 18, Section 20.3.1.4 of) the Medicare Claims Processing Manual, if an IDTF furnishes any type of mammography service (screening or diagnostic), it must have an FDA certification to perform such services. However, if you only perform diagnostic mammography services, you shouldn't enroll as an IDTF. Medicare does pay for screening mammographies (including those that are self-referred) when an IDTF performs them at the IDTF facility.