G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

NATIONAL LAB REPORTER™

Formerly: National Intelligence Report

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 42nd Year of Publication

Vol. 21, Iss. 6, June 2021

IN THIS ISSUE

The New CONNECT for Health Act: Getting Medicare Reimbursement for Telehealth Lab Services

Like most cliches, the one about the COVID-19 pandemic's transformation of medicine forever is laden with truth. Telemedicine is Exhibit A. Of course, telemedicine goes back decades. But the pandemic accelerated the breakdown of resistance on the parts of providers, regulators and above all, patients. It was supposed to be just temporary. But to use still one more cliché, now that the toothpaste is out of the tube, it becomes a matter of figuring out how to regulate it effectively. Ironically, but hardly unexpectedly, one of Congress' first attempts to impose systematic regulation involves recycling a piece of legislation that failed to gain support in pre-pandemic times but may make it into law this time. Here's a quick overview of the so-called CONNECT for Health Act and what lab managers should know about it.

Continued on page 2

New Laws: New HHS Policy Makes Labs Potentially Liable for LGBTQ Discrimination

While it doesn't directly relate to billing and reimbursement, federal civil rights laws have an impact on certain aspects of lab operations. These laws ban your lab from discriminating on the basis of protected personal characteristics, including sex. So, compliance managers need to be aware that on May 10, the Department of Health and Human Services (HHS) issued an important bulletin affecting how the ban on sex discrimination will be enforced from now. Specifically, sex discrimination will go beyond just a person's sex or gender but also their sexual orientation and/or gender identity. Here's a rundown of the law and how it might affect your operations.

Continued on page 11

The New CONNECT for Health Act: Getting Medicare Reimbursement for Telehealth Lab Services, *from page 1*

CONNECT Four May Be the Charm

Formally known as the Creating Opportunities Now for Necessary and Effective Care Technologies for Health Act of 2021, CONNECT is a massive amoeba of a bill introduced into Congress to address telehealth, connectivity and Medicare through the end of the pandemic and beyond. The 2021 version represents the fourth iteration of CONNECT introduced in Congress, the latest being in 2016. But this time things are different, the bill's backers insist, not the least of which is its bipartisan by 50 U.S. Senators led by Senator Brian Schatz (D-HI). The newly introduced CONNECT bill enjoys the support of more than 150 influential organizations, including Healthcare Information and Management Systems Society (HIMSS), American Telemedicine Association, eHealth Initiative, American Medical Association, American Nurses Association and the AARP.

NLR

National Lab Reporter
(ISSN 2332-1466) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 888-729-2315
Fax: 855-649-1623
Web site: www.G2Intelligence.com.

But what's really different this time around is that Americans have actually tried telehealth—and they like it. A March 2021 survey by Sykes found that of 2,000 Americans polled, almost 88 percent said they had tried and want to continue using telehealth for nonurgent consultations after COVID-19 has passed, while almost 80 percent say that it is possible to receive quality care virtually. These findings represent a dramatic contrast from a March 2020 Sykes survey in which roughly 65 percent of Americans said they felt hesitant or doubtful about the quality of telemedicine, and 56 percent didn't believe it possible to receive the same level of care as compared to in-person appointments.

Over 85 percent of 2021 surveyed respondents also agreed that telehealth has made it easier to get needed health care and over 64 percent said that going forward, they would like to have at least part of their annual exams done via telehealth. Another 74 percent said they would be willing to share data collected on a fitness tracker or smart medical devise with their physicians. Among the perceived benefits of telehealth is the convenience and ease of not having to commute to a doctor's office, and not having to wait in a doctor's waiting room around other sick patients. (For more details, see *DTET*, May 2021)

The 4 Key Coverage & Reimbursement Elements of the CONNECT Bill

CONNECT 2021 is a giant amoeba that incorporates 23 other different bills that have also been introduced into Congress. Here are the four parts of the bill that will likely have the most direct and immediate impact on freestanding, hospital and physician office labs.

1. Elimination of Statutory Barriers to Telehealth

First and foremost, CONNECT would make the temporary of expansion telehealth during the pandemic permanent after the public health emergency ends. Specifically, it would:

- Give HHS authority to waive current statutory restrictions banning Medicare reimbursement for telehealth services as long as it determines that there'd be no "adverse impact to quality of care," beginning Jan. 1, 2022;
- Eliminate the requirement that the originating site of the telehealth service be: (i) located in a rural health professional shortage area; (ii) located in a county not included in a Metropolitan Statistical Area (MSA); or (iii) an entity that participates in a federal telemedicine demonstration; and
- Expand originating sites to include the home, presumably including home collection of samples for lab testing.

While providing much more leeway than under current rules, many of the new forms of telehealth expansion must still run through HHS.

2. Elimination of Provider-Specific Telehealth Restrictions

CONNECT would also remove restrictions for specific types of providers or services potentially affecting many affiliated testing labs, including via:

- Permanently allowing Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) to furnish and get reimbursed for telehealth services as distant site providers;
- Removing originating site restrictions for Indian Health Services and Native Hawaiian Health Care Systems;
- Removing restrictions for emergency medical care services; and
- Allowing telehealth for recertification of a beneficiary for the hospice benefit.

3. Expansion of Medicare Reimbursable Telehealth Services

Old Rules: Before the pandemic, labs, hospitals and other stakeholders that wanted CMS to add a service to the Medicare Telehealth Services List had to submit a request under one of two categories:

- **Category 1** for services that were similar to the professional consultations, office visits and office psychiatrist services already on the List; or
- **Category 2** for services not similar to those already on the List.

CMS reviewed Category 2 requests once a year to determine whether: (i) the corresponding code accurately describes the service when delivered via telehealth, and (ii) use of telecommunications provides demonstrated clinical benefit to the patient. This rigid, two-tiered system made the expansion of new services to the List slow and cumbersome.

New Rules: CONNECT would permanently establish a new Category 3 pathway created as part of the 2021 Medicare Physician Fee Schedule (MPFS) allowing the temporary addition of telehealth services that have

Continued on page 4

The New CONNECT for Health Act: Getting Medicare Reimbursement for Telehealth Lab Services, *from page 3*

a "reasonable potential likelihood of clinical benefit and improved access to care." Although the details aren't fully clear yet, under CONNECT, Category 3 added services would presumably stay on the List even after the public health emergency ends. The other important details to be supplied is the standard for Category 3 approval.

Open Question:
Medicare Reimbursement Rate for Telehealth Services

Some of the most important aspects of the newly proposed CONNECT legislation is what it doesn't include. One significant omission deals with rates of Medicare reimbursement for telehealth services. Some have argued that Medicare providers should receive lower reimbursement rates for telehealth services because they require less overhead and costs to deliver than in-person services. Of course, while that might be true for most providers, labs might actually have to incur higher overhead to provide tests via telehealth given the logistic challenges of specimen collection that performing lab services ordered by a provider without in-person patient contact. Accordingly, labs may be better served with the school of thought that reimbursement should be based on time and complexity, regardless of whether the encounter occurs in person or via telehealth.

4. Kickback Liability for Telehealth Equipment

Lab compliance officers also need to be aware of the new "program integrity" rules designed to prevent telehealth services fraud and abuse. One big issue is whether labs and other providers would be liable under the Anti-Kickback, Stark and False Claims Act for network interfacing, interoperability and other technology they provide patients so for purposes of delivering telehealth services. The good news is that CONNECT includes clarification that providing technology necessary for delivery of services wouldn't be considered "remuneration" under fraud and abuse laws. However, the details will have to be ironed out. This offers labs much less comfort and room for maneuver than previous versions of the bill that included broader liability protections.

Meanwhile, CONNECT would provide the OIG $3 million to carry out telehealth audits and investigations. It also requires HHS to create training and educational resources for providers and patients on telehealth payment, privacy and security within six months after the law takes effect.

Open Question: Telehealth Privacy & Cybersecurity

CONNECT doesn't get into the telehealth privacy and cybersecurity implications of telehealth. Separate legislation will be needed to address questions like whether to preserve HIPAA waivers that allow continued access to telehealth resources via less secure but potentially more accessible means like Skype and FaceTime. There will also be a need for discussions about how to safeguard sensitive personal health information when more health care encounters occur via telehealth, as well as whether reporting obligations or penalties should be revised for telehealth practice and, if so, how.

Takeaway

Although it represents massive progress, the CONNECT bill is also a bit of a downer in the sense that it doesn't go as far as many had hoped in making telehealth services reimbursable and protecting labs and other providers from liability. Thus, for example, even though CONNECT establishes the home as an originating site for coverage purposes, it would still require that other originating sites be established via the administrative process. By contrast, rival legislation, including a bill called the Telehealth Modernization Act (TMA), would fully repeal both originating site and geographic restrictions.

On the positive side, it does go beyond the more conservative approach advocated by the Medicare Payment Advisory Commission and some members of Congress that the temporary telehealth coverage and payment changes be extended beyond the public health emergency but only for a limited duration and not on a permanent basis unless and until there's more definitive proof of the value and quality of telehealth services.

Utilization Management: Congress Moves to Limit Prior Authorization Protocols of Medicare Advantage Plans

Prior authorization has been a perennial source of friction between payors and providers. While payors have a legitimate need to ensure program integrity and manage utilization of covered health services, requiring prior authorization often imposes significant administrative burdens on providers and delays patients from receiving the care they need. The AMA has done an effective job of keeping the issue on the agenda, including via

Continued on page 6

Utilization Management: Congress Moves to Limit Prior Authorization Protocols of Medicare Advantage Plans, *from page 5*

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. Payors have also been feeling the heat from regulators and now Congress in the form of a new bill curbing the use of prior authorization for Medicare Advantage patients. Here's a quick look at what's been going on.

The Regulatory Effort to Curb Prior Authorization

In the Trump administration's final months, CMS issued a final rule requiring Medicaid, the Children's Health Insurance Plan (CHIP), Qualified Health Plans (QHPs) and other plans—but not Medicare Advantage plans—to build application program interfaces (APIs) to support prior authorization and data exchange. The APIs would make payor authorization requirements more transparent and easy to maneuver by enabling providers to determine in advance the documentation each payor requires, streamline documentation processes and facilitate the electronic transmission prior authorization information requests and responses.

The final rule would have also reduced the wait time for prior authorization decisions by requiring payors to issue decisions on urgent requests within 72 hours and non-urgent requests within seven calendar days. Payors would have also had to provide a specific reason for any denial, to give providers some transparency into the process. Immediately upon taking office, the Biden administration imposed a freeze on last-minute regulatory initiatives adopted by its predecessor, including the prior authorization rule. The administration hasn't yet announced a decision on the rule, leaving its present in limbo and its future uncertain.

The New Prior Authorization Bill

In 2019, a bill imposing similar restrictions for Medicare Advantage plans was introduced into Congress but didn't get far. But early this month (May 2021), a bipartisan group led by Rep. Susan DelBene (D-Wash.), Mike Kelly (R-Pa.), Ami Bera (D-Calif.) and Larry Bucshon (R-Ind.) reintroduced the bill believing it might get over the finish line this time. Specifically, the bill requires Medicare Advantage plans to establish electronic prior authorization programs and provide "real-time decisions" for certain services to be designated by the HHS secretary.

Parallel to the Trump regulation's requirement of Medicaid, CHIP and other covered plans, the bill would also require Medicare Advantage plans with prior authorization requirements to boost transparency by:

- Submitting 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;
- Reporting the average and median amount of time between the submission of a prior authorization request and a determination from the plan; and
- Making the above information available to their contract providers along with a statement of their criteria for making prior authorization determinations.

Takeaway

"The majority of the healthcare community agrees that prior authorization needs to be reformed," noted Congresswoman DelBene in a statement. "This bipartisan legislation creates sensible rules for the road and will offer transparency and oversight to the prior authorization process." Where the bill differs from the Trump rule is in requiring payors to create an API on their website. While they do promote interoperability, APIs are fairly controversial due to privacy concerns. As a result, key players in the healthcare industry have resisted their adoption.

LDTs: MCIT Medicare Coverage Rule Could Be Reimbursement "Breakthrough" for Makers of LDTs

Medical device makers and members of Congress are growing impatient as CMS sends signals of still further delay on a final decision on a final rule that would automatically provide initial Medicare coverage for new medical products cleared by the FDA as breakthrough devices under Section 510(k). Although it was finalized during the Trump administration, the rule is a long-term project that was slated to go into effect on March 15, 2021. But after imposing one delay of 60 days, CMS has been sending signals that it may prolong the process yet again while it continues to study the issue. All the while, the natives are growing increasingly restless.

What's at Stake for LDT Makers

There's a lot on the line for both diagnostics makers and patients. Under the final rule, newly approved breakthrough devices would be deemed to meet the "reasonable and necessary" standard set out in Section 1862((a)(1)(A) of the *Social Security Act* for purposes of Medicare coverage over

Continued on page 8

LDTs: MCIT Medicare Coverage Rule Could Be Reimbursement "Breakthrough" for Makers of LDTs, *from page 7*

a four-year period starting on the date of FDA market authorization. Once the initial period ends, CMS would perform a new "reasonable and necessary" evaluation of the device based on clinical and real-world evidence of improved health outcomes. (For more on the rule, see NLR, May 10, 2021).

Technically, the rule applies only to devices that pass through the Medicare Coverage of Innovative Technology (MCIT) pathway, which doesn't include laboratory developed tests (LDTs). However, the larger idea of deferring to the FDA and not keep Medicare beneficiaries waiting for innovative medical technology would translate equally well to LDTs. In fact, CMS has sent clear signals that it looks at the MCIT rule as a template that could be extended to breakthrough diagnostics, drugs and/or biologics that aren't currently in the MCIT pathway, including LDTs.

CMS Puts the Coverage Rule on Ice

The MCIT Medicare coverage rule was one of the many eleventh hour rules finalized at the tail end of the previous administration affected by the freeze on new health care regulations imposed by the Biden regime in its first hours of office. Opponents of the rule, including the bipartisan Medicare Payment Advisory Committee (MedPAC) contend that FDA breakthrough device authorization and Medicare "reasonable and necessary" coverage approval is an apples-to-oranges comparison requiring different forms of medical evidence. Forcing CMS to cover new devices just because they get 510(k) certification would strip the agency of its scientific review responsibilities and expose Medicare patients to new technologies of unproven effectiveness and safety, they argue. "The Medicare program, not the FDA, should adjudicate coverage and spending determinations based on the specific needs of the Medicare population," commented MedPAC in providing public feedback to CMS.

In addition to MedPAC, 96 others submitted public comments during the latest delay period, including Swiss pharmaceutical giant Novartis, which came out in support of the rule, and the National Comprehensive Cancer Network, which opposed it.

New Letter Calls on CMS to Stop the Foot Dragging

As the May 15 deadline approached, there were new rumors that CMS would again delay implementation and might even reissue a new proposed rule, which would delay things for months or even years. On May 4, 37 Democratic members of Congress wrote a letter urging acting CMS Liz Richter administrator to "move forward with implementation as soon as possible." Four of the authors also penned a letter to CMS back in February urging the agency to stick with the original March 15, 2021 implementation. Hoping the new letter will have a more potent impact,

they persuaded 33 of their colleagues to join them in signing the latest missive.

Time's a wasting, the letter stresses. "We remain concerned the delay may unfairly exclude breakthrough devices that would have been included in the original rule, had it been enacted on March 15, 2021." The letter calls on CMS to allow products that would have been eligible had the rule taken effect on March 15 to remain eligible if and when the rule does become final regardless of the length of delay.

Takeaway

Assurance of Medicare coverage would go a long way toward breaking down barriers to research and development and incentivizing investment in novel diagnostics. Ultimately, that would likely extend beyond MCIT devices to LDTs. Raising the stakes even higher is the potential that the rule would include a "lookback" window covering devices approved within the two-year period before the rule took effect. Echoing the wishes of many in the device industry, the new letter from Congressional members urges CMS to extend the "lookback" window beyond two years to cover all breakthrough devices approved by the FDA so far.

At the end of the day, it seems likely that CMS will ultimately approve some form of Medicare coverage rule for breakthrough devices given the bipartisan support for the initiative. But the question of how extensive the rule will be and when it will take effect remain very much in suspense.

Enforcement Trends: The Federal COVID-19 Relief Fraud Crackdown Begins

As with so many other businesses, federal COVID-19 relief was (and, in some cases, still is) the only thing that kept some labs afloat during the darkest days of the pandemic. But with the virus in apparent retreat, business is getting back to normal. And that includes the business of enforcing the federal laws. Among the first orders of business for federal investigators and prosecutors will be to crack down on recipients who took advantage of COVID-19 relief funds. While not uniquely a health care initiative, this new initiative will undoubtedly have a direct effect on medical practice, freestanding and hospital testing labs. In fact, it already has.

Colorado Physician Indicted for COVID-19 Ripoff

In one of the first of what's bound to be many cases, the U.S. Justice Department indicted a 56-year-old Colorado physician for stealing nearly

Continued on page 10

Enforcement Trends: The Federal COVID-19 Relief Fraud Crackdown Begins, *from page 9*

$300,000 from three different COVID relief programs. The DOJ claims the accused siphoned the money from a medical clinic's account into his own personal bank account and spent it on travel and lavish home improvements.

The COVID relief programs allegedly targeted in this case are the ones in which many labs and lab owners participated, including:

- The Accelerated and Advance Payment Program, which provides reimbursement funds in advance of service to help labs and other Medicare providers maintain cash flow during national emergencies;
- The $50 billion Provider Relief Fund for labs and other providers involved in coronavirus response; and
- The Paycheck Protection Program providing 1 percent loans to help small businesses meet their payroll, rent, mortgage and utilities obligations.

Bottom Line: Prepare for COVID-19 Relief Auditors

Almost from the moment Congress passed the COVID-19 relief programs, federal enforcement agents have been sounding the warning on relief fraud scams. And now the investigations and prosecutions have begun. So, if your lab accepted federal relief, anticipate an audit and be sure you have the accounting and program compliance records you'll need to survive it.

CPT Coding: AMA Creates New PLA Code 0247U for Sera Prognostics PreTRM Test

The most recent laboratory developed test (LDT) to garner CPT code recognition from the American Medical Association (AMA) is Sera Prognostics, Inc.'s PreTRM Test, a proteomic blood test for measuring a woman's risk of spontaneous preterm birth in time to allow for timely intervention. The new code 0247U, which was established under the AMA's Proprietary Laboratory Analysis (PLA) code program, was part of the revised set of PLA codes that took effect on April 1, 2021.

New PLA Code 0247U

The official Descriptor associated with new code 0247U states: "Obstetrics (preterm birth), insulin-like growth factor-binding protein 4 (IBP4), sex hormone-binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, combined with clinical data, reported as

predictive-risk stratification for spontaneous preterm birth." As such, the Descriptor is specific to the PreTRM Test.

"The receipt of this dedicated CPT PLA code is an important milestone in our commercial strategy to establish coding, coverage and payment for our proprietary PreTRM Test," Sera Prognostics chairman and CEO Gregory C. Critchfield, MD, MS. "We believe that the PreTRM® Test has an important role to play to improve risk identification that allows earlier proactive interventions designed to decrease adverse outcomes and thereby reduce healthcare costs. We are committed to making the test broadly accessible."

Preterm birth is a leading cause of illness and death in newborns. The PreTRM Test provides an early and individual risk prediction for spontaneous preterm birth in asymptomatic, singleton pregnancies, according to a company statement.

New Laws: New HHS Policy Makes Labs Potentially Liable for LGBTQ Discrimination, *from page 1*

Federal Discrimination Law, 101

The U.S. Civil Rights Act of 1964 makes it illegal to discriminate in different aspects of public activity, including employment and delivery of services, on the basis of a person's race, color, national origin, age, disability or sex. As with federal fraud and abuse laws, participating in Medicare, Medicaid and other federal healthcare programs makes you legally bound to comply with the Civil Rights Act.

Notice that the federal law mentions sex but not sexual orientation or gender identity—although several states have adopted their own civil rights laws that do afford protection to those characteristics. However, it has long been argued that "sex" includes orientation and identity. And in a landmark June 15, 2020 ruling called *Bostock v. Clayton County*, the U.S. Supreme Court endorsed that view in the context of Title VII of the Act, which applies to employment. In other words, the ban on discrimination "because of sex" in employment under Title VII also means employers can't discriminate against employees and job applicants based on their sexual orientation or gender identity.

On the first day President Biden took office, he issued an Executive Order calling on federal agencies to apply the *Bostock* reasoning to the parts of the Civil Rights Act in their own domain. Thus, for example, the Department of Housing and Urban Development (HUD), which administers federally assisted housing programs, issued guidelines stating that current Title VIII bans on housing discrimination by lenders, landlords and other participants in HUD programs based on sex would now be interpreted as also covering sexual orientation and gender identity.

Continued on page 12

New Laws: New HHS Policy Makes Labs Potentially Liable for LGBTQ Discrimination, *from page 11*

The significance of the new HHS bulletin is that it extends the *Bostock* principles to Title IX of the Civil Rights Act, which covers education programs or activities receiving federal financial assistance, including labs that participate in Medicare and other healthcare programs. Justification: In explaining the new rules, HHS says that discrimination in health care impacts health outcomes, citing research showing that one quarter of LGBTQ people who faced discrimination postponed or avoided receiving needed medical care for fear of further discrimination. The new policy will protect these people and hold providers who fail to comply accountable.

Takeaway: Practical Impact on Labs

The impact of the new HHS policy is that it exposes you to a new kind of liability, namely, discrimination on the basis of sexual orientation and gender identity under Title IX. The HHS agency in charge of cracking down on providers that commit illegal discrimination, e.g., labs that refuse to treat minorities or charge higher rates to black people because they're black, is the Office for Civil Rights (OCR), the same agency that enforces HIPAA.

Under the new policy, members of the LGBTQ community can file discrimination complaints against your lab. The OCR will investigate those complaints. If it finds evidence that your lab did, in fact, discriminate, it can initiate legal proceedings against you. In addition to money damages and potential corrective actions, this can lead to very unfavorable publicity against your lab.

Open Issue: Discrimination vs. Exercise of Religion?

One open question is how the new protections against discrimination on the basis of sexual orientation and gender identity will interact with the legal obligation of the OCR (under Section 1557 of the Affordable Care Act to enforce the civil rights rules in accordance with a law called the Religious Freedom Restoration Act which bans the government from unduly interfering with a person's exercise of religion.