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Medicare Reimbursement: New CMS Waivers Dramatically Expand Coverage Rules for COVID-19 Testing

CMS doesn't want the usual compliance red tape to stand in the way of desperately needed COVID-19 testing. So, on May 1, the agency issued regulatory waivers temporarily expanding coverage of testing for Medicare and Medicaid beneficiaries. Here are the five key changes:

1. Expansion of Eligible Test Orderers

CMS will no longer require an order from a treating physician or other practitioner for a beneficiary to get tested for COVID-19 but will cover testing ordered by any healthcare professional authorized to order tests under state law. The waiver also applies to other tests required as part of coronavirus testing.

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COVID-19: Testing Still Outpacing Supply, With Little Hope of Closing the Gap Soon

The U.S. has been behind the diagnostic testing eight ball since the COVID-19 crisis first began. Thus, unlike Australia, South Korea and other countries that pursued a strategy of widespread testing at the onset which ultimately enabled them to contain the spread of the virus, the U.S. was slow in recognizing the threat. As a result, it was extremely difficult for people showing symptoms to even get tested, and complete testing data was not available.

As it was in the early stages of the COVID-19 pandemic, diagnostic testing will be crucial to reopening the U.S. economy going forward. The good news is that the country has made up for lost time since the early stages, with nearly 100 different COVID-19 tests reaching the market, a figure that literally grows every day. The bad news is that the U.S. is still playing from behind as far as COVID-19 testing

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Medicare Reimbursement: New CMS Waivers Dramatically Expand Coverage Rules for COVID-19 Testing, *from page 1*

2. No Need for Written Order

CMS will also waive the requirement of a written practitioner's order for purposes of Medicare reimbursement for the COVID-19 test.

3. Green Light for Evaluation & Sample Collection by Pharmacists

Another CMS waiver allows pharmacists to work with practitioners to evaluate beneficiaries and collect samples for testing. Practitioners may bill Medicare for these services. To clear the way for drive-through testing, pharmacists enrolled in Medicare may perform certain COVID-19, in accordance with state law and licensing requirements.

4. Green Light for Evaluation & Sample Collection by Hospitals & Practitioners

CMS will also pay hospitals and practitioners to evaluate beneficiaries and collect lab samples for SARS-CoV-2 tests, and will provide separate payment when it's the only service the patient receives.

5. Coverage of Serology Tests

Last but not least, CMS said that Medicare and Medicaid will pay for coronavirus serology tests. The two programs will cover lab processing of certain FDA-authorized tests that beneficiaries self-collect at home.

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Fax: 855-649-1623
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COVID-19 Relief: HHS Clarifies Rules for Receipt of Provider Relief Fund Payments

If like so many other providers trying to survive COVID-19 business disruption, your lab is getting federal CARES relief payments, you need to be aware of the recent rule changes announced by HHS. Here's a quick debriefing.

The Provider Relief Fund

Created as part of the Coronavirus Aid, Relief, and Economic Security Act (CARES), the $50 billion Provider Relief Fund new (aka, Public Health and Social Services Emergency Fund), provides money to providers who furnish COVID-19-related treatment to the uninsured, rural health clinics and hospitals, Indian Health Service facilities, etc. Here are the 6 takeaways from CMS' recent Relief Fund guidance.

1. 15-Day Extension of Attestation Deadline

As with any federal aid, there are strings attached. recipients must complete an online attestation posted on the HHS Attestation Portal to

accept (or reject) each Provider Relief Fund payment agreeing to the Terms and Conditions governing the use of those funds within 30 days of receiving a payment. On May 7, HHS announced that it's extending the attestation deadline to 45 days. Thus, labs that received the first general distribution payment on April 10 now have until May 24 rather than May 9 to complete the attestation and accept the Terms and Conditions. Labs that don't return the payment within 45 days of the receipt date will be deemed to have accepted the Terms and Conditions.

2. No Need to Repay Relief Payments

One day earlier, HHS issued new guidance for relief fund recipients in the form of updated FAQs. The first takeaway from the guidance is that HHS isn't going to ask providers to repay Provider Relief payments as long as the "provider's lost revenue and increased expenses exceed the amount of Provider Relief funding a provider has received." But HHS reserves the right to audit recipients and require repayment if the provider:

- Receives relief payments that exceed its COVID-19 revenue losses or expense increases;
- Receives relief payment amounts made in error; and/or
- Violates any of the Terms and Conditions.

3. How to Respond to Overpayments

If a provider thinks it's received a Relief Fund overpayment (or erroneous payment), The new FAQs instruct it to reject the entire payment and submit appropriate documentation enabling HHS to determine the correct the payment via the General Distribution Portal. The provider should also tell its bank to refuse the Automated Clearinghouse (ACH) credit received by initiating an ACH return using the ACH return code of "R23 – Credit Entry Refused by Receiver."

4. How to Respond to Underpayments

Providers who get less than they expected should accept the payment and submit their revenues in the General Distribution Portal to determine their correct payment, according to the FAQs.

5. Deadline for Quarterly Reports

Providers receiving more than $150,000 from the Provider Relief Fund must submit quarterly reports to the government explaining how they're using the money. The FAQs confirm that the first quarterly reporting period will be for the "calendar quarter ending June 30" and the Terms and Conditions associated with the Provider Relief Funds indicate that reports will be due "[n]ot later than 10 days after the end of each calendar quarter." Absent additional guidance, this appears to indicate that the first reports are due by July 10.

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COVID-19 Relief: HHS Clarifies Rules for Receipt of Provider Relief Fund Payments, *from page 3*

6. Clarification on When Ban on Balance Billing Applies

The Terms and Conditions ban balance billing and billing patients above in-network rates for "all care for a presumptive or actual case of COVID-19." The FAQs clarify that a "presumptive case" is one "where a patient's medical record documentation supports a diagnosis of COVID-19, even if the patient does not have a positive in vitro diagnostic test result in his or her medical record."

Takeaway: Wiggle Room on Balance Billing

HHS also notes that most health insurers have publicly committed to reimbursing out-of-network providers treating health plan members for COVID-19-related care at the insurer's prevailing in-network rate. But if the health insurer doesn't meet that commitment, the FAQs say that the provider "may seek to collect from the patient out-of-pocket expenses, including deductibles, copayments, or balance billing, in an amount that is no greater than what the patient would have otherwise been required to pay if the care had been provided by an in-network provider."

COVID-19: HHS Puts Information Blocking and EHI Operability on Hold Due to COVID-19 Crisis

On March 9, 2020, the HHS Office of the National Coordinator for Health Information Technology (ONC) and CMS issued but didn't publish final rules designed to improve patient access to their own electronic health information (EHI) by banning providers, IT developers and health information networks from engaging in information blocking. The distinction between issuing and publishing is important because final rules don't take effect until 60 days after they're published in the Federal Register. But then the COVID-19 crisis intervened and publication of the final rule was delayed. And after 6 weeks of silence, the ONC, CMS and OIG officially confirmed what most suspected: Enforcement and implementation of information blocking rules is on hold for the time being.

OIG Delays Enforcement

On April 22, the OIG issued an unpublished proposed rule laying the groundwork for enforcement by amending the civil monetary penalty (CMP) regulations allowing the issuance of CMPs against providers that violate the ONC information blocking requirements (set out in the March 9 rules). But the agency also made it clear that it's not a question of if but

rather when enforcement should begin. At a minimum, the OIG proposed to delay enforcement until November 2, 2020.

CMS Delays Implementation

But the November 2 deadline got pushed even further back when CMS announced that it was extending by six more months the implementation timeline of certain parts of its own final rule affecting interoperability, including requirements admission, discharge and transfer notification Conditions of Participation (CoPs), which were originally supposed to take effect six months after the final rule was published. **Translation:** Those interoperability requirements will now take effect one year after publication of the final rule. Meanwhile, it remains unclear when the final rule will actually be published.

ONC Reissues Final Rule

On May 1, the ONC published the final rule, starting the 60-day effective date clock (i.e., June 30, 2020. But while the publication date triggers multiple compliance dates for various components of the interoperability and information blocking provisions (set at 60 days, 6 months, and 24 months following publication), the agency is changing that timeline for certain requirements in light of the COVID-19 crisis. Here's a summary of some of the key new enforcement discretion dates and implementation timelines.

Revised ONC Information Blocking & Interoperability Timelines

Step(s)	Original Compliance Date	Revised Compliance Date
Condition of Certification (CoC) assurances	June 30, 2020	September 30, 2020
*CoC: Information Blocking *CoC: Assurances – Information Blocking *CoC: Assurances – EHI Export Rollout *CoC: Application Programing Interface (API) – Compliance by Certified API Developers with health IT certified	November 2, 2020	February 2, 2021
*CoC: API – Rollout of new standardized API functionality *ONC-Authorized Certification Bodies (ONC-ACBs): Certification to Common Clinical Data Set/USCDI Criteria *ONC-ACBs: Certification to Application Access – Data Category Request Criterion	May 2, 2022	August 2, 2022
*CoC: Assurances – EHI Export Rollout *ONC-ACBs: Certification to Data Export Criterion	May 1, 2023	August 1, 2023
Information Blocking	November 2, 2020	November 2, 2020

Focus On: Doctors & Nurses Eager to Get Back to Work Despite COVID-19 Anxieties

Layoffs and furloughs are a new thing for many medical professionals who've come to expect stability in their employment. So, it's not surprising that a new survey suggests that medical professionals are eager to end lockdowns and get back to work; but like workers in so many other industries, the prospect of going back to work while COVID-19 remains at large is tinged with concern.

The CHG Healthcare Survey

The survey of 1,285 physicians, physician assistants, and nurse practitioners, by healthcare staffing agency CHG Healthcare, found that anxieties are up, even while workloads are down. Among respondents, 59% reported that they've treated patients who were either symptomatic but not tested or formally diagnosed as having COVID-19 or exhibiting symptoms who was not tested. When asked how their current anxiety levels compared to their pre-pandemic anxiety:

- 31% ranked current anxieties as being significantly higher;
- 41% said their current anxieties were slightly greater than before;
- 24% reported no change between their current and pre-pandemic anxiety levels;
- 1% said their anxieties were actually slightly lower than before the pandemic; and
- 2% reported having significantly less anxiety now than they did before.

About one-third of respondents (31%) said they were either extremely or very concerned about getting COVID-19 themselves, while 45% reported being either extremely or very concerned about someone in their family getting it.

Healthcare Workers Jobs and Income

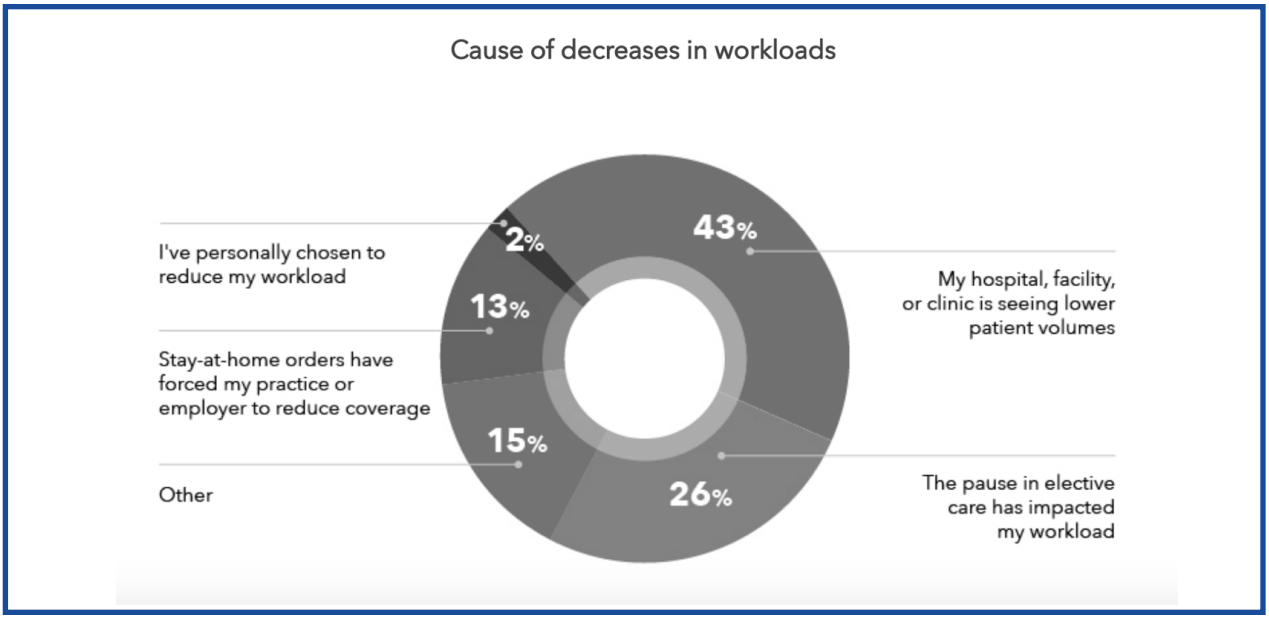
The survey also asked about respondents about their current financial situation, with 7% reporting that they were laid off and 6% that they were furloughed. When asked what they were doing to maintain their income during layoff or furlough:

- 62% said they were filing for unemployment benefits;
- 57% said they were reducing expenses; and
- 52% reported relying on savings or investments.

Forty-six percent of laid off or furloughed workers reported they were either looking for new permanent positions, another 37% were working locum tenens and 26% were working in telehealth.

Among those who reported that they were still working, 74% said they were working less than before the outbreak, with 56% reporting working

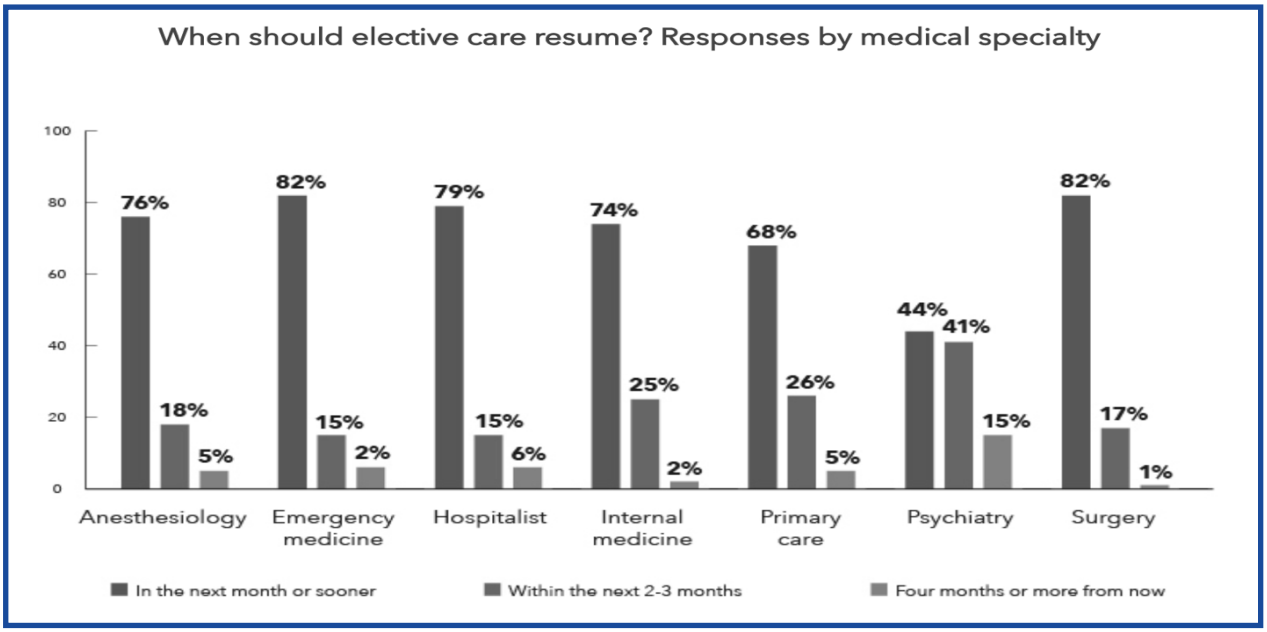
significantly less. The chart below summarizes the reasons attributed for decreased workloads.



Source: CHG Healthcare

How Healthcare Workers Feel about COVID-19 Restrictions

The majority of healthcare providers (73%) stated they wanted elective medical procedures to commence again within the next month or sooner, with responses varying slightly by medical field, as shown in the graph below.



Source: CHG Healthcare

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Focus On: Doctors & Nurses Eager to Get Back to Work Despite COVID-19 Anxieties, *from page 7*

Sixty-three percent also wanted stay at home orders lifted in the next month.

When asked about the response to the pandemic, healthcare workers rated themselves better than the government with 49% rating healthcare workers response as excellent and 48% rating the White House's response as poor:

Ratings on the response to the COVID-19 pandemic

FIELD	POOR	FAIR	GOOD	VERY GOOD	EXCELLENT
Healthcare workers	2%	3%	18%	28%	49%
My hospital, practice, or health system's administration	15%	21%	28%	22%	14%
My state government	13%	21%	29%	24%	13%
The U.S. Legislature	26%	44%	22%	7%	2%
The White House	48%	14%	13%	12%	13%

Source: CHG Healthcare

COVID-19 Politics & Lab Testing: $3 Trillion HEROES Stimulus Bill Clears House Will Die in Senate

On May 15, the U.S. House of Representatives passed, by a vote of 208 to 199, a new $3 trillion COVID-19 stimulus bill that includes $75 billion to support diagnostic testing and contact tracing activities to monitor and suppress the COVID-19 virus.

But that more than likely is the end of the road for the Health and Economic Recovery Omnibus Emergency Solutions (HEROES) Act. Weighing in at a robust 1,815 pages, the HEROES Act stands little chance of passage in the Republican-controlled Senate, whose Majority Leader Mitch McConnell described it as a "big laundry list of pet priorities" that has "no chance of becoming law." Indeed, President Trump has come out against the HEROES Act and promised to veto it in the unlikely prospect that it reaches his desk.

And don't believe for a moment that the House Democrats aren't aware of this. HEROES is more about bluff and posturing for upcoming negotiations on what would be the fifth piece of legislation providing federal relief to those impacted by the COVID-19 crisis. And unlike its predecessors, this bill doesn't have bipartisan support.

Bottom Line:

While a new federal stimulus bill containing funding to support COVID-19 lab testing isn't out of the question, it won't be the HEROES Act. How much support such a bill would provide for labs when and if it ever passed remains a great unknown.

CARES Act: CMS Issues Guidance on Private Payor Reimbursement of COVID-19 Testing

If your lab is performing COVID-19 testing for patients covered by private insurance and health plans, you need to be aware of the reimbursement rules set out in the new COVID-19 relief legislation. The laws mandate that payors cover COVID-19 testing without charging consumers for out-of-pocket expenses. On April 11, CMS issued guidance explaining how private payor lab test reimbursement will work under the scheme.

The FFCRA & CARES Acts

Enacted on March 18, the Families First Coronavirus Response Act (FFCRA) requires group health plans and health insurers offering group or individual health insurance coverage (but not short-term health plans) to provide benefits for certain items and services related to diagnostic testing for SARS-CoV-2 or diagnosing COVID-19 (which, for simplicity's sake, we'll refer to collectively as "COVID-19"). To ensure that testing is free, FFCRA bans imposition of:

- Cost-sharing requirements like deductibles, copayments and coinsurance; and
- Prior authorization and other medical utilization requirements.

On March 27, Congress passed the Coronavirus Aid, Relief, and Economic Security Act (CARES) to amend FFCRA to cover a broader range of diagnostic items and services that plans and issuers must cover without cost-sharing or prior authorization requirements. CARES also requires plans and issuers to reimburse providers of COVID-19 diagnostic testing an amount equal to its negotiated rate with the provider; if there is no negotiated rate, reimbursement must be at the cash price for such service listed by the provider on a public website. The plan or issuer may also negotiate—but not unilaterally apply—a rate with the provider that's lower than the listed cash price.

3 Key Takeaways from the CMS Guidance

There are three key points in the guidance that lab managers need to know to ensure they receive proper reimbursement for COVID-19 tests during the emergency:

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CARES Act: CMS Issues Guidance on Private Payor Reimbursement of COVID-19 Testing, *from page 9*

1. The Source of the Test Order

The guidance clarifies that the no-cost-sharing-requirement applies to COVID-19 tests ordered as a result of urgent care visits, emergency room visits and in-person and telehealth visits to a doctor's office.

2. The COVID-19 Tests Covered

According to the guidance, covered COVID-19 tests include:

- All FDA-authorized coronavirus tests, which includes serology tests receiving emergency use authorization (EUA);
- Tests that developers for which test makers have requested but not yet received EUA; and
- Diagnostic tests developed in and authorized by states.

3. The Effective Date

The COVID-19 testing reimbursement requirements apply to all testing and related services furnished on or after March 18, 2020 and will continue to apply for as long as the emergency lasts. is retroactive for testing and related services provided on or after March 18.

COVID-19: Testing Still Outpacing Supply, With Little Hope of Closing the Gap Soon, *from page 1*

is concerned. And it appears that the testing pipeline is still facing serious obstacles and testing is unlikely to continue lagging through at least the end of the year.

The Need for COVID Testing Data

One of the problems with evaluating the current state of COVID-19 testing in the U.S. is the lack of data. According to The COVID Tracking Project, a volunteer organization dedicated to collecting and publishing COVID-19 data, there is no complete account of COVID-19 testing data anywhere in the U.S. In other words, the U.S. government isn't tracking and reporting this data on a national level.

As a result, the COVID Tracking Project had to collect this data from the public health authority in each state, territory and the District of Columbia. Each of these authorities reports its data in its own way, including via online dashboards, data tables, PDFs, press conferences, tweets and Facebook posts. And while many states and territories have slowly moved toward more standard methods of reporting, the actual taxonomies and categories of information remain in flux.

COVID-19: Testing Still Outpacing Supply, With Little Hope of Closing the Gap Soon, *from page 10*

The COVID Tracking Project Findings

Based on the COVID-19 testing data it was able to gather from 56 different U.S. jurisdictions, the COVID Tracking Project reports that, as of May 12, 2020:

- 9,637,930 COVID-19 tests had been performed in the U.S.;
- 1,360,705 of those tests were positive;
- 8,277,225 of the tests were negative.

The Project also reports that daily test volumes are growing dramatically. Thus, the number of new COVID-19 tests performed on the day of May 12 was 289,472, as compared to the 140,562 new tests performed on April 12, and 5,137 new tests performed on March 12.

What the Test Numbers Mean

The numbers are sobering and scary. According to the COVID Tracking Project, as of May 12, 1,360,930 people in the U.S. have tested positive for COVID-19; among those to test positive, 76,617 have died. And, of course, those numbers don't account for the people who contracted and maybe died from the virus who weren't tested.

In addition to testing for clinical treatment, the reopening of the U.S. economy will precipitate a vast new demand for COVID-19 screening tests from employers. Factoring in the need for workplace screening, experts estimate that some 100 million to 200 million tests will be needed for the rest of the year. However, tests remain in short supply, as do testing personnel, reagents, swabs and other materials. And while the diagnostic testing manufacture pipeline is operating at a frantic pace, doubt remains about whether industry will be able to satisfy these soaring COVID-19 testing demands in the near future.

The Bottom Line

Based on the limited data available, it appears that COVID-19 testing in the U.S. continues to lag behind and that the gap between demand and supply isn't likely to close any time soon. Mass testing and screening is likely to remain an elusive objective as the tests that are available remain reserved for the sick and symptomatic.

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