What Clinical Diagnostic Laboratories and Manufacturers Need to Know about the CARES Act

Written by Brian P. Carey, Erik L. Schulwolf

March 31, 2020

Overview

On March 27, 2020, Congress passed the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), the third and by far the largest stimulus package passed by Congress to respond to the COVID-19 outbreak. As discussed in our main alert, the $2 trillion CARES Act amounts to what will be the biggest economic stimulus package in American history.

The CARES Act makes a number of significant changes for laboratory tests, both for COVID-19 and generally. For COVID-19 testing, CARES expands the types of tests that must be covered by commercial payers, Medicaid, and CHIP, and requires commercial payers to pay for COVID-19 testing performed by out-of-network laboratories at the advertised price or a lower negotiated rate. The CARES Act also delays PAMA reporting under the Medicare Clinical Laboratory Fee Schedule (CLFS) and exempts CLFS laboratory tests from market-based payment reductions for 2021. Finally, the CARES Act suspends the 2% sequester for all Medicare payments, including clinical diagnostic laboratory tests, from May through December 2020.

Key Points

Provisions Related to COVID-19 Testing:

- **Expanded Mandatory Coverage of COVID-19 Diagnostic Testing.** Section 6001(a) of the Families First Coronavirus Response Act (FFCRA) required health insurance issuers and group health plans to provide coverage, without cost sharing or medical management techniques like prior authorization, for in vitro diagnostic test products for COVID-19 that are approved, cleared, or authorized by the FDA (and for certain related services) during the emergency period defined in Section 1135(g)(1)(B) of the Social Security Act. Section 3201 of CARES expands this coverage requirement to include: 1) COVID-19 tests for which the developer has requested or intends to request emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA); 2) COVID-19 tests developed in and authorized by a state that has notified HHS of its intention to review tests for COVID-19; and 3) other tests determined by HHS in guidance.
- **Commercial Payer Payment for COVID-19 Diagnostic Testing.** Section 3902 of CARES would regulate the rate paid by health insurance issuers and group health plans for COVID-19 testing covered under Section 6001 of the FFCRA.Under Section 3902, such tests must be paid at the negotiated rate if one was in existence before the period governed by the public health emergency declared under Section 319 of the Public Health Service Act.If no such negotiated rate exists, the payer must make payment for the test "in an amount that equals the cash price for such service as listed by the provider on a public internet website," or at a negotiated rate less than that price. During the emergency period, each provider of a COVID-19 test must make public the cash price for the test on its website. Section 3902 provides for civil monetary penalties on providers of COVID-19 tests who do not comply with the public listing requirement.
- **Medicaid and CHIP Coverage for COVID-19 Tests.** Section 3717 of CARES eliminates the requirement established by Section 6004(a)(1)(C) of the FFCRA that COVID-19 tests covered by Medicaid and CHIP during the emergency under Section 1135(g)(1)(B) of the Social Security Act must be approved, cleared, or authorized by the FDA. Section 3716 of the CARES Act makes clarifications regarding uninsured individuals receiving coverage for COVID-19 testing through a state Medicaid program.
- **Laboratory Reporting of COVID-19 Test Results.** Section 18115 requires laboratories to report the results of COVID-19 tests to

HHS in a form and manner and at a timing and frequency that HHS may prescribe. HHS may designate which laboratories will be responsible for reporting.In setting rules for reporting, HHS is not bound by the rulemaking provisions of Administrative Procedure Act (5 USC § 553). This reporting requirement replaces the requirement in Section 1702 of the FFCRA for State Emergency Operations Centers to receive "regular and real-time reporting on aggregated data on testing and results from State and local public health departments" and to transmit such information to the Centers for Disease Control and Prevention.

- **Appropriations for COVID-19 Diagnostics.** The CARES Act includes significant appropriations to fund development and government acquisition of COVID-19 diagnostics. The legislation appropriates approximately $27 billion to "prevent, prepare for, and respond to coronavirus, domestically or internationally," including the development and purchase of COVID-19 diagnostics, vaccines, and therapeutics. However, CARES does not include direct funding for any immediate costs related to the rapid expansion of COVID-19 testing by private reference laboratories.

Medicare Clinical Diagnostic Laboratory Test Payment Provisions

- **Delay of CLFS Reporting.** Section 1834A of the Social Security Act (established in Section 216 of the Protecting Access to Medicare Act of 2014) creates a market-based payment system under the Medicare Clinical Laboratory Fee Schedule, with Medicare rates set triennially based on laboratory reporting. The first round of reporting took place in 2017 and has set payment rates since January 1, 2018. In December 2019, in the Further Consolidated Appropriations Act of 2020, the second reporting period was delayed from 2020 to 2021. Section 3718 of CARES further delays the second reporting period from 2021 to 2022.Payment rates for clinical diagnostic laboratory tests will remain at rates based on data reported in 2017 through December 31, 2022.
- **Delay of CLFS Payment Reductions.** Section 1834A of the Social Security Act also capped year-to-year payment reductions for 2021-2023 at 15%. Section 3718 of the CARES Act changed the payment reduction cap for 2021 to 0%, meaning tests on the Clinical Laboratory Fee Schedule in 2020 will be paid at the same rate for 2021. The 15% cap on payment reductions will now apply to 2022-24.
- **Relief from the 2% Medicare sequester.** The Budget Control Act of 2011, and later the American Taxpayer Relief Act of 2012, put in place a mandatory budget sequestration, resulting in a 2% reduction in Medicare fee-for-service claims beginning March 1, 2013. For example, since 2013 a laboratory providing a test for which Medicare allows $100 has been paid a rate of $98 (($100 – 2% = $98). Section 3709 of the CARES Act "freezes" this 2% reduction from May 1, 2020 through December 31, 2020. Laboratories (and health care providers billing for the performance of test kits) will see a temporary increase in payments during this time period. Note that to account for this temporary freeze, the legislation also extends the effect of sequestration by a year (now through fiscal year 2030).

Looking Ahead

An increase in the capacity of diagnostic testing is a key part of the COVID-19 public health response plan. Private payers will be required to cover COVID-19 testing even when laboratories are out-of-network, and to pay prices set by the laboratory (unless they are able to negotiate a lower rate).

Beyond the COVID-19 emergency provisions, the changes made by CARES to the CLFS market-based PAMA payment system will help provide more certainty for payment for hospital and reference laboratories. The reporting delay will allow for additional time for CMS to assess the MedPAC study required under December 2019 legislation. Furthermore, it freezes market-based payment rate cuts (based on rates reported in 2017) through the end of 2021.

Foley Hoag has formed a firm-wide, multi-disciplinary task force dedicated to client matters related to the novel coronavirus (COVID-19). For more guidance on your COVID-19 issues, visit our Resource Page or contact your Foley Hoag attorney. For guidance on CARES Act clinical diagnostic laboratories and manufacturers issues, please contact Brian Carey or Erik Schulwolf.

RELATED INDUSTRIES

- Life Sciences
- Professional Services
- Technology

RELATED PRACTICES

- COVID-19 Task Force

- Business Counseling
- Healthcare
- State Government Strategies
- State Government Strategies For Life Sciences
