

Summary of the CARES Act

On March 27, 2020, Congress passed and the President signed into law a third piece of legislation to respond to the economic toll COVID-19 has taken on the United States. The [Coronavirus Aid, Relief, and Economic Security \(CARES\) Act](#) provides \$2 trillion to stimulate the economy and respond to the COVID-19 pandemic. Expanded small businesses loans, assistance to hospitals, funding for public health agencies, and direct payments to lower- and middle-income Americans are just some of the provisions included in this sweeping bill.

Below is a summary of provisions that could affect AMP members related to diagnostic testing, including coverage and PAMA reporting.

Requires the Strategic National Stockpile to Include Diagnostics (Sec. 3102)

The legislation adds language to the Strategic National Stockpile authority to include medical devices and diagnostic tests (including supplies such as swabs) in the stockpile to help avoid shortages.

Coverage for COVID-19 Tests (Sec. 3201)

The Families First Coronavirus Response Act, a supplemental bill that passed on March 18, 2020, required coverage of testing for COVID-19. The bill required public and private insurers to provide coverage for tests and not to impose any cost sharing requirements to patients. However, coverage was only provided for tests that had received emergency use authorization (EUA) from the FDA, which left a significant gap in coverage for many tests, including those performed by laboratories that are authorized to develop and perform COVID-19 tests by their state or those tests that are performed and offered by laboratories concurrently while they seek EUA approval by the FDA. Section 3201 of the CARES Act effectively closes the coverage gap to include ALL tests, including those that are approved by the FDA, those awaiting FDA approval and those that are overseen by their individual state. AMP had advocated strongly to close this coverage gap for COVID-19 diagnostic tests and is relieved that Congress incorporated our feedback to address this problem.

Price Transparency for COVID-19 Tests (Sec. 3202)

The legislation sets out reimbursement rates for group health plans or health insurance issuers for reimbursing the provider of diagnostic tests. It also requires that for the duration of the public health emergency, providers of diagnostics tests for COVID-19 must publish the cash price on the public internet site of each provider. A civil monetary penalty, not to exceed \$300 per day, will be imposed on providers that do not comply or have not completed corrective action.

Medicaid Coverage for COVID-19 Tests (Sec. 3717)

The Families First Coronavirus Response Act included a provision that required coverage of testing for COVID-19 for Medicaid beneficiaries. The CARES Act expands the provision by removing the requirement that the test must be approved through the FDA process (similar to Sec. 3201).

Delays PAMA for One Year (Sec. 3718)

The legislation prevents scheduled reductions in Medicare payments for clinical diagnostic laboratory tests furnished to beneficiaries in 2021 and delays the upcoming laboratory data reporting period by one year. Specifically, it makes the following revisions to 42 U.S.C. 81395m-1(a)(1)(B):

(B) Revised reporting period

In the case of reporting with respect to clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests, the Secretary shall revise the reporting period under subparagraph (A) such that-

- (i) no reporting is required during the period beginning January 1, 2020, and ending ~~December 31, 2020~~ **December 31, 2021**;
 - (ii) reporting is required during the period beginning ~~January 1, 2021~~ **January 1, 2022**, and ending ~~March 31, 2021~~ **March 31, 2022**; and
 - (iii) reporting is required every three years after the period described in clause (ii).
- Revises in the implementation of the phase-in payment reductions so that it begins in 2022 instead of 2021, and extends from 2022 through 2024.

Mandatory Diagnostic Result Reporting (Sec. 18115)

Until the end of the public health emergency, every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2, or to diagnose a possible case of COVID-19, must report the results to the Secretary of Health and Human Services. The format, timing, and frequency of reporting will be determined by the Secretary through regulations.