

## SENATE RELEASES UPDATED CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY (CARES) ACT

On March 25, the Senate released an **updated version** of the **Coronavirus Aid, Relief, and Economic Security (CARES) Act** – a package of bills intended to strengthen the federal government and health care system’s response to COVID-19, as well as provide economic relief to individuals and businesses. The Senate is expected to vote on the package this afternoon. The House is expected to take up the package, though the timing of a vote is unclear.

**Snapshot** – Senate package includes:

- A \$340 billion “surge” in emergency funding to support the U.S. response to COVID-19 (Division B);
- Measures to address supply shortages of medical products, prescription drugs, and medical devices (Title III, Subtitle A, Part I);
- Provisions that would require private payers to cover certain COVID-19 diagnostic tests (Title III, Subtitle A, Part II)
- Support for health care providers, including grant funding (Title III, Subtitle A, Part II);
- Changes to the Health Insurance Portability and Accountability Act (HIPAA) rules, which would allow a covered entity to share a patient’s records relating substance use disorder for the purposes of treatment, payment, and health care operations after consent is given (Title III, Subtitle A, Part II);
- Additional flexibilities to Medicare telehealth requirements (Title III, Subtitle D);
- Provisions that delay requirements for enhanced Medicaid FMAP (Title III, Subtitle D);
- Limitations on paid leave (Title III, Subtitle C); and
- Provisions to provide economic relief to business through tax credits and loans (Title II)

Of note, the inclusion of several “health care extenders” that would reauthorize certain Medicare, Medicaid, and public health programs through **Nov. 30, 2020** (which were originally set to expire on May 22, 2020) would likely postpone congressional action on surprise medical billing and prescription drug pricing to the end of the year.

Please find **attached** the following:

- Legislative text of the CARES Act (Division A)
- Legislative text of the CARES Act (Division B – supplemental appropriations)
- Section-by-section of the CARES Act (Division A)
- Senate Appropriations Committee’s summary of Division B
- Senate Democrats summary of the CARES Act

**The companion appropriations package (Division B)** includes a \$340 billion “surge” in emergency funding to support the U.S. response to COVID-19. Over 80 percent of the total appropriations is directed to state and local governments and communities. Of note, \$117 billion is allocated to hospitals and veterans

care (\$100 billion of which is slated for hospitals and providers); \$16 billion is allocated to the Strategic National Stockpile; \$4.3 billion is allocated to the Centers for Disease Control and Prevention (CDC); and, \$11 billion is allocated to development vaccines, treatment, and diagnostics. Additional details follow.

- **Hospital Preparedness:** At least \$250 million will be allocated to improving the capacity of health care facilities to respond to COVID-19 service demand.
- **Rural Hospitals & Telehealth:** \$275 million will flow through the Health Resources and Services Administration (HRSA) to expand services and capacity for rural hospitals, including the use of telehealth services.
- **State and Local Preparedness:** The CDC will grant \$1.5 billion for state and local government preparedness and response activities.
- **Vaccines, Therapies, and Diagnostics:** the National Institutes of Health (NIH) will receive an additional \$945.5 million to continue research on vaccines, therapies, and diagnostics for COVID-19. The Food and Drug Administration (FDA) will receive \$80 million to support the development of necessary medical countermeasures and vaccines for COVID-19.
- **Access to Mental Health Services:** The Substance Abuse and Mental Health Services Administration (SAMHSA) will receive \$250 million to increase access to mental health care services.
- **Nursing Home Surveys:** The Centers for Medicare & Medicaid Services (CMS) will receive \$100 million to support additional infection control surveys for facilities that serve vulnerable populations, including the recent survey reprioritization efforts announced by CMS in regards to skilled nursing facilities (WHY client summary [here](#)).
- **Nutrition:** The Supplemental Nutrition Assistance Program (SNAP) will receive \$15.51 billion to cover the anticipated increase in participation as a result of the COVID-19 outbreak.
- **Education:** Allocates \$30.9 billion in “flexible funding” to imminently assist states, local school districts, and higher education institutions with immediate needs resulting from COVID-19, including support related to school closures, education technology, and distance education.

**Highlights** of the health-related provisions in **Title III (Division A)** follow:

### **Subtitle A – Health Provisions**

#### **Part I – Addressing Supply Shortages**

##### ***Subpart A – Medical Product Supplies***

- **Sec. 3101. National Academies Report on America’s Medical Product Supply** – Requires the Department of Health and Human Services (HHS) to contract with the National Academies of Sciences, Engineering, and Medicine (NASEM) to study the security of the United State medical product supply chain. The report will be used to evaluate the dependence of the U.S. on other countries for critical drugs and devices and the potential economic impact of increase domestic manufacturing.
- **Sec. 3102. Requiring Strategic National Stockpile to Include Certain Types of Medical Supplies** – Requires the Strategic National Stockpile (SNS) to include protective personal equipment (PPE), ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines, and other biological products, medical devices, and diagnostic tests.

- **Sec. 3103. Treatment of Respiratory Protective Devices as Covered Countermeasures** – Amends the definition of covered countermeasures to include respiratory devices that are deemed to be a priority by the Secretary during public health emergencies and are approved by the National Institute for Occupational Safety and Health (NIOSH).

***Subpart B – Mitigating Emergency Drug Shortages***

- **Sec. 3111. Prioritize Reviews of Drug Applications; Incentives** – Requires the HHS Secretary to prioritize and expedite the review and inspection of a new drug application to mitigate or prevent such shortage, if HHS suspects that there may be a drug shortage.
- **Sec. 3112. Additional Manufacturing Reporting Requirements in Response to Drug Shortages** – Requires a manufacturer of a drug or active pharmaceutical ingredient (API) that is critical to the public health during a public health emergency to notify the HHS Secretary if the drug or API is discontinued or production is interrupted. Notification must include reasons for discontinuation or interruption, if an active ingredient is the reason for discontinuation or interruption, and the source of the active ingredient. A manufacturer that produces a drug or API that is critical to the public health must develop a contingency and redundancy plan to help prevent or mitigate interruption in the supply of the drug or API. The HHS Secretary is required to transmit a report regarding the current drug and API shortage list every 90 days to the Centers for Medicare and Medicaid Services (CMS).

***Subpart C – Preventing Medical Device Shortages***

- **Sec. 3121 Discontinuance or Interruption in the Production of Medical Devices** – Requires a manufacturer of a device that is critical to public health during a public health emergency, including devices that are life-supporting, life-sustaining, or intended for use in emergency medical care to notify the HHS Secretary of a discontinuance or interruption in manufacturing. Notification must be made at least 6 months in advance of the discontinuance or interruption and the information will be made publicly available.

If the Secretary concludes that a shortage is likely, the Secretary may prioritize and expedite the review and inspection of medical devices to mitigate or prevent the shortage. Additionally, the Secretary is required to establish a medical device shortage list to be made available to the public.

**Part II – Access to Health Care for COVID-19 Patients**

***Subpart A – Coverage of Testing and Preventive Services***

- **Sec. 3201. Coverage of Diagnostic Testing for COVID-19** – This section would require all group health plans and issuers offering plans on the individual market to cover all testing and related services for testing and diagnosis of COVID-19 at no cost-sharing if –
  - The developer of a test has requested or intends to request an emergency use authorization (EUA);
  - The test was developed in and authorized by a State that has notified HHS of its intention to review COVID-19 diagnostic tests; or
  - HHS deems a particular diagnostic test to be appropriate in regulatory guidance.

- **Sec. 3202. Pricing of Diagnostic Testing** – Applies negotiated rates between health plans and providers for the reimbursement of administering diagnostic tests. If a negotiated rate does not exist, the bill would require a health plan to reimburse the provider for the cash price of the diagnostic test “as listed by the provider on a public internet website.” In relation to the reference to a publicized cash price, each provider of a diagnostic test for COVID-19 would be required to make the cash price of the test publicly available on a public-facing internet site of the provider. HHS would be permitted to impose a civil monetary penalty that does not comply with the requirement to publicize a diagnostic test’s cash price of up to \$300 per day that the provider is in violation of the requirement.
- **Sec. 3203. Rapid Coverage of Preventive Services and Vaccines for Coronavirus** – Requires group health plans and ACA plan issuers to cover any qualifying COVID-19 preventive service. Qualifying preventive services are defined as items, services, or immunizations recommended by the U.S. Preventive Service Task Force or the Advisory Committee on Immunization Practices.

*Subpart B – Support for Health Care Providers*

- **Sec. 3211. Supplemental Awards for Health Centers** – Appropriates \$1.32 billion to Federally Qualified Health Centers (FQHCs) for fiscal year 2020 for supplemental awards directed towards COVID-19 prevention, diagnosis, and treatment.
- **Sec. 3212. Telehealth Network and Telehealth Resource Grant Programs** – Makes changes to and broadens the scope of telehealth network grants available through the Telehealth Network Grant Program, administered by the Health Resources and Services Administration (HRSA).
- **Sec. 3213. Rural Health Care Services Outreach, Rural Health Network Development, and Small Health Care Provider Quality Improvement Grant Programs** – Enhances and broadens the scope of grants available through the rural emergency medical service training and equipment assistance program.
- **Sec. 3214. United States Public Health Service Modernization** – Clarifies rules around deployment of the Commissioned Corps and Ready Reserve Corps that permits deploying them in times of a public health emergency (instead of only during a national emergency), among other technical changes.
- **Sec. 3215. Limitation on Liability for Volunteer Health Care Professionals During COVID-19 Emergency Response** – Limits liability under federal and state law on health care providers acting as volunteers for any harm caused in the process of treating COVID-19 during the public health emergency.
- **Sec. 3216. Flexibility for Member of National Health Service Corps During Emergency Period** – Authorizes HHS to deploy members of the National Health Service Corps to voluntarily provide health service in locations and for durations as specified by HHS.

*Subpart C – Miscellaneous Provisions*

- **Sec. 3221. Confidentiality and Disclosure of Records Relating to Substance Use Disorder** – Amends Health Insurance Portability and Accountability Act (HIPAA) rules around sharing of patient records with substance use disorder. These changes include allowing a covered entity under

HIPAA to share a patient’s records for purposes of treatment, payment, and health care operations after consent is given once and for all by the patient.

- **Sec. 3222. Nutrition services.** Authorizes HHS to allow a state agency or area agency on aging (AAA) to transfer funds for use however the state or AAA sees fit to meet the needs of the area served. In addition to serving those who are homebound because they are ill, home-delivery nutrition services are also authorized for individuals who are unable to obtain food because of social distancing due to the emergency. Gives the Assistant Secretary of HHS the authority to waive dietary guidelines for meals provided.
- **Sec. 3223. Continuity of service and opportunities for participants in community service activities under title V of the Older Americans Act of 1965.** Authorizes the Secretary of Labor to allow participants in the Senior Community Service Employment Program ([details](#)) to continue participating longer than their currently defined participation periods. It also allows the Secretary to increase the average participation cap and the amount available to pay the administrative costs for a project “to an amount not to exceed 20 percent of the grant amount.”
- **Sec. 3224. Guidance on protected health information.** Within 180 days of enactment requires HHS to issue guidance on sharing patients’ protected health information that includes compliance with HIPAA as well as any other policies that may take effect during the emergency.
- **Sec. 3225. Reauthorization of healthy start program.** Reauthorizes the program and appropriates \$125,500,000 each fiscal year from 2020 through 2025. Makes technical changes and requires a GAO report within four years.
- **Sec. 3226. Importance of the blood supply.** Requires HHS to run a national campaign to increase awareness and generate support for donations to improve the nation’s blood supply. It also mandates a report to Congress within two years of enactment.

### **Part III – Innovation**

- **Sec. 3301. Removing the Cap on OTA During Public Health Emergencies** – Requires that competitive procedures be used when the Biomedical Advanced Research and Development Authority (BARDA) is entering into other transactions, other than procurement contracts, grants, and cooperative agreement
- **Sec. 3302. Prioritizing Zoonotic Animal Drugs** – Requires the HHS Secretary to expedite the review and approval process of new animal drugs if the preliminary clinical evidence indicates that the drug has the potential to treat a zoonotic disease that poses a serious threat to humans. The sponsor of the new animal drug may also request a “priority zoonotic animal drug” designation to expedite the approval process.

### **Part IV – Health Care Workforce**

- **Sec. 3401. Reauthorization of Health Professions Workforce Programs** – Appropriates \$23.7 million for each fiscal year 2021-2025 for the health professions workforce programs. The bill would also direct HHS to prioritize grant making for programs training residents in rural areas, including Tribes or Tribal Organizations. See p. 282.

- **Sec. 3402. Health Workforce Coordination** – Directs HHS to develop, within one year, a plan to support health care workforce development programs, in consultation with the Advisory Committee on Training in Primary Care Medicine and Dentistry, and the Advisory Council on Graduate Medical Education (ACGME). HHS would also be instructed to coordinate with other agencies that administer or fund health care workforce development programs. See more detail for the requirements of this plan on p. 288.
- **Sec. 3403. Education and Training Relating to Geriatrics** – Proposes changes to training programs for geriatric care begin on p. 290. Priority for grant making would be given to programs that demonstrate coordination with other federal or state entities; that benefit rural or underserved populations; and, that integrate primary and geriatric care.
- **Sec. 3404. Nursing workforce development** – Reauthorizes the Nursing Workforce Program and makes several updates, including allowing Nurse Corps loan repayment beneficiaries to serve at private institutions under certain circumstances.

#### **Subtitle D – Finance Committee**

- **Sec. 3701. Exemption for telehealth services** – Establishes a safe harbor for high deductible health plans (HDHPs) that provide benefits for telehealth and other remote care services before patients satisfy the applicable minimum deductible (applies to plan years beginning on or after December 31, 2021). Therefore, these plans would still be treated as HDHPs.
- **Sec. 3702. Inclusion of certain over-the-counter medical products as qualified medical expenses** – Adds menstrual care products to the list of qualified medical expenses that may be paid with health savings accounts (HSAs), Archer MSAs, flexible spending arrangements (FSAs), or health reimbursement arrangements (HRAs) (applies to amounts paid after December 31, 2019).
- **Sec. 3703. Increasing Medicare telehealth flexibilities during emergency period** – Authorizes HHS to waive certain telehealth requirements during the emergency period. Specifically, the provision allows Medicare payment for telehealth services furnished by a provider to a patient even if the provider does not have an existing relationship with that patient and waives originating site requirements and provider type requirements.
- **Sec. 3704. Enhancing Medicare telehealth services for Federally qualified health centers and rural health clinics during emergency period** – Requires HHS to pay for telehealth services that are furnished by a Federally qualified health center (FQHC) or a rural health clinic (RHC) to Medicare beneficiaries during the emergency period (payment will be based on comparable telehealth services under the physician fee schedule).
- **Sec. 3705. Temporary waiver of requirement for face-to-face visits between home dialysis patients and physicians** – Authorizes HHS to waive the requirement for face-to-face clinical

assessments for individuals with end stage renal disease receiving home dialysis during the emergency period.

- **Sec. 3706. Use of telehealth to conduct face-to-face encounter prior to recertification of eligibility for hospice care during emergency period** – Allows hospice care providers to use telehealth to conduct face-to-face encounters prior to hospice care re-certification during an emergency period.
- **Sec. 3707. Encouraging use of telecommunications systems for home health services furnished during emergency period** – Allows home health care providers to furnish home health services via telehealth during an emergency period.
- **Sec. 3708. Improving care planning for Medicare home health services** – Allows a nurse practitioner, clinical nurse specialist, or a physician assistant to provide home health services to Medicare beneficiaries and Medicaid beneficiaries for the purposes of payment.
- **Sec. 3709. Adjustment of Sequestration** – Temporarily suspends Medicare sequestration for May 1-December 31, 2020. Extends direct spending reductions through 2030 instead of through 2029.
- **Sec. 3710. Medicare Hospital Inpatient Prospective Payment System Add-On Payment for COVID-19 Patients During Emergency Period** – Increases the weighting factor by 20 percent for all discharges with a principal or secondary diagnosis of COVID-19 and this change will not be considered with respect to budget neutrality. Allows states with 1115 waivers related to this area to implement similar adjustments.
- **Sec. 3711. Increasing Access to Post-Acute Care During Emergency Period** – Increases access to post-acute care during an emergency period – i.e., waiver of the requirement that patients of an inpatient rehabilitation facility (IRF) receive at least 15 hours of therapy per week; and waives site-neutral payment rate provisions for long-term care hospital (LTCH) including the 50 percent rule and exclusion criteria from site-neutral IPPS payment rate.
- **Sec. 3712. Revising Payment Rates for Durable Medical Equipment Under the Medicare Program Through Duration of Emergency Period** – Modifies Medicare payment rates for DME in rural areas, noncontiguous areas, and areas that are neither rural or noncontiguous.
- **Sec. 3713. Coverage of the COVID-19 Vaccine Under Part B of the Medicare Program Without Any Cost-Sharing** – Ensures coverage of COVID-19 vaccine under Medicare Part B without cost-sharing.
- **Sec. 3714. Requiring Medicare Prescription Drug Plans and MA-PD Plans to Allow Prescriptions and Refills for Covered Part D Drugs to be Filled for Up to a 3-Month Supply During the COVID-19 Emergence Period** – Requires MA-PD plans to allow for up to a three-month supply (for fills and refills) of covered Part D drugs during the emergency period, with exceptions in certain areas due to safety.
- **Sec. 3715. Providing Home and Community-Based Services in Acute Care Hospitals** – Allows home and community-based services to be provided in acute care hospitals in certain circumstances

in light of COVID-19 including when identified in an individual’s person-centered plan of services and supports, or a comparable plan.

- **Sec. 3716. Clarification Regarding Uninsured Individuals** – Amends the Families First Coronavirus Response Act to clarify who will be treated as enrolled in a Federal health program. Specifies individuals without minimal essential coverage.
- **Sec. 3717. Clarification Regarding Coverage of COVID-19 Testing Products** – Clarifies that beneficiaries can receive all COVID-19 diagnostic tests for COVID-19 in Medicare Part B with no cost-sharing.
- **Sec. 3718. Amendments Relating to Reporting Requirements with Respect to Clinical Diagnostic Laboratory Tests** – Postpones reporting requirements for private sector payment rates for establishing Medicare payment rates for clinical diagnostic laboratory tests. Reporting would not be required during the period beginning January 1, 2020 and ending December 31, 2021. Reporting would be required during the period beginning January 1, 2022 and March 31, 2022.

Delays phase-in of reductions in Medicare payments for clinical diagnostic laboratory tests. Reductions would go into effect in 2025.

- **Sec. 3719. Expansion of the Medicare Hospital Accelerated Payment Program During the COVID-19 Public Health Emergency** – Expands the Medicare accelerated payment program during the emergency period to newly qualified hospitals, including hospitals whose inpatients are predominately under 18 years of age, cancer centers, and critical access hospitals. Authorizes the HHS Secretary to make accelerated payments on a periodic or lump sum basis; increase the amount of payment that would otherwise be made to hospitals under the program up to 100 percent (or, in the case of critical access hospitals, up to 125 percent); and extend the period that accelerated payments cover up to a 6-month period. Upon the request of the hospitals, the HHS Secretary is required to provide up to 120 days before claims are offset to recoup the accelerated payment and allow at least 12 months from the date of the first accelerated payment before requiring that the outstanding balance be paid in full.
- **Sec. 3720. Delaying Requirements for Enhanced FMAP to Enable State Legislation Necessary for Compliance** – Stipulates that, during the 30-day period beginning on the date of enactment, a state would still be eligible for the temporary enhanced 6.2 percent Federal Medical Assistance Percentage (FMAP) increase even if it imposes a premium in excess of the premium amount as of Jan. 1, 2020 – so long as the premium was in effect on the date of enactment.

### **Subtitle E – Health and Human Services Extenders**

Delineates provisions to address several Medicare, Medicaid and other health care “extenders” for which federal funding is generally otherwise slated to lapse May 22, 2020. In most cases, **funding below is extended through Nov. 30, 2020.**

- **Medicare Extenders (Part I)** – These include: (1) an extension of the current work component of the geographic practice cost index (GPCI) floor to Dec. 1, 2020; (2) additional funding for quality measure endorsement, input and selection; and (3) extended funding through FY 2020 for outreach and assistance for low-income programs, led by the Area Agencies on Aging (AoAs) and Aging and Disability Resource Centers (ADRCs).

- **Medicaid Extenders (Part II)** – These include: (1) an extension (without an expansion called for under prior iterations) of the Money Follows the Person (MFP) program through what appears to be Nov. 30, 2020; (2) an extension of spousal impoverishment protections; (3) delay of the statutorily-slated disproportionate share hospital (DSH) cuts to \$4 billion effective Dec. 1, 2020 through Sept. 30, 2021, while punting the slated \$8 billion in cuts to FYs 2022 through 2025; (4) an extension and expansion of the Community Mental Health Services demonstration (CCBHCs) through Nov. 30, 2020 for the 8 states currently participating in the demonstration, while directing the Secretary to select 2 additional states to participate in the 2-year demonstration program. Also calls for a Government Accountability Office (GAO) report on the demonstration.
- **Human Services and Other Programs (Part III)** – Includes provisions that extend: (1) the sexual risk avoidance education (SRAE) program; (2) the personal responsibility education program (PREP); (3) demonstration projects to address health professions workforce needs; and (4) Temporary Assistance for Needy Families (TANF).
- **Public Health Provisions (IV)** – Extends through Nov. 30, 2020 funding for community health centers (CHCs), the National Health Service Corps (NHSC) and teaching health centers that operate graduate medical education (THCGME) programs. Also extends the special diabetes programs’ for Type 1 diabetes and for American Indians through Nov. 30, 2020.

#### **Subtitle F – Over-the-Counter Drugs**

The legislation generally incorporates the provisions of the Senate-passed Over-the-Counter (OTC) Monograph Safety, Innovation, and Reform Act of 2019. Among other stipulations, it provides for 18 months of exclusivity for innovative OTC drugs and authorizes the collection of user fees for the FDA’s OTC monograph drug activities beginning for the first program year in FY 2021, which would be due in July 2020.

#### **Other Provisions**

The CARES Act also includes provisions intended to provide **economic relief to businesses and individuals**. A brief summary follows:

- **Sec. 1107. Small Business Administration.** Appropriates for FY 2020 (available through FY 2021) \$349 million for the Business Loans Program Account created under the CARES Act to provide guaranteed loans under the Paycheck Protection Program to businesses, including for payroll and health benefits costs. Provides \$675 million for salaries and expenses of the SBA. Among other direct appropriations, the bill provides \$17 million for the Business Loans Program Account under the CARES Act to provide support small businesses in making principal, interest, and fee payments on covered loans during the national emergency period.
- **Sec. 2301. Employee Retention Credit for Employers Subject to Closure Due to COVID-19** – Provides a quarterly tax credit against employment taxes of 50 percent of qualified wages for each employee. Eligible wages not to exceed \$10,000 and is limited to applicable employment taxes net of any reductions, e.g., under the Families First Coronavirus Response Act, among others.

Eligible businesses include those that were carrying on trades or business during calendar year 2020 that were “fully or partially suspended” due to governmental orders and experienced a significant decline (i.e., 50 percent) in gross receipts from the same quarter last year. Qualified health plan expenses paid or incurred by the employer to provide or maintain the group health plan may be

included in qualified wages, though only to the extent excluded from employees' gross income. See p., 179-184.

- **Paid Leave Provisions (Secs. 3601-3611)** – Among other provisions, sections under Subtitle C (beginning on p. 349) place upper limitations on the emergency Family Medical Leave and emergency Paid Sick Leave provisions that were enacted under [Section 5201](#) of the Families First Coronavirus Response Act (the second package). Specifically, that an employer shall not be required to pay more than \$511 per day or \$5,110 in the aggregate for each employee that is unable to work due to their own symptoms or need to self-quarantine; or no more than \$200 per day and \$2,000 in aggregate for an employee than cannot work because they are caring for a sick family member or child who is out of school. The bill also allows OMB to exclude certain Executive Branch employees from the Paid Family Leave and Paid Sick Leave mandates.

We hope this information is helpful. We'll continue to keep you apprised of key developments on this front. Please let us know if you have any questions.

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