CARES ACT: SUMMARY OF PROVISIONS SUPPORTING AMERICA'S HEALTH CARE SYSTEM

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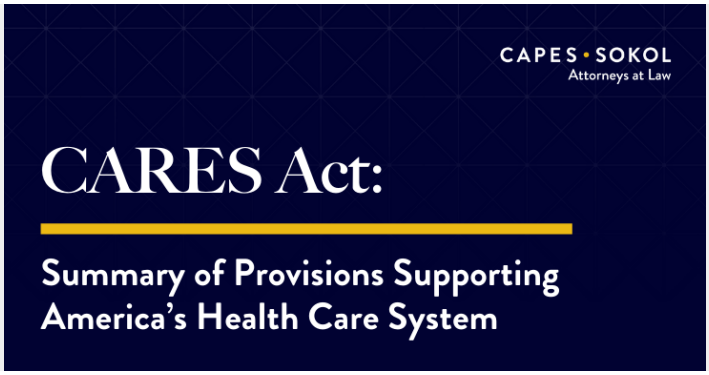

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On March 27, 2020, the President signed into law the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). The $2 trillion response to the coronavirus pandemic includes significant funding for a health care system under pressure from a surge of patients requiring intensive care, a shortage of equipment to treat those patients and to protect providers, and the cancelling or reduction of other types of patient care.

In addition to provisions like the Paycheck Protection Program (in Title I of the Act) and Employee Retention Payroll Tax Credit (in Title II of the Act), which benefit business both within and outside of health care, Title III of the CARES Act bolsters the health care industry specifically.

This post summarizes the provisions of Title III of the CARES Act, titled "Supporting America's Health Care System in the Fight Against the Coronavirus," but excludes Subtitles B (Education Provisions) and C (Labor Provisions).

Subtitle A: Health Provisions

Part I – Supply Chain Protection

Subpart A

Medical Product Supplies

Section 3101 & 3103

- Commissions a report on the nation's medical product supply chain security. Also requires the strategic national stockpile to include PPE and other supplies required for administration of drugs, vaccines, and other items in the stockpile.
- Further amends the Public Readiness and Emergency Preparedness Act, which authorized the Secretary of HHS to issue a declaration providing immunity from tort liability related to manufacture, distribution, administration, or use of countermeasures to agents which the Secretary deemed presented a threat to public health.
- The section amended was recently added by the Families First Coronavirus Response Act to include personal respiratory devices as covered countermeasures. This further amendment gives the Secretary greater flexibility in determining what respiratory devices are included in covered countermeasures.

Sections 3101-3103

Subpart B

Emergency Drug Shortages

Section 3111

- If the Secretary concludes that there is, or is likely to be, a drug shortage of a critical drug (described in 21 USC 356c(1)(a)), the CARES Act requires the Secretary to prioritize and expedite review of a new drug or prioritize and expedite inspection of a facility that could help mitigate or prevent such a shortage.

Section 3112

- Also adds active ingredients or any drug critical to public health during a declared public health emergency to the list of drugs for which manufacturers must keep the Secretary notified of discontinuance or interruption of the supply/manufacture.

- Requires manufacturer of listed drugs to develop risk management plans.
- Adds additional notification and reporting requirements for manufacturers (and agents inspecting their facilities) of critical drugs.

Sections 3111-3112

Subpart C

Medical Device Shortages

Section 3121

- Adds a section to the FDCA to protect against shortages in critical medical devices.
- Manufacturers of devices that are critical to public health during a public health emergency or for which the Secretary determines that information on meaningful supply disruptions of such device is needed for public health emergencies must notify the Secretary of discontinuances or interruptions in the manufacture of the device and the reasons for such discontinuance or interruption.
- The added section provides for timing of the notice, distribution of the information by the Secretary, protection of trade secrets, and penalties for failure to comply with the notice requirements.
- If the Secretary concludes that there is, or is likely to be, a shortage of a critical device, the Secretary is required to prioritize and expedite review of a submissions and notifications for devices that could help mitigate or prevent such a shortage or prioritize and expedite inspection of a facility that could help mitigate or prevent such a shortage.
- Also establishes a device shortage list similar to the critical drug shortage list.

Sections 3121

Part II – Care for COVID-19 Patients

Subpart A

Testing and Preventive Services

Section 3201

- Broadens the coverage of testing for COVID-19 first enacted in the Families First Coronavirus Response Act to include tests which may not have been approved, cleared, or authorized

under the FDCA so long as other conditions are met (such as emergency use authorization).

Section 3202

- All providers of a diagnostic test for COVID-19 must make public the cash price for such test on the internet. Health plans must either reimburse the provider for the cash price or may negotiate a lower rate with the provider.

Section 3203

- Health insurers (whether group or individual coverage) shall cover without cost-sharing any coronavirus preventive service which has been approved either by the US Preventive Services Task Force or the Advisory Committee on Immunization Practices of the CDC (for immunizations). Coverage must be effective 15 days after the preventive service is approved.

Sections 3201-3203

Subpart B

Support for Health Care Providers

Section 3211

- The CARES Act appropriates an additional $1,320,000,000 for fiscal year 2020 to health centers for the detection of SARS-CoV-2 or the prevention, diagnosis, and treatment of COVID-19.

Section 3212 & 3213

Expands and supports the widening use of telehealth by modifying the following grant programs:

- Telehealth network and telehealth resource centers grants
  - Re-designating grants once reserved for projects demonstrating how telehealth can be used to projects using telehealth for expanding and improving access to, and the quality of health care services.
  - Lengthening the duration of the grants by 1 year (from 4 to 5 years).
  - Expanding the qualification of recipients significantly (one primary element being the removal of the restriction that recipients only be a non-profit entity).
  - Authorizes $29,000,000 for such grants for each of fiscal years 20201 through 2025.
- Rural health care services outreach grants
  - Broadening the reach of such grants to including expanding *and improving* the delivery of health care services to include new and enhanced services in rural areas, *through*

community engagement and evidence-based or innovative, evidence-informed models.
    - Lengthening the maximum duration of the grants from 3 to 5 years.
    - Removing the eligibility requirement that the entity be a public or nonprofit entity, and instead requiring that the entity have demonstrated experience serving, or the capacity to serve, rural underserved populations.
- Rural health network development grants
    - Broadening the reach of such grants from merely promoting the development of networks to funding entities that plan, develop, and implement integrated health care networks that collaborate to better rural health care.
    - Lengthening the maximum duration of the grants from 3 to 5 years.
    - Removing the eligibility requirement that the entity be a public or nonprofit entity, and instead requiring that the entity have demonstrated experience serving, or the capacity to serve, rural underserved populations.
- Small health care provider quality improvement grants
    - Clarifying that such grants may be awarded for (at least) increasing care coordination, enhancing chronic disease management, and improving patient health outcomes.
    - Lengthening the maximum duration of the grants from 1-3 years to 5 years.
- Authorizes $79,500,000 for these telehealth grants for each of fiscal years 2021 through 2025.

Section 3214

- Amends portions of the Public Health Service Act to align the reserve corps of the Public Health Service more with the reserve corps of military branches.

Section 3215

- Protects volunteer health care providers from liability under any federal or state law for any harm caused by provision of health care services with respect to COVID-19, subject to conditions (must be a volunteer, within the scope of the person's license, registration, or certificate, etc.) and exceptions (no protection for willful or criminal misconduct, etc.).

Sections 3211-3215]

Subpart C

Miscellaneous

Section 3221

Amends the statute governing confidentiality of substance use disorder records:

- To permit disclosure for treatment, payment, and health care operations as permitted by the HIPAA regulation upon consent of the patient. The patient may consent to disclosures once for future disclosure (but the patient may revoke consent at a later date). The information, once disclosed for treatment, payment, and health care operations, then becomes PHI and covered by HIPAA. A Covered Entity must be able and will be required to provide an accounting of such disclosures.
- Substance use disorder records may be disclosed without patient consent to a public health authority after de-identification (using HIPAA standards for de-identification).
- Expands the protections of substance use disorder information in the context of criminal proceeds to also cover civil or administrative proceedings.
- Adds non-discrimination protections based on substance use disorder information in healthcare, employment, housing, access to courts, or access to social services and benefits.
- Adds a breach notification requirement following HIPAA standards for substance use disorder information.

Section 3222-3223

- During the COVID-19 public health emergency, loosens restrictions on use of funding and other project requirements by State agencies or area agencies on aging to meet the needs of the area served, including by expanding who may receive delivery of nutrition services to protect older Americans during the COVID-19 public health emergency.

Section 3224

- Directs the Secretary of HHS to issue guidance within 180 days on the sharing of PHI during the COVID-19 public health emergency.

Section 3226

- Requires the Secretary of HHS to carry out a national campaign to improve awareness of, and support outreach to the public and health care providers about the importance and safety of blood donation during the COVID-19 public health emergency.

Sections 3221-3226

Part III – Innovation

Section 3301

Prior to the CARES Act, the Biomedical Advanced Research and Development Authority ("BARDA") was established to foster the rapid development of drugs and vaccines against highly infectious pathogens.

- **Pursuant to BARDA**, the Secretary has the authority to enter into "other transactions" (which means transactions, other than procurement contracts, grants, and cooperative agreements). This authority is generally limited so that a project which is expected to cost more than $100,000,000 requires a written determination by the Assistant Secretary for Financial Resources that the use of such authority is essential to promoting the success of the project.
- **Pursuant to the CARES Act**, during a declared public health emergency, the Secretary has the authority to enter into other transactions under BARDA without requiring a written determination for any projects, regardless of cost. The CARES Act amendment protects those engaged by the Secretary under this authority by prohibiting the termination of such transactions solely due to the expiration of such public health emergency, if such public health emergency ends before the completion of the terms of such agreement. It also requires reporting on the use of the authority and use of funds.

Section 3302

- The CARES Act amends the FDCA to require expedited development and review of a new animal drug if preliminary clinical evidence indicates that such drug could treat a disease in animals that has the potential to cause adverse health consequences for humans (examples include bird flu, Ebola, etc.). Actions to expedite approval may include utilizing novel trial designs or drug development tools that may reduce the number of animals needed for studies.

Sections 3301-3302

Part IV – Health Care Workforce

Section 3401

Designated Health Professions Schools and Other Entities for Supporting Health Professions Education for Under-Represented Minority Individuals	**$23,711,000 for each of fiscal years 2021 through 2025**
Scholarships for Disadvantaged Students in Health Professions Programs	$51,470,000 for each of fiscal years 2021 through 2025 for scholarships for disadvantaged students in health professions programs
Loan Repayments and Fellowships for Individuals with Disadvantaged Backgrounds to Serve in Health Professions Education	$1,190,000 for each of fiscal years 2021 through 2025

Designated Health Professions Schools and Other Entities for Supporting Health Professions Education for Under-Represented Minority Individuals	**$23,711,000 for each of fiscal years 2021 through 2025**
Educational Assistance in Health Professions Regarding Individuals from Disadvantaged Backgrounds	$15,000,000 for each of fiscal years 2021 through 2025
Primary Care Training and Enhancement Programs	$48,924,000 for each of fiscal years 2021 through 2025
Dental Training Programs	$28,531,000 for each of fiscal years 2021 through 2025
Area Health Education Centers	$41,250,000 for each of fiscal years 2021 through 2025
Public Health and Preventive Medicine Training Programs	$17,000,000 for each of fiscal years 2021 through 2025
Pediatric Specialty Loan Repayment Program	such sums as may be necessary for each of fiscal years 2021 through 2025

Section 3403

- Establishes funding mechanisms for geriatrics workforce enhancement programs and authorizes $40,737,000 for each of fiscal years 2021 through 2025.

Section 3404

- Revises and updates funding mechanisms for nursing workforce development programs and authorizes $137,837,000 for each of fiscal years 2021 through 2025, as well as authorizes $117,135,000 for each of the fiscal years 2021 through 2025 for nursing school student loans.

Sections 3401-3404

Subtitle D: Finance Committee

Beginning Dec. 31, 2021, permits health plans which do not have deductibles for telehealth or other remote care services, or separate plans dedicated to telehealth or remote care, to maintain treatment as a high deductible health plan so long as they meet the other qualifications.

- In other words, a health plan that fully covers telehealth without a deductible can still be a HDHP. (*Section 3701*)
- Adds menstrual care products as medical care for purposes of HSAs, flex spending

arrangements, and HRAs. (*Section 3702*)
- Permits the Secretary of HHS broader waiver authority in emergencies as it relates to telehealth. (*Section 3703*)
- **Promotes and expands the potential use of telehealth during national emergencies, including:**
  - Broader reimbursement for FQHCs and rural health clinics for general provision of services. (*Section 3704*)
  - Allowing waiver of the requirement for face-to-face visits between home dialysis patients and physicians. (*Section 3705*)
  - Allowing a hospice physician or nurse practitioner to conduct a face-to-face encounter via telehealth for purposes of recertification during declared emergencies. (*Section 3706*)
  - Encouraging telehealth use in home health for remote patient monitoring, etc. (*Section 3707*)
- Expands the type of provider who may have authority over home health care elements from physician only to include nurse practitioners, clinical nurse specialists, and physician assistants. (*Section 3708*)
- Suspends any sequestration order (regardless of when issued) as it may affect Medicare through Dec. 31, 2020. (*Section 3709*)
- Waives certain requirements for inpatient treatment reimbursements during a public health emergency in order to increase payments made to inpatient facilities and to increase access to post-acute care. (*Section 3710-3711*)
- Adds coverage of the COVID-19 vaccine and its administration to Medicare Part B without any deductible or other cost sharing. (*Section 3713*)
- Permits Medicare prescription drug plans to allow prescription fills and refills for up to a 3-month supply during the COVID-19 public health emergency. (*Section 3714*)
- Permits caregivers under Medicaid waivers to deliver those services even if the patient is in an acute care hospital, or permits the acute care hospital to deliver those services. (*Section 3715*)
- Expands the coverage of the uninsured individuals' provision of the Families First Coronavirus Response Act to ensure access to COVID-19 testing. (*Section 3716*)
- Expands the Medicare accelerated payment program to include more types of hospitals, notably critical access hospitals. (*Section 3719*)

Sections 3701-3719

Subtitle E: Health and Human Services Extenders

Part I: Medicare Provisions

Sections 3801-3803

- Extends a number of funding programs to cover items such as physician fees in areas with low labor costs, quality measure endorsement, input and selection, outreach and assistance for low-income programs.

Part II: Medicaid Provisions

Sections 3811-3814

- Extends a number of programs including assistance in transitioning from nursing homes to home and community-based care programs, protecting spousal income when an individual qualifies to love in a nursing home, and community behavioral and mental health programs.

Part III: Human Services and Other Health Programs

Sections 3821-3824

- Extends funding for programs encouraging sexual risk avoidance, preventing teen pregnancy and HIV/STDs, supporting health care professions education and training for low-income individuals, and TANF.

Part IV: Public Health Provisions

Sections 3831-3832

- Extends funding for community health centers, the National Health Service Corps, and teaching health centers that operate graduate medical education programs, as well as diabetes programs for Type I and Native Americans.

Sections 3801-3832

Subtitle F: Over-the-Counter Drugs

Part I: OTC Drug Review

Sections 3851-3853

- Revises the way that over-the-counter (OTC) drugs are regulated by the FDA. The CARES Act incorporates the Over-the-Counter (OTC) Monograph Safety, Innovation, and Reform Act of 2019 which was passed by the Senate in December 2019 but had not been passed by the

House. In the new framework the FDA would regulate OTC drugs through an administrative order process instead of a notice and comment rulemaking process.

Sections 3854

- Permits an applicant for sunscreen active ingredients to elect to proceed under the new OTC administrative order process instead of the process under the Sunscreen Innovation Act, and requires the Sunscreen Innovation Act to sunset at the end of fiscal year 2022.

Part II: User Fees

Sections 3861-3862

- Establishes authority for the FDA to assess fees to manufacturers of OTC drugs and to those submitting requests under the OTC monograph process and requires such fees to be dedicated to OTC monograph drug activities.

Sections 3851-3862
