

CARES Act Summary of Provisions that Support America's Health Care System

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On March 27, 2020, the President signed into law the "Coronavirus Aid, Relief, and Economic Security Act" ("CARES Act"). The CARES Act is the third phase of the federal government's response to the coronavirus following two other laws to support American families and address health sector needs that were approved on March 6, 2020 (Phase I [here](#)) and March 18, 2020 (Phase II [here](#)).

The CARES Act includes provisions which provide cash payments and other resources to help individuals, small businesses, state and local governments and hospitals/healthcare providers. The CARES Act includes four sections (called "Titles") and each title addresses a different topic. This e-update summarizes Title III of the CARES Act titled "Supporting America's Health Care System in the Fight Against the Coronavirus". Title III provides much needed financial assistance to the health care industry, as well as additional guidance and other provisions which provide information on waivers and other benefits to help hospitals and others who are on the front lines of fighting the COVID-19 pandemic. The following is a summary of the major provisions of Title III, organized in order by section numbers under the CARES Act but does not address subtitle B – Education Provisions and subtitle C – Labor Provisions. We will provide links to summaries of other provisions in the CARES Act prepared by our colleagues throughout the firm as they become available.

TITLE III – SUPPORTING AMERICA'S HEALTH CARE SYSTEM IN THE FIGHT AGAINST THE CORONAVIRUS

SUBTITLE A – HEALTH PROVISIONS

PART I – ADDRESSING SUPPLY SHORTAGES

SUBPART A – MEDICAL PRODUCT SUPPLIES

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- Healthcare & Life Sciences
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Section 3101. National academies report on America's medical product supply chain security.

Not later than 60 days after the enactment of the CARES Act, the Secretary of Health and Human Services is required to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine to examine and report on the security of the United States medical product supply chain, considering input from various federal agencies and consulting with relevant stakeholders. The report will (1) assess and evaluate the dependence of the United States on critical drugs and devices that are sourced or manufactured outside of the United States; and (2) provide recommendations, which may include a plan to improve the resiliency of the supply chain for critical drugs and devices and to address any supply vulnerabilities or potential disruptions of such products that would significantly affect or pose a threat to public health security or national security.

Section 3102. Requiring the strategic national stockpile to include certain types of medical supplies.

The law adds the following items to the strategic national stockpile that the Secretary of Health and Human Services is required to maintain in the event of a bioterrorist attack or other public health emergency: personal protective equipment, ancillary medical supplies and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests.

Section 3103. Treatment of Respiratory Protective Devices as Covered Countermeasures.

The law provides for respiratory protective devices approved by the National Institute for Occupational Safety and Health. The law also states that the Secretary of Health and Human Services determines these devices to be a priority for use during a public health emergency qualify as "covered countermeasures" under Section 42 U.S. Code Section 247d-6d which provides targeted liability protection for pandemic and epidemic products and security countermeasures.

SUBPART B — MITIGATING EMERGENCY DRUG SHORTAGES

Section 3111 – Prioritize reviews of drug applications; incentives.

The Secretary is now required to expedite certain new drug applications to prevent drug shortages, when previously, expediting applications was optional.

Section 3112 – Additional manufacturer reporting requirements in response to drug shortages.

Drugs that are deemed critical during a public health emergency are added to the list of drugs that manufacturers must report to the FDA in the case of discontinuation or interruption. Additionally, this provision expands reporting requirements, including requiring manufacturers of these drugs to develop and implement a redundancy risk

management plan that must be submitted to the Secretary of Health and Human Services in the event of an inspection or request.

SUBPART C — PREVENTING MEDICAL DEVICE SHORTAGES

Section 3121 – Discontinuance or interruption in the production of medical devices.

Manufacturers of life-sustaining devices that are deemed critical to public health during a public health emergency must notify the Secretary of Health and Human Services six months prior to any discontinuance or interruption. If appropriate, the Secretary of Health and Human Services may distribute this information to entities the discontinuance or interruption could affect. The Secretary of Health and Human Services is to maintain a list of drug devices of which there is a shortage.

PART II—ACCESS TO HEALTH CARE FOR COVID-19 PATIENTS

SUBPART A – COVERAGE OF TESTING AND PREVENTIVE SERVICES

Section 3201 – Coverage of diagnostic testing for COVID-19.

The Families First Coronavirus Response Act which was signed into law on March 18, 2020 requires that a group health plan or a health insurance issuer offering group or individual health insurance coverage provide coverage and not impose any cost sharing (including deductibles, copayment and co-insurance) or prior authorization or other medical management requirements for an in vitro diagnostic test for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 and the administration of such a test. This section provides more specificity regarding the definition of a COVID-19 diagnostic test under the Families First Coronavirus Response Act by expanding the definition to include an in vitro diagnostic product that

1. is approved, cleared or authorized under sections 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (“FFDCA”);
2. the developer has requested or intends to request emergency use authorization under section 564 of the FFDCA unless and until the emergency use authorization request under section 564 has been denied or the developer of such test does not submit a request under such section within a reasonable timeframe,
3. is developed in and authorized by a State that has notified the Secretary of Health and Human Services of its intention to review tests intended to diagnose COVID-19; or
4. is another test that the Secretary of Health and Human Services determines appropriate in guidance.

Section 3202 – Pricing of diagnostic testing.

A group health plan or a health insurance issuer providing coverage of items and services described in section 6001(a) of division F of the Families First Coronavirus Response Act (which provides for coverage of testing for COVID-19) with respect to an enrollee shall reimburse the provider of the diagnostic testing provider as follows:

1. If the health plan or issuer has a negotiated rate with such provider in effect before the emergency declaration, such negotiated rate shall apply throughout the period of such declaration.
2. If the health plan or issuer does not have a negotiated rate with such provider, such plan or issuer shall reimburse the provider in an amount that equals the cash price for such service as listed by the provider on a public internet website, or such plan or issuer may negotiate a rate with such provider for less than such cash price.

During the emergency period described under the Families First Coronavirus Response Act, each provider of a diagnostic test for COVID-19 shall make public the cash price for such test on a public internet website of such provider. The Secretary of Health and Human Services may impose a civil monetary penalty on any provider that is not in compliance and has not completed a corrective action plan to comply in an amount not to exceed \$300 per day that the violation is going on.

Section 3203 – Rapid coverage of preventive services and vaccines for coronavirus.

The law requires full insurance coverage of yet to be created immunizations and preventive services for COVID-19. Specifically, the Secretary of Health and Human Services, the Secretary of Labor and the Secretary of Treasurer shall require group health plans and health insurance issuers offering group or individual health insurance to cover (without cost-sharing) a “qualifying coronavirus preventive service”. A “qualifying coronavirus preventive service” means an item, service or immunization that is intended to prevent or mitigate coronavirus disease 2019 that is:

1. an evidence-based item or service that has in effect a rate of “A” or “B” in the current recommendations of the US Preventative Services Task Force or
2. an immunization that has in effect a recommendation from the Advisory Committee on immunization practices of the Centers for Disease Control and Prevention with respect to the individual involved.

The requirements shall take effect on the date that is 15 business days after the date on which a recommendation is made relating to the qualifying coronavirus preventive service as described in such paragraph.

SUBPART B — SUPPORT FOR HEALTH CARE PROVIDERS

Section 3211 - Supplemental awards for health centers.

\$1.32 billion is appropriated for grants to health centers in medically underserved areas working towards the detection of SARS-CoV-2 or the prevention, diagnosis, and treatment of COVID-19.

Section 3212 – Telehealth network and telehealth resource centers grant programs.

This provision amends the National Telehealth Strategy and Data Advancement Act to include services for substance use disorders and to serve rural areas in addition to

medically underserved areas.

Section 3213 – Rural health care services outreach, rural health network development, and small health care provider quality improvement grant programs.

Awards under the National Telehealth Strategy and Data Advancement Act are granted for basic health care services, not only essential health care services.

Section 3214 – United States Public Health Service Modernization.

This section amends the Public Health Service Act (42 U.S.C. 204) with respect to Commissioned and Reserve Corps members. The amendments remove references to the “Ready Reserve Corps” and permit the Regular Corps to be deployed for service in time of a public health emergency, along with other technical amendments.

Section 3215 – Limitation on liability for volunteer health care professionals during COVID-19 emergency response.

With limited exceptions, a health care professional shall not be liable under Federal or State law for any “*harm*” caused by an act or omission of the professional in the provision of “*health care services*” during the public health emergency with respect to COVID-19 if (1) the professional is providing health care services in response to such public health emergency as a “*volunteer*”; and (2) the act of omission occurs:

1. in the course of providing health care services;
2. in the health care professional’s capacity as a volunteer;
3. in the course of providing health care services that (i) are within the scope of the license, registration, or certification of the volunteer, as defined by the State of licensure, registration, or certification; and (ii) do not exceed the scope of the license, registration, or certification of a substantially similar health professional in the State in which such act or omission occurs; and
4. in a good faith belief that the individual being treated is in need of health care services.

For this purpose, “harm” includes physical, non-physical, economic and noneconomic losses and “health care services” means any services provided by a health care professional, or by any individual working under the supervision of a health care professional that relate to – (A) the diagnosis, prevention, or treatment of COVID-19; or (B) the assessment or care of the health of a human being related to an actual or suspected case of COVID-19. A “volunteer” means a health care professional who, with respect to the health care services rendered, does not receive compensation or any other thing of value in lieu of compensation, which compensation (A) includes a payment under any insurance policy or health plan, or any Federal or State health benefits programs; and (B) excludes (i) receipt of items to be used exclusively for rendering health care services in the health care professional’s capacity as a volunteer; and (ii) any reimbursement for travel to the site where the volunteer services are rendered and any payments in cash or kind to cover room and board, if the services are being rendered

more than 75 miles from the volunteer's principal place of residence.

This limitation on liability does not apply if the harm was caused by an act or omission constituting willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious flagrant indifference to the rights or safety of the individual harmed by the health care professional or the health care professional rendered the health care services under the influence (as determined pursuant to applicable State law) of alcohol or an intoxicating drug.

The law clarifies that this section preempts the laws of a State or any political subdivision of a State to the extent that such laws are inconsistent with this section, unless such laws provide greater protection from liability and protections afforded by this section are in addition to those provided by the Volunteer Protection Act of 1997.

This section takes effect upon the date of enactment of the CARES Act and applies to a claim for harm only if the act or omission that caused such harm occurred on or after the date of enactment.

Section 3216 – Flexibility for members of National Health Service Corps during emergency period.

This section permits the Secretary of Health and Human Services to assign members of the National Health Service Corps, with voluntary agreement of such corps members, to deploy and provide health services as needed to respond to a public health emergency.

SUBPART C — MISCELLANEOUS PROVISIONS

Section 3221 – Confidentiality and disclosure of records relating to substance use disorder.

This section revises certain provisions found at 42 U.S.C. 290dd-d concerning confidentiality and disclosure of records relating to substance use disorders. First, outdated references to “substance abuse” are replaced with the term “substance use disorder.” Second, the provisions regarding consent and use of the content found in such records was overhauled to explicitly allow use not only specifically consented to by a patient but also as permitted by the HIPAA regulations. The consent and use provisions now also make clear that prior written consent applies for all such future uses or disclosures for purposes of treatment, payment, and health care operations. Third, disclosure of the de-identified record to a public health authority was added to the list of allowable disclosures. Fourth, a list of relevant definitions was added to the statute to be consistent with HIPAA. Fifth, in addition to criminal contexts, administrative and civil contexts were added as situations under which such records may not be disclosed, for example in an application for a warrant. Sixth, general anti-discrimination language was added to protect fair treatment of individuals with such records. Seventh, breach notification language in line with the HITECH Act was added. Finally, this section calls for the Department of Health and Human Services to issue additional regulations to appropriately implement the changes described above and require covered entities to

update their notices of privacy practices to account for such records.

Section 3222 – Nutrition services.

This section grants the Secretary of Health and Human Services the right to allow state agencies to transfer funds for the provision of nutrition services without the prior approval of the Secretary of Health and Human Services during a public health emergency.

Section 3223 – Continuity of service and opportunities for participants in community service activities under title V of the Older Americans Act of 1965.

This section grants the Secretary of Labor the ability to permit participants in community service activities under Title V of the Older Americans Act of 1965 to extend such participation and to increase the average participation cap as set forth therein.

Section 3224 – Guidance on protected health information.

No later than 180 days after enactment, the Department of Health and Human Services must issue guidance regarding the sharing of patients' protected health information during a public health emergency. The guidance must include information on compliance with regulations promulgated pursuant to HIPAA and applicable policies, including policies that may come into effect during such emergencies.

Section 3225 – Reauthorization of healthy start program.

Section 3225 reauthorizes the healthy start program and appropriates \$125,500,000 for each of the fiscal years 2021 through 2025. Among other things, the section requires that the Secretary of Health and Human Services ensure that the program is coordinated with other programs and activities related to the reduction of the rate of infant mortality and improved perinatal and infant health outcomes supported by the department.

Section 3226 – Importance of the blood supply.

The Secretary of Health and Human Services shall carry out a national campaign to improve awareness of, and support outreach to, the public and healthcare providers about the importance and safety of blood donation and the need for donations for the blood supply during the public health emergency declared by the Secretary of Health and Human Services. The Secretary of Health and Human Services may enter into contracts to establish a national blood donation awareness campaign. The Secretary of Health and Human Services is required to consult with the Commissioner of Food and Drugs, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, and the heads of other relevant Federal agencies, and relevant accrediting bodies and representative organizations. Not later than 2 years after the date of enactment, the Secretary of Health and Human Services shall submit to the Senate and House a report which will include a description of the activities carried out, a description of trends in blood supply donations,

and an evaluation of the impact of the public awareness campaign.

PART III – INNOVATION

Section 3301 – Removing the cap on OTA during public health emergencies.

Section 3301 amends the provisions that govern the Biomedical Advanced Research and Development Authority (BARDA) to remove the cap on “other transactions” authority (“OTA”) during a public emergency. Currently, the law authorizes the Secretary of Health and Human Services to enter into “other transactions” for a project that is expected to cost the Department of Health and Human Services in excess of \$100 million only upon the written determination by the Assistant Secretary for Financial Resources that the use of such authority is essential to promoting the success of the project. The amendment removes the foregoing approval for transactions necessary during a public health emergency. Notwithstanding the foregoing, the Secretary of Health and Human Services, to the maximum extent practicable, is required to use competitive procedures when entering into transactions to carry out projects for the purposes of a public health emergency. Any transaction entered into during such public health emergency shall not be terminated solely due to the expiration of the public health emergency if the public health emergency ends before the completion of the terms of such agreement.

Section 3302 – Priority zoonotic animal drugs.

Section 3302 amends Chapter V of the Federal Food, Drug, and Cosmetic Act by adding a new section 512A which provides a process for the Secretary of Health and Human Services to expedite the development and review of a new animal drug if preliminary clinical evidence indicates that the new animal drug, alone or in combination with 1 or more other animal drugs, has the potential to prevent or treat a zoonotic disease in animals, including a vector borne-disease, that has the potential to cause serious adverse health consequences for, or serious or life-threatening diseases in, humans.

PART IV – HEALTH CARE WORKFORCE

Section 3401 – Reauthorization of health professions workforce programs.

Section 3401 makes significant amendments to Title VII of the Public Health Service Act to add additional appropriations of \$23,711,000 for each of fiscal years 2021 through 2025 as well as extending funding for various programs.

In addition, under this section, the Secretary of Health and Human Services may award grants or contracts to eligible entities to increase the number of individuals in the public health workforce, to enhance the quality of such workforce, and to enhance the ability of the workforce to meet national, State, and local health care needs. The law authorizes the Secretary of Health and Human Services to give priority to qualified applicants that train residents in rural areas, including for Tribes or Tribal Organizations in such areas.

Section 3402 – Health workforce coordination.

Within one year after the date of enactment of the CARES Act, the Secretary of Health and Human Services in consultation with the Advisory Committee on Training in Primary Care Medicine and Dentistry and the Advisory Council on GME, shall develop a comprehensive and coordinated plan with respect to the health care workforce development programs of the Department of Health and Human Services including education and training programs. The plan will include performance measures to determine the extent to which the programs are strengthening the nation's health care system, identify any gaps that exist between the outcomes of programs and projected health care workforce needs identified in workforce production reports conducted by the Health Resources and Services Administration, identify actions and barriers and coordinate with other agencies and provide a report to the Senate and House not later than 2 years after the date of enactment of the CARES Act.

Section 3403 – Education and training relating to geriatrics.

This section provides that the Secretary of Health and Human Services shall award grants, contracts, or cooperative agreements to certain entities or other health professions schools for the establishment or operation of Geriatrics Workforce Enhancement Programs. These programs are designed to support the training of health professionals in geriatrics, including traineeships and fellowships, with an emphasis on patient and family engagement in an effort to address gaps in health care for older adults. The section sets forth permitted activities, duration of such programs, application requirements, program requirements, and reporting requirements. The section provides the Secretary of Health and Human Services with the authority to grant special consideration and priority to those entities and health professions schools operating in areas with a shortage of geriatric workforce professionals or who can otherwise demonstrate need.

The section further establishes the Geriatric Academic Career Awards program to promote the career development of such individuals as academic geriatricians or other academic geriatric health professionals.

Section 3404 – Nursing workforce development.

This section establishes clinics to “address national nursing needs” including addressing challenges related to the distribution of the nursing workforce and existing or projected nursing workforce shortages in geographic areas that have been identified as having, or that are projected to have, nursing shortage increase access to and the quality of health services, including by supporting the training of professional registered nurses, APRNs, and advanced education nurses within community based settings and in a variety of health delivery system settings or addressing the strategic goals and priorities. No later than September 30, 2020 and biennially thereafter, the Secretary of Health and Human Services will provide a report that contains an assessment of the programs and activities related to enhancing the nursing workforce.

This section also amends Section 296(j) which provides grants to projects that support the enhancement of advanced nursing education and practice to strike the requirements

of “master’s” degree program and adding “graduate” and by inserting “clinical nurse leaders” after “nurse administrators” in the list of nurses that qualify for the grants. The law also adds a clinical nurse specialist programs which are education programs that provide registered nurses with full-time clinical nurse specialist education, and have as their objective the education of clinical nurse specialists who will, upon completion of such a program, be qualified to effectively provide care through the wellness and illness continuum to inpatients and outpatients experiencing acute and chronic illness.

In addition, this section expands quality grants to make the quality and retention grants and expanding the high-risk groups to include mental health or substance use disorders in addition to those that are already listed.

Finally, this section adds an additional amount by amending 298(d) to strike \$338,000,000 for fiscal years 2011 through 2016 and to insert \$137,837,000 for each of the years 2021 through 2025 and to appropriate an additional \$117,135,000 for each of the fiscal years 2021 through 2025.

The Comptroller General will conduct an evaluation of the nurse loan repayment program administrated by the Health Resources and Services Administration. The evaluation will focus on the manner in which payments are made under such programs, the existing oversight functions necessary to ensure the proper use of such programs (including payments made as part of such programs), the identification of gaps, if any, in oversight functions and information on the number of nurses assigned to facilities pursuant to such programs (including the type of facility to which nurses are assigned and the impact of modifying the eligibility requirements for programs under the Public Health Services Act). Not later than 18 months after the enactment of the CARES Act, the Comptroller General shall submit a report to the House and Senate on the evaluation which may include recommendations to improve relevant nursing workforce loan repayment program.

SUBTITLE D—FINANCING COMMITTEE

Section 3701 – Exemption for telehealth services.

This section creates a temporary telehealth-related safe harbor for high deductible health plans. For plan years beginning on or before December 31, 2021, a high deductible health plan does not need to have a deductible for telehealth and other remote care services. In addition, coverage for telehealth and other remote care during such plan years will not be considered in determining whether someone is an eligible individual under a high deductible health plan.

Section 3702 – Inclusion of certain over-the-counter medical products as qualified medical expenses.

This section adds the costs of menstrual care products as qualified medical expenses for purposes of health savings accounts, Archer MSAs, health flexible spending arrangements, and health reimbursement arrangements for amounts paid after December 31, 2019.

Section 3703 – Increasing Medicare telehealth flexibilities during emergency period.

Federal law at 42 U.S.C. 1320b-5 provides authority to the Secretary of Health and Human Services to waive health care related requirements during a national emergency to ensure that there are sufficient health care items and services to meet patient need and to ensure that health care providers may be reimbursed and may be exempted from sanctions for noncompliance. The CARES Act improves upon Congress' recent efforts to enhance the availability of telehealth services for Medicare and Medicaid beneficiaries during this emergency period.

On March 6, 2020, Congress enacted the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, available [here](#), which amended 1320b-5(b) by adding paragraph (b)(8) to permit the Secretary of Health and Human Services to waive certain restrictions on telehealth provided to Medicare, Medicaid and SCHIP beneficiaries starting on March 6, 2020 (the "January law"). The January law allowed a waiver which would permit payment for telehealth services such as office visits, mental health counseling and preventative health screenings *even if a patient was not in a rural area and if the patient was at home*. Medicare had historically not paid for telehealth if a patient was at their home when they received the telehealth services, and also did not pay for telehealth for patients in urban areas. The January law, which allowed a waiver to be granted during an emergency period, to permit such payments for Medicare beneficiaries in urban areas and in their homes was a very substantial leap forward for Medicare.

However, the January law still limited the Secretary of Health and Human Services' ability to waive certain telehealth payment restrictions. Specifically, the January law did not permit the Secretary of Health and Human Services to waive the limitation on the payment of facility fees, which are only permitted if the patient is located at one of a specific list of "originating sites" (such as a physician office or a hospital, and notably, NOT at home) and the originating site is located in a rural area.

This new law removes the limitation on the Secretary of Health and Human Services' waiver authority for facilities fees related to telehealth. Now, the Secretary of Health and Human Services may determine that during an emergency period, facility fees can be paid for telehealth providers even if the patient is not in a rural area and even if the patient is at home during the telehealth visit.

The January law also included restrictions on the Secretary of Health and Human Services' ability to waive requirements for the types of telecommunications services used in telehealth. The Secretary was not permitted to waive telecommunications requirements if the communication did not have both audio and video capabilities. Under this new law, the Secretary now will have the authority to waive all of the requirements regarding the type of telecommunications services that can be used for telehealth.

Further, the January law included a definition of "qualified provider" which highlighted the fact that telehealth is only allowed for a Medicare or Medicaid beneficiary who is already

an established patient of the provider or the provider's practice. Despite this continued requirement, the Department of Health and Human Services stated in guidance documents, available [here](#), that it would not conduct audits to ensure that such prior relationship existed for claims submitted during the public health emergency. This new law will go farther than a "no audit" statement by the Department of Health and Human Services. Instead, this new law will remove the definition of "qualified provider", which means that the Secretary of Health and Human Services will have the authority to waive the "established patient" requirement during the emergency period.

In summary, under this new law the Secretary of Health and Human Services will now have the authority to waive all laws governing payment for telehealth services under Medicare, Medicaid and SCHIP. There are no more limitations to the Secretary of Health and Human Services' waiver authority pertaining to payment for telehealth services.

In particular, the Secretary of Health and Human Services now has the authority to waive: (1) the restrictions on the payment of a facility fee even if the patient is at home and not in a rural area during the telehealth visit; (2) all requirements for the type of telecommunications services that can be used- even if the telecommunications service only has audio capabilities; and (3) the requirement that telehealth services can only be provided to a provider's established patients.

Section 3704 – Enhancing Medicare telehealth services for Federally qualified health centers and rural health clinics during emergency period.

The Act provides that during the currently designated emergency period Medicare shall pay for telehealth services that are furnished via a telecommunications system by a Federally qualified health center ("FQHC") or a rural health clinic ("RHC") to an eligible telehealth individual who is an enrolled beneficiary notwithstanding that the FQHC or RHC providing the telehealth service is not at the same location as the beneficiary. The Secretary of Health and Human Services shall develop and implement payment methods for such telehealth services, which shall be based on payment rates that are similar to the national average payment rates for comparable telehealth services under the Medicare physician fee schedule. Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement such payment methods through program instruction or otherwise. Costs associated with the telehealth services would not be included in other reimbursement methods for the FQHC and RHC.

Section 3705 – Temporary waiver of requirement for face-to-face visits between home dialysis patients and physicians.

During the currently designated emergency period, the Secretary of Health and Human Services may waive the requirement for face-to-face clinical assessments between home dialysis patients and their physicians. This would allow Medicare beneficiaries determined to have end stage renal disease receiving home dialysis to choose to receive monthly end stage renal disease-related clinical assessments via telehealth.

Section 3706 – Use of telehealth to conduct face-to-face encounter prior to

recertification of eligibility for hospice care during emergency period.

For purposes of recertifying a Medicare beneficiary for hospice care, during the currently designated emergency period a hospice physician or nurse practitioner may conduct the required face-to-face encounters via telehealth, as determined appropriate by the Secretary of Health and Human Services.

Section 3707 – Encouraging use of telecommunications systems for home health services furnished during emergency period.

The Secretary of Health and Human Services shall consider ways to encourage the use of telecommunications systems, including for remote patient monitoring as described in 42 CFR Section 409.46(e) (or any successor regulations) and other communications or monitoring services, consistent with the plan of care for the individual, including by clarifying guidance and conducting outreach, as appropriate.

Section 3708 – Improving care planning for Medicare home health services.

For purposes of certifying the need for home health services for a Medicare or Medicaid beneficiary, and for establishing a plan of care for furnishing home health services to an eligible beneficiary and periodically reviewing such a care plan, the CARES Act adds the following practitioners to physicians as permitted to so certify, establish and review: nurse practitioners, clinical nurse specialists, and physician assistants (as the case may be) after a date specified by the Secretary of Health and Human Services in regulations (but in no case later than the date that is 6 months after the date of the enactment of the CARES Act).

Section 3709 – Adjustment of sequestration.

During the period beginning on May 1, 2020 and ending on December 31, 2020, the Medicare programs under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) shall be exempt from reduction under any sequestration order issued before, on, or after the date of enactment of the CARES Act.

Section 3710 – Medicare hospital inpatient prospective payment system add-on payment for COVID–19 patients during emergency period.

For hospital discharges of Medicare beneficiaries occurring during the emergency period, in the case of a discharge of an individual diagnosed with COVID–19, the Secretary of Health and Human Services shall increase the weighting factor that would otherwise apply to the diagnosis-related group (“DRG”) to which the discharge is assigned by 20 percent. The Secretary of Health and Human Services shall identify a discharge of such an individual through the use of diagnosis codes, condition codes, or other such means as may be necessary. Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement this change by program instruction or otherwise. States that have received an applicable 1115A Medicaid demonstration waiver from the Secretary may implement a similar adjustment for hospital discharges of

Medicaid beneficiaries diagnosed with COVID–19.

Section 3711 – Medicare hospital inpatient prospective payment system add-on payment for COVID-19 patients during emergency period.

Access to post-acute care during the emergency period will be increased as follows: rehabilitation facilities will not be required to comply with the requirement for coverage that they provide at least fifteen hours of therapy per patient per week; and the Secretary of Health and Human Services will exercise discretion in enforcement of certain long-term care hospital discharge rate requirements. These modifications allow for additional resources and flexibility for facilities treating patients during this emergency period.

Section 3712 – Receiving payment rates for durable medical equipment under the Medicare program through duration of emergency period.

The transition period for the recently enacted revised payment methodology for durable medical equipment under the Medicare program (See 42 CFR 414.210) will be extended, effective through the duration of emergency period. The intent of this section is to ensure durable medical equipment reimbursement is not reimbursed at a potentially reduced level, as initially required by the regulation, until after the emergency period.

Section 3713 – Coverage of the COVID-19 vaccine under part B of the Medicare program without any cost-sharing.

Any approved COVID-19 vaccine will be covered under part B of the Medicare program without any cost-sharing mechanism, such as a deductible. The COVID-19 vaccine will be treated the same as the influenza vaccine in that regard.

Section 3714 – Requiring Medicare prescription drug plans and MA–PD plans to allow during the COVID-19 emergency period for fills and refills of covered part D drugs for up to a 3-month supply.

Understanding that access to pharmacies and ability to travel may be restricted, Medicare prescription drug plans and Medicare Advantage Part D plans will be required to allow refills of covered part D drugs for an amount elected by the enrollee, up to a 3-month supply during the emergency period. Note that this section does not allow for refills of prescriptions that are inconsistent with an applicable safety edit, such as opioid prescriptions.

Section 3715 – Providing home and community-based services in acute care hospitals.

Acute care hospitals will not be prohibited from providing home and community-based services in acute care hospitals during the emergency period so long as such services are identified in a patient's care plan, provided to meet the needs of the of the patient not already met by the receipt of hospital services, not offered as a substitute for hospital services, and designed to ensure a smooth transition between acute care and home and

community based settings.

Section 3716 – Clarification regarding uninsured individuals.

Access to care and coverage related to COVID-19 under the Families First Coronavirus Response Act will be expanded to include several categories of individuals, including individuals who reside in a state that does not make medical assistance available and individuals who are enrolled in a federal program, but whose plan does not have “minimum essential coverage” as that term is defined in the Internal Revenue Code, Section 5000A(f)(1).

Section 3717 – Clarification regarding coverage of COVID-19 testing products.

COVID-19 testing products that are not approved under certain sections of the Federal Food, Drug, and Cosmetic Act will now be covered “medical assistance” products for applicable grants to states for medical assistance programs, pursuant to 42 U.S.C. § 1396d.

Section 3718 – Amendments relating to reporting requirements with respect to clinical diagnostic laboratory tests.

No reporting of payment and volume rates for non-advanced clinical diagnostic laboratory tests under 42 U.S.C. § 1395m-1(a) is required until January of 2022. Additionally, phase-in of reduction in payments for a clinical diagnostic laboratory test under 42 U.S.C. 1395m-1(b) is extended to 2024 and the applicable percentage by which the payment for a test cannot be reduced from the year 2020 for 2021 is reduced from 15 percent to 0 percent.

Section 3719 – Providing Hospitals Medicare Advance Payments

An existing Medicare accelerated payment program is expanded during the emergency period to give hospitals, especially rural hospitals, (along with other Medicare Part A and Part B providers and suppliers) faster access to Medicare Parts A and B payments in order to meet the increase in demand due to the pandemic. The Centers for Medicare & Medicaid Services (CMS) has already issued guidance on this new program, available [here](#). To qualify for advance/accelerated payments the provider/supplier must: 1. Have billed Medicare for claims within 180 days immediately prior to the date of signature on the provider’s/supplier’s request form, 2. Not be in bankruptcy, 3. Not be under active medical review or program integrity investigation, and 4. Not have any outstanding delinquent Medicare overpayments. Qualified providers/suppliers will be asked to request a specific amount using an Accelerated or Advance Payment Request form provided on each Medicare Administrative Contractor’s (MAC’s) website. The advanced payment is based on net reimbursement represented by unbilled discharges or unpaid bills.

Most providers and suppliers will be able to request up to 100% of the Medicare payment amount for a three-month period. Inpatient acute care hospitals, children’s hospitals, and

certain cancer hospitals are able to request up to 100% of the Medicare payment amount for a six-month period. Critical access hospitals (CAH) can request up to 125% of their payment amount for a six-month period. Advanced payments may be in the form of a lump sum or alternatively, periodic payments. CMS has extended the repayment of these accelerated/advance payments to begin 120 days after the date of issuance of the payment. The repayment timeline is broken out by provider type: Inpatient acute care hospitals, children's hospitals, certain cancer hospitals, and Critical Access Hospitals (CAH) have up to one year from the date the accelerated payment was made to repay the balance; and all other Part A providers and Part B suppliers will have 210 days from the date of the accelerated or advance payment was made to repay the balance.

Section 3720 – Providing State Access to Enhanced Medicaid FMAP

The Families First Coronavirus Response Act of 2020 temporarily increased Medicaid payments to the states by 6.2% so long as the states met certain requirements. This section amends the Families First Coronavirus Response Act of 2020 to ensure that, during the 30 days following enactment, states are able to receive the Medicaid 6.2 percent "federal medical assistance percentage" increase, even if the states did not comply with the requirement that, to receive such increase, the premium charged by the state is not greater than the premium charged on January 1, 2020, provided that the premium in effect on the enactment date is not increased during the emergency period.

Subtitle E—HEALTH AND HUMAN SERVICE EXTENDERS

PART I — MEDICARE PROVISIONS

Section 3801 – Extension of the work geographic index floor under the Medicare program.

The work geographic floor index was set to expire on May 23, 2020. The new law extends this out to December 1, 2020.

Section 3802 – Extension of funding for quality measure endorsement, input, and selection.

The law increases the \$4,830,000 to \$20,000,000 and extends the funding which was originally set to expire on May 22, 2020 through FY 2020 and adds additional pro rata funding for the period beginning on October 1, 2020 through November 30, 2020.

Section 3803 – Extension of funding outreach and assistance for low-income programs.

The law provides additional funding for various area agencies on aging, aging and disability resource centers, and the National Center for Benefits and Outreach Enrollment and extends such funding through FY 2020 and adds additional pro rata funding for the period beginning on October 1, 2020 through November 30, 2020.

PART II — MEDICAID PROVISIONS

Section 3811 – Extension of the money follows the person rebalancing demonstration program.

The law increases funding for the program from \$176,000,000 to \$337,500,000 for the period beginning on January 1, 2020 and ending on September 30, 2020 and extends such additional pro rata funding for the period beginning on October 1, 2020 through November 30, 2020.

Section 3812 – Extension of spousal impoverishment protections.

The spousal impoverishment protections are to be based on an income or resource disregard under a methodology authorized under Section 1902(r)(2) to the income or resources of an individual described in 1902(a)(10)(A)(ii)(VI) or on the basis of an individual's need for home and community-based services authorized under subsection (c), (d), (i), or (k) of Section 1915 or disregarding an individual's spousal income and assets under a plan amendment to provide medical assistance for home and community-based services for individuals by reason of being determined eligible under Section 1902(a)(10)C) or otherwise on the basis of reduction of income based on costs incurred for medical or other remedial care under which the State disregarded the income and assets of the individual's spouse in determining the initial and ongoing financial eligibility of an individual for such services in place of the spousal impoverishment provisions applied under Section 1924 of the CARES Act.

Section 3813 – Delay of DSH reductions.

The reduction in Medicaid Disproportionate Share Hospital (DSH) payments alters certain time frames set forth in the current law out to 2022.

Section 3814 – Extension and expansion of Community Mental Health Services.

The program as provided under Section 223(d) of the Protecting Access to Medicare Act of 2014 (42 U.S.C. 1396a), originally set to expire on May 22, 2020, is extended out to November 30, 2020.

This section further compels the Secretary, no later than 6 months after the enactment of the law, to select two states to participate in a two-year demonstration program. The section further sets forth provisions for the selection of states and requirements of states selected to participate. No later than 18 months after the enactment of the law, the Comptroller General shall submit a report to the House and Senate describing the demonstration program, including information on state's experiences, information on federal efforts to evaluate the demonstration program, and recommendations for improving reporting, accuracy, and validity of encounter data.

PART III — HUMAN SERVICES AND OTHER HEALTH PROGRAMS

Section 3821 – Extension of sexual risk avoidance education program.

This section extends allotments to states for sexual risk avoidance education programs originally set to end on May 22, 2020 through 2020. This section replaces also references to FY 2020 with FY 2021. This section also extends the funding for such programs through CY 2020 and adds additional funding for the period beginning on October 1, 2020 and ending on November 30, 2020 an amount equal to the pro rata portion of the amount appropriated for such FY 2020.

Section 3822 – Extension of personal responsibility education program.

This section extends allotments to states for personal responsibility education originally set to end on May 22, 2020 through 2020 and provides an adjusted timeframe for the Secretary of Health and Human Services to determine the allotment for such programs. This section also extends the funding for such programs through CY 2020 and adds additional funding for the period beginning on October 1, 2020 and ending on November 30, 2020 an amount equal to the pro rata portion of the amount appropriated for such FY 2020.

Section 3823 – Extension of demonstration projects to address health professions.

This section authorizes the extension of demonstration projects through November 30, 2020 in the same manner in which such projects were authorized for FY 2019 and further authorizes the appropriation of money for such programs.

Section 3824 – Extension of the temporary assistance for needy families program and related programs.

This section authorizes the extension of the temporary assistance for needy families program and other related programs through November 30, 2020 and further authorizes the appropriation of money for such programs.

PART IV – PUBLIC HEALTH PROVISIONS

Section 3831 – Extension for community health centers, the National Health Service Corps, and teaching health centers that operate GME programs.

The law revises the enhanced funding as set forth under Section 330 of the Public Health Service Act to extend the program past the May 22, 2020 deadline and provide an additional \$4,000,000,000 for FY 2020 and \$668,493,151 for the period beginning on October 1, 2020 and ending on November 30, 2020 for community health centers.

The law revises the enhanced funding provisions for the National Health Services Corps, as well, providing \$310,000,000 for FY 2020 and \$51,808,291 for the period beginning on October 1, 2020 and ending on November 30, 2020.

The law revises the funding for the Teaching Health Centers that Operate Graduate Medical Education Programs by extending the term of such funding through November

30, 2020, with an additional \$21,141,086 for the period beginning on October 1, 2020 and ending on November 30, 2020.

Section 3832 – Diabetes programs.

This section extends diabetes programs as authorized under the Public Health Service Act through 2020 and provides an additional \$25,068,493 for the period beginning on October 1, 2020 and ending November 30, 2020.

PART V – MISCELLANEOUS PROVISIONS

Section 3841 – Prevention of duplicate appropriations for fiscal year 2020.

This section provides that any expenditures made under the law shall be charged to the applicable appropriation or authorization for such program for such fiscal year.

SUBTITLE F – OVER THE COUNTER DRUGS

PART I – OTC DRUG REVIEW

Sec. 3851 - Regulation of certain nonprescription drugs that are marketed without an approved drug application.

The legislation amends the Federal Food, Drug, and Cosmetic Act to provide, for many over-the-counter (“OTC”) drug products, a conclusion to FDA’s OTC drug product review process. That process was intended to evaluate the safety and effectiveness of OTC drug products marketed in the U.S. before 1972. Although proceeding for nearly 50 years, for many OTC drug products that process remains incomplete.

Under the new legislation, OTC drugs that were part of the OTC drug product review are for the most part to be deemed Generally Recognized as Safe and Effective (“GRASE”) and not a new drug under the following conditions:

1. They are subject to an FDA OTC final monograph, conform to that monograph, and are in a dosage form that immediately prior to enactment has been used to a material extent and for a material time;
2. They were classified in Category I during the OTC drug review (meaning they were found GRASE for the clinical therapeutic indication), subject to an OTC tentative final monograph, conform to that monograph, and are in a dosage form that immediately prior to enactment has been used to a material extent and for a material time;
3. They were classified in Category I during the OTC drug review, subject to a proposed monograph or Advanced Notice of Proposed Rulemaking (“ANPR”), conform to that proposed monograph or ANPR, and are in a dosage form that immediately prior to enactment has been used to a material extent and for a material time;
4. They were classified in Category III during the OTC drug review (meaning there was insufficient evidence to permit final classification of the OTC drug), subject to a tentative final monograph, conform to that monograph, and are in a dosage form that immediately prior to enactment has been used to a material extent and for a material time.

If an OTC drug was classified in Category II during the OTC drug review (meaning the drug was found not to be GRASE or that the indication(s) for the drug were unacceptable), then the drug will be considered a new drug and would require a new drug application to be marketed from 180 days after enactment of the legislation unless the FDA determines that it is in the interest of public health to extend the period in which the product can be marketed without an approved new drug application.

The legislation also sets out a process for FDA to process requests for administrative orders to determine whether there are conditions under which a specific drug, drug class, or combination of drugs are OTC and GRASE, and thus may be marketed without a new drug application. There is a lengthy comment period of 180 days on any proposed administrative orders from FDA. If the active pharmaceutical ingredient is new, then the requestor must provide prima facie evidence that the drug has a verifiable history of being marketed and safely used by consumers in the U.S. as an OTC drug under comparable conditions of use, or similar evidence of use in another country. If FDA issues an administrative order pursuant to a request, then the requester can receive 18 months of exclusivity to market drugs that either incorporate an active pharmaceutical ingredient not previously incorporated or that provides for a change in the conditions of use of a drug for which new human data studies conducted or sponsored by the requestor were essential to the issuance of the order.

Sections 3852, 3853, and 3854 of the statute make changes to the definition of misbranding to comport with the amendments above, clarifies that nothing in the changes apply to drugs that FDA excluded from its OTC drug review, and includes specific provisions addressing sunscreen products.

Sec. 3855. Annual update to Congress on appropriate pediatric indication for certain OTC cough and cold drugs.

This provision requires FDA to provide an annual report to Congress on the OTC cough and cold drug monograph with respect to children under the age of 6.

PART II – USER FEES

Section 3861 and Section 3862 – Fees relating to OTC drugs.

These sections authorize 2 types of user fees, with the charges to be dedicated to FDA's OTC drug monograph activities.

First, an annual fee will be charged beginning in 2020 to each person that owns a facility engaged in manufacturing or processing of the finished dosage form of an OTC monograph drug. Contract manufacturing organization pay 2/3 of the annual fee charged to other OTC monograph drug facilities. FDA is directed to publish the amount of such annual fees by May 11. For 2020, the fees are due the later of the first business day of July 2020 or 45 days after FDA publishes a notice in the federal register setting

forth the fees.

In addition, to the annual OTC monograph drug facility fees, FDA will charge a fee to anyone requesting an administrative order under Section 3851 of the legislation. That fee is due on the date of the order request submission and will generally equal \$500,000. However, the fee will be \$100,000 for more minor administrative order requests, such as merely asking for additional drug facts, or the reordering of ingredients.

Both fees are subject to annual inflation adjustments.