Key Small Business, Labor, and Healthcare Provisions included in the CARES Act (COVID-19 Response Legislation)

The CARES Act was signed into law on March 27, 2020. It included an expansion of small business loan, loan guarantee, and loan forgiveness programs that are now available to sole-proprietors, independent contractors, and self-employed individuals. It included an expansion of Unemployment Insurance (UI) benefits, which also now included self-employed and independent contractors. Workers are now eligible for COVID-19 specific paid sick leave, as a result of Department of Labor guidance published following the passage of the COVID-19 response legislation passed earlier this month. Finally, the CARES Act included health policy provisions and supplemental healthcare appropriations, including a new $100 billion program to provide grants to hospitals, public entities, not-for-profit entities, and Medicare and Medicaid enrolled suppliers and institutional providers to cover unreimbursed healthcare related expenses or lost revenues attributable to the COVID-19 crisis.

Below is a more detailed summary of these key provisions:

Assistance for Small Businesses Including Sole-Proprietors, Independent Contractors, and Self-Employed Individuals

The vast majority ($349B) of the $377B in small business assistance in the Phase 3 COVID-19 response legislation comes via that Paycheck Protection Program. This is a broad new program that introduces new eligible borrowers and new eligible lenders into the 7(a) program. Loans under this program will be 100 percent federally guaranteed and if the borrower maintains its payroll then the portion of the loan used to cover payroll costs, interest on mortgage obligations, rent, and utilities would be forgiven. **Newly eligible borrowers include sole-proprietors, independent contractors, and other self-employed individuals.**

To reduce the anticipated strain on U.S. Small Business Administration (SBA) resources, this legislation provides a pathway for additional non 7(a) lenders to make these loans. These lenders can receive expedited approval to do this from the U.S. Department of Treasury. Further, the legislation delegates authority to 7(a) lenders to make determinations of borrower eligibility and creditworthiness without the normal consultation of SBA personnel.

Business Eligibility:

- Small businesses already eligible for 7(a) loans before this legislation. For purposes of eligibility, check this list.
- Newly eligible: 501(c)(3) nonprofits, 501(c)(19) veteran's organizations, or Tribal businesses with not more than 500 employees, or the size standard for that industry which can sometimes be higher as determined by SBA. Note we have been told some hospitals will be eligible as 501(c)(3) nonprofits that meet other criteria.
- Newly eligible: Sole-proprietors, independent contractors, and other self-employed individuals.
- Certain affiliation rules apply for entities with more than one physical location trying to qualify as a small business. However, affiliation rules are waived for businesses in the hospitality and restaurant industries, franchises approved on the SBA Franchise

Directory, and small businesses that receive financing through the Small Business Investment Company (SBIC) program.

Loan Terms and Details:

- SBA must register each loan within 15 days.
- The beginning of the covered loan period is retroactive to February 15, 2020 and ends June 30, 2020.
- Establishes a formula that ties loan amount to payroll costs to determine loan size, with a cap of $10 million through the end of 2020.
- Waives borrower and lender fees for participation in the Paycheck Protection Program.
- Waives the credit elsewhere test for funds provided under this program.
- Waives collateral and personal guarantee requirements under this program.
- For any portion of loan not used for forgiveness purposes, loan will not have a maturity of more than 10 years.
- Caps interest rate at 4%.
- No prepayment fees.
- Allows complete deferment of 7(a) loan payments for at least six months and not more than a year
- Additional guidance provided for loans sold on the secondary market.
- Requires SBA to provide a lender with a process fee for servicing the loan. Sets lender compensation fees at five percent for loans of not more than $350,000; three percent for loans of more than $350,000 and less than $2,000,000; and one percent for loans of not less than $2,000,000.
- Temporarily increases the maximum loan for a SBA Express loan from $350,000 to $1 million (through the end of 2020).

Allowable Uses:

- Payroll support including salary but also paid sick or medical leave, insurance premiums, mortgage, rent, and utility payments.

Loan Requirements

- Lenders instructed to determine whether a business was operational on February 15 with employees receiving paid salaries and payroll taxes, or paid an independent contractor. Lenders do not look at ability to repay.
- Borrowers make good faith certification that loan is unnecessary due to economic conditions caused by COVID-19; and that they will use the fund to retain workers and maintain payroll, lease and utility payments.

Lending Institutions:

- Current SBA 7(a) lenders
- Lenders who join the SBA 7(a) program
- Additional lenders that receive approval through U.S. Department of Treasury to make loans under the Paycheck Protection Program

Economic Injury Disaster Loans (EIDL) Including Sole Proprietors and Independent Contractors

Expands eligibility for access to Economic Injury Disaster Loans (EIDL) to include Tribal businesses, cooperatives, and ESOPs with fewer than 500 employees or any individual operating

as a sole proprietor or an **independent contractor** during the covered period (January 31, 2020 to December 31, 2020). Private non-profits are also eligible for both grants and EIDLs.

Requires that for any SBA EIDL loans made in response to COVID-19 before December 31, 2020, the SBA shall waive any personal guarantee on advances and loans below $200,000, the requirement that an applicant needs to have been in business for the 1-year period before the disaster, and the credit elsewhere requirement.

Pandemic Unemployment Assistance

Creates a new program providing unemployment benefits for individuals that do not qualify for regular unemployment compensation and are unable to work because of the COVID-19 public health emergency. This includes self-employed workers including independent contractors, along with part-time workers.

Department of Labor Updated Guidance on Family Medical Leave Act

The Department of Labor published updated guidance as a result of the second COVID-19 response bill passed by Congress: The Families First Coronavirus Response Act. The bill requires certain employers to provide employees with paid sick leave or expanded family and medical leave for specified reasons related to COVID-19. The provisions will apply from the effective date through December 31, 2020.

Generally, the Act provides that employees of covered employers are eligible for:

- *Two weeks (up to 80 hours) of **paid sick leave** at the employee's regular* rate of pay where the employee is unable to work because the employee is quarantined (pursuant to Federal, State, or local government order or advice of a health care provider), and/or experiencing COVID-19 symptoms and seeking a medical diagnosis; or
- *Two weeks (up to 80 hours) of **paid sick leave** at two-thirds the employee's regular rate of pay* because the employee is unable to work because of a bona fide need to care for an individual subject to quarantine (pursuant to Federal, State, or local government order or advice of a health care provider), or to care for a child (under 18 years of age) whose school or child care provider is closed or unavailable for reasons related to COVID-19, and/or the employee is experiencing a substantially similar condition as specified by the Secretary of Health and Human Services, in consultation with the Secretaries of the Treasury and Labor; and
- *Up to an additional 10 weeks of **paid expanded family and medical leave** at two-thirds the employee's regular rate of pay* where an employee, who has been employed for at least 30 calendar days, is unable to work due to a bona fide need for leave to care for a child whose school or child care provider is closed or unavailable for reasons related to COVID-19.

Covered employers that must provide these benefits include certain public employers, as well as private businesses with fewer than 500 employees.

Summary of Healthcare Policy Provisions and Appropriations

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

Section 3101. National Academies Report on America's Medical Product Supply Chain Security.
This section requires the HHS Secretary to conduct a report with the National Academies on the medical supply chain within 60 days of enactment. The report will examine the dependence of the U.S. on other countries for manufacturing critical drugs or devices. The report must also analyze the economic impacts of increasing domestic manufacturing, examine methods for improving planning considerations of supply chain capacity during shortages, and include recommendations on ways to improve supply chain resiliency. The National Academies are directed to consult with relevant supply chain entities, including manufacturers, wholesalers, pharmacists, public health departments, and group purchasing organizations.

Section 3102. Requiring the Strategic National Stockpile to Include Certain Types of Medical Supplies.
This section amends the Public Health Service Act to require the following medical supplies to be included in the Strategic National Stockpile: personal protective equipment, ancillary medical supplies, and other applicable supplies for the administration of drugs, vaccines, biological products, medical devices, and diagnostic testing.

Section 3103. Treatment of Respiratory Protective Devices as Covered Countermeasures.
This section designates federally approved masks and respirators as covered countermeasures that are essential for use during a public health emergency. This section protects manufacturers of such countermeasures from liability related to the products.

Subpart B – Mitigating Emergency Drug Shortages

Section 3111. Prioritize Reviews of Drug Applications; Incentives.
This section amends the Federal Food, Drug, and Cosmetic Act to direct the HHS Secretary ("the Secretary shall, as appropriate" rather than "the Secretary may") to prioritize and expedite the review and inspection of drug applications in order to mitigate potential shortages.

Section 3112. Additional Manufacturer Reporting Requirements in Response to Drug Shortages.
This section amends the Federal Food, Drug, and Cosmetic Act to require manufacturers to report on products which could face a disruption in production due to the sourcing of active pharmaceutical ingredients (APIs). Manufacturers are required to report on the potential causes of a disruption, identify any known alternatives for producing the drug's APIs, identify any production devices that could cause disruptions, and project the expected duration of a disruption. Manufacturers are also directed to develop and submit to the Secretary a risk management plan. The Secretary is required, within 180 days of enactment and every 90 days thereafter, to submit to

CMS a report regarding the drugs that could be subject to a shortage. food. A copy of all inspections or reports on drugs that have either been in shortage within the past five years or could be subject to a shortage (based on reporting under this section) will be sent to the appropriate offices at FDA for review.

Manufacturers that register under this section need to submit an annual report to the Secretary that details the amount of the drug that was manufactured, prepared, propagated, compounded or processed for commercial distribution. The Secretary could also require additional reports during the time of a public health emergency. Certain biological products or categories of biological production may be exempt from some or all reporting requirements if they are determined not to be necessary for protecting public health. The Secretary is not authorized to disclose any information that is considered a trade secret or confidential information. All amendments take effect 180 days after enactment.

Subpart C – Preventing Medical Devices Shortages

Section 3121. Discontinuance or Interruption in the Production of Medical Devices.
This section requires manufacturers of medical devices which are considered critical to public health during a public health emergency, or for which the Secretary determines more information is needed to evaluate potential supply chain disruption, to report on possible interruptions or discontinuations of production. Disruptions in manufacturing components or raw materials would not need to be reported. Reports need to be submitted at least six months prior to any interruption or discontinuance, or as soon as practicable. The Secretary is directed to distribute this information to physicians, health providers, patient organizations, and supply chain partners.

Manufacturers that fail to submit necessary reports will be required to justify noncompliance within 30 days. The Secretary will make these justifications public on the FDA website.

The Secretary could expedite the review or inspection of any device determined to be at risk of shortage. The Secretary is also tasked with establishing and maintaining an up-to-date list of devices in shortage. This list includes the following: (1) the category or name of the device in shortage; (2) the manufacturer of the device; (3) the reason for the shortage, as determined by the Secretary; and (4) the estimated duration of the shortage. However, the Secretary could exclude certain information that they determine could negatively impact public health. The Secretary is not authorized to disclose any information that is considered a trade secret or confidential information.

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

Subpart A – Coverage of Testing and Preventative Services

Section 3201. Coverage of Diagnostic Testing for COVID-19.
This section amends the Families First Coronavirus Response Act to mandate private insurance coverage of in vitro diagnostic tests approved under the Federal Food, Drug, and Cosmetic Act, emergency use authorizations, or developed by HHS.

Section 3202. Pricing of Diagnostic Testing.

This section requires a group health plan or health insurance issuer providing coverage of services under the Families First Coronavirus Response Act to reimburse providers for diagnostic tests at previously negotiated rates or in an amount that equals the cash price for such a service as listed by the provider on a public website. Providers are required to list the cash price for such tests on their public internet website. The Secretary could impose a civil monetary penalty on any provider that does not comply and has not completed a corrective action plan to come into compliance. The penalty could not exceed $300 per day during the period of violation.

Section 3203. Rapid Coverage of Preventative Services and Vaccines for Coronavirus.
This section requires a group health plan or health insurance issuer to cover any qualifying coronavirus preventative service without cost-sharing. A qualifying coronavirus preventative service is defined as an item, service, or immunization that is intended to prevent or mitigate COVID-19. These services need to be either: (1) evidence-based with a rating of "A" or "B" under recommendations by the U.S. Preventative Service Task Force; or (2) an immunization that is recommended by CDC's Advisory Committee on Immunization Practices with respect to the patient involved. Requirements to cover immunizations take effect 15 days after the Advisory Committee's recommendation.

Subpart B – Support for Health Care Providers

Section 3211. Supplemental Awards for Health Centers.
This section authorizes $1.32 billion in Fiscal Year (FY) 2020 for supplemental awards for the detection of SARS-CoC-2 or the prevention, diagnosis, and treatment of COVID-19.

Section 3212. Telehealth Network and Telehealth Resource Centers Grant Programs.
This section amends language in the Public Health Service Act related to telehealth network and telehealth resource centers grant programs to prioritize "evidence-based projects that utilize telehealth technologies through telehealth networks." This section also adds access to telehealth services as criteria for awarding grants. It further adds "substance use disorder" to the list of services the HHS Secretary shall prioritize when awarding grants. The Secretary is also directed to consider an entity's record of serving rural areas in addition to medically underserved areas.

The Secretary is required to submit a report within four years of enactment, and every five years thereafter, to the Senate HELP and House Energy and Commerce Committees. It authorizes $29 million annually for these activities from FY 2021-2025.

Section 3213. Rural Health Care Services Outreach, Rural Health Network Development, and Small Health Care Provider Quality Improvement Grant Programs.
This section amends language in the Public Health Service Act to award grants on the basis of expanding access to and improving the quality of "basic," as opposed to "essential," health care services. The section also clarifies that grants could be awarded for improving, as well as expanding, the delivery of health care services. The maximum period for a grant is extended from three to five years. The section changes qualification criteria to cover any entity with the capacity or demonstrated experience to serve rural underserved populations.

The Secretary is directed to submit a report within four years of enactment, and every five years thereafter, to the Senate HELP and House Energy and Commerce committees. The section authorizes $79.5 million annually for these activities from FY 2021-2025.

Section 3214. United States Public Health Service Modernization.
This section amends the Public Health Service Act to differentiate the Active Reserve Corps, referred to as the "Reserve Corp" from the "Regular Corps." The section also clarifies the role of the Reserve Corps in responding to public health emergencies.

Section 3215. Limitation on Liability for Volunteer Health Care Professionals During COD-19 Emergency Response.
This section prevents health care professionals or volunteers from being liable under Federal or State law for harm caused by an act or omission of services for the diagnosis, prevention, or treatment of COVID-19 during the period of the public health emergency. This limitation applies to any health care worker or volunteer acting in good faith and practicing within the scope of their license or volunteer certification. The exemption does not apply to cases of willful or criminal misconduct, gross negligence, reckless misconduct, or conscious flagrant indifference to patients' rights or safety.

This section preempts state laws, takes effect at the time of enactment, and will sunset at the time when the HHS Secretary lifts the public health emergency declaration.

Section 3216. Flexibility for Members of National Health Service Corps During Emergency Period.
This section empowers the HHS Secretary to assign members of the National Health Service Corps, with the voluntary agreement of such members, to provide designated health services at such locations (within a reasonable distance), times, and durations as the Secretary deems necessary. The total number of hours assigned could not exceed those required of members before enactment of this section.

Subpart C – Miscellaneous Provisions

Section 3221. Confidentiality and Disclosure of Records Relating to Substance Use Disorder.
This section amends the Public Health Service Act to align 42 CFR regulations with privacy regulations under the Health Insurance Portability and Accountability Act (HIPAA) by allowing disclosure of substance use information to covered entities. Substance use records could be disclosed by the person maintaining the records if they receive prior written consent from the patient. With prior written consent, substance use information could be disclosed by a covered entity, associate, or program for the purposes of treatment, payment, or health care operations consistent with HIPAA regulations. Information could also be redisclosed in accordance with HIPAA. A patient would be able to give blanket prior consent for disclosure at any future time, and a patient would be also able to revoke such consent at any time.

De-identified information could be disclosed to public health authorities. Information disclosed under this section could not be used in criminal, civil, or administration proceedings unless authorized by a court order. The section also includes language to prevent individuals who disclose

information under this section from being subject to discrimination with respect to health care services, housing, law enforcement, and employment.

The section directs the HHS Secretary, in consultation with other federal agencies, to consider necessary revisions for implementing and enforcing these amendments. The Secretary is required to promulgate rules to covered entities for developing easily understandable notices of privacy practices. These notices must include a statement of the patient's rights and a description of cases in which information could be shared without consent.

The section includes a Sense of Congress which encourages anyone treating a patient through a program or activity involving substance use privacy rules to access state-based prescription drug monitoring programs (PDMPs) when clinically appropriate. It also encourages covered entities to make a reasonable effort to comply with patients' requests to restrict disclosures, while discussing with patients the benefits of consenting to sharing such records.

Section 3222. Nutrition services.
This section waives nutrition requirements for Older Americans Act (OAA) meal program during the COVID-19 public health emergency so seniors are able to get meals if certain food options are unavailable.

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 allows the Department of Labor Secretary to extend older adults' participation in community service projects under the OAA and creates administrative changes to facilitate their continued employment under the program.

Section 3224. Guidance on Protected Health Information.
This section directs the HHS Secretary to issue guidance on the sharing of patients' protecting health information during the public health emergency. The guidance is required to include information on compliance with regulations under HIPAA and other applicable policies that come into effect during emergencies.

Section 3225. Reauthorization of healthy start program.
This section reauthorizes the Healthy Start Program, which provides grants to help women and their families who may need additional support during the COVID-19 public health emergency gain access to services.

Section 3226. Importance of the blood supply.
This section directs the Secretary of HHS to conduct an initiative to improve public awareness of the importance and safety of donating blood and the continued need for blood donations during the COVID-19 public health emergency.

Part III – Innovation

Section 3301. Removing the Cap on OTA During Public Health Emergencies.

This section amends the Public Health Service Act to direct the HHS Secretary to use competitive procedures when entering into transactions on projects during a public health emergency. It clarifies that transactions entered into during this period will not be terminated at the end of the emergency declaration if the terms of such transactions extend beyond that time. The Secretary is also required to submit a report to the Senate HELP and House Energy and Commerce committees on the use of funds spent by HHS under its authority during the emergency.

Section. 3302. Priority Zoonotic Animal Drugs.
This section amends the Federal Food, Drug, and Cosmetic Act to direct the Secretary to designate certain animal drugs for expedited development and review. This is limited to animal drugs for which preliminary clinical evidence shows the potential of the drug, or the drug in combination with one of more other animal drugs, to treat a zoonotic disease in animals. This specifically includes drugs with the potential to treat a vector borne-disease that could cause serious or life-threatening health conditions in humans. The sponsor of such a drug could request this designation by the Secretary concurrently or at any time after the submission of an application under other approval pathways. The Secretary is then given 60 days to make a determination.

The section recommends to HHS the following methods for expediting development: (1) utilizing novel trial designs or drug development tools (including biomarkers); (2) providing timely advice to the drug's sponsor on relevant clinical and nonclinical evidence for approval; (3) involving senior managers and review staff with relevant expertise in zoonotic or vector-borne diseases; and (4) implementing additional administrative or process enhancements to facilitate an efficient timeline for review.

Part IV – Health Care Workforce

Section 3401. Reauthorization of Health Professions Workforce Programs.
This section reauthorizes and updates Title VII of the Public Health Services Act (PHSA), which supports clinician training and faculty development, particularly training of providers in family medicine, internal medicine, geriatrics, pediatrics, and other specialties.

Section 3402. Health Workforce Coordination.
This section directs the Secretary to develop a coordinated plan, in consultation with other agencies, to strengthen health care workforce programs. The Secretary is authorized to include performance metrics.

Section 3403. Education and Training Related to Geriatrics.
This section authorizes $40.737 million annually from FY 2021 through FY 2025 for geriatrics education and training.

Section 3404. Nursing Workforce Development.
This section reauthorizes nursing workforce training programs under Title VIII of the PHSA. The section introduces reporting requirements and performance metrics for program evaluation. The section allows Nurse Corps loan repayment beneficiaries to serve at private institutions during public health emergencies. The Comptroller General is directed to issue a report with

recommendations on nursing workforce loan repayment programs to the Senate HELP and House Energy and Commerce committees within 18 months of enactment.

Subtitle D – Finance Committee

Section 3701. Exemption for Telehealth Services.
This section amends the Internal Revenue Code to clarify that high-deductible plans with a health savings account (HSA) will cover telehealth services prior to an enrollee reaching their deductible. This section takes effect on the date of enactment.

Section 3702. Inclusion of Certain Over-the-Counter Medical Products as Qualified Medical Expenses.
This section amends the Internal Revenue Code to treat amounts paid for menstrual care products as costs for medical care for patients in HSAs. These products are defined to include tampons, pads, liners, cups, sponges, or similar products used with respect to menstruation. This section applies to expenses incurred after December 31, 2019.

Section 3703. Increasing Medicare Telehealth Flexibilities During Emergency Period.
This section amends a section of the Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020 to clarify that during an emergency period, a provider does not need to have treated a patient in the previous three years in order to furnish telehealth services.

Section 3704. Enhancing Medicare Telehealth Services for Federally Qualified Health Centers and Rural Health Clinics During Emergency Period.
This section amends Section 1135 of the Social Security Act to clarify that Federally qualified health centers and rural health clinics qualify as "distant sites" and are eligible for payments for telehealth services. The section directs the HHS Secretary to pay for telehealth services that are furnished via a telecommunication system by a federally qualified health center or rural health clinic, regardless of whether the eligible telehealth beneficiary is at the same location. The Secretary is instructed to determine payment rates based on the national average payment rates for comparable telehealth services under the physician fee schedule. Costs associated with telehealth services will not be used to determine payment amounts for federally qualified health center services under the prospective payment system or for rural health clinic services under the methodology for all-inclusive rates.

Section 3705. Temporary Waiver of Requirement for Face-to-Face Visits Between Home Dialysis Patients and Physicians.
This section allows the Secretary to temporarily waive the requirement for face-to-face visits between physicians and patients receiving dialysis.

Section 3706. Use of Telehealth to Conduct Face-to-Face Encounter Prior to Recertification of Eligibility for Hospice Care During Emergency Period.
This section allows hospice physicians or nurse practitioners to conduct their face-to-face encounters with hospice patients via telehealth.

Section 3707. Encouraging Use of Telecommunications Systems for Home Health Services Furnished During Emergency Period.
This section directs the HHS Secretary to consider ways of encouraging the use of telecommunications systems for administering services during the emergency period, particularly for remote patient monitoring.

Section 3708. Improving Care Planning for Medicare Home Health Services.
This section expands eligible providers under Part A and Part B to include nurse practitioners, clinical nurse specialists, and physician assistants for the purposes of expanding access to home health services. The section directs the HHS Secretary to promulgate regulations which shall become effective six months after enactment.

Section 3709. Adjustment of Sequestration.
This section exempts any Medicare program under title XVIII of the Social Security Act from any reduction or sequestration from May 1, 2020 to December 31, 2020. The section also extends the direct spending reductions under the Balanced Budget and Emergency Deficit Control Act from FY 2029 to FY 2030.

Section 3710. Medicare Hospital Inpatient Prospective Payment System Add-On Payment for COVID-19 Patients During Emergency Period.
This section directs the HHS Secretary to increase by 20 percent the weighting factor for payments that would otherwise apply to the diagnosis-related group for discharges of patients diagnosed with COVID-19 during the emergency period. These adjustments will not be taken into account in applying budget neutrality.

Section 3711. Increasing Access to Post-Acute Care During Emergency Period.
This section directs the HHS Secretary to waive, for the duration of the emergency period, the requirement that patients at inpatient rehabilitation facilities must receive at least three hours of therapy each day.

This section also allows the Secretary to exercise enforcement discretion with respect to the following rules for long-term care hospitals (LTCHs): (1) the payment adjustment for LTCHs that have a discharge payment percentage of at least 50 percent; (2) exclusion criteria from site-neutral inpatient prospective payment system (IPPS) rate.

Section 3712. Revising Payment Rates for Durable Medical Equipment Under the Medicare Program Through Duration of Emergency Period.
This section directs the HHS Secretary to apply transition rule payments for durable medical equipment in rural and noncontiguous areas.

Section 3713. Coverage of the COVID-19 Vaccine Under Part B of the Medicare Program Without any Cost-Sharing.
This Section amends the Social Security Act to provide Medicare coverage for a COVID-19 vaccine and its administration to patients with no cost-sharing. The amendments take effect on the date of enactment and apply to any COVID-10 vaccine licensed under the Public Health Service Act. The Secretary is authorized to implement this section by program instruction or other means.

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 Drug for Up to a 3-Month Supply.
This section amends the Social Security Act to allow Part D enrollees to fill prescriptions with up to a three-month supply of medication. Medicare Advantage and Part D plans are instructed to apply applicable safety standards when permitting beneficiaries to fill such prescriptions. The Secretary is authorized to implement this section by program instruction or other means.

Section 3715. Providing Home and Community-Based Services in Acute Care Hospitals.
This section amends the Social Security Act to allow acute care hospitals to provide self-directed personal assistance services pursuant to a written plan of care or home and community-based attendant services. The section clarifies that these activities need to meet the needs of an individual and are not a substitute for services hospitals are obligated to provide under existing Federal or State law.

Section 3716. Clarification Regarding Uninsured Individuals.
This section clarifies that individuals enrolled in State or Federal health care programs whose benefits do not include coverage of a COVID-19 vaccine or an in vitro testing product are eligible to receive those products and accompanying administration at no cost-sharing.

Section 3717. Clarification Regarding Coverage of COVID-19 Testing Products
This section clarifies that in-vitro COVID-19 diagnostic products administered during the emergency period will be fully covered by Medicaid and CHIP, even if such products are not yet approved and authorized under the Federal Food, Drug, and Cosmetic Act.

Section 3718. Amendments Relating to Reporting Requirements with Respect to Clinical Diagnostic Laboratory Tests.
This section extends by one year the reporting period for primate sector payment rates used for establishing Medicare payment rates for advanced laboratory diagnostic tests. No reporting is required until December 31, 2021 and reporting will now be required during every period from January 21, 2022 to March 31, 2022. The section also revises the phase-in of reductions from private payor rate implementation to 0 percent in 2021 and extends the 15 percent reduction from 2021 through 2022 to 2022 through 2024.

Section 3719. Expansion of the Medicare Hospital Accelerated Payment Program During the COVID-19 Public Health Emergency.
This section expands Medicare's accelerated payments for hospitals during the public health emergency period to include: (1) U.S. hospitals other than psychiatric hospitals, rehabilitation hospitals, hospitals whose inpatients are predominantly under 18 years of age; hospitals with an average inpatient stay exceeding 15 days; (2) hospitals classified by the Secretary as being involved extensively in the treatment or research of cancer; and (3) critical access hospitals.

The Secretary is authorized to make accelerated payments on a periodic or lump sum, increase the payment amount to up to 100 percent (or 125 percent for critical access hospitals), and extend the period of accelerated payments for up to six months. Hospitals can request that the Secretary

provide up to 120 days before claims are offset to recoup the accelerated payment and delay full repayment for up to 12 months after the date of the first accelerated payment.

Section 3720. Exception for Certain States from Enhanced FMAP Requirements.
This section allows states that do not, at the time of enactment, meet the Federal Medical Assistance Percentages (FMAP) reporting requirements under the Families First Coronavirus Response Act to still receive the 6.2 percent increase. Such states would need to certify to the Secretary within 30 days of enactment that they are unable to meet the requirements.

Subtitle E – Health and Human Services Extenders

Part I – Medicare Provisions

Section 3801. Extension of the Work Geographic Index Floor Under the Medicare Program.
This section extends the work geographic practice cost index floor from May 23, 2020 until January 1, 2022.

Section 3802. Extension of Funding for Quality Measure Endorsement, Input, and Selection.
This section expands and extents funding for quality measures from $4.83 million from October 1, 2019 to May 22, 2020 to $20 million annually in FY 2020 and FY 2021.

Section 3803. Extension of Funding Outreach and Assistance for Low-Income Programs.
This section authorizes the following funds for outreach and low-income assistance programs: (1) $13 million each year for state health insurance programs in FY 2020 and FY 2021; (2) $7.5 million each year for area agencies in FY 2020 and FY 2021; (3) $5 million each year for aging and disability resource centers in FY 2020 and FY 2021; and (4) $12 million each year for the National Center for Benefits Outreach and Enrollment in FY 2020 and FY 2021.

Part II – Medicaid Provisions

Section 3811. Extension of the Money Follows the Person Rebalancing Demonstration Program.
This section amends the Deficit Reduction Act of 2005 to authorize $450 million annually for the Money Follows the Person demonstration program in FY 2020 and FY 2021.

Section 3812. Extension of Spousal Impoverishment Protections.
This section extends existing Medicaid spousal impoverishment rules from May 22, 2020 to September 30, 2021.

Section 3813. Delay of DSH Reductions.
This section delays payment reductions to disproportionate share hospitals (DSH) until 2028.

Section 3814. Extension and Expansion of Community Mental Health Services Demonstration Program.
This section amends the Protecting Access to Medicare Act of 2014 to extend the period of the Certified Community Behavioral Health Clinics (CCBHC) demonstration program until

September 30, 2021 for the eight participating states. The section also requires the HHS Secretary to identify two additional states for participation within six months of enactments. States are required to submit plans on how they would monitor CCBHCs and collect data under the demonstration.

This section also requires the Comptroller General to submit a report to the Senate Finance and House Energy and Commerce committees within 18 months of enactment. The report must detail the impacts of the demonstration on patient health and the cost of care, as well as impacts on engagement in treatment and screening and testing for comorbid conditions.

Part III – Human Services and Other Health Programs

Section 3821. Extension of Sexual Risk Avoidance Education Program.
This section extends current funding levels for the Sexual Risk Avoidance Education program through November 30, 2020.

Section 3822. Extension of Personal Responsibility Education.
This section extends current funding levels for the Personal Responsibility Education Program (PREP) through November 30, 2020.

Section 3823. Extension of Demonstration Project to Address Health Professions Workforce Needs.
This section extends FY 2020 funding levels for the Health Professional Opportunity Grants (HPOG) demonstration program through November 30, 2020. Grants and payments will be made on a prorated portion of the total amount authorized for such activities in FY 2019.

Section 3824. Extension of the Temporary Assistance for Needy Families Program and Related Programs.
This section extends the Temporary Assistance for Needy Families (TANF) program and related programs through November 30, 2020.

Part IV – Public Health Provisions

Section 3831. Extension for Community Health Centers, the National Health Services Corps, and Teaching Health Centers that Operate GME Programs.
This section extends FY 2020 funding levels for Community Health Centers (CHC), the National Health Services Corps, and Teaching Health Centers through November 30, 2020.

Section 3832. Diabetes Programs.
This section extends FY 2020 funding levels for the Special Diabetes Program and the Special Diabetes Program for Indians through November 30, 2020.

Subtitle F – Over-the-Counter Drugs

Part I – OTC Drug Review

Section 3851. Regulation of Certain Nonprescription Drugs that are Marketed without an Approved Drug Application.
This section amends Section 505G of the Federal Food, Drug, and Cosmetic Act to change regulations on over-the-counter (OTC) drugs that are marketed without an approved drug application. Category I drugs subject to a tentative final monograph are recognized as safe and effective if the drug is in conformity with requirements for nonprescription use of a final monograph and in a dosage form has been used for a material time. Category III drugs are subject to a tentative final monograph.

The section changes the monograph rulemaking process to an administrative order process, subject to judicial review, under the same legal authority that applies to other medical product approvals. It establishes processes for manufacturers to request administrative orders, or FDA to request such orders in response to citizens' petitions. It allows manufacturers to request meetings with FDA in a similar fashion to those conducted for prescription drugs.

The section creates a new 18-month exclusivity period to reward innovation in OTC products. Only one 18-month will be granted for a product and the exclusivity period will not be awarded for safety-related changes or changes related to methods of testing safety or efficacy.

Section 3852. Misbranding.
This section amends the Federal Food, Drug, and Cosmetic Act to clarify that misbranded drugs will not be regulated under the previous section. It also excludes products that were prepared, propagated, compounded, or processes at facilities which failed to pay required fees.

Section 3853. Drug Excluded from the Over-the-Counter Drug Review.
This section clarifies that any nonprescription drug excluded by FDA from the Over-the-Counter Drug Review is excluded from new approval processes in this Act.

Section 3854. Treatment of Sunscreen Innovation Act.
This section allows sponsors of nonprescription sunscreen active ingredients to petition the Secretary to transition to being regulated under Section 505G. Determinations will be made based on sun protection factor levels. The section also allows sponsors to request confidential meetings with HHS regarding considerations for data requirements as well as safety and efficacy standards. Qualifying products will receive the 18 months of marketing exclusivity.

This section will sunset in FY 2022 and the Secretary is directed to issue a revised order on nonprescription sunscreen within 18 months of enactment.

Section 3855. Annual Update to Congress on Appropriate Pediatric Indication for Certain OTC Cough and Cold Drugs.
This section requires the Secretary to report to the Senate HELP and House Energy and Commerce committees annually on the evaluation of the cold and cough monograph with respect to children under the age of six.

Section 3856. Technical Corrections.

This section makes technical and conforming corrections to the Federal Food, Drug, and Cosmetic Act and the FDA Reauthorization Act of 2017.

Part II – User Fees

Section 3861. Finding.
This section clarifies that new user fees collected on OTC productions will be used on the evaluation and monitoring of such products.

Section 3862. Fees Relating to Over-the-Counter Drugs.
This section imposes user fees on OTC monograph drug facilities, at one location and including contracted facilities, that manufacture the ingredients or finished dosage form. Separate buildings or locations within close proximity are considered one geographic location.

This section authorizes FDA to collect user fees in the form of facility fees and OTC monograph order request fees ($500,000 for Tier 1 OTC monographs and $100,000 for Tier 2 OTC monographs). The Secretary is also directed to adjust the fees, on a declining scale, from FY 2021 through FY 2025. The Secretary is required to establish the FY 2021 facility fee no later than the second Monday in May of 2020. The Secretary is required to set the fee, and any adjustments, at the same time in all subsequent years.

The Secretary is directed to issue fiscal and performance reports, related to activities in carrying out this section, to the Senate HELP and House Energy and Commerce committees within the first 120 days of each calendar year. The Secretary is also directed to consult with the aforementioned committees and industry experts on reauthorization of the user fees.

Division B – Emergency Appropriations for Coronavirus Health Response and Agency Operations

Division B of the CARES Act provides emergency appropriations which includes funding for a number of health care programs. These funds include:

- *Department of Agriculture* – To remain available until expended, $25 million for the Distance Learning, Telemedicine, and Broadband Program to prepare for and respond to the coronavirus including for telemedicine and distance learning in rural areas.
- *Food and Drug Administration* – To remain available until expended, $80 million for "Salaries and Expenses" to prevent, prepare for, and respond to the coronavirus including the development of necessary medical countermeasures and vaccines, advanced manufacturing, monitoring of medical product supply chains, and related administrative activities.
- *Centers for Disease Control and Prevention* – To remain available until September 30, 2024, $4.3 billion of which $1.5 billion is for grants to or cooperative agreements with states, localities, territories, tribes, tribal organizations, and Indian health organizations for surveillance, epidemiology, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities; $500 million for global disease detection and emergency response; $500 million for public health data surveillance and analytics infrastructure modernization; and $300 million transferred to and merged with amounts in the Infectious Diseases Rapid Response Reserve Fund.

- *National Institutes of Health* – To remain available until September 30, 2024, $103,400,000 for the National Heart, Lung, and Blood Institute; $706 million for the National Institute of Allergy and Infectious Diseases of which $156 million shall be for equipment and facilities for vaccine and infectious disease research; $60 million for the National Institute of Biomedical Imaging and Bioengineering; $10 million for the National Library of Medicine; $36 million for the National Center for Advancing Translational Sciences; and $30 million to the Office of the Director.
- *Substance Abuse and Mental Health Services Administration* – To remain available through September 30, 2021, $425 million for "Health Surveillance and Program Support" including $250 million for Certified Community Behavioral Health Clinics; $50 million for suicide prevention and $100 million for grants, contracts, or cooperative agreements to public entities to address emergency substance abuse or mental health needs in local communities.
- *Centers for Medicare and Medicaid Services* – To remain available through September 30, 2023, $200 million including $100 million for necessary expenses of the survey and certification program prioritizing nursing home facilities in areas with community transmission of the coronavirus.
- *Public Health and Social Services Emergency Fund* –
    - To remain available until September 30, 2024, $27,014,500,000 including for the development of necessary countermeasures and vaccines, prioritizing platform-based technologies with U.S. manufacturing capabilities, the purchase of vaccines, therapeutics, diagnostics, necessary medical supplies, and medical surge capacity; to allow the Secretary to purchase vaccines in accordance with the Federal Acquisition Regulation guidance on fair and reasonable pricing; to require that any vaccines, therapeutics, and diagnostics to be developed from funds provided in this Act shall be affordable in the commercial market; $16 billion for the Strategic National Stockpile; $250 million for grants to or cooperative agreements with grantees or sub-grantees of the Hospital Preparedness Program; and $3.5 billion for the Biomedical Advanced Research and Development Authority. Under this paragraph, $1.5 million shall be for the Secretary to work with the National Academies on a report on the security of the medical product supply chain.
    - To remain available until September 30, 2022, $275 million including $90 million transferred to the Health Resources and Services Administration (HRSA) for the Ryan White HIV/AIDS Program; and $180 million for HRSA Rural Health to carryout telehealth and rural activities.
    - To remain available until expended, $100 billion in reimbursement for hospitals and health care providers for health care related expenses or lost revenues directly attributable to the COVID-19.
- *Indian Health Service* – To remain available until September 30, 2021, $1,032,000,000 to respond to the coronavirus including surveillance, testing capacity, community health representatives, public health support, telehealth, Purchased/Referred Care, and other health service activities.
- *Veterans Health Administration* – To remain available until September 30, 2021, $14,432,000,000 for Medical Services for related impacts on health care delivery and support of veterans who are homeless or at risk of being homeless; $2.1 billion for Medical

Community Care; $100 million for Medical Support and Compliance; and $606 million for Medical Facilities.