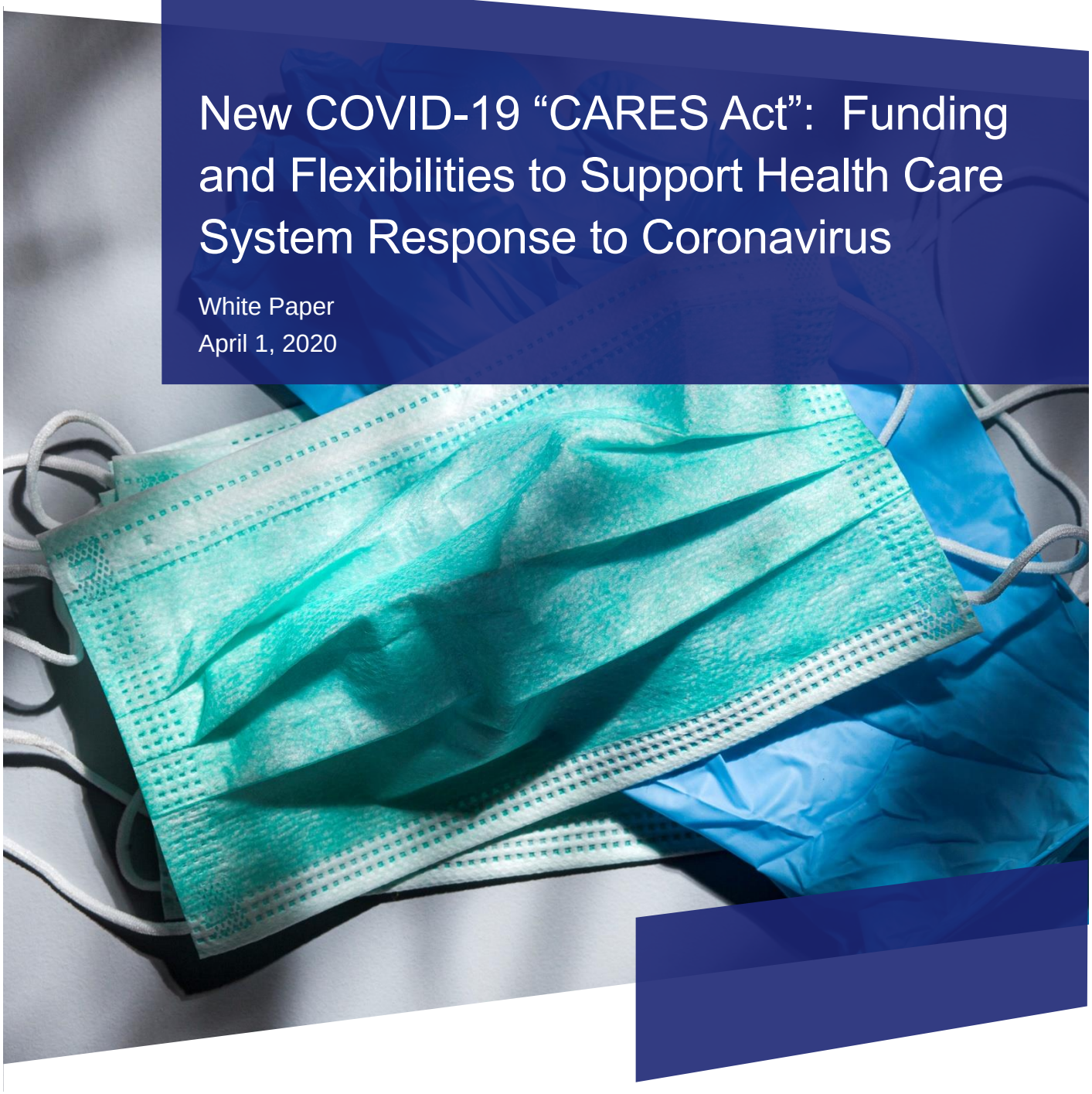
New COVID-19 “CARES Act”: Funding and Flexibilities to Support Health Care System Response to Coronavirus

White Paper
April 1, 2020



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New COVID-19 CARES Act: Funding and Flexibilities to Support Health Care System Response to Coronavirus

President Trump has signed into law the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act or Act),[1] sweeping legislation intended to bolster the nation's response to the COVID-19 pandemic. In addition to offering economic relief to individuals and impacted businesses, the Act shores up the nation's supply of drugs and equipment, expands coverage of COVID-19 testing and preventative services, addresses health care workforce needs, eases restrictions on telehealth services during the crisis, increases Medicare regulatory flexibility, and authorizes $100 billion for eligible health care providers, among many other things. This was the third emergency COVID-19 response measure signed into law to date, following the Coronavirus Preparedness and Response Supplemental Appropriations Act[2] and the Families First Coronavirus Response Act (Families First Act).[3] Congressional leaders have indicated that additional legislative action is contemplated.

The following is an analysis of the major health care policy and funding provisions in the CARES Act. We would be pleased to provide you with additional information or answer any questions you may have about the Act, the status of Department of Health and Human Services (HHS) implementation efforts, or any other aspect of the government policy response to the COVID-19 pandemic.

For more information on this issue, please contact any of the authors listed below. In addition, our broader Reed Smith Coronavirus team includes multidisciplinary lawyers from Asia, EME and the United States who stand ready to advise you on the issues below or others you many face related to COVID-19, including those specific to the CARES Act.

Businesses may also be interested in Reed Smith's CARES Act Overview, which covers all portions of the Act. Additional information on the legal and business implications of COVID-19 is available at the Reed Smith Coronavirus (COVID-19) Resource Center, the firm's CARES Act Resource Center, or by contacting us at COVID-19@reedsmith.com.

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[1] P.L. 116-136, *available at* https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf.
[2] P.L. 116-123, *available at* https://www.congress.gov/bill/116th-congress/house-bill/6074/text.
[3] Pub. L. No. 116-127, *available at* https://www.congress.gov/bill/116th-congress/house-bill/6201/text.

Addressing supply shortages

Medical product supplies

National Academies report on America's medical product supply chain security (Sec. 3101)

Section 3101 of the Act requires HHS to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine (National Academies) to examine, and, in a manner that does not compromise national security, report on, the security of the U.S. medical supply chain. HHS has 60 days to enter into this agreement. The Act does not specify a deadline for issuing the report. Once final, the report must assess and evaluate the dependence of the public and private commercial sectors of the United States on critical drugs and devices that are sourced or manufactured outside of the US. It also requires the National Academies to provide recommendations as appropriate, which may include a plan to improve the resiliency of the supply chain for critical drugs and devices or 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.

Requiring the strategic national stockpile to include certain types of medical supplies (Sec. 3102)

Section 3102 of the Act clarifies that some of the "other supplies" that are to be included in the US Strategic National Stockpile are personal protective equipment, ancillary medical supplies, and other applicable supplies that are required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests that are included already within the stockpile.

Treatment of respiratory protective devices as covered countermeasures (Sec. 3103)

Section 3103 of the Act adds respiratory protective devices that are approved by the National Institute for Occupational Safety and Health, and that the Food and Drug Administration (FDA) determines to be a priority for use during a public health emergency, as products eligible for the liability protections of the Public Readiness and Emergency Preparedness Act (PREP Act), Pub. L. No. 109-148 (2005), 42 U.S.C. sections 247d-6d. The PREP Act provides extraordinarily broad protections from all tort claims under federal or state law (except for those based on willful misconduct) for any type of loss, including death; physical, mental, or emotional injury; fear of such injury; or property damage or loss, including business interruption loss (with any causal relationship to any stage of development), distribution, administration, dispensing, or use of the covered countermeasure recommended in the PREP Act declaration. Importantly, this new provision eliminates the need for FDA to jump through an intended-use analysis in order to characterize a product as covered under the PREP Act. As a result, all such respiratory protective devices (e.g., N95 face masks) will qualify automatically as covered countermeasures for PREP Act coverage.

Mitigating emergency drug shortages

Prioritize reviews of drug applications (Sec. 3111)

Section 3111 of the Act forces FDA, upon receipt of a manufacturer notice concerning the potential discontinuance or interruption in the production of a life-saving drug, to prioritize and expedite drug application reviews and inspections (or inspections of establishments) related to such drugs when these reviews and inspections could help mitigate or prevent a potential drug shortage. This requirement applies to all life-saving drug shortages, not just shortages related to COVID-19 or any other declared public health emergency.

Additional manufacturer reporting requirements in response to drug shortages (Sec. 3112)

Section 3112 of the Act expands manufacturer reporting requirements to FDA in response to drug shortages concerning life-saving drugs to include any drugs that are critical to a declared public health emergency. It further expands the reporting requirement for such drugs to require notifications of any permanent discontinuance or meaningful interruption in the supply chain of their active pharmaceutical ingredients (API), with any such notification to include the reasons for the discontinuation or interruption. If the disclosure relates to a potential discontinuation or interruption in the supply chain for the applicable API, then the notification must also inform FDA of the source of the API and any alternative sources for the API known by the manufacturer; whether any associated device used for preparation or administration included in the drug is a reason for, or a risk factor in, such discontinuation or interruption; the expected duration of the interruption; and any other information as FDA may require.

Additionally, section 3112 of the Act requires manufacturers of these drugs, manufacturers of the APIs contained in these drugs, and manufacturers of any medical device used for the preparation or administration of the drug, to develop, maintain, and implement a redundancy risk management plan that identifies and evaluates risks to the supply of the drug, if any, for each establishment in which such drug or API of such drug is manufactured. These plans will be subject to inspection by FDA, making it important for manufacturers to implement record retention policies related to such plans.

All drug manufacturers also must submit annual, drug-volume reports to FDA concerning the amount of drug(s) the drug manufacturer, prepared, propagated, compounded, or processed for commercial distribution. FDA may exclude from this reporting requirement certain biological products that it determines are not necessary to protect the public health.

In addition to the new reporting requirements imposed on manufacturers, section 3112 of the Act imposes new reporting requirements on FDA. First, it requires FDA to transmit an updated drug shortage list to the Centers for Medicare and Medicaid Services (CMS) every 90 days. Second, FDA will be required to transmit inspection reports to FDA shortage offices and departments immediately after any inspection of an establishment that manufactures a product that has been on FDA's drug shortage list at any point during the last five years or that falls within an active FDA-mandated, manufacturer-declared potential permanent discontinuance or meaningful interruption in the supply chain of a life-saving drug.

All changes contained in section 3112 take effect 180 days after the date of enactment of the Act.

Preventing medical device shortages

Discontinuance or interruption in the production of medical devices (Sec. 3121)

Similar to the requirements imposed on drug manufacturers, section 3121 of the Act adds a new reporting requirement for manufacturers of devices that are (1) critical to public health during a public health emergency, including devices that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery; or (2) for which FDA determines that information on potential meaningful supply disruptions of such devices is needed during, or in advance of, a public health emergency.

Specifically, manufacturers of these devices must notify FDA of any permanent discontinuance in the manufacturing of the devices (except for discontinuances resulting from an approved device modification) or an interruption in manufacturing that is likely to lead to a "meaningful disruption" in the supply of that device in the U.S. "Meaningful disruption" means a change in production that is reasonably likely to lead to a reduction in the supply of a device by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product. It **does not include** certain enumerated circumstances: (1) interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing, so long as the manufacturer expects to resume operations in a short period of time, not to exceed 6 months; (2) interruptions in manufacturing of components or raw materials, so long as such interruptions do not result in a shortage of the device and the manufacturer expects to resume operations in a "reasonable period of time"; and (3) interruptions in manufacturing that do not lead to a reduction in procedures or diagnostic tests associated with a medical device designed to perform more than one procedure or diagnostic test. Discontinuation and interruption reports must be submitted at least six months prior to the anticipated discontinuance or interruption, or, if reporting during that time period is not possible, then a report must be made as soon as practicable. All reports must include a reason for the discontinuance or interruption.

Section 3121 of the Act also imposes certain requirements on FDA with respect to these devices. First, it requires FDA to communicate this information to appropriate organizations, including physicians, health providers, patient organizations, and supply chain partners. This communication must be done to the maximum extent practicable, but in a way that protects against hoarding or other activities that could adversely affect the public health. Second, FDA must prioritize and expedite

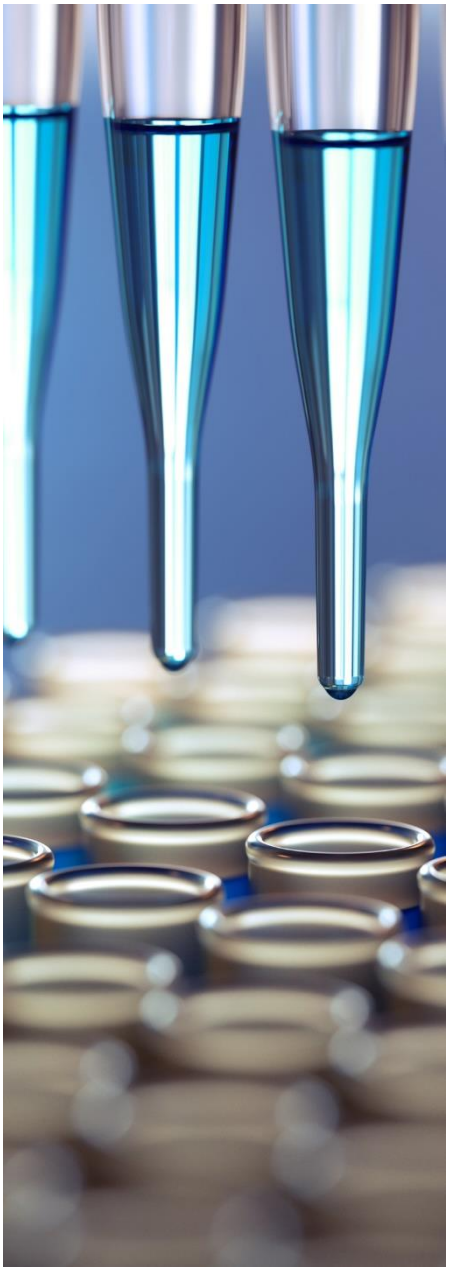
device application reviews and inspections (or inspections of establishments) when such reviews and inspections could help mitigate or prevent a shortage in the above referenced devices. Third, FDA has to establish and maintain a list of devices that FDA determines to be in shortage in the United States. FDA must make this shortage list publicly available, to the extent possible. FDA may elect not to disclose certain information if it determines that disclosure of such information would adversely affect public health. This includes disclosures that might increase the possibility of hoarding or other disruption of the availability of a device to patients.

Access to health care for COVID-19 patients

Coverage of testing and preventive services

Coverage and pricing of diagnostic testing for COVID-19 (Sections 3201 and 3202)

Section 3201 of the Act revises the Families First Act with regard to mandated coverage by commercial health plans of diagnostic testing for COVID-19, and certain testing-related services during the COVID-19 public health emergency, which HHS Secretary Alex M. Azar declared to have begun January 27, 2020 (hereafter designated the Emergency Period).[4]



The Families First Act required group health plans (such as self-insured employer plans) and group or individual health insurance coverage (including grandfathered plans under the Affordable Care Act) to cover, from the date of the enactment of that law through the end of the Emergency Period, without a deductible or other cost-sharing, and without imposition of prior authorization or other medical management requirements, the following:

1. In vitro diagnostic products for the detection of SARS-CoV-2 (the virus that causes COVID-19) or the diagnosis of COVID-19 that are approved, cleared or authorized under specified sections of the Food, Drug and Cosmetic Act (FDCA), and the administration thereof
2. Items and services furnished to an individual during health care provider office visits (including both in-person and telehealth visits), urgent care center visits, or emergency room visits, that result in an order for or administration of such a COVID-19 test, but only to the extent such services relate to furnishing or administering the test or evaluating a patient to determine the need for the test.

The Act updates the description of the tests to which this coverage mandate applies to include additional COVID-19 tests that have **not** been approved byFDA, but which FDA has allowed to be used under alternative regulatory mechanisms. Specifically, the language now also includes within the covered tests any COVID-19 tests for which the developer has requested, or intends to request, an emergency use authorization fromFDA, tests developed in and authorized by a state that has notified HHS of its intention to review tests to diagnose COVID-19, and other tests that the HHS Secretary (Secretary) determines appropriate in guidance. This change also applies with respect to coverage of such testing and related services for uninsured individuals provided under the Families First Act.

Additionally, section 3202 of the Act specifies that these plans “shall reimburse the provider of the diagnostic testing” at the rate negotiated between the plan and the provider, if the provider and plan had such a negotiated rate in effect before January 27, 2020, the date the public health emergency was declared by the Secretary to have begun, or at the “cash price

[4] On January 31, 2020, Secretary Azar signed a determination that a nationwide public health emergency under section 319 of the Public Health Service Act exists, and has existed since January 27, 2020. *See* https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

for such service as listed by the provider on a public internet website" unless the plan and the provider negotiate a lower rate. Providers of COVID-19 diagnostic tests are required to publish their cash prices for such a test on the provider's public internet website, with a civil monetary penalty of up to $300 per day payable for non-compliance.

Rapid coverage of preventive services and vaccines for coronavirus (Sec. 3203)

Section 3203 of the Act requires commercial health plans and insurers to cover a COVID-19 vaccine (once developed) and certain other preventative items or services. Specifically, coverage is required for an immunization that has a recommendation from the Advisory Committee on Immunization Practices of the CDC with respect to the individual involved, and for evidence-based items or services intended to prevent or mitigate COVID-19 with a rating of A or B in the recommendations of the United States Preventative Services Task Force. Coverage is required within 15 business days following the applicable recommendation.

Support for health care providers

Supplemental awards for health centers (Sec. 3211)

The Act amends the Public Health Service Act's section regarding authorization of appropriations (42 U.S.C. 254b(r)) to provide for appropriations of $1,320,000,000 for fiscal year (FY) 2020 for supplemental awards related to the detection of SARS-CoV-2 or the prevention, diagnosis, and treatment of COVID-19. Amounts appropriated under this section must meet the requirements under the Public Health Service Act related to health care facilities providing primary health care.

Telehealth Network and Telehealth Resource Centers Grant Programs (Sec. 3212)

The Act provides $29 million for each FY from 2021 through 2025 for Health Resources and Services Administration (HRSA) grant programs that promote the use of telehealth technologies for health care delivery, education, and health information services. At least 50% of the funds awarded must be for projects in rural areas. Finally, the Secretary must report to Congress on the activities and outcomes of these grant programs no later than four years after enactment of the Act and every five years thereafter.

Rural health care services outreach, rural health network development, and small health care provider quality improvement grant programs (Sec. 3213)

The Act amends the Public Health Service Act section related to rural health care services to provide for grants to expand access to, coordinate, and improve the quality of **basic** health care services rather than **essential** health care services. Notably, the Act increases the time period of such grants from three to five years. It also revises grant eligibility requirements to remove the requirement that an eligible entity be a "rural public or rural nonprofit private entity," and instead requires that eligible entities just have "demonstrated experience serving, or the capacity to serve rural underserved populations." The Act also revises language throughout to focus grants on "the **rural underserved populations** in the local community or region" rather than just "the local community or region." With respect to rural health care services outreach grants, the Act adds language to note that grants should support services that improve and expand the delivery of health care services through community engagement and evidence-based or innovative, evidence-informed models. Further, with respect to small health care provider quality improvement grants, the Act indicates that quality improvement activities include increasing care coordination, enhancing chronic disease management, and improving patient health outcomes. The Act provides $79,500,000 per year for FYs 2021 through 2025 for rural health care services outreach, rural health network development, and small health care provider quality improvement grant programs. The Act also imposes certain reporting requirements regarding the impact of projects funded under the grants on the health status of rural residents with chronic conditions.

United States Public Health Service modernization (Sec. 3214)

The Act clarifies certain sections of the Public Health Service Act to confirm that the Regular Corps and the Ready Reserve Corps are available for service in time of national emergency, including a public health emergency.

Limitation on liability for volunteer health care professionals during COVID-19 emergency response (Sec. 3215)

The Act creates a "good Samaritan" protection for certain health care professionals treating COVID-19 patients. Specifically, the Act provides that there shall be no liability under federal or state law for any harm caused by the act or omission of a licensed, registered or certified health care professional in the course of providing **volunteer** health care services during the duration of the COVID-19 public health emergency. The limitation on liability extends only to health care services provided within the scope of the health professional's license and in the good faith belief that the individual being treated needed the services.

The term “health care services” means services relating to the diagnosis, prevention, or treatment of COVID-19 or where the assessment or care of a person relates to an actual or suspected case of COVID-19. The term “harm” is defined and includes physical, nonphysical, economic, and noneconomic losses.

The limitation on liability does not apply where the act or omission that caused the harm constitutes willful or criminal misconduct, gross negligence, reckless misconduct or a “conscious flagrant indifference to the rights or safety of the person harmed,” or where the health care professional was under the influence of alcohol or drugs.

The protection is limited to volunteer services, that is, those health care services for which the health professional does not receive compensation or any other thing of value. The volunteer may receive travel reimbursement and payments in cash or kind to cover room and board if the services are rendered more than 75 miles from the volunteer’s principal place of residence. The limitation on liability is in effect only for the duration of the public health emergency.

Flexibility for members of National Health Service Corps during Emergency Period (Sec. 3216)

The Act clarifies that during the Emergency Period, the Secretary may assign members of the National Health Service Corps, with such members’ voluntary agreement, to provide health services to respond to the COVID-19 emergency, as determined necessary by the Secretary. Notably, such assignments must be within a reasonable distance of the site to which such members were originally assigned and must not exceed the total number of hours required of such members prior to the enactment of the Act.

Miscellaneous provisions

Confidentiality and disclosure or records relating to substance abuse disorder (Sec. 3221)

The Act contains several clarifying provisions related to the records of substance use disorder patients. As an initial matter, the Act replaces the term “substance abuse” with the term “substance use disorder,” conforming to current clinical terminology. In addition, the Act clarifies that the contents of a substance use disorder patient record may be used or disclosed with the prior written consent of the patient, but once such consent is obtained, the contents of the record may be used or disclosed in accordance with Health Insurance Portability and Accountability Act (HIPAA) regulations. The consent will apply to all future uses or disclosures for purposes of treatment, payment, and health care operations until such time as the patient revokes the consent. The Act aligns implementing regulations at 42 C.F.R. Part 2 (Part 2) with HIPAA by incorporating several HIPAA requirements to apply to Part 2 programs. Most notably, the Act indicates that the HIPAA Breach Notification Rule shall apply to Part 2 programs with respect to breaches of records protected under Part 2. Previously, Part 2 did not contain any breach notification provisions.

In addition, the Act elaborates on the use of substance abuse disorder records in civil, criminal or administrative proceedings. Specifically, such records, or testimony relaying the content of such records, may not (1) be disclosed or used against the patient in any criminal or civil action, (2) form part of the record for decision or otherwise be taken into account in any proceeding, (3 be used for a law enforcement purpose or to conduct a law enforcement investigation, or (4) be used in any application for a warrant. These restrictions on use apply to any civil, criminal, administrative, or legislative proceeding conducted by any governmental authority, whether state, federal, or local, unless such use is consented to by the patient or authorized by court order.

Penalties for violation of the confidentiality rules include monetary penalties as set forth in 42 U.S.C. 1320d-5 (general penalties for failure to comply with requirements and standards) as well as civil money penalties and imprisonment as set forth in 42 U.S.C. 1320d-6 (knowing, wrongful disclosure of individually identifiable health information).

The Act further delineates broad antidiscrimination principles. Of note, no entity may discriminate against an individual on the basis of information pursuant to an inadvertent or intentional disclosure of a substance use disorder record with regard to admission to, access to, or treatment for health care; hiring, firing or terms of employment, or receipt of worker’s

compensation; the sale, rental, or continued rental of housing; access to state, federal, or local courts and access to services and benefits provided by federal, state, or local governments.

Nutrition services transfer criteria, home delivered nutrition services waiver, and dietary guidelines waiver (Sec. 3222)

The Act provides that a state agency or an area agency on aging may transfer up to 100 percent of the funds received by the state agency or area agency for nutrition services under the Older Americans Act, provided that the applicable state considers such transfer appropriate to meet the needs of the state or area served. Further, the Act allows the U.S. Assistant Secretary for Aging to waive the provision of nutritional services because of social distancing restrictions and to waive the requirements that meals provided under the Older Americans Act comply with the most recent Dietary Guidelines for Americans.

Continuity of service and opportunities for participants in community service activities under Title V of the Older Americans Act of 1965 (Sec. 3223)

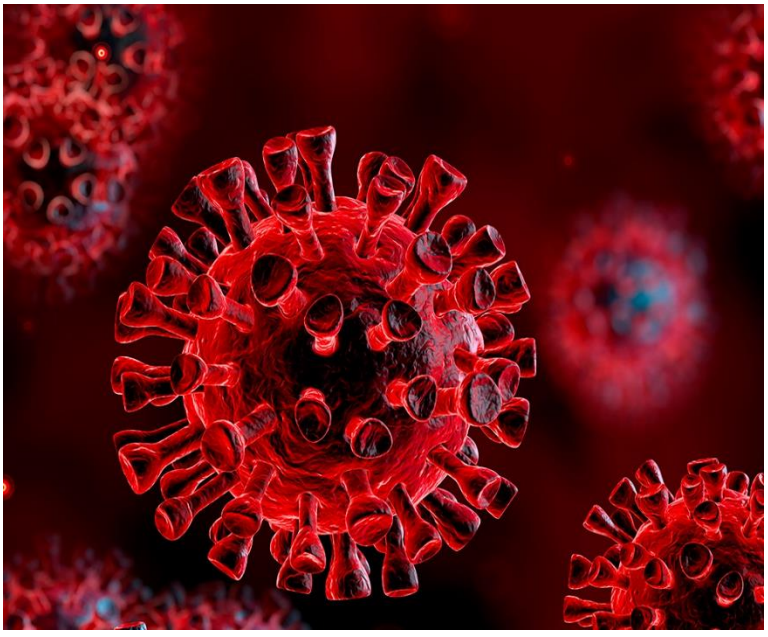
To ensure continuity of service and opportunities for participants in community service activities under Title V of the Older Americans Act, the Secretary of Labor may allow participants in projects under the Older Americans Act, as of March 1, 2020, to extend their participation if the Secretary of Labor determines such extension is appropriate due to the effects of the COVID–19 public health emergency. Additionally, the Secretary of Labor may increase the average participation cap for eligible individuals applicable to grantees and may increase the amount available to pay the authorized administrative costs for a project if the Secretary of Labor determines that these actions are appropriate due to the effects of the COVID–19 public health emergency.

Guidance on protected health information (Sec. 3224)

The Act requires HHS to issue guidance on the sharing of patients' protected health information (PHI) and complying with HIPAA during the COVID-19 public health emergency within 180 days of enactment. Although the Act does not specify what the guidance should be, even before passage of the Act, HHS through the Office of Civil Rights (OCR) provided several bulletins related to the "HIPAA flexibilities" made available by OCR, including, for example, a bulletin that empowers first responders and others who receive PHI about individuals who have tested positive or been exposed to COVID-19 to help keep both first responders and the public safe. Please see our previous client alert, "In face of COVID-19 emergency, HHS mobilizes authority to waive requirements binding health care providers under section 1135", for additional information on HIPAA waivers.

Reauthorization of Healthy Start Program for Infants (Sec. 3225)

The Act includes various amendments to the Healthy State Program for Infants that reauthorize and update the text of this section, including revising the applicable fiscal years (FYs 2021 through 2025) for fund appropriations and updating evaluation criteria for projects under the program.



Importance of the blood supply awareness campaign (Sec. 3226)

The Act requires the Secretary to carry out a national campaign to improve awareness of, and support outreach to the public and health care providers about, the importance and safety of blood donation and the need for donations for the blood supply during the COVID–19 public health emergency.

Innovation

Removing the cap on OTA during public health emergencies (Sec. 3301)

Section 3301 of the Act allows the Biomedical Advanced Research and Development Authority (BARDA) to more easily partner with the private sector on research and development by removing the cap on other transaction authority (OTA) during a public health emergency. Under this modification, ongoing OTA research and development projects may not be terminated solely due to the expiration of the public health emergency. This section also requires a report to be submitted to Congress regarding the use of OTA funds, including any outcomes, benefits, and risks associated with the use of the funds, and a description of the reasons for exercising OTA authority.

Priority zoonotic animal drugs (Sec. 3302)

Section 3302 of the Act provides breakthrough therapy designations for animal drugs that have demonstrated preliminary clinical evidence that the new drug, alone or in combination with one or more other animal drugs, has the potential to prevent or treat an animal disease that also has the potential to cause serious adverse health consequences for, or serious or life-threatening diseases in, humans. Actions to expedite the development and review may include: (1) taking steps to ensure that the design of clinical trials is as efficient as practicable, when scientifically appropriate, such as by utilizing novel trial designs or drug development tools (including biomarkers) that may reduce the number of animals needed for studies; (2) providing timely advice to, and interactive communication with, the sponsor (which may include meetings with the sponsor and review team) regarding the development of the new animal drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; (3) involving senior managers and review staff with experience in zoonotic or vector-borne disease to facilitate collaborative, cross-disciplinary review, including, as appropriate, across agency centers; and (4) implementing additional administrative or process enhancements, as necessary, to facilitate an efficient review and development program.

As with other priority requests, this new breakthrough pathway may be made concurrently with, or at any time after, the opening of an investigational new animal drug file or the filing of an application. FDA will have 60 days to respond.

Health care workforce

Reauthorization of health professions workforce programs (Sec. 3401)

The Act amends the Public Health Services Act to reauthorize appropriations to provide funds for:

- Health profession education programs for under-represented minorities ($23,711,000 for each of FYs 2021 through 2025).
- Scholarships for health profession students from disadvantaged backgrounds with financial needs ($51,470,000 for each of FYs 2021 through 2025).
- Repaying educational loans of faculty from disadvantaged backgrounds at health profession schools and for fellowships for under-represented minorities at health profession schools ($1,190,000 for each of FYs 2021 through 2025).
- Facilitating the education of health profession students from disadvantaged backgrounds ($15,000,000 for each of FYs 2021 through 2025).
- Supporting and developing primary care training programs ($48,924,000 for each of FYs 2021 through 2025) and dental training programs ($28,531,000 for each of FYs 2021 through 2025).
- Entities that operate programs designed to recruit, train and retain quality health practitioners in medically underserved (especially rural) populations ($41,250,000 for each of FYs 2021 through 2025).
- The National Center for Health Workforce Analysis ($5,663,000 for each of FYs 2021 through 2025).
- Increasing the size and quality of the public health workforce to meet national, state and local health needs ($17,000,000 for each of FYs 2021 through 2025).
- Repaying educational loans of pediatric health professionals serving medically underserved populations (such sums as may be necessary for each of FYs 2021 through 2025).

Health workforce coordination (Sec. 3402)

As the COVID-19 pandemic continues to develop, the United States is beginning to face shortages of health care workers in certain areas. The Act directs the Secretary to identify actions necessary to address any recognized gaps between health care workforce development program outputs and projected health care workforce needs. The Secretary must, within one year of the Act's passage, include those findings in a comprehensive plan for evaluating and improving the efficacy of health care workforce development programs. The Secretary will subsequently deliver, no later than two years after the Act's passage, a report describing the plan and any actions taken to implement the plan.

Education and training relating to geriatrics (Sec. 3403)

The Act amends the Public Health Services Act to reauthorize appropriations to provide funds for education and training relating to geriatrics ($40,737,000 for each of FYs 2021 through 2025).

Nursing workforce development (Sec. 3404)

The Act amends the Public Health Services Act to reauthorize appropriations to provide funds for the education, training, recruitment, distribution, and retention of nursing professionals ($137,837,000 for each of FYs 2021 through 2025) as well as funds for making and repaying educational loans for nursing students ($117,135,000 for each of FYs 2021 through 2025).

Finance Committee

Exemption for telehealth services (Sec. 3701)

Telehealth services are generally considered eligible expenses for high-deductible health plans (HDHP) with a health savings account (HSA), although these expenses cannot be covered by the HDHP until the patient meets a minimum deductible. The Act creates a safe harbor to allow HDHPs with an HSA to cover telehealth services before the plan's deductible is satisfied without disqualifying a patient from participating in an HSA. This is a temporary provision and only applies to plan years beginning on or before December 31, 2021.

Inclusion of certain over-the-counter medical products as qualified medical expenses (Sec. 3702)

The Act allows individuals to use funds in Health Savings Accounts and Flexible Spending Accounts for the purchase of menstrual care products, applicable to amounts paid after December 31, 2019.

Increasing Medicare telehealth flexibilities during Emergency Period (Sec. 3703)

The Act expands the temporary waiver of certain Medicare restrictions in order to permit physicians and other health care professionals to provide telehealth services to beneficiaries who the professional had not treated in the past three years. In early March, section 3703 of the Social Security Act (42 U.S.C. sections 1320b-5) was amended to temporarily waive certain Medicare restrictions with respect to telehealth services to respond to the COVID-19 public health crisis. However, the temporary waiver only extended to relationships in which the health care provider had previously treated that patient within the past three years. HHS previously announced that it would not conduct audits to ensure that such a prior relationship existed for claims submitted during the Emergency Period. The Act now removes this requirement entirely, expanding the

access of beneficiaries to use a greater number of telehealth providers during the COVID-19 Emergency Period. For more information on HHS' comprehensive telehealth waivers, see our "Telehealth: COVID-19 Legal Developments" client alert.

Enhancing Medicare telehealth services for Federally Qualified Health Centers and Rural Health Clinics during Emergency Period (Sec. 3704)

The Act permits Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) to serve as "distant sites" in providing telehealth services to beneficiaries during the COVID-19 Emergency Period. This means physicians and other healthcare professionals are now permitted to provide telehealth services from FQHCs and RHCs to Medicare beneficiaries in their homes. The Act also states that Medicare will provide reimbursement for telehealth services "based on payment rates that are similar to the national average payment rates for comparable telehealth services" under the Medicare Physician Fee Schedule. Finally, subsection (m)(8) excludes costs associated with telehealth services from the FQHC prospective payment system and from the RHC all-inclusive rate calculation.

Temporary waiver of requirement for face-to-face visits between home dialysis patients and physicians (Sec. 3705)
Under the Bipartisan Budget Act of 2018, an individual with end stage renal disease (ESRD) receiving home dialysis may choose to receive monthly clinical assessments via telehealth, but only if the individual receives a face-to-face clinical assessment at least monthly during the initial three months of home dialysis, and then at least once every three consecutive months thereafter.

The Act authorizes the Secretary to waive these face-to-face assessment requirements during the COVID-19 Emergency Period, which will permit patients receiving home dialysis to observe social distancing requirements and still continue to receive dialysis at home during this period.

Use of telehealth to conduct face-to-face encounters prior to recertification of eligibility for hospice care during Emergency Period (Sec. 3706)
Hospices participating in the Medicare program are required to conduct face-to-face encounters with patients prior to the hospice patient's 180th-day recertification (third benefit period), and every subsequent recertification, to certify the patient's eligibility for hospice care. Under prior law, hospice physicians and nurse practitioners could not use telehealth to conduct face-to-face encounters. The Act permits qualified hospice physicians and nurse practitioners to use telehealth (as determined appropriate by the Secretary) to conduct these encounters during the Emergency Period.

Encouraging use of telecommunications systems for home health services furnished during Emergency Period (Sec. 3707)

Medicare certified home health agencies (HHAs) are permitted to use telehealth under limited circumstances. For home health services furnished during the Emergency Period, the Act directs the Secretary to consider ways "to encourage" the

use of telehealth for home care services, including for remote patient monitoring as described at 42 C.F.R. section 409.46(e)[5] and other communications or monitoring services, consistent with the patient's plan of care. The Act directs the Secretary to clarify guidance and conduct outreach on telehealth, as appropriate. Note that the provision does not authorize additional reimbursement for the use of telehealth by HHAs.

Improving care planning for Medicare home health services (Sec. 3708)

Under prior law, only physicians could certify a patient as eligible for Medicare home health services. In a change that the home healthy industry has been seeking for over a decade, the Act permits nurse practitioners (NPs), physician assistants (PAs) and clinical nurse specialists (CNSs) to certify eligibility for home health (including conducting and documenting the required face-to-face encounter), and to establish and periodically review the patient's plan of care.[6] The expansion of non-physician extenders to certify home health services applies under Medicaid home health services to the same extent and in the same manner as under the Medicare statute and implementing regulations. Note that the expansion of the ability of non-physician extenders to order and certify home health services is not limited to the provision of services during the Emergency Period.

Adjustment of sequestration (Sec. 3709)

Under the Budget Control Act of 2011, as subsequently amended, Medicare provider and plan payments are subject to a 2 percent across-the-board "sequestration" reduction through FY 2029. The Act temporarily suspends the sequestration requirement during the period of May 1, 2020 through December 31, 2020, which has the effect of providing an immediate payment boost to providers and plans. To avoid "worsening Medicare's long-term financial outlook,"[7] the Act extends the current Medicare sequester requirement through FY 2030.[8]

Medicare hospital inpatient prospective payment system add-on payment for COVID–19 patients during Emergency Period (Sec. 3710)

In recognition of the substantial resources devoted to treating hospitalized COVID-19 cases, and the increased lengths of stay frequently associated with those patients, the Act provides a 20 percent boost to Medicare inpatient prospective payment system (IPPS) payments for COVID-19 cases. Specifically, for discharges during the Emergency Period (i.e., on or after January 27, 2020 until the Emergency Period is declared over),[9] the Secretary must increase by 20 percent the weighting factor that would apply to the diagnosis-related group (DRG) to which the discharge is assigned. The Secretary must identify impacted discharges through the use of diagnosis codes, condition codes, or other such means, and the policy may be implemented through program instruction or otherwise.[10] Any such adjustments will not be taken into account for budget neutrality purposes. The Secretary may implement this policy by program instruction or otherwise.

Increasing access to post-acute care during Emergency Period (Sec. 3711)

To facilitate the transfer of non-COVID-19 cases out of acute care beds to alternative treatment facilities, the Act eases a variety of Medicare requirements applicable to post-acute facilities during the COVID-19 Emergency Period. Inpatient Rehabilitation Facilities (IRFs) are relieved of the requirement that a beneficiary be reasonably expected to actively participate in, and benefit from, an intensive rehabilitation therapy. Accordingly, the Act waives the three-hour rule, which

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[5] Remote patient monitoring is defined "as the collection of physiologic data (for example, ECG, blood pressure, or glucose monitoring) digitally stored and transmitted by the patient or caregiver or both to the home health agency. 42 C.F.R. 409.46(e). Under the regulation, if remote patient monitoring is used by the home health agency to augment the care planning process, the costs of the equipment, set-up, and service related to this system are allowable only as administrative costs. Visits to a beneficiary's home for the sole purpose of supplying, connecting, or training the patient on the remote patient monitoring equipment, without the provision of a skilled service are not separately billable.

[6] The Act directs the Secretary to issue regulations to implement these amendments, which must become effective within six months of enactment. The Secretary is required to issue an interim final rule, if necessary, to comply with the required date.

[7] *See* https://www.help.senate.gov/imo/media/doc/CARES%20Section-by-Section%20FINAL.PDF, page 22.

[8] Note that for FY 2030, the Medicare savings are "front loaded," with a 4 percent reduction imposed during the first six months of the fiscal year and no reduction is applied during the second half.

[9] As noted, on January 31, 2020, Secretary Azar announced that the COVID-19 public health emergency has existed since January 27, 2020 (the "Emergency Period"). *See* https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

[10] The CDC has announced implementation of a new International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis code, U07.1, COVID-19, effective April 1, 2020. The Centers for Medicare and Medicaid Services (CMS) recently released the MS-DRG assignments for discharges reporting diagnosis code U07.1; *see* https://edit.cms.gov/files/document/icd-10-ms-drgs-version-371-r1-effective-april-1-2020-updated-march-23-2020.pdf.

ordinarily requires that a beneficiary be expected to participate in at least three hours of intensive rehabilitation at least five days per week to be admitted to an IRF.

Long Term Care Hospitals (LTCHs) will not lose their designation (and payment status) as an LTCH if more than 50 percent of the LTCH's cases are less intensive and do not meet the standard criteria for LTCH admission. In addition, LTCHs will not be subject to the lower site-neutral payment methodology for Medicare patients not meeting the LTCH admission criteria. Under existing law, LTCHs are reimbursed at the prospective payment rate applicable to LTCHs only if, immediately preceding the patient's LTCH admission, the patient was discharged from a short-term acute care hospital and either the patient's stay included at least three days in an intensive care unit (ICU) or coronary care unit (CCU), or the patient was assigned to a Medicare severity long-term care diagnosis-related group for cases receiving at least 96 hours of ventilator services in the LTCH. The LTCH admission criteria are waived for a discharge if the admission occurs during the COVID-19 Emergency Period and is in response to the COVID-19 emergency.

Revising Medicare payment rates for durable medical equipment program through duration of Emergency Period (Sec. 3712)

CMS previously established[11] a complex framework for updating the Medicare durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) fee schedule during gaps in the competitive bidding program (CBP). This policy adjusts DMEPOS fee schedule amounts based on previous CBP pricing, depending on the geographic area in which the items and services are furnished. The framework included temporary blended rates for items and services furnished through 2020 in rural areas or areas not located in the contiguous United States; the transition rates are based on a blend of 50 percent of rates that are adjusted based on CBP pricing information and 50 percent of unadjusted amounts.

The Act directs CMS to continue to apply this 50/50 blended transition rate through 2020 and through the duration of the Emergency Period, if longer. Furthermore, the Act establishes a new adjusted rate for DMEPOS furnished in non-rural and noncontiguous areas. Specifically, rather than being paid at a 100 percent adjusted payment amount, the Act establishes a new blended rate of a 75percent adjusted rate and a 25 percent unadjusted rate for dates of service from March 6, 2020, through the remainder of the Emergency Period.

Coverage of the COVID-19 vaccine under Part B of the Medicare Program without any cost-sharing (Sec. 3713)

The Act expands the definition of Part B-covered medical and other health services to include the COVID-19 vaccine, when developed, and its administration. The Act further provides that the Part B deductible shall not apply to such services. Similarly, the COVID-19 vaccine and its administration is added to the list of benefits to be provided under Medicare Advantage without cost sharing.

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 (Sec. 3714)

Section 3714 of the Act requires that, during the Emergency Period, Medicare Part D prescription drug and MA-PD plans must permit enrollees to obtain up to a 90-day supply of Part D drugs covered under their plan, to the extent that such quantity has been prescribed to them, except where inconsistent with a safety edit under the plan. Such supply must be available in a single fill or refill, at the option of the enrollee. This requirement has the practical effect of allowing patients to obtain a larger supply of prescription drugs at one time, reducing the need for additional in-person refills and improving access to necessary drugs for these individuals during the COVID-19 pandemic. The Secretary may implement this requirement by program instruction or otherwise.

In previous guidance CMS, has noted that opioids, benzodiazepines, and stimulants are examples of drugs that may be subject to safety edits. Notably, the Act does not state whether a plan may require beneficiaries to pay higher cost sharing if they obtain a 90-day supply at a retail pharmacy instead of a mail order pharmacy, as permitted under current CMS regulations at 42 C.F.R. section 423.120(a)(10). Similarly, CMS will presumably need to clarify whether this new provision

[11] 83 Fed. Reg. 56,922 (Nov. 14, 2018).

supersedes current CMS regulations at 42 C.F.R. sections 423.154 requiring that solid oral doses of most brand-name drugs for residents of certain types of long term care facilities be dispensed in supplies of no more than 14 days.

Providing home and community-based services in acute care hospitals (Sec. 3715)

The Act specifies that certain home and community-based services may be provided in an acute care hospital setting under designated state Medicaid waivers programs and demonstration projects. To qualify, the care or services must be: (1) identified in an individual's plan of care; (2) provided to meet the needs of the individual that are not met through the provision of hospital services; (3) designed to ensure smooth transitions between acute care settings and home and community based settings; and (4) intended to preserve the individual's functional abilities. Such services may not be a substitute for services that the hospital is obligated to provide through its conditions of participation or under federal or state law or other applicable requirements.

Clarification regarding uninsured individuals (Sec. 3716)

The Act clarifies the Families First Act to allow "non-expansion" states to offer to certain uninsured individuals COVID-19 testing and related services with no cost sharing. It also clarifies eligibility for coverage under this option for certain other populations with limited Medicaid coverage (e.g., certain individuals enrolled for treatment of tuberculosis, breast cancer, or cervical cancer).

Clarification regarding coverage of COVID-19 testing products (Sec. 3717)

The Act clarifies that laboratory and x-ray services for which payment may be made under the Medicaid program are those that are approved, cleared or authorized under pertinent provisions of the FDCA.

Amendments relating to reporting requirements with respect to clinical diagnostic laboratory tests (Sec. 3718)

The Act extends for one year, to January 1, 2022, the start date for reporting of private sector payment rates for clinical diagnostic lab tests that are not advanced diagnostic lab tests, and revises the phase-in of reductions in payment amounts.

Expansion of the Medicare hospital accelerated payment program during the COVID-19 public health emergency (Sec. 3719)

The Act expands the Secretary's existing authority to make accelerated Medicare payments to certain acute care hospitals that have "significant cash flow problems resulting from operations of its intermediary or from unusual circumstances of the hospital's operation." During the Emergency Period, the hospital accelerated payment program is expanded to children's hospitals, cancer hospitals and critical access hospitals (CAHs). "Subject to appropriate safeguards against fraud, waste, and abuse," the Secretary must, upon request of a qualified hospital, provide up to a six-month lump sum or periodic payment to the hospital. Hospitals can request up to 100 percent of the payment that would otherwise be made, or, in the case of CAHs, 12 percent of payments. Hospitals would have up to 120 days before claims are offset to recoup the accelerated payment, and at least 12 months from the date of the first accelerated payment before being required to pay the outstanding balance in full.[12]

Delaying requirements for enhanced FMAP to enable state legislation necessary for compliance (Sec. 3720)

The Families First Act provided a temporary 6.2 percentage point increase to each qualifying state and territory's Medicaid Federal Medical Assistance Percentage (FMAP), effective January 1, 2020 and extending through the last day of the calendar quarter in which the Emergency Period terminates. In order to qualify, states were required to meet maintenance of effort requirements, including that the state did not charge premiums that exceed those that were in place as of January 1, 2020.

To give states additional time to enact conforming legislation, the Act provides that during the 30-day period beginning on the date of enactment, a state will not be considered ineligible for the FMAP increase on the basis that the state imposes a premium that violates this requirement.

[12] Note that on March 28, 2020, CMS announced that it is expanding the accelerated payment program to "all Medicare providers throughout the country during the public health emergency related to COVID-19," including hospitals, doctors, durable medical equipment suppliers and other Medicare Part A and Part B providers and suppliers. To qualify, the provider or supplier must: (1) have billed Medicare for claims within the 180 days immediately prior to the date of signature on the provider's or 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. For additional details, see https://www.cms.gov/newsroom/press-releases/trump-administration-provides-financial-relief-medicare-providers.

Health and Human Services extenders (Sec. 3801 – 3832)

Section 3813 of the Act eliminates a scheduled $4 billion cut to Medicaid disproportionate share hospital (DSH) payments for FY 2020, reduces from $8 billion to $4 billion the cut applicable for FY 2021, and delays implementation of the FY 2021 reduction until December 1, 2020.

The Act also extends through November 30, 2020 a number of Medicare, Medicaid, and public health programs and policies scheduled to expire on May 22, 2020, including:

- The work geographic index floor under the Medicare physician fee schedule (Sec. 3801)
- Funding for quality measure development and related activities (Sec. 3802)
- Outreach and education assistance programs for low-income beneficiaries (Sec. 3803)
- The Money Follows the Person rebalancing demonstration program (Sec. 3811)
- Medicaid spousal impoverishment protections for recipients of home- and community-based services (Sec. 3812)
- The Medicaid Community Mental Health Services demonstration (which is also extended to two additional states) (Sec. 3814)
- Health professions workforce demonstration programs (Sec. 3823)
- The Temporary Assistance for Needy Families program (Sec. 3824)
- The Community Health Center Fund, the National Health Service Corps, and teaching health centers that operate graduate medical education programs (Sec. 3831)
- The Special Diabetes Program for Type I Diabetes and the Special Diabetes Program for Indians (Sec. 3832)

Over-the-Counter Drugs

OTC drug review

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

The Act creates a new section 505G in the FDCA and provides for a comprehensive update of FDA's over-the-counter (OTC) drug review process, which has been ongoing for almost 50 years since 1972. Section 505G provides for a new administrative order framework that FDA can utilize to expedite the OTC drug review process rather than having to rely on notice-and-comment rulemaking, which can take years to complete. Under this new framework, FDA can declare an administrative order stating that a drug does not require an approval under section 505 of the FDCA if it is (1) not a drug that requires a healthcare practitioner's supervision for safe use, and (2) generally recognized as safe and effective. The Act also provides a formal dispute resolution and hearing process for drug sponsors who are affected by such administrative orders. Importantly, this new section 505G is not limited in application to the COVID-19 Emergency Period.

Finally, to incentivize innovation, companies that request certain types of administrative orders and are issued such orders will be granted 18 months of marketing exclusivity for the drug. This exclusivity will be granted only for new active ingredients that were not previously used in lawful OTC drugs, or for new conditions of use for which the company sponsored or conducted (or has the exclusive right of reference to) new human data studies. It appears that section 3851 may expedite and streamline FDA's OTC drug review process, and may also result in new OTC drugs being developed, given the new framework and exclusivity provided in this section.

Misbranding (Sec. 3852)

Section 3852 of the Act adds new provisions in the FDCA to state explicitly that OTC drugs that (1) do not comply with OTC monographs, and (2) are manufactured at facilities that have not paid the newly required fees under the Act are misbranded. Even before the Act, FDA considered OTC drugs that do not comply with OTC monographs to be misbranded or unapproved new drugs, depending on the exact nature of non-compliance. However, this provision simplifies FDA's enforcement process for misbranding charges against products that do not comply with monographs; for example, FDA previously needed to show how a drug is misbranded (e.g., lack of adequate directions for use), but now FDA can cite this new provision and simply state that the drug does not comply with the applicable monograph.

Drugs excluded from OTC review (Sec. 3853)

Section 3853 states that the Act's requirements will not apply to any homeopathic OTC drugs that were excluded from FDA's 1972 OTC drug review in response to the American Institute of Homeopathy's request to have homeopathic drugs be excluded from the OTC drug review process. This decision likely reflects FDA's prior stance on homeopathic drugs, which FDA previously excluded due to "the uniqueness of homeopathic medicines," and has stated that FDA would "review them as a separate category at a later time after the present OTC drug review is complete."[13]

Treatment of Sunscreen Innovation Act (Sec. 3854)

Section 3854 states that OTC sunscreen drug sponsors with pending reviews of proposed orders may transition the pending sunscreen drug application to a request under the new OTC drug review process described in section 3851 of the Act. This request must be submitted within 180 days of the enactment of the Act; if received by FDA within the required timeframe, the application will be deemed to have been accepted for review under the OTC drug review process. Sponsors of proposed orders that wish to transition to the new review process should do so quickly, as the request must be submitted by September 23, 2020 (180 days from March 27, 2020).

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

Section 3855 includes a provision that requires the Secretary to provide a report annually on the progress that FDA makes on its evaluation of the cough and cold monograph for children under the age of six, or if needed, on the progress FDA is making on revising the cough and cold monograph to address children under the age of six. This provision will continue to be in effect until the Secretary submits a letter stating that the Secretary has completed its review of the cough and cold monograph for such children. It appears that this provision is intended to apply pressure on FDA to expedite its review of the cough and cold monograph, and it is possible that we will see the agency focusing more resources on review of the cough and cold monograph in the future.

User fees

Fees relating to over-the-counter drugs (Secs. 3861 and 3862)

Section 3861 states that the user fees that are to be collected under section 3862 are to be used for FDA's regulation of OTC monograph drugs, including review of OTC monographs and inspection of facilities associated with OTC drugs (e.g., drug manufacturing facilities).

Section 3862 then establishes a new fee for OTC drug facilities and OTC monograph order requests, which FDA must dedicate to activities that are associated with OTC monograph drugs, such as review and evaluation of OTC monographs, inspections of OTC drug facilities, monitoring of clinical and other studies that are carried out in relation to OTC drugs, developing and reviewing safety information, and developing an improved adverse event reporting system. The OTC drug facility fee will become applicable beginning fiscal year 2021 – any person that owns a facility on December 31 of the fiscal year or at any time during the preceding 12-month period will be required to pay this fee. The OTC monograph order request fee will be due on the day when the request is submitted to FDA, and may be $100,000 or $500,000 depending on the type of request being made to FDA.

[13] 37 Fed. Reg. 9466.

Emergency appropriations for coronavirus health response and agency operations

Division B of the Act contains three key appropriations provisions related to funding health care provider responses to the COVID-19 pandemic: (1) $100 billion for eligible health care providers, (2) $3.5 billion in grants to support child care for health care sector employees, and (3) $200 million to CMS for program management. Each category of funding is described further below.

$100 billion for "eligible health care providers"

Press reports surrounding the legislation that eventually became the Act frequently suggested that the Act provides $100 billion in grants "**for hospitals**" to help combat COVID-19. The actual language of the Act is much broader, appropriating $100 billion to the Secretary "for necessary expenses to reimburse, through grants or other mechanisms, **eligible health care providers** for health care related expenses or lost revenues that are attributable to coronavirus[.]" The Act defines "eligible health care providers" broadly as "public entities, Medicare or Medicaid enrolled suppliers and providers, and such for-profit entities and not-for-profit entities not otherwise described in this proviso as the Secretary may specify . . . that provide diagnoses, testing, or care for individuals with possible or actual cases of COVID-19[.]" The Act states that such funds "shall be available for building or construction of temporary structures, leasing of properties, medical supplies and equipment including personal protective equipment and testing supplies, increased workforce and trainings, emergency operation centers, retrofitting facilities, and surge capacity[.]" However, such funds "may not be used to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse[.]"

Those seeking such funds must submit an application to the Secretary "that includes a statement justifying the need of the provider for the payment[.]" The Secretary, in turn, must "review applications and make payments" on a "rolling basis." Payments may include "pre-payment, prospective payment, or retrospective payment, as determined appropriate by the Secretary[.]"

The Secretary has not yet announced details regarding how this new program will be administered. In the meantime, those businesses that believe they may qualify are well-advised to seek legal counsel in order to best position themselves to receive such funds on a timely basis.

$3.5 billion in grants to support child care for "health care sector employees," among others

An effective pandemic response requires that employees in the health care sector show up for work. Congress recognized that fact when it created new paid-leave requirements in the Families First Act, giving covered employers of health care providers and emergency responders the discretion to exclude such employees from the new paid-leave provisions.[14] The personal sacrifice that employees in the health care sector are being asked to make is made all the more difficult by the recent closure of day care centers across the US as part of states' efforts to combat the spread of COVID-19.

In a provision that has received little press, Title VIII within Division B of the Act provides $3.5 billion in grants to states to support child care. Importantly, the Act specifically provides that states are authorized to use such grant funds "to provide child care assistance to health care sector employees, emergency responders, sanitation workers, and other workers deemed essential during the response to coronavirus by public officials, without regard to [certain] income eligibility requirements" provided elsewhere in statute. While states' receipt and implementation of these grants is an integral part of this funding initiative, this well-intentioned appropriation recognizes the reality that many employees in the health care sector need child care support to in turn continue to provide critical services to patients during the current pandemic.

$200 million to CMS for "program management" with a survey-and-certification focus

Historically, CMS's "program management" account has been used for funding needed to administer and oversee CMS's traditional programs, including Medicare and Medicaid. Title VIII appropriates $200 million to that account in order to "prevent, prepare for, and respond to coronavirus, domestically and internationally[.]" While this appropriation appears broad on its face, note that CMS must direct at least half of that amount toward "necessary expenses of the survey and certification program, prioritizing nursing home facilities in localities with community transmission of coronavirus[.]"

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[14] *See* Families First Coronavirus Response Act, Pub. L. No. 116-127, §§ 3105, 5102(a), 134 Stat. ---, ---, --- (2020).

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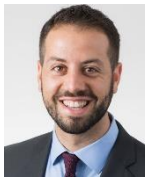

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