

Title III of the CARES Act: Supporting America's Health Care System in the Fight Against the Coronavirus

Client Alert

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On Friday, March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was signed into law.

Title III of the Act, "Supporting America's Health Care System in the Fight Against the Coronavirus," is subdivided into six Subtitles, as follows:

- Subtitle A: Health Provisions (*including supply shortages, access to healthcare for COVID-19 patients, innovation, and the healthcare workforce*)
- Subtitle B: Education Provisions
- Subtitle C: Labor Provisions
- Subtitle D: Finance Committee (*including payment issues*)
- Subtitle E: Health and Human Services Extenders (*including Medicare and Medicaid provisions, Human Services and other public health programs*)
- Subtitle F: Over-the-Counter Drugs

The CARES Act repeatedly references the "emergency period," which is defined by reference to Section 1135(g)(1)(B) of the Social Security Act, which is the period during which there exists: (i) the public health emergency declared by the Secretary on January 31, 2020, entitled "Determination that a Public Health Emergency Exists Nationwide as the Result of the 2019 Novel Coronavirus"; and (ii) any renewal of such declaration.

The following is a summary of key provisions of Title III.

Subtitle A: Health Provisions

Part I – Addressing Supply Shortages

Sections 3101 through 3121 address medical supply and drug shortages by:

- Tasking the National Academies of Sciences, Engineering and Medicine with: (i) examining and reporting on the security of the United States medical product supply chain and assessing and evaluating the dependence on critical drugs and devices sourced or manufactured outside of the United States; and (ii) making recommendations to improve the resiliency of the supply chain of critical drugs and devices and to address any supply vulnerabilities or potential disruptions of such products that would significantly affect or pose a threat to public health security or national security.
- Requiring the Strategic National Stockpile to include personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests in the stockpile.
- Expanding the definition of covered countermeasures to include respiratory protective devices utilized during a public health emergency.
- Requiring the Secretary of the FDA to prioritize the review of drug applications to help mitigate the potential for drug shortages.
- Expanding the reporting requirements for manufacturers under the federal Food, Drug & Cosmetic Act to include the reporting of the discontinuance or interruption of active pharmaceutical ingredients.
- Requiring manufacturers of certain drugs and medical devices to develop, maintain, and implement a redundancy risk management plan that identifies and evaluates risks to the supply of the drugs or medical devices along with requiring annual notification by the manufacturers to the Secretary regarding what was manufactured, prepared, propagated, compounded or processed for commercial distribution.
- Requiring the manufacturer of a device that is critical to the 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 for which the FDA Secretary determines such devices are needed, to notify the Secretary of a permanent discontinuance in the manufacturing of the device or an interruption that is likely to lead to a disruption in supply of the device in the United States.
- Empowering the FDA Secretary to inspect and review situations where there have been notifications of shortages to help mitigate or prevent such shortages.

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

Sections 3201 through 3226 address access to healthcare for COVID-19 patients by:

- Expanding the definition of COVID-19 testing that group health plans and insurers are permitted under the Families First Coronavirus Response Act to cover and reimburse providers of diagnostic testing relating to COVID-19 without cost-sharing.
- Requiring providers of a diagnostic test for COVID-19 to publicize cash price for such tests on their internet website. Failure to comply with these requirements could result in HHS assessing a civil monetary penalty of up to \$300 per day.

- Requiring health plans and issuers to provide for rapid coverage of “qualifying coronavirus preventative services” defined as an item or service included in recommendations of the US Preventive Services Task Force or an immunization recommended by the Advisory Committee on Immunization Practices of the CDC intended to prevent or mitigate coronavirus without cost-sharing.
- Appropriating \$1.3 billion for FY 2020 for supplemental awards to healthcare centers for the prevention, diagnosis, and treatment of COVID-19.
- Amending the Public Health Service Act relating to Telehealth Network and Telehealth Resource Centers Grant Programs and to the Rural Health Care Services Outreach, Rural Health Network Development, and Small Healthcare Provider Quality Improvement Grant Programs.
- Providing for modernization of the Public Health Service to include more specific references to public health emergencies and not just national emergencies generally and revising the Officers in the Ready Reserves Corp.
- Limiting potential tort liability under federal or state law for volunteer health care professionals—who provide services without compensation or other thing of value—for harm caused to patients relating to the diagnosis, prevention, or treatment of COVID-19 except in circumstances of willful or criminal misconduct, gross negligence, or wanton disregard or if services rendered under the influence of alcohol or drugs. This provision expressly preempts more restrictive state or local law. This protection is in addition to the protections pursuant to the Volunteer Protection Act of 1997, 42 U.S.C. 14501 et seq., for services related to COVID-19.
- Providing that during the public health emergency persons belonging to the National Health Service Corp program which funds students training to be health care workers, whether medical, dental, mental or behavioral health, in exchange for work in underserved areas may be assigned to provide services at such places and or such hours as determined necessary to respond to the emergency.
- Amending certain federal regulations governing the confidentiality and disclosure of substance use disorder patient records, including allowing certain re-disclosures to covered entities, business associates, or other programs subject to HIPAA after obtaining the patient’s prior written consent.
- Permitting a state agency or area agency on aging to transfer, without prior approval, up to 100% of the funds received by the agency to meet the needs of the state or area served, and provides that the same meaning shall be given to an individual unable to obtain nutrition due to social distancing as one who is homebound due to illness.
- Extending participation under the Older Americans Act, which established authority for grants to states for community planning and social services, research and development projects, and personnel training in the field of aging.
- Providing that within 180 days, the Secretary of HHS shall issue guidance on the sharing of patients’ protected health information (PHI) related to COVID-19, including guidance on compliance with HIPAA regulations and applicable policies
- Appropriating \$125.5M for each of fiscal years 2021 through 2025 for the Healthy Start Program to help reduce infant mortality and address health disparities.
- Providing that the Secretary of HHS shall carry out a national awareness campaign relating to the importance and safety of blood donation, and the need of for donations for the blood supply during a public health

emergency.

Part III – Innovation

Sections 3301 and 3302 address innovation by:

- Removing the cap on Other Transaction Agreements (OTA) during public health emergencies. During a public health emergency, the Secretary of HHS, to the greatest extent practicable, should use competitive procedures when entering into transactions to carry out projects for the Biomedical Advanced Research and Development Authority (BARDA), and would not require a written determination from the Assistant Secretary for Financial Resources for transactions in excess of \$100 million under an OTA.
- Providing Breakthrough Therapy designations for animal drugs that can prevent human diseases. It speeds up the development of drugs requested by the drug's sponsor to treat animals to help prevent animal-to-human transmission, which is suspected to have occurred with outbreak of novel coronavirus, leading to the SARS-CoV-2 pandemic

Part IV – Health Care Workforce

Sections 3401 through 3404 address the healthcare workforce by:

- Approving substantial appropriations for a variety of health professions-related programs, with focus on programs serving medically underserved populations (rural and geriatric).
- Directing the Secretary of HHS to develop a comprehensive and coordinated plan for health workforce programs, which may include performance measures and the identification of gaps between the outcomes of such programs and relevant workforce projection needs
- Providing Title VII funding to programs intended to strengthen the health professions workforce to better meet the health care needs of certain populations, such as older individuals and those with chronic diseases, who could be at increased risk of contracting COVID-19
- Reauthorizing Title VIII of the Public Health Service Act, concerning nurse workforce training programs, and updating the reporting requirements to include information on the extent to which Title VIII programs meet the goals and performance measures for such activities, and the extent to which HHS coordinates with other Federal departments on related programs. It also permits Nurse Corps loan repayment beneficiaries to serve at private institutions under certain circumstances. Title VIII programs help to address current and emerging health care challenges by supporting the development of the nursing workforce, as nurses are considered critical in responding to the COVID-19 pandemic and future like public health emergencies.

Subtitle B: Education Provisions

Sections 3501 through 3519 apply to the Higher Educational Act of 1965 (20 USC §1091) and, during a period of qualified emergency:

- Waives requirement for certain higher education institutions to match federal funding (except for private for-profit institutions) and allows certain institutions to transfer unexpended allotment for emergent care.

- Permits certain higher education institutions to use their allocations of Supplemental Educational Opportunity Grants for emergency financial aid for students.
- Permits certain higher education loan borrowers flexibility in repaying loans or waive repayment if withdrawal is caused by a qualified emergency.
- Permit certain students to complete distance education and certain students of foreign institutions to take classes in the United States.
- Cancels certain loans if students are forced to withdraw because of qualified emergency.
- Allows the Secretary of Education to issue waivers upon request relating to assessments, accountability, and related reporting requirements, and requirements for state and local educational agencies and Indian Tribes to receive funding.
- Allows the Secretary of Education to grant a deferment to an institution that received a loan under Part D of Title III of the Higher Education Act and grant waivers to required statutory provisions under the Secondary Education Act.
- Payments on student loans held by the Department of Education are suspended for six (6) months, and the Secretary of Education shall suspend all involuntary collection activities during the period of payment suspension.
- The Corporation for National and Community Service can allow individuals to accrue service hours and may permit certain grants funds.
- Not more than 20% of the total relief amount allocated to a local area under 29 U.S.C. §3151 et seq. may be used for administrative costs.
- Allows the Secretary authority to waive certain eligibility requirements, wait periods, and allotment requirements under the Higher Education Act for a period of time.
- Authorizes the Secretary to modify the required and allowable uses of funds for grants and to modify any federal share or other financial matching requirement for a grant awarded under certain provisions of the Higher Education Act to an institution of higher education or other grant recipient (not including an individual recipient of Federal student financial assistance) as a result of a qualifying emergency.
- Allows the Secretary to modify the categories of extenuating circumstances under which a grant recipient may be excused from fulfilling a portion of a service obligation under title IV of the Higher Education Act and must consider teaching service that is part-time or temporarily interrupted due to the emergency to be full-time service. Requires the Secretary to waive certain years of teaching service requirements under the Higher Education Act in certain circumstances.
- The Secretary shall suspend all payments due for loans from the Department of Education under subpart B and D through September 30, 2020. Such suspension shall be treated as if payments were made. The Secretary shall also suspend all involuntary collection efforts during this period. The Secretary must notify all borrowers of the suspended payments and when the normal payment obligation will resume.

Subtitle C: Labor Provisions

Sections 3601 through 3611 address labor provisions by:

- Amending the Family Medical Leave Act to limit an employer’s paid leave obligation to \$200 per day and \$10,000 in the aggregate per employee.
- Amending the recently enacted Emergency Paid Sick Leave Act to limit the employer’s minimum contribution to \$511 per day, \$5,110 in the aggregate per employee if the employee is unable to work due to the following reasons:
 - The employee is subject to a Federal, State, or local quarantine or isolation order related to COVID-19;
 - The employee has been advised by a health care provider to self-quarantine due to concerns related to COVID-19; and/or
 - The employee is experiencing symptoms of COVID-19 and seeking a medical diagnosis.
- Amending the Emergency Paid Sick Leave Act to limit the employer’s minimum contribution to \$200 per day, \$2,000 in the aggregate per employee if the employee is unable to work due to the following reasons:
 - The employee is caring for an individual who is subject to a quarantine or isolation order or the employee is caring for an individual who has been advised by a health care provider to self-quarantine due to concerns related to COVID-19;
 - The employee is caring for a son or daughter of such employee if the school or place of care of the son or daughter has been closed, or the childcare provider of such son or daughter is unavailable, due to COVID-19 precautions; and/or
 - The employee is experiencing any other substantially similar condition specified by the Secretary of Health and Human Services in consultation with the Secretary of the Treasury and the Secretary of Labor.
- Making it easier to file for unemployment by requiring that unemployment applications be available in at least two of the following three formats: electronic/online, phone, and/or in person.
- Regarding an employee’s request for leave, clarifying that the definition of an eligible employee applies to an employee that has been laid off, so long as (1) the employee has been employed for at least 30 calendar days by an employer, including an employee who was laid off by that employer on or after March 1, 2020 and (2) the employee had worked for employer for not less than 30 of the last 60 calendar days prior to the employees layoff, and was rehired by the employer.
- Allowing employers to apply a payroll credit for both Required Sick Leave and Required Paid Family Leave in the amount to be calculated under subsection (a) of Section 7001 or 7003 of the Families First Coronavirus Response Act, subject to limitations set forth in subsection (b) of Section 7001 and 7003. The credit amount will be calculated through the end of the most recent payroll period in the current quarter. The credit may be advanced to employers according to forms and instructions to be provided by the Secretary of Labor.
- Enabling the Secretary of Treasury to waive any penalty under section 6656 of the Internal Revenue Code of 1986 for failure to make a deposit of the tax imposed under section 3111 (a) or 3221(a) of the IRC if failure was due to anticipation of credit allowed.
- Amending the current ERISA requirements by adding “public health emergency” as one of the enumerated circumstances in which the Department of Labor may postpone the ERISA filing deadline for up to a one-year period.
- Delaying any minimum funding contributions under ERISA that would have been due during calendar year 2020 to January 1, 2021. The amount of the minimum required contribution will be increased by any interest

that accrues between the original due date and the payment date at the effective rate of interest for the plan year.

- Allowing for an ERISA plan sponsor to elect to treat the plan's adjusted funding target attainment percentage (AFTAP) for the last plan year ending before January 1, 2020 as the AFTAP for plan years, which includes plan year 2020.
- Expands Cooperative and Small Employer Charity Pension Plans to certain charitable employers so long as the employer meets the following requirements:
 - As of January 1, 2020, was (1) maintained by an employer described in section 501(c)(3) of the Internal Revenue Code of 1986, (2) who has been in existence since at least 1938, (3) who conducts medical research directly or indirectly through grant making, and (4) whose primary exempt purpose is to provide services with respect to mothers and children.
- With regard to federal contractor authority, funds made available to an agency by the CARES Act may be used to modify the terms and conditions of an agreement without consideration, as a means to reimburse at the minimum applicable contract billing rates not to exceed an average of 40 hours per week any paid leave, including sick leave, a contractor provides to keep its employees or subcontractors in available to work, including to protect the life and safety of Government and contractor personnel. Note: This authority applies solely to a contractor whose employees or subcontractors cannot perform work on a site that has been approved by the Federal Government, due to facility closures or other restrictions, and whose employees cannot telework because their job duties cannot be performed remotely. This provision expires on September 30, 2020.

Subtitle D: Finance Committee

Sections 3701 through 3720 address a host of healthcare payment issues and:

- Eliminate considerations of insurance coverage for telehealth or other remote services from the determination of whether an individual qualifies as an "eligible individual" for a Health Savings Account and also precludes a health plan from exclusion in the definition of "high deductible plan" for failing to have a deductible for telehealth and other remote care serviced.
- Add "menstrual care products" as deductible expenses permitted to be paid for through Health Savings Accounts, Archer MSAs and Flexible Spending Accounts. "Menstrual Care Product" means "tampon, pad, liner, cup, sponge, or similar product used by individuals with respect to menstruation or other genital tract secretions."
- Remove certain qualifying conditions to 42 U.S.C. §1320b-5 on the ability of the Secretary of HHS to waive or modify sections of the Social Security Act as it pertains to telehealth services provided in an emergency area during an emergency period. The Amendment eliminates any reference to the term "qualified provider" and removes limitations on the Secretary's ability to waive provisions related to facility fees being paid based on the location of the originating site and the use of telephones that do not have both audio and video capabilities. The Act does not modify these requirements but, empowers the Secretary to do so.

- Provide that Federally Qualified Health Centers (“FQHC”) and Rural Health Clinics (“RHC”) will receive Medicare payments for telehealth services provided during the emergency period via telecommunications systems to qualified individuals notwithstanding the fact that the FQHC or RHC providing the telehealth service is not in the same location as the beneficiary.
- Direct the Secretary to develop payment methods similar to the national average payment rates for similar telehealth services under the Physician Fees Schedule in Section 1848 of the Social Security Act. It also provides that the costs of telehealth services shall not be used in determining an FQHC’s rates under the prospective payment system or an RHC’s rates under the methodology for all-inclusive rates.
- Authorize the Secretary to waive, during the emergency period, provisions requiring patients suffering from end stage renal disease who are receiving home dialysis treatments to have periodic face-to-face clinical assessments in order to qualify to receive monthly clinical assessments by telemedicine.
- Permit payment for hospice services where the determination for recertification of continued eligibility for hospice care was made by a physician or nurse practitioner via telehealth, rather than through the previously required face-to-face encounter.
- Direct the Secretary of HHS to consider ways to encourage the use of telecommunications systems in home health services during the emergency period consistent with the plan of care for an individual by clarifying guidance and conducting outreach as appropriate.
- Expand Medicare and Medicaid coverage for home health services where the need for such services are certified to by a nurse practitioner, clinical nursing specialist or physician’s assistant in addition to where the need for such services is certified by a physician. The provision requires the Secretary to promulgate regulations implementing its provisions within six months of the adoption of the Act.
- Exempt the Medicare program from reduction under any sequestration order issued before or after the adoption of the Act for the period beginning May 1, 2020 through December 31, 2020, but extends the direct spending reductions contained in the Balanced Budget and Emergency Deficit Control Act of 1985 through Fiscal Year 2030.
- Adjust the weighing factors applied to the Medicare DRG Rates for patients diagnosed with COVID-19 and discharged during the emergency period by 20 percent. Such adjustments are not to be considered when determining budget neutrality.
- Waive the requirement that patients in an inpatient rehabilitation facility receive at least 15 hours of therapy per week during the Emergency Period. For inpatient hospital services provided at long term care hospitals, the Act waives payment adjustments for facilities that do not have a discharge payment percentage of at least 50 percent as well as the application of the site neutral payment rate for discharges occurring during the emergency period.
- Through the duration of the emergency period items and services furnished in rural and noncontiguous areas will be reimbursed pursuant to the transition rule, described in 42 C.F.R. §414.210(g)(9)(iii). For areas other than rural and noncontiguous areas, items and services shall be reimbursed pursuant the transition rule described in 42 C.F.R. §414.210(g)(9)(iv) for the 30-day period following the exactment of the Act. Thereafter, and through the remainder of the emergency period, the fee schedule amount shall be equal to 75 percent of

the adjusted payment amount and 25 percent of the unadjusted payment amount.

- Designate the COVID-19 vaccine developed and its administration as covered services under Medicare Part B and Medicare Advantage and waives any deductible related to the vaccine and its administration.
- Permit Medicare Part D eligible individuals enrolled in a prescription drug plan or MA-PD plan to obtain a single fill or refill for up to a 3-month supply of covered Medicare Part D medications.
- Prohibit the Secretary from limiting the amount of payment under Medicare for home and community-based services, self-directed personal assistance services, or home and community-based attendant services. The Act further permits such services to be provided in an acute care hospital provided they are: (1) identified in the patient's person-centered service plan; (2) provided to meet needs of the individual that are not met through hospital services; (3) not a substitute for services that the hospital is obligated to provide; and (4) designed to ensure smooth transitions between acute care settings and home and community-based settings.
- Clarify the definition of "uninsured individuals" as set forth in the recently enacted Families First Coronavirus Response Act to include individuals who would be insured under the provisions described in 42 U.S.C. §1396a(a)(10)(A)(i)(VIII) (often referred to as Medicaid expansion) if they reside in a State that does not provide the medical assistance described in that section.
- Remove the requirement that COVID-19 testing products must be approved, cleared, or authorized under sections 510(k), 513, 514, or 564 of the Federal Food, Drug, and Cosmetic Act in order for a patient receiving such testing to be eligible for medical assistance.
- Extend the deadlines in 42 U.S.C. §1395m-1 for laboratories to report payment rates for, and volume of, clinical diagnostic laboratory tests and the implementation of related payment reductions by one year.
- Expand the Medicare accelerated payment program to hospitals experiencing significant cash flow problems during the emergency period to include: (1) hospitals whose inpatients are predominantly individuals under the age of 18; (2) hospitals extensively involved in the treatment of, or research on, cancer as described in 42 U.S.C. §1395ww(d)(1)(B)(v); and (3) Critical Access Hospitals.
- At the request of the hospital the Secretary shall: (1) provide up to 120 days before claims are offset to recoup any accelerated payments; and (2) allow not less than 12 months from the date of the first accelerated payment before requiring the outstanding balance be paid in full. At the request of the hospital the Secretary may: (1) make accelerated payments on a periodic or lump sum basis; (2) increase the amount of payment that would normally be made under the program by 100 percent (or 125 percent for Critical Access Hospitals); and (3) extend the period covered by accelerated payments up to 6 months.
- Permit states, during the 30-day period following the enactment of the CARES Act, to receive an increase of Medicaid Federal Medical Assistance Percentage (FMAP) as authorized under the Families First Coronavirus Response Act notwithstanding the requirement to not impose premiums on beneficiaries, if a premium was in effect on the date the Act was enacted.

Subtitle E: Health and Human Services Extenders

Sections 3801 through 3803 extend Medicare funding for the current fiscal year, ending on October 1, 2020, and for the first two-month period of the new fiscal year, beginning on October 1, 2020 and ending on November 30,

2020, by an amount equal to the pro rata portion of the increased annual funding. The following programs are affected by these changes:

- Quality Measure Endorsement, Input, and Selection funding is increased for the current fiscal year from \$4.83M to \$20M, and for the first two months of the new fiscal year by \$3.34M.
- Funding Outreach and Assistance for Low-Income Programs will be:
 - \$13M for the current fiscal year for state health insurance programs and \$2.167M for the first two months of the new fiscal year;
 - \$7.5M for area agencies on aging and \$1.25M for the first two months of the new fiscal year;
 - \$5M for aging and disability resource centers and \$834K for the first two months of the new fiscal year; and
 - \$12M for grant or contract with national center for benefits and outreach enrollment and \$2M for the first two months of the new fiscal year.

Sections 3811 through 3814 address the Medicaid Program, as follows:

- With respect to Extension of Money Follows the Person Rebalancing Demonstration Program, the Deficit Reduction Act of 2005 section 6071(h)(1)(G) is amended to allocate \$337.5M for the period beginning on January 1, 2020 and ending on September 30, 2020. For the two-month period beginning on October 1, 2020 and ending on November 30, 2020, the amount available will be \$56.25M, i.e., the pro rata portion of \$337.5M.
- Spousal Impoverishment Protections, allowing the State to disregard the income of a spouse and conduct an analysis solely on an individual's eligibility for medical assistance based on reduction of income, are extended through November 30, 2020.
- Delays the \$4 billion disproportionate share hospital (DSH) cuts for federal fiscal year 2020 from taking effect on December 1, 2020.
- Extends and expands the Community Mental Health Services Demonstration Program, found in the Protecting Access to Medicare Act of 2014, as follows:
 - In 6 months, the Secretary will select two states, in addition to the eight States already listed, to participate in two-year demonstration programs that:
 - Were awarded planning grants, and
 - Had applied to participate in the demonstration programs but were not selected.
 - The Secretary will use the results of its evaluation of the state's original application and will not require the submission of any additional application.
 - If a state is selected, it is required to:
 - Submit a plan to monitor certified community behavioral health clinics under the demonstration program to ensure compliance with certified community behavioral health criteria during the demonstration period; and
 - Commit to collecting data, notifying the Secretary of any planned changes that would deviate from the prospective payment system methodology outlined in the state's demonstration application, and obtaining approval from the Secretary of any such change before implementing change.

- The Federal matching percentage applicable to amounts expended by states participating in the demonstration program will apply to amounts expended by the state during the fiscal period that begins on January 1, 2020 if the state was participating in the demonstration program as of January 1, 2020 and will apply to amounts expended by the state during the first fiscal period the state participates if the state was selected pursuant to the expansion.
- Within 18 months, the U. S. Comptroller General must submit to the House Committee on Energy and Commerce and the Senate Committee on Finance a report on the community and mental health services demonstration program, which must include:
 - Information on States' experiences participating in the demonstration program, including the extent to which States:
 - measure the effects of access to certified community behavioral health clinics on patient health and cost of care, including: (i) engagement in treatment for behavioral health conditions; (ii) relevant clinical outcomes, to the extent collected; (iii) screening and treatment for comorbid medical conditions; and (iv) use of crisis stabilization, emergency department, and inpatient care.
 - Information on Federal efforts to evaluate the demonstration program, including (i) quality measures used to evaluate the program; (ii) assistance provided to States on data collection and reporting; (iii) assessments of the reliability and usefulness of State-submitted data; and (iv) the extent to which such efforts provide information on the relative quality, scope, and cost of services as compared with services not provided under the demonstration program, and in comparison to Medicaid beneficiaries with mental illness and substance use disorders not served under the demonstration program.
 - Recommendations for improvements to the following: (i) the reporting, accuracy, and validation of encounter data; (ii) accuracy in payments to certified community behavioral health clinics under State plans or waivers under title XIX of the Social Security Act.

Sections 3821 through 3824 extend the following Human Services and Other Health Programs:

- Sexual Risk Avoidance Education Program is extended through the end of 2020 (instead of ending on May 22, 2020) and the fiscal year is changed to 2021.
- Demonstration Projects to Address Health Professions Work-Force Needs are extended through November 30, 2020.
- Temporary Assistance for Needy Families and Related Programs are extended through November 30, 2020.

Sections 3831 through 3832 extend the following Human Services and Other Health Programs:

- Increases the amount allocated for community health centers under the Patient Protection and Affordable Care Act to \$4M for fiscal year 2020 and \$668,493,151 for the two-month period beginning on October 1, 2020 and ending on November 30, 2020.
- Allocates \$310M for the National Health Service Corps for fiscal year 2020 and \$51,808,219 for the two-month period beginning on October 1, 2020 and ending in November 30, 2020.
- Extends the amount allocated for teaching health centers that operate graduate medical education programs through fiscal year 2020 and allocates \$21,141,096 for the two-month period beginning on October 1, 2020 and ending on November 30, 2020.
- Diabetes Programs:

- The amount allocated under the Public Health Service Act for Type I diabetes is extended through the fiscal year 2020 and \$25,068,493 is allocated for the two-month period beginning on October 1, 2020 and ending on November 30, 2020.
- The amount allocated under the Public Health Services Act for Indians is extended through fiscal year 2020 and \$25,068,493 is allocated for the two-month period beginning on October 1, 2020 and ending on November 30, 2020.

Subtitle F: Over-the-Counter Drugs

Sections 3851 through 3862 amend the Federal Food, Drug, and Cosmetic Act to address certain nonprescription drugs that are marketed without an approved drug application. The regulatory process for certain OTC drug approvals is reformed, permitting the FDA more flexibility to make changes administratively, rather than through the full notice and comment rulemaking process. Note: This is not a waiver of the process for all OTC drugs, but for those that meet several detailed requirements.

- Pharmaceutical companies are given an eighteen (18) month market-exclusivity period for certain new OTC drugs.
- An OTC drug which does not comply with the requirements of its OTC monograph is considered misbranded. The same is also true for any drug that is manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid.
- None of the changes or exceptions apply to drugs previously excluded by the FDA from the Over-the-Counter Drug Review under the 1972 Federal Register.

Furthermore, the following changes are made to the Sunscreen Innovation Act:

- A sponsor of a nonprescription sunscreen active ingredient or a combination of nonprescription sunscreen active ingredients that, as of March 27, 2020, is subject to a proposed sunscreen order may elect, within 180 days of the actual enactment of the CARES Act, to transition into the new review process implemented by the CARES Act.
- A sponsor may request confidential meetings to discuss data requirements that support a general recognition of safety and effectiveness, which involve confidential information and public information related to a proposed sunscreen order, as appropriate. The Secretary of Health and Human Services will have the discretion to determine if more than one confidential meeting is appropriate and shall publish a post-meeting summary of each confidential meeting that does not disclose confidential commercial information or trade secrets. A final sunscreen order shall permit the requestor with respect to the to market the subject sunscreen ingredient exclusively for eighteen (18) months.
- The Secretary is to make an annual update to Congress on the progress of evaluating the conditions under which nonprescription drugs containing antitussive, expectorant, nasal decongestant, or antihistamine active ingredients (or combinations) are recognized as safe and effective for children under the age of six. This requirement will sunset once the Secretary certifies that the FDA has completed its evaluation and issued a final order.
- Also makes limited technical corrections to the FDA Reauthorization Act of 2017.

A new FDA user fee plan is also established:

- Beginning with fiscal year 2021, each owner of a facility identified as an OTC monograph drug facility on December 31 of the fiscal year or at any time during the preceding twelve-month period shall be assessed an annual fee for each facility, with limited exceptions.
- For fiscal year 2021, the fees shall be due on the later of (i) the first business day of July 2020; or (ii) forty-five days after publication of the Federal Register notice establishing the fees.
- For each fiscal year after fiscal year 2021, the fees shall be due on the later of (i) the first business day of June of such year; or (ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year.
- For fiscal year 2021, facility fees shall be established to generate a total facility fee revenue amount equal to the sum of (i) the annual base revenue for fiscal year 2021 (\$8,000,000); (ii) the dollar amount equal to the operating reserve adjustment for the fiscal year; and (iii) additional direct cost adjustments as specified.
- Thereafter, fees shall be established to generate a total facility fee revenue amount equal to the sum of (i) the annual base revenue for the fiscal year; (ii) the dollar amount equal to the inflation adjustment for the fiscal year; (iii) the dollar amount equal to the operating reserve adjustment for the fiscal year; (iv) additional direct cost adjustments as specified; and (v) additional dollar amounts for each fiscal year as specified.
- Additionally, each person that submits an OTC monograph order request shall be subject to a fee for an OTC monograph order request. The amount of such fee shall be (i) for a Tier 1 OTC monograph order request, \$500,000, adjusted for inflation for the fiscal year; and (ii) for a Tier 2 OTC monograph order request, \$100,000, adjusted for inflation for the fiscal year. The OTC monograph order request fees shall be due on the date of submission of the OTC monograph order request.
- The fees are intended to be used to defray increases in the costs of the resources allocated for OTC monograph drug activities.

Please contact the following co-authors of this Alert with questions or to discuss specific circumstances related to the provisions of the CARES Act.

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