ALSTON & BIRD

CARES Act – Health Provisions (enacted March 27, 2020)

Section	*Summary*
TITLE III—SUPPORTING AMERICA'S HEALTH CARE SYSTEM IN THE FIGHT AGAINST THE CORONAVIRUS	
Subtitle A— Heath Provisions	
Sec. 3001. Short title.	This subtitle may be cited as the "Coronavirus Aid, Relief, and Economic Security Act."
PART I—Addressing Supply Shortages	
SUBPART A—MEDICAL PRODUCT SUPPLIES	
Sec. 3101. National Academies report on America's medical product supply chain security.	This section requires the Secretary of the Department of Health and Human Services (HHS) to engage the National Academies of Sciences, Engineering, and Medicine within 60 days of enactment to examine and report on the security of the U.S. medical product supply chain. The report is to assess the dependence of the U.S. on critical drugs and devices that are sourced or manufactured outside of the U.S., which may include analysis of: (1) the supply chain of critical drugs and devices of greatest priority to providing health care; (2) health and national security risks associated with reliance on critical drugs sources or manufactured outside the U.S.; (3) any existing supply chain information gaps; and (4) potential economic impact of increased domestic manufacturing. The report is to provide recommendations to improve the resiliency of the supply chain of critical drugs and devices and address any supply vulnerabilities and potential disruptions that would significantly affect or pose a threat to public health security or national security. The report may include strategies to: (1) promote supply chain redundancy and contingency planning; (2) encourage domestic manufacturing; (3) improve supply chain information gaps; (4) improve planning considerations for medical product supply chain capacity during public health emergencies; and (5) promote the accessibility of critical drugs and devices. The study and report are to include input from the Departments of HHS, Homeland Security (DHS), Defense (DoD), Commerce, State, Veterans Affairs (VA), and Justice, as well as input from relevant stakeholders through public meetings and other forms of engagement, as appropriate. The terms "device" and "drug" are defined by reference to § 201 of the Food, Drug, and Cosmetics Act (FDCA) (21 USC § 321).
Sec. 3102. Requiring the Strategic National Stockpile to include	This section requires 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.

certain types of medical supplies.	
Sec. 3103. Treatment of respiratory protective devices as covered countermeasures.	This section amends a change required by section 6005 of the Families First Coronavirus Response Act (FFCRA) to the Public Readiness and Emergency Preparedness (PREP) Act (42 USC § 247d-6d). According to this provision, National Institute for Occupational Safety and Health (NIOSH)-approved respiratory protective devices are added to the definition of "covered countermeasure" during a public health emergency declared by the Secretary of HHS under § 319 of the Public Health Service Act (PHSA) ("Section 319") (including but not limited to the COVID-19 emergency period) and manufacturers receive immunity from liability for their use when the Secretary makes a determination that their use is a priority during a Section 319 public health emergency. The amended language changes the duration from specified years (i.e., January 27, 2020 to October 1, 2024) to any time the Secretary determines respiratory protective devices to be a priority for use during a Section 319 public health emergency.
SUBPART B—MITIGATING EMERGENCY DRUG SHORTAGES	
Sec. 3111. Prioritize reviews of drug applications; incentives.	This section directs the Secretary of HHS to prioritize the review of New Drug Application (NDA) supplements, Abbreviated New Drug Applications (ANDAs), and ANDA supplements that could mitigate or prevent a shortage of a drug that is: (1) life-supporting; (2) life-sustaining; or (3) intended for use in the prevention or treatment of a debilitating disease or condition, including any such drug used in emergency medical care or during surgery or any such drug that is critical to the public health during a Section 319 public health emergency.
Sec. 3112. Additional manufacturer reporting requirements in response to drug shortages.	This section requires manufacturers of drugs that are critical due to a public health emergency to notify HHS of a permanent discontinuance or interruption of manufacture, or a discontinuance or interruption in the manufacture of the active pharmaceutical ingredients (API) of the drug, that is likely to lead to a disruption in the U.S. supply of the drug, and to report the reasons for and expected duration of such discontinuance or interruption. If an API is a reason for, or risk factor in, the discontinuance or interruption of a drug, the notification must also include the source of the API and any known alternative sources for the API. The notice must include whether any associated medical devices used in preparation or administration included in the drug is a reason or risk factor in the discontinuance or interruption. All manufacturers of life-saving drugs (those described in 21 USC § 356c(a)), APIs thereof, or associated medical devices used to prepare or administer such drugs must maintain redundancy risk management plans for each applicable manufacturing plant to help prevent or mitigate supply interruptions.

	The Secretary of HHS is directed to submit a drug shortage report every 90 days to the Centers for Medicare & Medicaid Services (CMS) Administrator. Inspection reports for facilities that manufacture any drug on the drug shortage list within the last five years are to be sent to the appropriate offices of the Food and Drug Administration (FDA) with expertise regarding drug shortages. FDA-registered manufacturers must report annually to the Secretary on the amount of each drug that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution. The Secretary may require such information to be submitted at the time a public health emergency is declared under Section 319. The Secretary may exempt certain biological products or categories of biological products from these reporting requirements if the Secretary determines that applying such requirements is not necessary to protect public health. The Secretary may not disclose trade secret or confidential information.
SUBPART C—PREVENTING MEDICAL DEVICE SHORTAGES	
Sec. 3121. Discontinuance or interruption in the production of medical devices.	This section establishes reporting requirements for discontinuance of or meaningful disruption in the supply of life-supporting, life-sustaining, or emergency or surgical medical devices that are critical to public health during a public health emergency and medical devices with respect to which the Secretary of HHS determines that information on potential supply disruptions would be needed during or in advance of a public health emergency. Manufacturers of such devices must notify the Secretary during or in advance of a Section 319 public health emergency of discontinuances or disruptions in the supply and the reasons for such discontinuance or disruption. Such notice must be provided at least six months prior to the date of discontinuance or interruption, or as soon as possible if six months' notice is not possible. The Secretary will make such information on discontinuances and disruptions publicly available to relevant provider organizations and supply chain entities, as appropriate. The Secretary may choose not to disclose such information if it would adversely affect the public health, such as by causing unnecessary over-purchasing. The Secretary may not disclose trade secrets or confidential information.

	Device manufacturers that fail to meet disclosure requirements will receive a letter and will have 30 days to respond setting forth the basis for noncompliance and providing the required information. Letters without response after 45 days will be posted on the FDA's public website. The Secretary can prioritize and expedite device submission reviews and establishment inspections that could mitigate or prevent a shortage. The Secretary will maintain an up-to-date, detailed list of devices on shortage in the U.S. A "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. This term does not include interruptions in manufacturing due to routine maintenance or insignificant changes in manufacturing as long as the manufacturer expects to resume operations in less than six months. It also does not include interruptions in manufacturing of components or raw materials so long as the interruption does not result in a shortage of the device and the manufacturer expects to resume operations in a reasonable period of time. It also does not include 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.
PART II—Access to Health Care for COVID-19 Patients	
SUBPART A—COVERAGE OF TESTING AND PREVENTIVE SERVICES	
Sec. 3201. Coverage of diagnostic testing for COVID-19.	Section 6001 of FFCRA requires group health plans and insurance insurances issuers in the group or individual market (including grandfathered plans) to cover FDA-approved diagnostic testing for COVID-19 and certain related items/services without any cost-sharing (deductibles, copayments, and coinsurance) and without prior authorization or other medical management requirements. Related items/services are those provided during health care provider office visits (including telehealth visits), urgent care center visits, and emergency room visits that result in an order for or administration of the test, but only to the extent the items and services relate to the furnishing or administration of such product or to the evaluation of such individual for purposes of determining the need of such individual for such product. This provision amends FFCRA to expand the tests required to be covered to include the following in addition to tests that are FDA-approved or cleared: (1) those that are subject to an emergency use authorization; (2) those for which the developer has requested or intends to request emergency use authorization, unless the emergency use authorization has been denied or the developer fails to submit a request within a reasonable timeframe; (3) those developed in and authorized by a State that has

	notified the Secretary of HHS of its intention to review tests intended to diagnose COVID-19; and (4) any other test that the Secretary determines appropriate in guidance.
Sec. 3202. Pricing of diagnostic testing.	This section states that group health plans and health insurance issuers covering testing as required under § 6001 of FFCRA must reimburse the provider for the diagnostic testing at either the negotiated rate in effect before the public health emergency period or, if there is not a negotiated rate, at the cash price as listed by the provider on a public internet website. Plans or issuers may negotiate a rate with such provider for less than the cash price. Each provider of a diagnostic test for COVID-19 must make public the cash price for such test on the provider's public internet website. Providers of diagnostic tests for COVID-19 that do not post the cash price are subject to civil monetary penalties of $300 per day.
Sec. 3203. Rapid coverage of preventive services and vaccines for coronavirus.	This section states that group health plans and health insurance issuers in the group or individual market must cover any qualifying coronavirus preventive service as a preventive service for which no cost sharing is imposed within 15 business days after the date that the qualifying coronavirus preventive service is recommended. A qualifying coronavirus preventive service is an item, service, or immunization intended to prevent or mitigate coronavirus disease that is either (1) an evidence-based item or service with an "A" or "B" rating by the United States Preventive Services Task Force, or (2) an immunization recommended by the CDC Advisory Committee on Immunization Practices.
SUBPART B—SUPPORT FOR HEALTH CARE PROVIDERS	
Sec. 3211. Supplemental awards for health centers.	This section authorizes and appropriates $1.32 billion for supplemental grant awards to health centers for the prevention, diagnosis, and treatment of COVID-19. A health center is defined at 42 USC § 254b(a) as an entity that provides primary health care services to a population that is medically underserved, or a special medically underserved population comprised of migratory and seasonal agricultural workers, the homeless, and residents of public housing. Health centers must generally serve all residents of the catchment area. As drafted, it appears that at least $200 million of the funds must be used to support and enhance behavioral health, mental health, or substance use disorder services.[1]
Sec. 3212. Telehealth network and telehealth resource centers grant programs.	This section modernizes the telehealth network grant program and telehealth resource centers grant program. The telehealth network grant program's changes reflect a shift from demonstration of telehealth technology to delivery of telehealth services. The telehealth resource centers grant program shifts from demonstration to telehealth initiative support services. Both grant programs are extended from four-year periods to five-year periods. Both grant programs remove the requirement that the

[1] The amounts appropriated pursuant to this section are subject to requirements contained in the Further Consolidated Appropriations Act, 2020 (FCAA) for funds for programs authorized under sections 330 through 340 of the PHSA. Section 401(d) of the FCAA requires that funds for programs authorized under sections 330 through 340 of the PHSA be subject to the requirements for funds for such programs contained in Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, which requires that "funds provided for the Health Centers program, as defined by section 330 of the PHSA, by the PHSA or any other Act for fiscal year 2019, not less than $200,000,000 shall be obligated in fiscal year 2019 for improving quality of care or expanded service grants under section 330 of the PHS Act to support and enhance behavioral health, mental health, or substance use disorder service."

	recipient be a nonprofit entity, permitting for-profit entities to participate. The percentage of funds that may be utilized for purchase or lease of equipment is reduced from 40 to 20 percent of the award. Within four years after enactment, the Secretary of HHS must report on activities and outcomes of these grant programs to the Senate Health, Education, Labor, and Pensions (HELP) Committee and the House Energy and Commerce (E&C) Committee. Such report must be issued every five years. This section authorizes $29 million for each of fiscal years 2021 through2025 for such grants.
Sec. 3213. Rural health care services outreach, rural health network development, and small health care provider quality improvement grant programs.	This section modifies the rural health care services outreach, rural health network development, and small health care provider quality improvement grant programs. The grant period for each program is extended from three to five years. The section also provides $79.5 million of funding for each of fiscal years 2021 through 2025. The rural health care services outreach and rural health network development grant programs are modified to permit for-profit entities to participate. The small health care provider quality improvement grant program is modified to permit regional, not just local, providers to participate, and to apply to efforts to increase care coordination and chronic disease management. Within four years after enactment, the Secretary of HHS must report on activities and outcomes of these grant programs to the Senate HELP Committee and the House E&C Committee. Such report must be issued every five years.
Sec. 3214. United States Public Health Service Modernization.	This section updates references throughout the PHSA to clarify that the Ready Reserve Corps assists in times of public health and national emergencies, and updates references of "Reserve Corps" and the "reserve" of the Public Health Service to refer to the Ready Reserve Corps. Under the statute that grants Commissioned officers of the Public Health Service the rights, benefits, privileges, and immunities provided to commissioned officers of the Army through specified statutory provisions, this section adds “retired pay for non-regular service,” “compensation: reserve on active duty accepting from any person,” and “reserves: separation for absence without authority or sentence to imprisonment” to the provisions that apply to Public Health Service Commissioned officers.
Sec. 3215. Limitation on liability for volunteer health care professionals during COVID-19 emergency response.	This section provides volunteer health care professionals immunity from liability under Federal or State law for harm from acts or omissions in the provision of health care services during the COVID-19 public health emergency as long as the act or omission occurs: (1) in the course of providing health care services; (2) in the health care professional’s capacity as a volunteer; (3) in the course of providing health care services that (a) are within the volunteer provider's scope of licensure, and (b) do not exceed the scope of license of a substantially similar health professional in the State in which such act or omission occurs; and (4) in a good faith belief that the patient is in need of health care services. The immunity does not apply to willful or criminal misconduct, gross negligence, reckless misconduct, or acts done under the influence of drugs or alcohol.

	This section preempts state law to "the extent that such laws are inconsistent with this section, unless such laws provide greater protection from liability." The section defines "health care services" to mean any services that relate to the diagnosis, prevention, or treatment of COVID-19, or the assessment or care of the health of a human being related to an actual or suspected case of COVID-19. "Volunteer" means a health care professional who does not receive compensation or anything of value in lieu of compensation, including insurance payment, but excludes: (1) the receipt of items to be used exclusively for rendering health care services in the health care professional's capacity as a volunteer; and (2) reimbursement for travel to the site where volunteer services are rendered and any payments in cash or kind to cover room and board if the services are being rendered more than 75 miles from the volunteer's principal place of residence. This section is effective upon enactment and applies only to acts or omissions on or after enactment. This section will be in effect only for the length of the COVID-19 Section 319 public health emergency.
Sec. 3216. Flexibility for members of National Health Service Corps during emergency period.	During the COVID-19 public health emergency, the Secretary of HHS may assign members of the National Health Service Corps, with the voluntary agreement of such corps members, to provide health services at places and for the length of time as the Secretary determines necessary to respond to the emergency, provided that such places are within a reasonable distance to the site to which the members were originally assigned, and the total number of hours required are the same as were required prior to the date of enactment of this Act. This section overrides the normal procedures set forth in 42 USC § 254f, which require that corps members be assigned to health professional shortage areas and only after health care entities submit an application and the Secretary evaluates the need and demand for health manpower for the area.
SUBPART C—MISCELLANEOUS PROVISIONS	
Sec. 3221. Confidentiality and disclosure of records relating to substance use disorder.	This section modifies the 42 CFR Part 2 regulations governing privacy protections of substance use disorder records (often referred to as "Part 2 records") to align with those of Health Insurance Portability and Accountability Act (HIPAA) if the patient consents in writing. Once prior written consent of the patient has been obtained, the contents of the record may be used or disclosed by a covered entity, business associate, or other programs subject to the confidentiality requirements of 42 USC § 290dd-2 for purposes of treatment, payment, and health care operations as permitted by HIPAA regulations. Such records may be redisclosed in accordance with HIPAA regulations. The patient's prior written consent may be given once for all such future uses or disclosures for treatment, payment, and operations, until the consent is revoked in writing. This section also permits de-identified substance use disorder record information to be disclosed to a public health authority without patient consent.

	This section also clarifies that the penalties for breaches and wrongful disclosure of individually identifiable health information apply to substance use disorder records. This section prohibits discrimination against an individual on the basis of information received through inadvertent or intentional disclosure of information in substance use disorder records in the context of health care, employment, housing, legal processes, or government benefits. The Secretary of HHS must make conforming revisions to regulations. Regulations regarding the requirement for notice of privacy practices must be revised to require inclusion of a statement of the substance use disorder patient's rights, as well as self-pay patients, with respect to protected health information and a brief description of how the individual may exercise these rights, and a description of each purpose for which the covered entity is permitted or required to use or disclose protected health information without the patient's written authorization. This section also prohibits the use of records against the patient in criminal, civil, or administrative, or legislative proceedings conducted by any Federal, State, or local authority, except as authorized by a court order or by the consent of the patient. The implementing regulations must be effective one year after the date of enactment.
Sec. 3222. Nutrition services.	This section permits States and area agencies on aging to transfer up to 100 percent of funds received under the Older Americans Act (OAA) between subparts 1 (Congregate Nutrition Services) and 2 (Home Delivered Nutrition Services) of Part C, Title III, for use as the State or agency considers appropriate to meet the needs of the State or area served, without prior approval, during the COVID-19 public health emergency. Currently, Section 308(a)(4)(A) of the OAA permits no more than 40 percent of the funds to be transferred between subparts 1 and 2. During the COVID-19 public health emergency, for purposes of State agencies determining the delivery of nutrition services under section 337 of the OAA, an individual who is unable to obtain nutrition because of social distancing due to the emergency is treated as an individual who is homebound due to illness. Also, during the COVID-19 public health emergency, requirements to comply with dietary guidelines may be waived for meals provided as Congregate Nutrition Services and Home Delivered Nutrition Services.
Sec. 3223. Continuity of service and opportunities for participants in community service activities under title V of	For individuals who are participating in the community service activities as of March 1, including the Older American Community Service Employment Program, under the Community Service Senior Opportunities Act (Title V of the OAA), the Secretary of Labor may allow such individuals to extend their participation for a period that exceeds the normal limit of 48 months if the Secretary of Labor determines such extension is appropriate due to the effects of the COVID-19 public health emergency. The Secretary of Labor may also increase the average participation cap for eligible individuals applicable to

the Older Americans Act of 1965.	grantees from 27 months (or 36 months under extenuating circumstances) to a cap the Secretary of Labor determines is appropriate due to the COVID-19 public health emergency. The Secretary of Labor also may increase the amount available to pay the authorized administrative costs for a project to an amount not to exceed 20 percent of the grant amount (currently capped at 13.5 percent, or 15 percent for certain situations) if the Secretary of Labor determines that such increase is necessary for additional administrative needs to respond to the COVID-19 public health emergency.
Sec. 3224. Guidance on protected health information.	This section requires the Secretary of HHS to issue guidance on the sharing of patients' protected health information under HIPAA regulations during the Section 319 public health emergency declaration, the Stafford Act emergency declaration, and the national emergency under the National Emergencies Act with respect to COVID-19. Guidance must be issued no later than 180 days after enactment.
Sec. 3225. Reauthorization of healthy start program.	This section reauthorizes the Healthy Start program and makes modifications to encourage grant recipients to target social determinants of health and poor birth outcomes in addition to infant mortality. The section appropriates $125.5 million for the program for each of fiscal years 2020 through 2025. Not later than four years after enactment, the Government Accountability Office (GAO) must conduct and submit a report to Congress on the Healthy Start program, including outcomes and coordination between agencies.
Sec. 3226. Importance of the blood supply.	The Secretary of HHS must carry out a national campaign to raise awareness of the need for donations for the blood supply during the COVID-19 public health emergency. The Secretary may enter into contracts with nonprofit entities to establish an awareness campaign. The Secretary must consult with the FDA Commissioner, the Assistant Secretary for Health, the Centers for Disease Control and Prevention (CDC) Director, the National Institutes of Health (NIH) Director, and the heads of other relevant Federal agencies, accrediting bodies, and representative organizations. The Secretary must submit a report to Congress within two years of enactment of this Act to the Senate HELP and House E&C Committees on the activities carried out under this section, trends in blood donations, and evaluation of impact of the public awareness campaign.
PART III —Innovation	
Sec. 3301. Removing the cap on OTA during public health emergencies.	This section removes the cap on Biomedical Advanced Research and Development Authority's (BARDA) other transactions authority (OTA) (transactions other than procurement contracts, grants, and cooperative agreements) to carry out projects for purposes of a Section 319 public health emergency to allow the BARDA to contract more easily with the private sector on research and development. Any transactions entered into during such public health emergency will not be terminated solely due to the expiration of such public health emergency. After the expiration of the public health emergency, the Secretary of HHS must report to Senate HELP and House E&C Committees on any funds used under this added provision and descriptions and outcomes of such projects.
Sec. 3302. Priority zoonotic animal drugs.	This section creates a new program to expedite the development and review of "priority zoonotic animal drugs," which will operate similarly to the breakthrough therapy designation. This expedited process is for applications for approval or

	conditional approval of a new animal drug where preliminary clinical evidence indicates that the new animal drug, alone or in combination with one or more other animal drugs, has the potential to prevent or treat a zoonotic disease in animals, including a vector borne-disease, that has the potential to cause serious adverse health consequences for, or serious or life-threatening diseases in, humans. The Secretary of HHS will determine whether the new animal drug meets the criteria for priority zoonotic animal drug designation within 60 calendar days after receipt of request for such designation.
PART IV – HEALTH CARE WORKFORCE	
Sec. 3401. Reauthorization of health professions workforce programs.	This section, along with sections 3402 and 3403, reauthorizes and updates programs under Title VII of the PHSA. It authorizes $23,711,000 for each of fiscal years 2021 through 2025 for grants to designated health professions schools that have a significant number of under-represented minority students for the purpose of assisting the schools in supporting programs of excellence in health professions education for under-represented minority individuals. This section authorizes $51,470,000 for each of fiscal years 2021 through 2025 for financial hardship scholarships to disadvantaged students in health professions schools. This section authorizes $1,190,000 for each of fiscal years 2021 through 2025 for loan repayments to individuals from disadvantaged backgrounds who agree to serve as members of faculties in eligible health professions schools. This section authorizes $15 million for each of fiscal years 2021 through 2025 for grants to health professions schools to assist individuals from disadvantaged backgrounds to undertake education to enter a health profession. By September 30, 2025, and every five years thereafter, the Secretary of HHS must submit to the Senate HELP and House E&C Committees a report concerning the efforts of the Secretary to address the need for a representative mix of individuals from historically minority health professions schools. This section also permits the Secretary to make primary care training and enhancement grants and contracts with medical and physician assistant schools to plan, develop, and operate a program that identifies or develops innovative models of providing care and trains primary care physicians on such models. The section also permits the Secretary to give priority in issuing such grants or contracts to qualified applicants that train residents in rural areas, including for Tribes or Tribal Organizations in such areas. The section authorizes $48,924,000 for each of fiscal years 2021 through 2025 for such grants and contracts. This section also authorizes $28,531,000 for fiscal years 2021 through 2025 for training in general, pediatric, and public health dentistry.

	This section updates the titles of the Senate HELP and House E&C Committees for the purposes of receiving reports from the Advisory Committee on Training in Primary Care Medicine and Dentistry. This section authorizes $41,250,000 for each of fiscal years 2021 through 2025 for area health education center awards for infrastructure development and point of service maintenance and enhancement. This section modifies the Quentin N. Burdick program for rural interdisciplinary training grants and contracts to be available for projects designed to use innovative or evidence-based methods to train health care practitioners to provide services in rural areas. This section also modifies allied health grants or contracts under 42 USC § 294e to include assistance for expansion of enrollments in allied health professions whose services are most needed for geriatric populations or for maternal and child health. This section appropriates $5,663,000 for each of fiscal years 2021 through 2025 for the National Center for Health Care Workforce Analysis. This section reactivates the Advisory Council on Graduate Medical Education (the Council) and adds the HRSA Administrator to the membership. It also updates the titles of the Senate HELP and House E&C Committees for the purposes of receiving recommendations from the Council. The Council must submit a report on recommendations to the Secretary of HHS and to the Senate HELP and House E&C Committees by September 30,2023, and every five years thereafter. This section updates the eligible entities for grants or contracts for public health training centers to public health schools that plan, develop, operate, and evaluate projects to improve preventative medicine, health promotion and disease prevention, or access to and quality of health care services in rural or medically underserved communities. This section authorizes $17 million for each of fiscal years 2021 through 2025 for grants or contracts to increase the number of individuals in the public health workforce. This section also authorizes such sums as may be necessary for each of fiscal years 2021 through 2025 for the pediatric specialty loan repayment program.

Sec. 3402. Health workforce coordination.	Within one year of enactment, the Secretary of HHS, in consultation with the Advisory Committee on Training in Primary Care Medicine and Dentistry and the Advisory Council on Graduate Medical Education, will develop a comprehensive and coordinated plan with respect to the health care workforce development programs within HHS, including education and training programs. The plan must include performance measures, identification of gaps, identification of actions to address such gaps, and identification of barriers, if any, to implementing such actions. The Secretary must coordinate with other Federal agencies and departments that fund or administer health care workforce development programs to evaluate the performance of such programs and identify opportunities to improve the quality and consistency of information collected to evaluate such programs. The Secretary must submit a report of the plan and actions taken to implement it not later than two years after enactment to Senate HELP and House E&C Committees.
Sec. 3403. Education and training related to geriatrics.	This section reauthorizes and updates the Geriatrics Workforce Enhancement Program. This program allows the Secretary of HHS to support programs (through grants, contracts or cooperative agreements) that train health professionals in geriatrics (examples below). The Secretary is required to give priority to programs that demonstrate coordination with another Federal or state program or another public or private entity as well as those that benefit rural or medically underserved populations. The Secretary may give priority to any program that: integrates geriatrics into primary care practice; provides training to integrate geriatric care into other specialties across care settings; emphasizes integration of geriatric care into existing service delivery locations and across care settings (including primary care clinics, Federally Qualified Health Centers (FQHC), Critical Access Hospitals (CAHs), emergency care, assisted living and nursing facilities, and home-and community-based services, which can include adult daycare); supports training and retraining of faculty, primary care providers, other direct care providers, and other appropriate professionals on geriatrics; emphasizes education and engagement of family caregivers on disease management and strategies to meet the needs of caregivers of older adults; and conducts outreach to communities that have a shortage of geriatric professionals. The Secretary also may give special consideration for entities that provide services in geriatric workforce shortage areas. This section also outlines reporting requirements for entities that are selected for the program. Further, the Secretary must submit a report to Congress within four years after enactment and every five years afterward on activities and outcomes from the program. The Secretary must establish or maintain a program to provide geriatric academic career awards to individuals. An eligible individual for the award would have to be someone who is board certified or has “completed training in a discipline” and is

	employed by a health professions school or graduate program. The individual also must have completed a fellowship in geriatrics or reviewed specialty training in geriatrics and has a junior, nontenured, faculty appointment at a health professions school. The individual must be nominated by a geriatrics program or a participant in the geriatric grant program. The award amounts under the Geriatrics Workforce Enhancement Program must be at least $75,000 for fiscal year 2021 and adjusted by the consumer price index for subsequent years. This section authorizes $40,737,000 from fiscal year 2021 through 2025 to carry out these provisions. The awards may be up to five years in duration.
Sec. 3404. Nursing workforce development.	This section reauthorizes and updates programs under Title VIII of the Public Health Service Act. It modifies the nursing workforce development grants and contracts. The goals of the program are modified to fund innovative demonstration projects or provide for strategic workforce supplementation activities as needed to address national nursing needs, including: (1) addressing challenges related to the distribution of the nursing workforce and existing or projected workforce shortages in geographic areas; (2) increasing health care services access and quality, including by supporting training of nurses, advanced practice registered nurses (APRNs), and advanced education nurses within community based settings and other health delivery system settings; and (3) addressing other strategic goals and priorities identified by the Secretary of HHS. Contracts may be made with public or private entities. Continued funding is conditioned on the reporting of data that demonstrate satisfactory progress. The section adds clinical nurse leaders to the definition of "advanced education nurses" for purposes of advanced education nursing grants under 42 USC § 296j and adds authorized clinical nurse specialist programs as programs eligible for support under such grants. The subsection for retention program grants and contracts (42 USC § 296p(c)) is consolidated to include programs to: (1) promote training of professional nurses, APRNs, and nurses with graduate nursing education; (2) train licensed practical nurses (LPNs), certified nurse assistants (CNAs), home health aides, associate degree nurses, and others to become registered nurses with baccalaureate degrees or nurses with graduate nursing education; and (3) encourage development and implementation of internships, fellowships, and residency programs to encourage the development of specialties. The preference for education technology and nurse retention program is removed. The eligible entities for grants and contracts are expanded to include nursing schools, health care facilities including FQHCs or nurse-managed health clinics, and partnerships of such schools and facilities. The loan repayment program for a nurse or APRN that agrees to serve as a nurse at a facility with a critical shortage of nurses or as nurse faculty for at least two years, which limited nurse/APRN assignment to public or nonprofit private entities, is modified to permit assignment to for profit private entities.

	Clinical nurse specialists are added to the composition of the National Advisory Council on Nurse Education and Practice. Such Advisory Council must report on the activities, findings, and recommendations of the Advisory Council to the Senate HELP and House E&C Committees within two years of enactment. The section authorizes $137,837,000 for each of fiscal years 2021 through 2025 for purposes of carrying out Advanced Education Nursing Grants (part B), Workforce Diversity Grants (part C), and Nurse Education, Practice and Quality Grants (part C), and $117,135,000 for each of fiscal years 2021 through 2025 for carrying out the Student Loans repayment program (part E). GAO must evaluate and report on the nurse loan repayment programs and submit a report to the Senate HELP and House E&C Committees within 18 months. A "nurse managed health clinic" is a nurse practice arrangement, managed by an advanced practice nurse and associated with a nursing school, federally qualified health center, or independent nonprofit health or social services agency, that provides primary care or wellness services to underserved or vulnerable populations. The Secretary must submit a report on nursing workforce enhancement programs and activities of HHS to the Senate HELP and E&C Committees every two years beginning no later than September 30, 2020. The Secretary must include information on the grants and contracts awarded for advanced education nursing grants in the biennial report on nursing workforce enhancement programs and activities.
Subtitle D—Finance Committee	
Sec. 3701. Exemption for telehealth services.	This section permits high-deductible health plans to provide telehealth or other remote care services before the deductible is satisfied. It also permits an individual covered by a high-deductible health plan to have coverage for telehealth and other remote care without losing eligibility for health savings accounts (HSA).
Sec. 3702. Inclusion of certain over-the-counter medical products as qualified medical expenses.	This section allows HSAs, health FSAs, health reimbursement arrangements (HRAs), and Archer Medical Savings Accounts (MSAs) to reimburse over-the-counter medicines and drugs without a prescription. In addition, menstrual care products qualify as a permitted expenses. This section has an effective date of January 1, 2020.
Sec. 3703. Increasing Medicare telehealth	This section permits the Secretary of HHS to waive under section 1135 of the Social Security Act any requirement of section 1834(m) of the Social Security Act (SSA) relating to telehealth services during the COVID-19 public health emergency.

flexibilities during emergency period.	
Sec. 3704. Enhancing Medicare telehealth services for Federally qualified health centers and rural health clinics during emergency period.	This section establishes payment (to be developed and implemented by the Secretary of HHS) for telehealth services provided by a FQHC or a rural health clinic during the COVID-19 public health emergency. The payment methods will be based on payment rates that are similar to the national average payment rates for comparable telehealth services under the Medicare Physician Fee Schedule. The Secretary may implement such payment methods through program instruction or otherwise. Costs associated with telehealth services will not be used to determine the amount of payment for FQHC services under the FQHC prospective payment system or for rural health clinic services under the methodology for all-inclusive rates.
Sec. 3705. Temporary waiver of requirement for face-to-face visits between home dialysis patients and physicians.	This section permits the Secretary of HHS to waive the requirement to have a non-telehealth face-to-face visit monthly within the first three months of home dialysis and once every three months thereafter and allow such visits to occur via telehealth during the COVID-19 public health emergency.
Sec. 3706. Use of telehealth to conduct face-to-face encounter prior to recertification of eligibility for hospice care during emergency period.	Hospice care is available to terminally ill patients and eligibility is determined by physician certification for two 90-day periods and then an unlimited number of 60-day periods. Generally, a physician or nurse practitioner must have a face-to-face encounter with an individual in hospice care prior to the 180th-day recertification and each subsequent recertification. This section amends the conditions of payment for hospice services to allow recertification of hospice services to be conducted via telehealth during the COVID-19 public health emergency.
Sec. 3707. Encouraging use of telecommunications systems for home health services furnished during emergency period.	This section directs the Secretary of HHS to consider ways to encourage the use of telecommunication systems, including for remote patient monitoring and other communications or monitoring systems, for home health services furnished during the COVID-19 public health emergency, including by guidance and outreach.
Sec. 3708. Improving care planning for Medicare home health services.	This section allows a nurse practitioner or clinical nurse specialist who is working in accordance with state law, or a physician assistant under the supervision of a physician, to order home health services. This section aligns the conditions of participation and conditions for payment (under Medicare Parts A & B) for home health services that apply to the aforementioned non-physician practitioners. The section amends relevant portions of Sections 1814(a) of the SSA to specify that such non-physician practitioners may review a home health care plan and engage in face-to-

	face encounters. The section requires the Secretary of HHS to implement the section and promulgate regulations within six months. This section also updates the definition of "Home Health Services" to include nurse practitioners, clinical nurse specialists, and physician assistants as professionals who can establish and review a care plan. It also amends this definition to allow these clinicians to direct medical social services in home health settings and to allow them to supervise services in home health settings. The section also amends the definition of a "covered osteoporosis drug" to mean an injectable drug for the treatment of menopausal osteoporosis provided to an individual by a home health agency in compliance with regulations. This also allows a nurse practitioner or clinical nurse specialist, mid-wife, or physician assistant to certify certain health conditions related to post-menopausal osteoporosis. This section also amends the Home Health Prospective Payment System provisions to allow a nurse practitioner, clinical nurse specialist, or physician assistant to submit claims for home health services. This section applies these changes to the Medicaid program as well. The Secretary must promulgate regulations to implement this entire section within six months of date of enactment.
Sec. 3709. Adjustment of sequestration.	This section exempts Medicare programs from reduction under any sequestration order issued before, on, or after enactment. This exemption applies during the period of May 1, through December 31, 2020. In addition, this section extends the sequestration required in Section 251A(6) of the Balanced Budget and Emergency Deficit Control Act (BBEDCA) of 1985 from fiscal year 2029 to fiscal year 2030.
Sec. 3710. Medicare hospital inpatient prospective payment system add-on payment for COVID–19 patients during emergency period.	For discharges occurring during the COVID-19 emergency period for COVID-19 diagnoses, the Secretary of HHS must increase the weighting factor by 20 percent for such diagnoses. This effectively increases Medicare payment to hospitals for treating Medicare beneficiaries for COVID-19. The Secretary must identify a discharge of the patient through diagnosis codes, condition codes, or "other such means as may be necessary." According to summaries from congressional committees, this is an effort to "expedite the use of a COVID-19 diagnosis" and develop appropriate payments to hospitals for treating COVID-19 patients. This payment adjustment does not consider budget neutrality requirements.

	If a state has waived all or part of this section under 1115A waiver authority, then the state may develop its own payment adjustment. The Secretary may implement this section by program instruction or otherwise.
Sec. 3711. Increasing access to post-acute care during emergency period.	This section will give hospitals flexibility to transfer patients out of their facilities and into hour inpatient rehabilitation facility (IRFs) and long-term care hospitals (LTCHs). It waives the three-hour IRF rule, which requires the patient to receive three hours of therapy per day over a five-day period or 15 hours over a week, during the COVID-19 emergency period. This section also waives the site neutral payment rate provisions in LTCHs during the emergency period. Specifically, it waives: • the 50 percent rule that relates to the payment adjustment for LTCHs that do not have a discharge payment percentage for the period that is at least 50 percent; and • the site neutral Inpatient Prospective Payment System rate (described at 42 USC § 1395ww(m)(6)(A)(i)).
Sec. 3712. Revising payment rates for durable medical equipment under the Medicare program through duration of emergency period.	This section would require the Secretary of HHS to apply certain transition rules for a scheduled payment reduction related to durable medical equipment (DME) through the COVID-19 emergency period. This would effectively delay an upcoming DME payment reduction through the COVID-19 emergency period. For items and services furnished in rural areas and non-contiguous areas (Alaska, Hawaii, and U.S. territories), the payment adjustment transition period originally in effect from June 1, 2018 through December 31, 2020 (during which payment is 50 percent of the adjusted payment amount and 50 percent of the unadjusted fee schedule amount) is extended through the duration of the COVID-19 public health emergency, if longer. For items and services furnished in areas other than rural and non-contiguous areas, the payment adjustment transition amount originally in effect from June 1, 2018 through December 31, 2020 (during which payment is 100 percent of the adjusted payment amount) is modified to be 75 percent of the adjusted payment amount and 25 percent of the unadjusted fee schedule amount, and the payment adjustment transition period is extended through the duration of the COVID-19 public health emergency.
Sec. 3713. Coverage of the COVID-19 vaccine under part B of the	This section allows a FFS Medicare beneficiary to receive a COVID-19 vaccine without it applying to his or her deductible. It is intended to allow beneficiaries to receive the vaccine with no cost-sharing obligations. This would apply to Medicare Advantage (MA) as well.

Medicare program without any cost-sharing.	This section applies when a vaccine is licensed pursuant to section 351 of the PHSA. The Secretary of HHS may implement this section through program instruction or otherwise.
Sec. 3714. Requiring Medicare prescription drug plans and MA-PD plans to allow during the COVID-19 emergency period for fills and refills of covered part D drugs for up to a 3-month supply.	This section allows beneficiaries on a Medicare prescription drug plan or a MA prescription drug plan (MA-PD) to fill prescriptions for a three-month period. This applies regardless of any cost and utilization management, medication therapy management, or other similar program for covered drugs. This section allows an exception for individuals with a "safety edit" (e.g., restrictions on non-medically necessary opioid refills). The Secretary of HHS may implement this through program instruction or otherwise.
Sec. 3715. Providing home and community-based services in acute care hospitals.	This section adds language to the Medicaid statute (section 1902(h) of the SSA) to allow personal assistance services and home and community-based attendant services to be provided and reimbursed by state Medicaid programs during a beneficiary's acute care hospital stay. This is intended reduce hospital lengths of stay.
3716. Clarification regarding uninsured individuals.	This section amends the definition of uninsured individuals for the purposes of a state wishing to elect the state option to use its Medicaid program to provide coverage of COVID-19 testing and related services for such individuals during the COVID-19 public health emergency. This definition was added by the FFCRA. The section modifies the definition to include individuals who would be eligible for Medicaid in a state with Medicaid expansion but do not live in such a state and individuals who receive certain limited Medicaid benefits. It clarifies that if states choose this option, an uninsured individual (and one receiving limiting benefits) can be furnished a test and testing-related service with no cost-sharing obligations.
3717. Clarification Regarding Coverage of COVID-19 Testing Products	This section strikes language, added by FFCRA, that Medicaid and CHIP coverage policies for COVID-19 testing must be for vitro diagnostic tests "that are approved, cleared, or authorized" under certain sections of the FDCA. This modification effectively removes FDA approval, clearance, or authorization from the Medicaid and CHIP coverage requirement for COVID-19 tests. The language in the FFCRA would have omitted coverage of some tests that are legally marketed during the COVID-19 public health emergency.
3718. Amendments Relating to Reporting Requirements with Respect to Clinical Diagnostic Laboratory Tests	This section delays the reporting period for private sector payment rates for the purposes of establishing Medicare payment rates through 2021. It also delays the scheduled Medicare payment reductions for clinical diagnostic laboratory tests for 2021. The scheduled reductions continue in 2022 through 2024.

3719. Expansion of the Medicare Hospital Accelerated Payment Program During the COVID-19 Public Health Emergency	This section amends a program that allows the Secretary of HHS to provide payments to hospitals that have significant cashflow problems resulting from unusual circumstances (see Sec. 1815(e)(3) of the SSA). Specifically, during the emergency period, this section expands the above-mentioned program to children's hospitals, cancer hospitals and critical access hospitals (CAHs). Subject to fraud, waste, and abuse safeguards, the Secretary may make accelerated payments upon request from the hospitals. The Secretary may make the payments on a periodic or lump sum basis. The payments may be based on 100 percent (or 125 percent for CAHs) of prior payments. The period for the payments may be up to six months. Qualifying hospitals would not be required to pay back HHS for 120 days and would have 12 months to complete the payment. The Secretary may implement this section through program instruction or otherwise.
3720. Special Rules Related to Temporary Increase Medicaid FMAP	This section adds exceptions to the requirements for the increased Federal medical assistance percentage (FMAP), which was authorized by the FFCRA. Among other provisions, the FFCRA prohibited a state from receiving the 6.2 percent increase in FMAP if the state restricted eligibility or raised premiums (see Sec. 6008(b)(1)-(4) of the FFCRA) during the emergency period. This section would allow a state to receive the increase, regardless of the requirements if 60 days after enactment the state certifies it is unable to meet the requirements and the state does not enact stricter eligibility standards or higher premiums than what were in place on the date of enactment. The section also clarifies that federal financial participation would be available for medical assistance furnished to individuals whom the state is required to treat as eligible.
Subtitle E- Health and Human Services Extenders.	
PART I – MEDICARE PROVISIONS	
Sec. 3801. Extension of the work geographic index floor under the Medicare program.	This section extends the Work Geographic Index floor through December 2020. This allows the Secretary of HHS to provide larger payments to physicians in areas that have labor costs lower than the national average through December 2020.
Sec. 3802. Extension of funding for the quality measure endorsement, input, and selection.	This section authorizes $20 million for HHS to contract with a "multi-stakeholder group" to provide input on the selection of and efficiency of quality measures (i.e., the National Quality Forum) through November 2020. This section retroactively enacts this provision from December 20, 2019.

Sec. 3803. Extension of funding outreach and assistance for low-income programs.	This section provides $13 million through November 2020 for grants to states for health insurance assistance programs, which are effectively outreach programs that provide insurance counseling and assistance to Medicare-eligible individuals. This section also provides $7.5 million for Area Agencies on Aging through November 2020. This section provides $5 million through November 2020 for Aging and Disabled Resource Centers. This section provides $12 million through November for a contract with the National Center for Benefits and Outreach Enrollment. The provisions in this section are in effect retroactively to December 20, 2019.
PART II – MEDICAID PROVISIONS	
Sec. 3811. Extension of the Money Follows the Person rebalancing demonstration program.	This section extends the Money Follows the Person demonstration program (MFP), which supports state efforts in improving their long-term services and support systems, and, in particular, to reduce the use of institutional-based services. This section extends the MFP through November 2020.
Sec. 3812. Extension of spousal impoverishment protections.	This section extends the spousal impoverishment protections, which allow the spouse of an individual qualifying for nursing home services to live at home. The section clarifies that nothing in the section prohibits states from applying income tests that follow applicable law or disregarding the spouse's income and assets to provide medical assistance for home and community-based services.
Sec. 3813. Delay of DSH reductions.	This section delays the Medicaid Disproportionate Share Hospital (DSH) allotment reductions from May 23, 2020 through September 30, 2020 to December 1, 2020 through September 30, 2021.
Sec. 3814. Extension and expansion of Community Mental Health Services demonstration program.	The section expands the Community Mental Health Services Demonstration (CMHSD) through November 2020. Within six months, the Secretary of HHS must select two additional states to participate (currently eight states are participating in the CMHSD). The Secretary must select two states that had been awarded planning grants and applied to participate in the program, but were not selected. A total of 24 states received planning grants. Prior to services being delivered under the demonstration, the selected states must submit a plan to monitor certified community behavioral health clinics under the demonstration program to ensure compliance with applicable criteria during the demonstration period. Further, the state must commit to collecting data; notifying the Secretary of any planned changes

	that would deviate from the prospective payment methodology outlined in the demonstration application; and obtain approval from the Secretary for any change before implementation. This section also makes changes to the payment methodology for payments after 2019. It also requires a GAO report within 18 months regarding state experiences and program effects on patient health and cost of care, among other things. The report must include recommendations to improve validation of encounter data and accuracy in payments to community behavioral health clinics in Medicaid.
PART III – HUMAN SERVICES AND OTHER HEALTH PROGRAMS	
Sec. 3821. Extension of sexual risk avoidance education program.	This section extends the Sexual Risk Avoidance Education (SRAE) program, which provides funding to states to provide education exclusively focused on sexual risk avoidance. This section extends SRAE from May 22, 2020 through November 30, 2020 at current funding levels.
Sec. 3822. Extension of personal responsibility education program.	This section extends the Personal Responsibility Education Program (PREP), which provides states, community groups, tribes, and tribal organizations with grants to implement evidence-based, innovative strategies for teen pregnancy and HIV/STD prevention, youth development, and adulthood preparation for young people. This section extends PREP from May 22, 2020 through November 30, 2020 at current funding levels.
Sec. 3823. Extension of demonstration projects to address health professions workforce needs.	This section extends the Health Professions Opportunity Grants (HPOG), which provides funding to help low-income individuals obtain education and training in health care jobs. This section extends HPOG through November 30, 2020 at current funding levels.
Sec. 3824. Extension of the temporary assistance for needy families program and related programs.	This section extends Temporary Assistance for Needy Families (TANF) and related programs through November 30, 2020 at current funding levels. TANF was previously expected to expire May 22, 2020.
PART IV – PUBLIC HEALTH PROVISIONS	
Sec. 3831. Extension for community health centers, the National Health Service Corps, and teaching health centers	This section extends mandatory funding for community health centers, the National Health Service Corps, and teaching health centers that operate Graduate Medical Education (THC GME) programs. This section extends these programs from May 22, 2020 through November 30, 2020 at current funding levels. During this extension, community health centers will receive $668.5 million, the National Health Service Corps will receive $51.8 million, and THC GME programs will receive $21.1 million.

that operate GME programs.	
Sec. 3832. Diabetes programs.	This section extends mandatory funding for the Special Diabetes Program for Type I Diabetes and the Special Diabetes Program for Indians. This section extends funding for these programs from May 22, 2020 through November 30, 2020 at current funding levels ($25.1 million).
PART V – MISCELLANEOUS PROVISIONS	
Sec. 3841. Prevention of duplicate appropriations for fiscal year 2020.	This section prevents duplicate appropriations for fiscal year 2020 by clarifying that expenditures made by the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019, the Further Continuing Appropriations Act of 2020, and Further Health Extenders Act of 2019, and the Further Consolidated Appropriations Act, 2020 will be charged to the applicable appropriation or authorization provided by the amendments made by this title of the CARES Act.
Subtitle F – Over-the-Counter Drugs	
PART I – OTC DRUG REVIEW	
Sec. 3851. Regulation of certain nonprescription drugs that are marketed without an approved drug application.	This section codifies and reforms the current review process for over-the-counter (OTC) drugs. A nonprescription drug is deemed to be generally recognized as safe and effective (GRASE), and not a new drug for which approval of an application under section 505 of the FDCA would be required, if: • the drug conforms to a final monograph (a published "recipe" of active ingredients, dosage form, dose, and labeling) and is in a dosage form that has been used to a material extent and for a material time • the drug is a category I drug (GRASE) subject to a tentative final monograph and is in a dosage form that has been used to a material extent and for a material time A nonprescription drug is not a new drug for which approval of an application under section 505 of the FDCA would be required if: • the drug is a category III drug (i.e., insufficient information to determine if GRASE) subject to a tentative final monograph and is in a dosage form that has been used to a material extent and for a material time; or • the drug is a category I drug subject to a proposed monograph or advance notice of proposed rulemaking and is in a dosage form that has been used to a material extent and for a material time. Drugs classified as category II drugs (not GRASE) under a tentative final monograph or subject to a determination to be not GRASE in a proposed rule are new drugs, are misbranded under section 502(ee), and are subject to the requirement for an approved new drug application under section 505 beginning 180 days after enactment, unless the Secretary of HHS decides to extend the marketing period in the interest of public health.

	Drugs that are not GRASE are new drugs, are misbranded under section 502(ee), and are subject to the requirement for an approved new drug application under section 505 (with no 180-day grace period). This section establishes a process to determine whether a drug is GRASE and not a new drug through administrative order, rather than the current process of notice-and-comment rulemaking. The administrative order process can be initiated by the Secretary or by request from a requestor. The process includes issuing a proposed administrative order on the FDA website and a notice of availability in the *Federal Register*, and at least 45 days for public comment. The process also includes formal dispute resolution and opportunity for judicial review. This section also provides an expedited administrative order process for drugs that present an imminent hazard to public health. Where a requestor requests an administrative order, the Secretary must determine whether the request is sufficiently complete before proceeding with the administrative order process. A final administrative order in response to a request under this section **results in an 18-month period of exclusivity** beginning on the date the requestor may lawfully market the drug. Such exclusivity may be granted for: • a drug that contains a new active ingredient; and • a drug with a new condition of use for which new human data studies conducted or sponsored by the requestor were essential to the issuance of such order. Minor changes in dosage form of a drug can be made by a requestor without issuance of an order if the requestor maintains information necessary to demonstrate that the change will not affect the safety or effectiveness of the drug and will not materially affect the extent of absorption or other exposure to the active ingredient compared to a suitable reference product, and the change conforms to requirements as set forth in a general administrative order to set rules for minor changes.
Sec. 3852. Misbranding.	This section clarifies that an OTC drug that does not comply with the monograph requirements is misbranded.
Sec. 3853. Drugs excluded from the over-the-counter drug review.	This section clarifies that this Act will not apply to any nonprescription drug that was excluded from OTC review in 37 Fed. Reg. 9466 (May 11, 1972), which established the OTC review process.
Sec. 3854. Treatment of Sunscreen Innovation Act.	A sponsor of a nonprescription sunscreen active ingredient or combination thereof that is subject to a proposed sunscreen order under laws added by the Sunscreen Innovation Act may, within 180 days of enactment, elect to transition to review under the new streamlined review process set forth in this Act. A sponsor of such nonprescription sunscreen may request one or more confidential meetings with respect to a proposed sunscreen order. A final order under the Sunscreen Innovation Act will grant an 18-month period of exclusivity. The Sunscreen Innovation Act is amended to sunset at the end of fiscal year 2022.
Sec. 3855. Annual update to Congress on	The Secretary of HHS must submit annual reports to the Senate HELP and House E&C Committees beginning one year after the date of enactment describing the progress of the FDA in evaluating the cough and cold monograph for children under age six

appropriate pediatric indication for certain OTC cough and cold medicines.	and revisions, as appropriate, thereto. The reporting requirement ends when the FDA has completed review and revised the cough and cold monograph.
Sec. 3856. Technical corrections.	This section updates internal cross-references.
PART II – USER FEES	
Sec. 3861. Finding.	This section clarifies that fees collected pursuant to this part will be dedicated to OTC monograph drug activities.
Sec. 3862. Fees relating to over-the-counter drugs.	The Secretary of HHS will assess fees for facilities and for OTC monograph order requests (essentially, a "user fee" similar to that which applies to review of drugs and devices). The user fee for requestors of OTC monograph orders will be $500,000 for a Tier 1 OTC monograph order request and $100,000 for a Tier 2 OTC monograph order request. Such fees are due upon submission of the order request. • A Tier 1 OTC monograph order request is one that is not a Tier 2 OTC monograph order request. • A Tier 2 OTC monograph request is an OTC monograph request for relatively simple changes, including labeling changes, modification of directions for use, or any request that the Secretary determines is a Tier 2 request based on program implementation experience or other appropriate factors. The facility fees apply to persons that own OTC monograph drug facilities and will be assessed annually. A contract manufacturing organization facility will be assessed 2/3 of the facility fee. The amount of the facility fee will be established to generate a total facility fee revenue based on annual base revenue targets, operating reserve adjustments, and additional direct cost adjustments. Both fees are subject to inflation adjustments.