



TITLE III—SUPPORTING AMERICA’S HEALTH CARE SYSTEM IN THE FIGHT AGAINST THE CORONAVIRUS

Subtitle A—Health Provisions

- Section 3001. Short title

PART I—ADDRESSING SUPPLY SHORTAGES

SUBPART A—MEDICAL PRODUCT SUPPLIES

Section 3101. National Academies report on America’s medical product supply chain security

- Directs the National Academies to study the manufacturing supply chain of drugs and medical devices and provide Congress with recommendations to strengthen the U.S. manufacturing supply chain.

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

- Clarifies that the Strategic National Stockpile can stockpile medical supplies, such as the swabs necessary for diagnostic testing for COVID-19.

Section 3103. Treatment of respiratory protective devices as covered countermeasures

- Provides permanent liability protection for manufacturers of personal respiratory protective equipment, such as masks and respirators, in the event of a public health emergency, to incentivize production and distribution.

SUBPART B—MITIGATING EMERGENCY DRUG SHORTAGES

Section 3111. Prioritize reviews of drug applications; incentives

- Requires the Food and Drug Administration (FDA) to prioritize and expedite the review of drug applications and inspections to prevent or mitigate a drug shortage.

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

- Requires drug manufacturers to submit more information when there is an interruption in supply, including information about active pharmaceutical ingredients, when active pharmaceutical ingredients are the cause of the interruption. Requires manufacturers to

maintain contingency plans to ensure back up supply of products. Requires manufacturers to provide information about drug volume.

SUBPART C—PREVENTING MEDICAL DEVICE SHORTAGES

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

- Clarifies that during a public health emergency, a medical device manufacturer is required to submit information about a device shortage or device component shortage upon request of the FDA.

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

SUBPART A—COVERAGE OF TESTING AND PREVENTIVE SERVICES

Section 3201. Coverage of diagnostic testing for COVID-19

- Clarifies that all testing for COVID-19 is to be covered by private insurance plans without cost sharing, including those tests without an EUA by the FDA.
- Section 3202. Pricing of diagnostic testing.
- For COVID-19 testing covered with no cost to patients, requires an insurer to pay either the rate specified in a contract between the provider and the insurer, or, if there is no contract, a cash price posted by the provider.

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

- Provides free coverage without cost-sharing of a vaccine within 15 days for COVID-19 that has in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force or a recommendation from the Advisory Committee on Immunization Practices (ACIP).

SUBPART B—SUPPORT FOR HEALTH CARE PROVIDERS

Section 3211. Supplemental awards for health centers.

- Provides \$1.32 billion in supplemental funding to community health centers on the front lines of testing and treating patients for COVID-19.

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

- Reauthorizes Health Resources and Services Administration (HRSA) grant programs that promote the use of telehealth technologies for health care delivery, education, and health information services. Telehealth offers flexibility for patients with, or at risk of contracting, COVID-19 to access screening or monitoring care while avoiding exposure to others.

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

- Reauthorizes HRSA grant programs to strengthen rural community health by focusing on quality improvement, increasing health care access, coordination of care, and integration

of services. Rural residents are disproportionately older and more likely to have a chronic disease, which could increase their risk for more severe illness if they contract COVID-19.

Section 3214. United States Public Health Service Modernization.

- Establishes a Ready Reserve Corps to ensure we have enough trained doctors and nurses to respond to COVID-19 and other public health emergencies.

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

- Makes clear that doctors who provide volunteer medical services during the public health emergency related to COVID-19 have liability protections.

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

- Allows the Secretary of Health and Human Services (HHS) to reassign members of the National Health Service Corps to sites close to the one to which they were originally assigned, with the member's agreement, in order to respond to the COVID-19 public health emergency.

SUBPART C—MISCELLANEOUS PROVISIONS

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

- Allows for additional care coordination by aligning the 42 CFR Part 2 regulations, which govern the confidentiality and sharing of substance use disorder treatment records, with Health Insurance Portability and Accountability Act (HIPAA), with initial patient consent.

Section 3222. Nutrition services.

- Waives nutrition requirements for Older Americans Act (OAA) meal programs during the public health emergency related to COVID-19 to ensure seniors can get meals in case certain food options are not available.

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

- Allows the Secretary of Labor to extend older adults' participation in community service projects under OAA and make administrative adjustments to facilitate their continued employment under the program.

Section 3224. Guidance on protected health information.

- Requires the Department of Health and Human Services (HHS) to issue guidance on what is allowed to be shared of patient record during the public health emergency related to COVID-19.

Section 3225. Reauthorization of healthy start program.

- Reauthorizes Healthy Start, which is a program that provides grants to improve access to services for women and their families, who may need additional support during the public health emergency related to COVID-19.

Section 3226. Importance of the blood supply.

- Directs the Secretary of HHS to carry out an initiative to improve awareness of the importance and safety of blood donation and the continued need for blood donations during the COVID-19 public health emergency.

PART III—INNOVATION

Section 3301. Removing the cap on OTA for public health emergencies.

- Allows the Biomedical Advanced Research and Development Authority (BARDA) to more easily partner with private sector on research and development, which includes helping to scale up manufacturing as appropriate, by removing the cap on other transaction authority (OTA) during a public health emergency.

Section 3302. Priority zoonotic animal drugs.

- Provides Breakthrough Therapy designations for animal drugs that can prevent human diseases – i.e. speed up the development of drugs 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

Section 3401. Reauthorization of health professions workforce programs.

Section 3402. Health workforce coordination.

Section 3403. Education and training relating to geriatrics.

- Reauthorizes and updates Title VII of the Public Health Service Act (PHSA), which pertains to programs to support clinician training and faculty development, including the training of practitioners in family medicine, general internal medicine, geriatrics, pediatrics, and other medical specialties.
- Directs 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.
- Title VII programs 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.

Section 3404. Nursing workforce development.

- Reauthorizes and updates Title VIII of the PHSA, which pertains to nurse workforce training programs. Updates 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. 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 a robust nursing workforce, as nurses are critical in responding to the COVID-19 pandemic and future public health emergencies.

Subtitle B—Education Provisions

- Section 3501. Short Title

Section 3502. Definitions

- Sets definitions for terms of “coronavirus,” “qualifying emergency,” “institution of higher education,” and “Secretary.”

Section 3503. Campus-Based Aid Waivers

- Waives the institutional matching requirement for campus-based aid programs. Allows institutions to transfer unused work-study funds to be used for supplemental grants.

Section 3504. Use of Supplemental Educational Opportunity Grants for Emergency Aid

- Allows institutions to award additional SEOG funds to students impacted by COVID-19.

Section 3505. Federal work-study during a qualifying emergency

- Allows institutions to issue work-study payments to students who are unable to work due to work-place closures as a lump sum or in payments similar to paychecks.

Section 3506. Adjustments of Subsidized Loan Limits

- For students who dropped out of school as a result of COVID -19 excludes the term from counting toward lifetime subsidized loan eligibility.

Section 3507. Exclusion from Federal Pell Grant Duration Limit

- For students who dropped out of school as a result of COVID -19 excludes the term from counting toward lifetime Pell eligibility.

Section 3508. Institutional Refund and Federal Student Loan Flexibility

- For students who dropped out of school as a result of COVID -19, the student is not required to return Pell grants or federal student loans to the Secretary. Waives the requirement that institutions calculate the amount of grant or loan assistance that the institution must return to the Secretary in the case of students who dropped out of school as a result of COVID-19.

Section 3509. Satisfactory Progress

- For students who dropped out of school as a result of COVID -19, the student's grades do not effect a student's federal academic requirements to continue to receive Pell Grants or student loans.

Section 3510. Continuing Education at Affected Foreign Institutions

- Permits foreign institutions to offer distance learning to U.S. students receiving title IV funds for the duration of the COVID-19 declaration of disaster.

Section 3511. National Emergency Educational Waivers

- Provide the Secretary of Education with waiver authority to provide waivers from the Elementary and Secondary Education Act, except civil rights laws, that are necessary and appropriate due to the COVID-19 declaration of disaster.

Section 3512. HBCU Capital Financing Program

- Authorizes the Secretary of Education to defer payments on current HBCU Capital Financing loans during the national emergency period so HBCUs can devote financial resources to COVID-19 efforts.

Section 3513. Temporary Relief for Federal Student Loan Borrowers

- Requires the Secretary to defer student loan payments, principal, and interest for 6 months, through September 30, 2020, without penalty to the borrower for all federally owned loans. This provides relief for over 95 percent of student loan borrowers.

Section 3514. Provisions Related to the Corporation for National and Community Service

- Provide participants serving in the National Service Corps programs with the educational award they were due to receive before their duties had been suspended or placed on hold during the COVID-19 declaration of disaster. Extend the age limits and the terms of service to allow individuals serving in national service programs to continue participating in programs after the COVID-19 declaration of disaster ends.

Section 3515. Workforce Response Activities

- Provides local workforce boards with additional flexibility to use funds received under the Workforce Innovation and Opportunity Act for administrative costs, including for online

resources. Allows Governors to utilize reserved workforce funds on rapid response activities in response to COVID-19.

Section 3516. Technical Amendments

- Makes technical edits to the FUTURE Act to improve implementation and aid student loan borrowers.

Section 3517. Waiver Authority and Reporting Requirements for Institutional Aid

- Authorizes the Secretary of Education to waive certain outcome requirements for FY2021 grant programs for HBCU and other Minority Serving Institutions.

Section 3518. Authorized Uses and Other Modifications for Grants

- Authorizes the Secretary of Education to waive or modify current allowable uses of funds for institutional grant programs (TRIO/GEARUP/Title III/Title V/and sections of Title VII) so colleges can re-deploy resources and services to COVID-19 efforts. Permits institutions to request waivers from the Secretary of Education for financial matching requirements in competitive grant and other MSI grant programs in the Higher Education Act so colleges can devote institutional resources to COVID-19 efforts.

Section 3519. Service Obligation to Teachers

- For teachers who could not finish their year of teaching service as a result of COVID-19, their partial year of service shall be counted as a full year of service toward TEACH grant obligations or Teacher Loan Forgiveness. Waives a requirement that teachers must serve consecutive years of teaching service for Teacher Loan Forgiveness eligibility, if a teacher's service is not consecutive as a result of COVID-19.

Subtitle C—Labor Provisions

Section 3601. Limitation on Paid Leave

- Creates a limitation stating an employer shall not be required to pay more than \$200 per day and \$10,000 in the aggregate for each employee under this section.

Section 3602. Emergency Paid Sick Leave Limitation

- Creates a limitation stating an employer shall not be required to pay more than \$511 per day and \$5,110 in the aggregate for sick leave or more than \$200 per day and \$2,000 in the aggregate to care for a quarantined individual or child for each employee under this section.

Section 3603. Unemployment Insurance

- Provides that applications for unemployment compensation and assistance with the application process, to the extent practicable, be accessible in two ways: in person, by phone, or online.

Section 3604. OMB Waiver of Paid Family and Paid Sick Leave

- Allows the Director of the Office of Management and Budget to exclude for good cause certain Executive Branch employees from the Paid Family Leave mandate. Allows the Director of the Office of Management and Budget to exclude for good cause certain Executive Branch employees from the Paid Sick Leave mandate.

Section 3605. Paid Leave for Rehired Employees

- Allows an employee who was laid off by an employer March 1, 2020, or later to have access to paid family and medical leave in certain instances if they are rehired by the employer. Employee would have had to work for the employer at least 30 days prior to being laid off.

Section 3606. Advance Refunding of Credits

- Allows employers to receive an advance tax credit from Treasury instead of having to be reimbursed on the back end. Creates regulatory authority to implement the tax credit advances.

Section 3607. Expansion of DOL Authority to Postpone Certain Deadlines

- Amends Section 518 of ERISA to provide the Department of Labor the ability to postpone certain ERISA filing deadlines for a period of up to one year in the case of a public health emergency.

Section 3608. Single-Employer Plan Funding Rules

- Provides single employer pension plan companies with more time to meet their funding obligations by delaying the due date for any contribution otherwise due during 2020 until January 1, 2021. At that time, contributions due earlier would be due with interest. The bill also provides that a plan's status for benefit restrictions as of December 31, 2019, will apply throughout 2020.

Section 3609. Application of Cooperative and Small Employer Charity Pension Plan Rules to Certain Charitable Employers whose primary Exempt Purpose is Providing services with respect to Mothers and Children

- Amends the definition of CSEC Plans to provide that a pension plan will be a CSEC plan if, as of January 1, 2000, the plan was sponsored by an employer that (i) is exempt from taxation under Code section 501(c)(3), (ii) has been in existence since 1938, (iii) conducts medical research directly or indirectly through grant making, and (iv) has as its primary

exempt purpose providing services with respect to mothers and children. This section is effective for plan years beginning after December 31, 2018.

Section 3610. Federal Contractor Authority

- Ensures that federal contractors who cannot perform work at their duty-station or telework because of the nature of their jobs due to COVID-19, continue to get paid.

Section 3611. Technical Corrections

Subtitle D—Finance Committee

Section 3701. Health Savings Accounts for Telehealth Services

- This section would allow a high-deductible health plan (HDHP) with a health savings account (HSA) to cover telehealth services prior to a patient reaching the deductible, increasing access for patients who may have the COVID-19 virus and protecting other patients from potential exposure.

Section 3702. Over-the-Counter Medical Products without Prescription

- This section would allow patients to use funds in HSAs and Flexible Spending Accounts for the purchase of over-the-counter medical products, including those needed in quarantine and social distancing, without a prescription from a physician.

Section 3703. Expanding Medicare Telehealth Flexibilities

- This section would eliminate the requirement in Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020 (Public Law 116-123) that limits the Medicare telehealth expansion authority during the COVID-19 emergency period to situations where the physician or other professional has treated the patient in the past three years. This would enable beneficiaries to access telehealth, including in their home, from a broader range of providers, reducing COVID-19 exposure.

Section 3704. Allowing Federally Qualified Health Centers and Rural Health Clinics to Furnish Telehealth in Medicare

- This section would allow, during the COVID-19 emergency period, Federally Qualified Health Centers and Rural Health Clinics to serve as a distant site for telehealth consultations. A distant site is where the practitioner is located during the time of the telehealth service. This section would allow FQHCs and RHCs to furnish telehealth services to beneficiaries in their home. Medicare would reimburse for these telehealth services based on payment rates similar to the national average payment rates for comparable telehealth services under the Medicare Physician Fee Schedule. It would also exclude the costs associated with these services from both the FQHC prospective payment system and the RHC all-inclusive rate calculation.

Section 3705. Expanding Medicare Telehealth for Home Dialysis Patients

- This section would eliminate a requirement during the COVID-19 emergency period that a nephrologist conduct some of the required periodic evaluations of a patient on home dialysis face-to-face, allowing these vulnerable beneficiaries to get more care in the safety of their home.

Section 3706. Allowing for the Use of Telehealth during the Hospice Care Recertification Process in Medicare

- Under current law, hospice physicians and nurse practitioners cannot conduct recertification encounters using telehealth. This section would allow, during the COVID-19 emergency period, qualified providers to use telehealth technologies in order to fulfill the hospice face-to-face recertification requirement.

Section 3707. Encouraging the Use of Telecommunications Systems for Home Health Services in Medicare

- This section would require the Health and Human Services (HHS) to issue clarifying guidance encouraging the use of telecommunications systems, including remote patient monitoring, to furnish home health services consistent with the beneficiary care plan during the COVID-19 emergency period.

Section 3708. Enabling Physician Assistants and Nurse Practitioners to Order Medicare Home Health Services

- This section would allow physician assistants, nurse practitioners, and other professionals to order home health services for beneficiaries, reducing delays and increasing beneficiary access to care in the safety of their home.

Section 3709. Increasing Provider Funding through Immediate Medicare Sequester Relief

- This section would provide prompt economic assistance to health care providers on the front lines fighting the COVID-19 virus, helping them to furnish needed care to affected patients. Specifically, this section would temporarily lift the Medicare sequester, which reduces payments to providers by 2 percent, from May 1 through December 31, 2020, boosting payments for hospital, physician, nursing home, home health, and other care. The Medicare sequester would be extended by one-year beyond current law to provide immediate relief without worsening Medicare's long-term financial outlook.

Section 3710. Medicare Add-on for Inpatient Hospital COVID-19 Patients

- This section would increase the payment that would otherwise be made to a hospital for treating a patient admitted with COVID-19 by 20 percent. It would build on the Centers for Disease Control and Prevention (CDC) decision to expedite use of a COVID-19 diagnosis to enable better surveillance as well as trigger appropriate payment for these complex

patients. This add-on payment would be available through the duration of the COVID-19 emergency period.

Section 3711. Increasing Medicare Access to Post-Acute Care

- This section would provide acute care hospitals flexibility, during the COVID-19 emergency period, to transfer patients out of their facilities and into alternative care settings in order to prioritize resources needed to treat COVID-19 cases. Specifically, this section would waive the Inpatient Rehabilitation Facility (IRF) 3-hour rule, which requires that a beneficiary be expected to participate in at least 3 hours of intensive rehabilitation at least 5 days per week to be admitted to an IRF. It would allow a Long Term Care Hospital (LTCH) to maintain its designation even if more than 50 percent of its cases are less intensive. It would also temporarily pause the current LTCH site-neutral payment methodology.

Section 3712. Preventing Medicare Durable Medical Equipment Payment Reduction

- This section would prevent scheduled reductions in Medicare payments for durable medical equipment, which helps patients transition from hospital to home and remain in their home, through the length of COVID-19 emergency period.

Section 3713. Eliminating Medicare Part B Cost-Sharing for the COVID-19 Vaccine

- This section would enable beneficiaries to receive a COVID-19 vaccine in Medicare Part B with no cost-sharing.

Section 3714. Allowing Up to 3-Month Fills and Refills of Covered Medicare Part D Drugs

- This section would require that Medicare Part D plans provide up to a 90-day supply of a prescription medication if requested by a beneficiary during the COVID-19 emergency period.

Section 3715. Providing Home and Community-based Support Services during Hospital Stays

- This section would allow state Medicaid programs to pay for direct support professionals, caregivers trained to help with activities of daily living, to assist disabled individuals in the hospital to reduce length of stay and free up beds.

Section 3716. Clarification Regarding Uninsured Individuals

- This section would clarify a section of the Families First Coronavirus Response Act of 2020 (Public Law 116-127) by ensuring that uninsured individuals can receive a COVID-19 test and related service with no cost-sharing in any state Medicaid program that elects to offer such enrollment option.

Section 3717. Clarification Regarding Coverage of Tests

- This section would clarify a section of the Families First Coronavirus Response Act of 2020 (Public Law 116-127) by ensuring that beneficiaries can receive all tests for COVID-19 in Medicare Part B with no cost-sharing.

Section 3718. Preventing Medicare Clinical Laboratory Test Payment Reduction

- This section would prevent scheduled reductions in Medicare payments for clinical diagnostic laboratory tests furnished to beneficiaries in 2021. It would also delay by one year the upcoming reporting period during which laboratories are required to report private payer data.

Section 3719. Providing Hospitals Medicare Advance Payments

- This section would expand, for the duration of the COVID-19 emergency period, an existing Medicare accelerated payment program. Hospitals, especially those facilities in rural and frontier areas, need reliable and stable cash flow to help them maintain an adequate workforce, buy essential supplies, create additional infrastructure, and keep their doors open to care for patients. Specifically, qualified facilities would be able to request up to a six month advanced lump sum or periodic payment. This advanced payment would be based on net reimbursement represented by unbilled discharges or unpaid bills. Most hospital types could elect to receive up to 100 percent of the prior period payments, with Critical Access Hospitals able to receive up to 125 percent. Finally, a qualifying hospital would not be required to start paying down the loan for four months, and would also have at least 12 months to complete repayment without a requirement to pay interest.

Sec. 3720. Providing State Access to Enhanced Medicaid FMAP

- This section would amend a section of the Families First Coronavirus Response Act of 2020 (Public Law 116-127) to ensure that states are able to receive the Medicaid 6.2 percent FMAP increase.

Subtitle E—Health and Human Services Extenders

PART I—MEDICARE PROVISIONS

Section. 3801. Extension of Physician Work Geographic Index Floor

- This section would increase payments for the work component of physician fees in areas where labor cost is determined to be lower than the national average through December 1, 2020.

Section 3802. Extension of Funding for Quality Measure Endorsement and Selection

- This section would provide funding for HHS to contract with a consensus-based entity, e.g., the National Quality Forum (NQF), to carry out duties related to quality measurement and performance improvement through November 30, 2020.

Section 3803. Extension of Funding Outreach and Assistance for Low-Income Programs

- This section would extend funding for beneficiary outreach and counseling related to low-income programs through November 30, 2020.

PART II—MEDICAID PROVISIONS

Section 3811. Extension of Money Follows the Person Demonstration Program

- This section would extend the Medicaid Money Follows the Person demonstration that helps patients transition from the nursing home to the home setting through November 30, 2020.

Section 3812. Extension of Spousal Impoverishment Protections

- This section would extend the Medicaid spousal impoverishment protections program through November 30, 2020 to help a spouse of an individual who qualifies for nursing home care to live at home in the community.

Section 3813. Delay of Disproportionate Share Hospital Reductions

- The section would delay scheduled reductions in Medicaid disproportionate share hospital payments through November 30, 2020.

Section 3814. Extension and Expansion of Community Mental Health Services Demonstration

- This section would extend the Medicaid Community Mental Health Services demonstration that provides coordinated care to patients with mental health and substance use disorders, through November 30, 2020. It would also expand the demonstration to two additional states.

PART III—HUMAN SERVICES AND OTHER HEALTH PROGRAMS

Section 3821. Extension of Sexual Risk Avoidance Education

- This section extends the Sexual Risk Avoidance Education (SRAE) program through November 30, 2020 at current funding levels. This program provides funds to states to provide education exclusively focused on sexual risk avoidance (meaning voluntarily refraining from sexual activity).

Section 3822. Extension of Personal Responsibility Education

- This section extends the Personal Responsibility Education Program (PREP) through November 30, 2020 at current funding levels. PREP provides states, community groups,

tribes, and tribal organizations with grants to implement evidence-based, or evidence-informed, innovative strategies for teen pregnancy and HIV/STD prevention, youth development, and adulthood preparation for young people.

Section 3823. Extension of Demonstration Projects to Address Health Professions Workforce Needs

- This section extends the Health Professions Opportunity Grants (HPOG) program through November 30, 2020 at current funding levels. This program provides funding to help low-income individuals obtain education and training in high-demand, well-paid, health care jobs.

Section 3824. Extension of the Temporary Assistance for Needy Families Program and Related Programs

- This section extends TANF and related programs through November 30, 2020.

PART IV—PUBLIC HEALTH PROVISIONS

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

- Extends mandatory funding for community health centers, the National Health Service Corps, and the Teaching Health Center Graduate Medical Education Program at current levels through November 30, 2020.
- Section 3832. Diabetes programs
- Extends mandatory funding for the Special Diabetes Program for Type I Diabetes and the Special Diabetes Program for Indians at current levels through November 30, 2020.

PART V—MISCELLANEOUS PROVISIONS

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

Subtitle F—Over-the-Counter Drugs

Part I—OTC DRUG REVIEW

Section 3851. Regulation of certain nonprescription drugs that are marketed with an approved drug application

- Reforms the regulatory process for over-the-counter (OTC) drug monographs by allowing the Food and Drug Administration (FDA) to approve changes OTC drugs administratively, rather than going through a full notice and comment rulemaking. Currently, FDA can approve all other drugs without going through a full notice and comment rulemaking, and this legislation makes sure OTC medicines receive the same treatment as other drugs. Incentivizes companies to create more innovative products by providing an 18-month market-exclusivity component that rewards a return on investment for new OTC drugs.

Section 3852. Misbranding

- Clarifies that an OTC drug that does not comply with the monograph requirements is misbranded.

Section 3853. Drugs excluded from over-the-counter drug review

- Clarifies that nothing in this bill will apply to drugs previously excluded by the FDA from the Over-the-Counter Drug Review under a specified Federal Register document.

Section 3854. Treatment of Sunscreen Innovation Act

- Clarifies that sponsors of sunscreen ingredients with pending orders have the option to see review in accordance with the Sunscreen Innovation act or to see review under the new monograph review process.

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

- Requires an annual update to Congress regarding FDA's progress in evaluating certain pediatric indications for certain cough and cold monograph drugs for children under age six.

Section 3856. Technical corrections

- Includes technical corrections to the Food and Drug Administration Reauthorization Act of 2017 and existing law.

PART II—USER FEES**Section 3861. Finding**

- Declares that the fees paid pursuant to this section will be dedicated to FDA review of over-the-counter monograph drugs.

Section 3862. Fees relating to over-the-counter drugs

- Establishes a new FDA user fee to allow the agency to hire additional staff members to ensure there is adequate agency oversight to approve changes to OTC drugs.