Health Care in the CARES Act the Coronavirus Stimulus Package

Health Care $150 Billion.—*includes $100 Billion for grants to hospitals, public and nonprofit health organizations and Medicare and Medicaid Suppliers*

Medical Product Supplies

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.

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.

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.

Mitigating Emergency Drug Shortages

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.

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.

Preventing Medical Device Shortages

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.

Coverage Of Testing And Preventive Services

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.

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).

Support For Health Care Providers

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.

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.

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.

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.

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.

Miscellaneous Provisions

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.

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.

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.

Innovation

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.

Health Insurance

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.

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.

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.

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.

. 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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

Health And Human Services Extenders

Medicare Provisions

. 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.

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.

. 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.

Medcaid Provisions

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.

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.

Delay of Disproportionate Share Hospital Reductions

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

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

. 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).

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.

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.

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

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

Public Health Provisions

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.

Otc Drug Review

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.

Misbranding

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

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.

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.

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.

Emergency Appropriations

Food and Drug Administration – The bill provides $80 million for the Food and Drug Administration to continue the agencies important work of responding to COVID-19. Funding will be used to continue efforts related to shortages of critical medicines, enforcement work on counterfeit and misbranded products, emergency use authorizations and pre and post market work on medical countermeasures, therapies, vaccines, and research**.**

Centers for Disease Control and Prevention – $4.3 billion to support federal, state, and local public health agencies to prevent, prepare for, and respond to the coronavirus, including:

- $1.5 billion to support States, locals, territories, and tribes in their efforts to conduct public health activities, including:
    - Purchase of personal protective equipment;
    - surveillance for coronavirus;
    - laboratory testing to detect positive cases;
    - contact tracing to identify additional cases;
    - infection control and mitigation at the local level to prevent the spread of the virus; and
    - other public health preparedness and response activities.
- $1.5 billion in flexible funding to support CDC's continuing efforts to contain and combat the virus, including repatriation and quarantine efforts, purchase and distribution of diagnostic test kits (including for state and local public health agencies) and support for laboratory testing, workforce training programs, combating antimicrobial resistance and antibiotic resistant bacteria as a result of secondary infections related to COVID-19, and communicating with and informing public, state, local, and tribal governments and healthcare institutions.
- $500 million for global disease detection and emergency response;
- $500 million for public health data surveillance and analytics infrastructure modernization; and
- $300 million for the Infectious Diseases Rapid Response Reserve Fund, which supports immediate response activities during outbreaks.

National Institutes of Health – The bill includes $945 million to support research to expand on prior research plans, including developing an improved understanding of the prevalence of COVID-19, its transmission and the natural history of infection, and novel approaches to diagnosing the disease and past infection, and developing countermeasures for the prevention and treatment of its various stages.

Assistant Secretary for Preparedness and Response – $127 billion for medical response efforts, including:

- $100 billion for a new program to provide grants to hospitals, public entities, not-for-profit entities, and Medicare and Medicaid enrolled suppliers and institutional providers to cover unreimbursed health care related expenses or lost revenues attributable to the public health emergency resulting from the coronavirus.
- More than $27 billion for the Biomedical Advanced Research and Development Authority (BARDA) to support research and development of vaccines, therapeutics, and diagnostics to prevent or treat the effects of coronavirus, including:
    - $16 billion for the Strategic National Stockpile for critical medical supplies, personal protective equipment, and life-saving medicine;
    - At least $3.5 billion to advance construction, manufacturing, and purchase of vaccines and therapeutics to the American people. This is in addition to the major investments provided for these activities in the first supplemental.
    - At least $250 million for the Hospital Preparedness Program, including the National Ebola and Special Pathogens Training and Education Center (NETEC),

regional, State and local special pathogens treatment centers, and hospital preparedness cooperative agreements;
- Funding for innovations in manufacturing platforms to support a U.S.-sourced supply chain of vaccines, therapeutics, and small molecule active pharmaceutical ingredients;
- Funding to support U.S.-based next generation manufacturing facilities;
- Increased medical surge capacity at additional health facilities;
- Enhancements to the U.S. Commissioned Corps;
- Funding to support research related to antibiotic resistant secondary infections associated with coronavirus; and
- Workforce modernization and increased telehealth access and infrastructure to increase access to digital healthcare delivery.

Health Resources and Services Administration (HRSA) – The bill includes $275 million for HRSA, including $90 million for Ryan White HIV/AIDS programs and $185 to support rural critical access hospitals, rural tribal health and telehealth programs, and poison control centers.

Administration for Community Living (ACL) – The bill includes $955 million for ACL to support nutrition programs, home and community based services, support for family caregivers, and expand oversight and protections for seniors and individuals with disabilities.

Centers for Medicare & Medicaid Services (CMS) – The bill includes $200 million for CMS to assist nursing homes with infection control and support states' efforts to prevent the spread of coronavirus in nursing homes.