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Selected Health Provisions in Title III of the CARES Act (P.L. 116-136)

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The global pandemic of Coronavirus Disease 2019 (COVID-19) is affecting communities around the world and throughout the United States, with the number of confirmed cases and fatalities growing daily. Containment and mitigation efforts by U.S. federal, state, and local governments have been undertaken to “flatten the curve”—that is, to slow the widespread transmission that could overwhelm the nation’s health care system.

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act, P.L. 116-136) was enacted on March 27, 2020. It is the third comprehensive law enacted in 2020 to address the pandemic. In addition to a number of broad health care provisions, the CARES Act provides additional supplemental appropriations to support federal response efforts and authorizes a number of economic stimulus measures, among other things.

This report describes the majority of health-related sections in Division A, Title III, of the CARES Act, “Supporting America’s Health Care System in the Fight Against the Coronavirus.” Relevant background is provided for context. Specifically, this report describes provisions regarding, among other things, the following:

- The availability of medical countermeasures (MCMs)—drugs, tests, treatments, medical devices, and supplies such as personal protective equipment (PPE)—including research and development; product regulation by the Food and Drug Administration (FDA); the Strategic National Stockpile (SNS); and other supply chain matters.
- The health workforce, including telehealth programs, the rural health care system, and the Commissioned Corps of the U.S. Public Health Service (USPHS). Additional workforce provisions described in this report include reauthorization and extension of appropriations for existing HHS health workforce programs, and liability limitation.
- Provisions addressed at the Medicare and Medicaid programs and on private health insurance plans that temporarily require, or increase payment for, telehealth services and specified services related to COVID-19 testing, diagnosis, or treatment.
- A newly established FDA authority for over-the-counter (OTC) drug review.

This report does not address education or labor provisions in Subtitle B or C in Part IV of Title III, or provisions in Subtitle E of Part IV of Title III, “Health and Human Services Extenders,” which are described in other CRS reports. The report also does not include Division B of the act, which provides emergency supplemental appropriations for the COVID-19 response.

The **Appendix** catalogues deadlines, effective dates, and reporting requirements for provisions described in the report.

This report is intended to reflect the CARES Act at enactment (i.e., March 27, 2020). It does not track the law’s implementation or funding and will not be updated.

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Introduction

The global pandemic of Coronavirus Disease 2019 (COVID-19) is affecting communities around the world and throughout the United States, with the number of confirmed cases and fatalities growing daily. Containment and mitigation efforts by U.S. federal, state, and local governments have been undertaken to “flatten the curve”—that is, to slow the widespread transmission that could overwhelm the nation’s health care system.¹

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act, P.L. 116-136) was enacted on March 27, 2020. It is the third comprehensive law to address the pandemic. In addition to its health provisions, the CARES Act provides additional supplemental appropriations to support federal response efforts and authorizes a number of economic stimulus measures, among other things.

The CARES Act follows two other laws that made supplemental appropriations and amended health care financing and public health authorities to respond to the pandemic. The first, the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123), enacted on March 6, 2020, provides roughly \$7.8 billion in discretionary supplemental appropriations to the Department of Health and Human Services (HHS), the Department of State, and the Small Business Administration.² This act also waives certain telehealth restrictions to make telehealth services more available during the emergency.³ The second, the Families First Coronavirus Response Act (FFCRA, P.L. 116-127), enacted on March 18, 2020, provides authority, funding, and/or requirements to cover COVID-19 testing and related services under federal programs, many private health insurance plans, and for the uninsured (as defined in the act). Among other provisions, it temporarily increases the federal share of Medicaid assistance to states, provides additional Medicaid assistance to territories, and waives liability and establishes injury compensation for certain respiratory protection devices.⁴

A Snapshot of CARES Act Health Provisions

Medical supply shortages. The COVID-19 pandemic has affected the medical product supply chain both globally and domestically, resulting in widespread shortages of medical countermeasures (MCMs) and other critical medical supplies. MCMs are medical products that may be used to treat, prevent, or diagnose conditions associated with emerging infectious diseases or chemical, biological, radiological, or nuclear threats. Examples of MCMs include biologics (e.g., vaccines), drugs (e.g., antivirals), and devices (e.g., diagnostic tests and personal protective equipment, or PPE).

The CARES Act includes several provisions to address such shortages, including expanding reporting requirements for firms that experience interruptions in drug and device manufacturing; explicitly requiring that the Strategic National Stockpile (SNS) contain PPE, ancillary medical supplies, and other applicable supplies; and extending liability protections for certain respiratory protective devices used during emergencies. The CARES Act also requires a study of U.S.

¹ For an overview of domestic Coronavirus Disease 2019 (COVID-19) health response efforts and a compilation of federal agency websites, see CRS Insight IN11253, *Domestic Public Health Response to COVID-19: Current Status*.

² CRS Report R46285, *Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123): First Coronavirus Supplemental*; and CRS Insight IN11236, *Oversight Provisions in H.R. 6074, the Coronavirus Preparedness and Response Supplemental Appropriations Act*.

³ CRS Report R46239, *Telehealth and Telemedicine: Frequently Asked Questions*.

⁴ CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*.

dependence on critical drugs and medical devices imported from or manufactured in other countries.

Vaccine access and cost. A vaccine(s) for the COVID-19 virus, if and when it becomes available, will be provided or required to be covered without cost-sharing to patients and beneficiaries of federal health programs and most private health insurance enrollees, pursuant to numerous provisions in Division A, Title III, of the CARES Act. The CARES Act does not explicitly address vaccine access for the uninsured. However, with available appropriations and preexisting authorities, the HHS Secretary could assist safety net providers (e.g., health centers), health departments, and other entities in furnishing vaccines to this population.

The medical workforce. The CARES Act makes a number of changes to health workforce programs. Some changes aim to extend the services available during the COVID-19 period and beyond, particularly for rural or otherwise underserved populations. For example, the CARES Act confers medical malpractice liability on health professionals who choose to volunteer during the emergency period and amends the program rules for the National Health Service Corps (NHSC) program to permit individuals to volunteer during the emergency period. The CARES Act also reauthorizes a number of health workforce programs that had been considered for reauthorization during the 116th Congress, but prior to the CARES Act no reauthorization of these programs was enacted.

Marketing of over-the-counter drugs. The CARES Act establishes a new process for the marketing of certain over-the-counter (OTC) drugs, including hand sanitizer and sunscreen. Specifically, Title III replaces the current OTC drug monograph rulemaking process with an administrative order process—a less burdensome alternative. It also provides an expedited process for removing from the market certain OTC drugs that pose a public health hazard and for requiring certain safety labeling changes. The CARES Act provides an incentive—18 months of marketing exclusivity—to firms that make certain changes to previously marketed OTC drugs and creates a new user fee program to fund FDA’s OTC monograph drug activities.

Report Contents

This report describes the majority of health-related sections in Division A, Title III of the CARES Act, “Supporting America’s Health Care System in the Fight Against the Coronavirus.” Relevant background is provided for context. Specifically, this report describes provisions regarding, among other things the following:

- The medical countermeasures (MCMs)—drugs, tests, treatments, medical devices, and supplies such as PPE—including research and development; product regulation by the Food and Drug Administration (FDA); the strategic national stockpile (SNS); and other supply chain matters.
- The health workforce, including telehealth programs, the rural health care system, and the Commissioned Corps of the U.S. Public Health Service (USPHS). Additional workforce provisions described in this report include reauthorization and extension of appropriations for existing Health and Human Services (HHS) health workforce programs, and liability limitation.
- Provisions addressed at the Medicare and Medicaid programs and on private health insurance plans to temporarily require, or increase payment for, telehealth services and specified services related to COVID-19 testing, diagnosis, or treatment.
- A newly established FDA authority for OTC drug review.

This report does not address education or labor provisions in Subtitle B or C in Part IV of Title III,⁵ or provisions in Subtitle E of Part IV of Title III, “Health and Human Services Extenders,” which are described in another CRS report.⁶ The report also does not include Division B of the act, which provides emergency supplemental appropriations for the COVID-19 response. Division B includes additional funding for numerous HHS public health and social services activities, and a \$100 billion fund to reimburse eligible health care providers for health care-related expenses or lost revenues attributable to COVID-19.⁷ This report concludes with an **Appendix** that catalogues deadlines, effective dates, and reporting requirements for provisions described in the report.

The report does not discuss cost estimates for specific provisions; however, the Congressional Budget Office (CBO) and the Joint Committee on Taxation (JCT) provided a preliminary estimate of the budget effects of the CARES Act.⁸ Overall, the act is estimated to increase federal deficits by \$1.8 trillion over the 2020-2030 period. This estimate breaks down these budgetary effects into three categories: a \$988 billion increase in mandatory outlays; a \$446 billion decrease in revenues; and a \$326 billion increase in discretionary outlays from supplemental appropriations. The estimates that CBO generated for health programs in Title III include programs in Subtitle E of Part IV of Title III, “Health and Human Services Extenders,” which are not discussed in this report. Among the provisions discussed in this report, JCT estimates that Section 3702, which expands the products that are eligible for tax-advantaged distributions from health savings accounts (HSAs), health flexible spending arrangements (FSAs), and other similar tax-advantaged savings arrangements, will reduce revenues by \$9 billion over a ten-year period from 2020-2030. CBO also estimated the costs of a number of Medicare payment changes included in CARES Sections 3701-3715. These provisions generally increase the amount that Medicare will reimburse for services; as such, CBO estimates that they will increase Medicare spending from 2020-2030. CBO also noted that some provisions—e.g., the requirement for Medicare to cover the costs of vaccines for COVID-19—cannot be estimated because no such vaccine has been developed at this time. In general, these CBO estimates are based on assumptions about the severity and duration of the pandemic, and they may vary substantially from final estimates to be provided later this year.

This report is intended to reflect the CARES Act at enactment (i.e., March 27, 2020). It does not track the law’s implementation or funding and will not be updated. This report is one of a number of CRS reports related to COVID-19; additional CRS products on COVID-19 are available at <https://www.crs.gov/resources/coronavirus-disease-2019>.

⁵ Education provisions are described in CRS In Focus IF11497, *CARES Act Higher Education Provisions*, and CRS In Focus IF11509, *CARES Act Elementary and Secondary Education Provisions*.

⁶ CRS Report R46331, *Health Care-Related Expiring Provisions of the 116th Congress, Second Session*.

⁷ For more information on the new fund, see U.S. Department of Health and Human Services (HHS), “CARES Act Provider Relief Fund,” April 13, 2020, <https://www.hhs.gov/provider-relief/index.html>. The Paycheck Protection Program and Health Care Enhancement Act enacted on April 24, 2020 (P.L. 116-139) appropriated an additional \$75 billion to the CARES Act Provider Relief Fund and provided an additional \$25 billion to HHS for COVID-19 testing. See CRS Report R46325, *Fourth COVID-19 Relief Package (P.L. 116-139): In Brief*.

⁸ For the complete preliminary cost estimate, see Congressional Budget Office, “Letter from Phillip L. Swagel, Director, Congressional Budget Office, to Honorable Mike B. Enzi, Chairman Senate Committee the Budget, U.S. Senate, April 16, 2020, <https://www.cbo.gov/system/files/2020-04/hr748.pdf>.

Definitions, Abbreviations, and Acronyms

“Section 319” Public Health Emergency

Numerous provisions in the CARES Act refer to the Public Health Emergency declaration made pursuant to Section 319 of the Public Health Service Act (PHSA). The “Section 319” authority allows the HHS Secretary to carry out a specified set of actions to address public health emergencies, such as expediting or waiving certain administrative requirements that would otherwise apply to federal activities or federally administered grants.⁹ Some provisions refer to “the emergency period declared under section 319” or similar construction, meaning the time during which a Section 319 declaration is in effect. The declaration for COVID-19 was made on January 31, 2020, retroactive to January 27, 2020. It is in effect for 90 days and is expected to be renewed and remain in effect for the duration of the response.¹⁰

Several provisions in Title III, Subtitle D, regarding health care financing and amending the Social Security Act (SSA), refer to “the emergency period described in section 1135(g)(1)(B)” or comparable construction. Section 1135 allows the HHS Secretary, under certain conditions, to waive specified requirements and regulations to ensure that health care items and services are available to enrollees in the Medicare, Medicaid, and State Children’s Health Insurance Program (CHIP) programs during emergencies.¹¹ Paragraph (1)(B) of SSA Section 1135(g) refers specifically to “the public health emergency declared with respect to the COVID-19 outbreak by the Secretary on January 31, 2020, pursuant to section 319 of the [PHSA],” and any renewal of such declaration.¹² Hence, these references to SSA Section 1135(g)(1)(B) simply mean the period during which the Section 319 public health emergency declaration for COVID-19—whether initial or renewed—is in effect.

Additional Definitions and Acronyms

Throughout this report, unless otherwise stated, the “Secretary” means the HHS Secretary. Mentions of “this section” refer to matters addressed under that specific section of the CARES Act. This report uses a number of acronyms, listed in the table below.

Table I. Acronyms Used in This Report

Acronyms	Definition
AAA	Area Agency on Aging
ACA	Patient Protection and Affordable Care Act (P.L. 111-148, as amended)
ACIP	Advisory Committee on Immunization Practices
ACL	Administration for Community Living

⁹ 42 U.S.C. §247d. For more information, see HHS, “Public Health Emergency Declaration,” <https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx>.

¹⁰ HHS, “Determination that a Public Health Emergency Exists Nationwide as the Result of the 2019 Novel Coronavirus,” January 31, 2020, <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>. An emergency determination under Section 319 terminates after 90 days, unless terminated earlier by the HHS Secretary, and is renewable for additional 90-day periods. Section 319 emergencies declared in response to the 2009 H1N1 influenza pandemic and the 2016-2017 Zika virus outbreak were each renewed several times.

¹¹ For more information, see CRS Legal Sidebar LSB10430, *Section 1135 Waivers and COVID-19: An Overview*.

¹² This amendment to Section 1135 was made by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, P.L. 116-123, div. B, §102(a)(1), (2), (b), March 6, 2020, 134 Stat. 156.

Acronyms	Definition
ANDA	Abbreviated New Drug Application
API	Active Pharmaceutical Ingredient
ASPR	Assistant Secretary for Preparedness and Response
BA	Business Associate
BARDA	Biomedical Advanced Research and Development Authority
BBA 2018	Bipartisan Budget Act of 2018 (P.L. 115-23)
BBEDCA	Balanced Budget and Emergency Deficit Control Act of 1985 (P.L. 99-177)
BCA	Budget Control Act of 2011 (P.L. 112-25)
CAH	Critical Access Hospital
CARES Act	Coronavirus Aid, Relief, and Economic Security Act (P.L. 116-136)
CBO	Congressional Budget Office
CDC	Centers for Disease Control and Prevention
C.F.R.	Code of Federal Regulations
CHIP	State Children’s Health Insurance Program
CLFS	Clinical Laboratory Fee Schedule
CMS	Centers for Medicare & Medicaid Services
COGME	Council on Graduate Medical Education
COVID-19	Coronavirus Disease 2019
CPI	Consumer Price Index
CRS	Congressional Research Service
CSEOA	Community Service Employment for Older Americans Program
DME	Durable Medical Equipment
DMEPOS	Durable Medical Equipment, Prosthetics, Orthotics and Supplies
DOL	Department of Labor
DRI	Dietary Reference Intakes
EPA	Environmental Protection Agency
ESRD	End-stage Renal Disease
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FEHBP	Federal Employees Health Benefits Program
FFCRA	Families First Coronavirus Response Act (P.L. 116-127)
FFDCA	Federal Food, Drug, and Cosmetic Act (P.L. 75-717, as amended)
FMAP	Federal Medical Assistance Percentage
FORHP	Federal Office of Rural Health Policy
FQHC	Federally Qualified Health Center
FSA	Flexible Spending Account
FY	Fiscal Year

Acronyms	Definition
GACA	Geriatrics Academic Career Awards
GAO	Government Accountability Office
GME	Graduate Medical Education
GRASE	Generally Recognized as Safe and Effective
GWEP	Geriatrics Workforce Enhancement Program
HBV	Hepatitis Virus B
HCBS	Home and Community-based Services
HDHP	High-deductible Health Plan
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act (P.L. 104-191, as amended)
HPSA	Health Professional Shortage Area
HRA	Health Reimbursement Arrangement
HRSA	Health Resources and Services Administration
HSA	Health Savings Account
IHS	Indian Health Service
IMR	Infant Mortality Rate
IPPS	Inpatient Prospective Payment System
IRC	Internal Revenue Code
IRF	Inpatient Rehabilitation Facility
IRF PPS	Inpatient Rehabilitation Facility Prospective Payment System
IVD	In Vitro Diagnostic
JCT	Joint Committee on Taxation
LTCH	Long-term Care Hospital
LTCH PPS	Long-term Care Hospital Inpatient Prospective Payment System
LUPA	Low-utilization Payment Adjustment
MA	Medicare Advantage
MA-PD	Medicare Advantage Prescription Drug Plan
MCM	Medical Countermeasure
MPFS	Medicare Physician Fee Schedule
MS-DRG	Medicare Severity-diagnosis Related Group
MSA	Medical Savings Account
MUA	Medically Underserved Area
NASEM	National Academies of Science, Engineering, and Medicine
NDA	New Drug Application
NHSC	National Health Service Corps
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health

Acronyms	Definition
OAA	Older Americans Act (P.L. 89-73, as amended)
OCR	Office for Civil Rights (within the Department of Health and Human Services)
OTA	Other Transaction Authority
OTC	Over-The-Counter
PAMA	The Protecting Access to Medicare Act (P.L. 113-93)
PDUFA	Prescription Drug User Fee Act (P.L. 102-571)
PHI	Protected Health Information
PHSA	Public Health Service Act
PPE	Personal Protective Equipment
PPS	Prospective Payment System
PREP Act	Public Readiness and Emergency Preparedness Act (P.L. 109-417)
RHC	Rural Health Clinic
SCSEP	Senior Community Service Employment Program
SG	U.S. Surgeon General
SIA	Sunscreen Innovation Act (P.L. 113-195)
SNS	Strategic National Stockpile
SSA	Social Security Act
STLDI	Short-term, Limited Duration Insurance
TNGP	Telehealth Network Grant Program
TRC	Telehealth Resource Center
USC	United States Code
USPHS	U.S. Public Health Service
USPSTF	U.S. Preventive Services Task Force
VPA	Volunteer Protection Act of 1997 (P.L. 105-19)

CARES Act Health Provisions in Title III

Subtitle A—Health Provisions

Part I—Addressing Supply Shortages—Subpart A—Medical Product Supplies

The COVID-19 pandemic has affected the medical product supply chain both globally and domestically. Domestically, the pandemic has highlighted existing limitations in the U.S. medical product supply chain, including lack of transparency regarding where specific medical products and their components are manufactured and heavy reliance on foreign countries for drugs and medical devices. Perhaps most salient has been the impact of COVID-19 on the availability of PPE, such as respirators for health care personnel, and other respiratory devices, such as ventilators for patients. Although the federal government and states generally have stockpiles of PPE and ventilators to distribute during public health emergencies, stockpiled quantities have been insufficient to meet current needs. FDA, with other agencies, has taken various steps to

prevent and mitigate shortages of critical PPE and respiratory devices, for example, by waiving certain regulatory requirements and by enabling access to respirators and other medical devices that have not received agency clearance prior to marketing.

Section 3101. National Academies Report on America's Medical Product Supply Chain Security

Background

The extent to which the United States relies on other countries for medical products is not completely known, but available data suggest a heavy reliance. According to FDA, as of August 2019, 72% of facilities that manufacture active pharmaceutical ingredients (APIs) and 53% of facilities manufacturing finished drugs for the U.S. market are located outside of the United States.¹³ FDA is unable to determine the volume of APIs that a specific country manufactures for the domestic or global market. The 2019 annual report from the U.S.-China Economic and Security Review Commission states that the United States sources 80% of its APIs from foreign countries and has identified China as the world's largest producer of APIs.¹⁴ Recent reports have identified limitations in FDA's ability to oversee foreign drug manufacturing facilities and have indicated that FDA inspections of these facilities have decreased since 2016.¹⁵ The COVID-19 pandemic has further restricted FDA's ability to oversee the increasingly globalized medical product supply chain, causing FDA to postpone most foreign facility inspections until at least May 2020.¹⁶

Provision

Section 3101 requires the Secretary, within 60 days of enactment, to enter into an agreement with the National Academies of Science, Engineering, and Medicine (NASEM) to examine and report, "in a manner that does not compromise national security," on the security of the U.S. medical product supply chain. The report must assess and evaluate U.S. dependence on critical drugs and devices from other countries; provide recommendations (e.g., a plan to improve resiliency of the supply chain); and address any supply vulnerabilities or potential disruptions that would significantly affect or pose a threat to public health or national security, as appropriate. In conducting the study and developing the report, NASEM must consider input from federal departments and agencies and consult with stakeholders through public meetings and other forms of engagement.

¹³ Food and Drug Administration (FDA), Testimony of Dr. Janet Woodcock, Director the Center for Drug Evaluation and Research, "Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program," December 10, 2019, <https://www.fda.gov/news-events/congressional-testimony/securing-us-drug-supply-chain-oversight-fdas-foreign-inspection-program-12102019>.

¹⁴ 2019 Report to Congress of the U.S. China Economic and Security Review Commission, 116th Congress First Session, November 2019, Chapter 3 Section 3- "Growing U.S. Reliance on China's Biotech and Pharmaceutical Products," <https://www.uscc.gov/annual-report/2019-annual-report>.

¹⁵ See, for example, U.S. Government Accountability Office (GAO), *Preliminary Findings Indicate Persistent Challenges with FDA Foreign Inspections*, GAO-20-262T, December 10, 2019, <https://www.gao.gov/products/GAO-20-262T>.

¹⁶ FDA Statement, "Coronavirus Disease 2019 (COVID-19) Update: Foreign Inspections," March 10, 2020, <https://www.fda.gov/news-events/press-announcements/coronavirus-disease-2019-covid-19-update-foreign-inspections>.

Section 3102. Requiring the Strategic National Stockpile to Include Certain Types of Medical Supplies

Background

The federal government maintains a supply of medicine and medical supplies to respond to a public health emergency severe enough to deplete local supplies (e.g., hurricane, infectious disease outbreak, or terrorist attack). This supply, known as the Strategic National Stockpile (SNS),¹⁷ includes antibiotics, intravenous fluids, and other medical supplies such as PPE and ventilators. In addition, the SNS contains certain medicines, such as anthrax and smallpox vaccines and treatments that may not be otherwise available for public use. In 2019, HHS stated the SNS contained approximately \$8 billion worth of supplies.¹⁸ In FY2018, management of the SNS transferred from the Centers for Disease Control and Prevention (CDC) to the Assistant Secretary for Preparedness and Response (ASPR).

Provision

This section amends PHS Section 319F-2(a)(1) to require the Secretary to maintain a stockpile of “drugs, vaccines and other biological products, medical devices, and other supplies.” This act further defines “other supplies” as “including PPE, 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.” Some of these types of supplies, such as PPE, were included in the stockpile even before enactment of this clarifying language.

Section 3103. Treatment of Respiratory Protective Devices as Covered Countermeasures

Background

In 2005 Congress passed the Public Readiness and Emergency Preparedness Act (PREP Act, P.L. 109-417), which authorizes the federal government to waive liability (except for willful misconduct) for manufacturers, distributors, and providers of MCMs, such as drugs and medical supplies, needed to respond to a public health emergency.¹⁹ The act also authorizes the federal government to establish a program to compensate eligible individuals who suffer injuries from administration or use of products covered by the PREP Act’s immunity provisions.²⁰ Section 6005 of FFCRA (P.L. 116-127) explicitly added personal respiratory protective devices used for the COVID-19 response to the list of countermeasures covered by the PREP Act.²¹

¹⁷ See HHS, Assistant Secretary for Preparedness and Response (ASPR), Public Health Emergency, “Strategic National Stockpile,” <https://www.phe.gov/about/sns/Pages/default.aspx>.

¹⁸ HHS, *FY2021 Public Health and Social Services Emergency Fund Congressional Justification*, p. 103.

¹⁹ HHS, ASPR, “Public Readiness and Emergency Preparedness Act,” <https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>.

²⁰ HHS, Health Resources and Services Administration (HRSA), “Countermeasures Injury Compensation Program (CICP),” <https://www.hrsa.gov/cicp/index.html>.

²¹ For more information on respiratory protective devices, and the certification program run by the National Institute for Occupational Safety and Health (NIOSH), see CRS In Focus IF11488, *Personal Protective Equipment and Ventilators for COVID-19: FDA Regulation and Related Activities*; and the Centers for Disease Control and Prevention (CDC), NIOSH, “National Personal Protective Technology Laboratory: About NPPTL,” <https://www.cdc.gov/niosh/npptl/about.html>.

Provision

Section 3103 amends PHS Section 317F-3 to change the definition of such covered devices to apply more broadly, to “a respiratory protective device that is approved by the National Institute for Occupational Safety and Health (NIOSH) under part 84 of title 42, Code of Federal Regulations (or any successor regulations), and that the Secretary determines to be a priority for use during a public health emergency declared under [PHSA] section 319.”²²

Subpart B—Mitigating Emergency Drug Shortages

Background

Drug shortages have remained a serious and persistent public health concern, despite the prevention and mitigation efforts of Congress, FDA, and the private sector. Causes of drug shortages include manufacturing and quality issues, lack of transparency in the supply chain, and business decisions made by individual firms (e.g., low profit margins leading to market exit).²³ The Federal Food Drug and Cosmetic Act (FFDCA) and FDA regulations require manufacturers of certain drugs to submit to FDA specified information related to product shortages. In addition, the FFDCA and FDA regulations allow FDA to take action to mitigate or prevent shortages and require FDA to make public certain information about drug shortages. More specifically, FFDCA Section 506C(a) requires that the manufacturer of a drug that is life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition notify the Secretary (FDA by delegation of authority) of any permanent discontinuance or interruption in the manufacture of the drug that is likely to disrupt its U.S. supply.²⁴ The notification must include the reasons for the interruption or discontinuance. FFDCA Section 506C(g) allows FDA, based on notifications received pursuant to Section 506C(a), to expedite facility inspections and review of supplements to new drug applications (NDAs), abbreviated NDAs (ANDAs), and supplements to ANDAs that could help mitigate or prevent a drug shortage.²⁵ FFDCA Section 506E requires FDA to maintain a public, up-to-date list of drugs that are in shortage. The list must include the name of the drug in shortage, the name of the manufacturer, and, as determined by FDA, the estimated duration of and reason for the shortage.²⁶

Persons that engage in the “manufacture, preparation, propagation, compounding or processing” of a drug must register their facility with FDA.²⁷ FFDCA Section 510(j) requires that at the time of registration, such persons must file a list of all drugs being “manufactured, prepared, propagated, compounded or processed” for commercial distribution.²⁸

Facilities registered with FDA are subject to inspection by the agency. FFDCA Section 704(b) requires that after a facility has been inspected, the inspector must provide a report, in writing, to

²² Of note, the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (the first supplemental appropriation for the COVID-19 response), P.L. 116-123, and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act, P.L. 116-136) authorized the HHS Secretary to transfer unspecified amounts of appropriated funds to the Covered Countermeasure Process Fund.

²³ FDA, “Drug Shortages: Root Causes and Potential Solutions,” published October 2019 and updated February 21, 2020, <https://www.fda.gov/media/131130/download>.

²⁴ 21 U.S.C. §356c(a).

²⁵ 21 U.S.C. §356c(g).

²⁶ 21 U.S.C. §356e.

²⁷ 21 U.S.C. §360.

²⁸ 21 U.S.C. §360(j).

the person in charge of that facility detailing the observations that led the inspector to determine that a product made in that facility may be adulterated. A copy of this report also must be sent to FDA.²⁹

Section 3111. Prioritize Reviews of Drug Applications; Incentives

Section 3111 amends FDCA Section 506C(g) to *require*—rather than *allow* as was the case prior to the CARES Act—FDA to *prioritize* and *expedite*—rather than *expedite* as prior to CARES—facility inspections and review of ANDAs and supplements to NDAs and ANDAs that could help mitigate or prevent a drug shortage.

Section 3112. Additional Manufacturer Reporting Requirements in Response to Drug Shortages

Section 3112(a) amends FDCA Section 506C(a) to extend notification requirements to the manufacturer of any drug “that is critical to the public health during a public health emergency declared by the Secretary” under PHS Act Section 319. It also requires a manufacturer to notify FDA of any permanent discontinuance or interruption in the manufacture of an API—not just the finished drug—that is likely to lead to a meaningful disruption in the supply of the API of such drug. The notification must include, in addition to the reasons for the drug’s discontinuance or interruption, as applicable, information about the source of the API and alternative sources, as well as whether any associated device used in the preparation or administration of the drug has contributed to the shortage, among other information.

Section 3112(b) amends FDCA Section 506C to add a new subsection (j). New FDCA Section 506C(j) requires the manufacturer of a drug, API, or associated medical device subject to the notification requirements under FDCA Section 506C(a), as amended, to develop, maintain, and implement a redundancy risk management plan, as appropriate. Such plan should identify and evaluate risks to the supply of the drug, as applicable, for each facility in which the drug or API is manufactured. The plan is subject to inspection and copying by the Secretary.

Section 3112 (c) amends FDCA Section 506E to require the Secretary, not later than 180 days after enactment and every 90 days thereafter, to transmit to the Centers for Medicare & Medicaid Services (CMS) a report regarding the drugs on the current drug shortage list.

Section 3112 (d) amends FDCA Section 704(b) to require that following the inspection of a facility manufacturing a drug at risk of shortage or with limited competition, a copy of the inspection report be sent “promptly” to all appropriate FDA offices with expertise in drug shortages. Specifically, this requirement applies to the inspection of a facility manufacturing a drug—approved under an NDA or ANDA—for which a notification has been submitted under FDCA Section 506C(a) (regarding an interruption in manufacturing or discontinuance), a drug that has been on the shortage list under FDCA Section 506E in the past five years, or a drug with no blocking patents or exclusivities for which there are not more than three approved drugs listed in the Orange Book.³⁰

Section 3112(e) amends FDCA Section 510(j) to require each drug manufacturer that registers with FDA to report annually to the Secretary for each listed drug “the amount that was

²⁹ 21 U.S.C. §374(b).

³⁰ The Orange Book satisfies the statutory requirement that FDA make publicly available, and revise every 30 days, a list of drugs that have been approved for safety and effectiveness and any patent information submitted with respect to such drugs. It also lists any unexpired periods of exclusivity covering an approved drug, in addition to other information applicants may find helpful.

manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution.” The Secretary may require this information to be submitted in electronic format, may require that this information be submitted at the time a public health emergency is declared under PHSa Section 319, and may exempt certain biologics from these reporting requirements if the Secretary determines it is not necessary to protect the public health.

Subpart C—Preventing Medical Device Shortages

Section 3121. Discontinuance or Interruption in the Production of Medical Devices

Background

FDA regulates the safety and effectiveness of medical devices in the United States. All medical device manufacturers are required to register their establishments with FDA,³¹ and such establishments are subject to inspections by FDA personnel or representatives. In addition, most medical devices are required to be reviewed by the agency prior to marketing; such premarket review mechanisms include premarket notification (510(k)),³² premarket approval,³³ de novo classification request,³⁴ and humanitarian device exemption,³⁵ among others.

Prior to the COVID-19 outbreak, concerns arose about potential medical device shortages due to the closure of ethylene oxide sterilization facilities that were not in compliance with U.S. Environmental Protection Agency (EPA) standards.³⁶ In contrast to the agency’s authority to compel manufacturers of certain drugs to report discontinuances or interruptions in production,³⁷ FDA did not have such authority for medical devices prior to the CARES Act. Rather, FDA relied on manufacturers to voluntarily report such information to the agency. In its FY2021 Congressional Justification, FDA requested additional authority to “require firms to notify FDA of an anticipated significant interruption in the supply of an essential device; require all manufacturers of devices determined to be essential to periodically provide FDA with information about the manufacturing capacity of the essential device(s) they manufacture; and authorize the temporary importation of devices whose risks presented when patients and healthcare providers lack access to critically important medical devices outweigh compliance with U.S. regulatory standards.”³⁸

Legislation introduced in the 116th Congress would provide FDA with additional authority to mitigate potential device shortages, generally through adding required reporting requirements on device manufacturers and allowing for expedited premarket review and inspections in certain

³¹ 21 U.S.C. §360; 21 C.F.R. Part 807.

³² 21 U.S.C. §360(k); 21 C.F.R. Part 807.

³³ 21 U.S.C. §360e; 21 C.F.R. Part 814.

³⁴ 21 U.S.C. §360c(f)(2).

³⁵ 21 U.S.C. §360j(m).

³⁶ FDA, “Statement on concerns with medical device availability due to certain sterilization facility closures,” October 25, 2019, <https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures>.

³⁷ 21 U.S.C. §356c.

³⁸ FDA FY2021 *Justification of Estimates for Appropriations Committees*, p. 36.

cases of shortage.³⁹ However, some bills propose providing FDA with more authority than others, such as those allowing for importation of unapproved devices in the case of a device shortage.⁴⁰

Provision

Section 3121 creates a new FFDCa Section 506J, which requires medical device manufacturers to report to FDA during or prior to a public health emergency⁴¹ any permanent discontinuance of production, or interruption in production, likely to lead to a meaningful disruption in supply of a medical device, including the reasons for the discontinuance or interruption. Medical device manufacturers are required to report this information to FDA at least six months prior to occurrence, or as soon as is practical. In turn, FDA is required to make such information public to appropriate organizations (e.g., physicians, supply chain partners) unless such a disclosure would adversely affect the public's health. If a manufacturer fails to submit information about discontinuances or interruptions, FDA is required to submit a letter to the manufacturer documenting this failure. The manufacturer is required to respond with reasons for noncompliance, as well as with information on interruptions or discontinuances as originally required, within 30 days. FDA would make such information public within 45 days of receipt but is not able to disclose to the public any information considered confidential or a trade secret.

New FFDCa Section 506J also requires FDA to establish and maintain a device shortage list that includes, among other things, the category or name of the device in shortage and, as determined by FDA, the reason(s) for the shortage (e.g., demand increase for the device) and the expected duration of the shortage. Such information must be made public, except if such information is considered confidential, a trade secret, or determined by FDA to be harmful to the public's health (e.g., increases the possibility of hoarding). Finally, new FFDCa Section 506J requires FDA to expedite premarket review and facility inspections of medical devices considered to be, or likely to be, in shortage and defines the terms "meaningful disruption" and "shortage."

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

Subpart A— Coverage of Testing and Preventive Services

This subpart includes three provisions related to coverage of COVID-19 tests and subsequent vaccines that may be developed to prevent COVID-19. They primarily address private health insurance coverage, including insurer payments to providers who furnish the test. One provision expands the FFCRA definition of testing that must be covered without cost-sharing by most private health insurance plans, and by other public and private health coverage programs and plans that reference the FFCRA definition.

Section 3201. Coverage of Diagnostic Testing for COVID-19

Background

Through multiple provisions in Divisions A and F, FFCRA provides payment for or requires coverage of testing for the COVID-19 virus, and items and services associated with such testing,

³⁹ See for example, S. 3468 (116th Congress); S. 3343 (116th Congress); H.R. 6049 (116th Congress); H.R. 6062 (116th Congress).

⁴⁰ H.R. 6062 (116th Congress).

⁴¹ See ""Section 319" Public Health Emergency".

without any cost-sharing.⁴² Several of these provisions refer to a definition for COVID-19 testing established in FFCRA Section 6001(a)(1), which defines such tests to include in vitro diagnostics (IVDs), as defined in FDA regulation, that detect the SARS-CoV-2 virus⁴³ or diagnose COVID-19 and that have received either 510(k) clearance, premarket approval, authorization pursuant to de novo classification, or emergency use authorization (EUA) for marketing.

This definition is used or cross-referenced in the following provisions providing payment for or requiring coverage of testing for the COVID-19 virus: (1) Section 6001(a)(1)-(2), with respect to specified types of private health insurance coverage; (2) Section 6006, with respect to TRICARE, veterans' health care, and federal civilian employee health coverage (Federal Employees Health Benefits Program or FEHBP); and (3) Section 6007, with respect to the Indian Health Service (IHS). In addition, appropriations provided in FFCRA Division A to the Defense Health Program, Veterans Health Administrations, IHS, and Public Health and Social Services Emergency Fund are to be used, in whole or in part, to pay for COVID-19 testing and related services, with reference to FFCRA Section 6001(a)(1).

On March 16, 2020, FDA updated guidance relating to COVID-19 diagnostic tests during the public health emergency.⁴⁴ In this guidance, the agency detailed four policies, whereby manufacturers or laboratories could develop, use, or market laboratory-developed tests or test kits for COVID-19. Two of these policies allowed for laboratories and test kit manufacturers to begin using or distributing their tests prior to receiving an EUA from the agency, as long as they submitted an EUA application within 15 business days of beginning clinical testing or distribution of the test kit and notified the agency that the test was in use. Therefore, tests and test kits would be in clinical use without having been granted an EUA (or 510(k) clearance, de novo authorization, or premarket approval). In addition, the agency outlined a policy allowing states to authorize laboratories within their state to carry out testing without FDA involvement; therefore, these tests would also be in clinical use without authorization from the FDA (or 510(k) clearance, de novo authorization, or premarket approval). Therefore, pursuant to the FDA's updated March 16 guidance, some tests in clinical use would fall outside the definition at FFCRA Section 6001(a)(1) and may not be included in the above-referenced provisions' requirements providing payment for or requiring coverage of testing for the COVID-19 virus.

Provision

Section 3201 amended FFCRA Section 6001(a)(1) to include those IVDs (1) that have received either 510(k) clearance, premarket approval, authorization pursuant to de novo classification, or an EUA; (2) where the developer has requested, or intends to request, an EUA; (3) that are developed in and authorized by a state that has notified the Secretary of its intention to review tests intended to diagnose COVID-19; and (4) that are determined appropriate through guidance by the Secretary.

Section 3202. Pricing of Diagnostic Testing

Background

⁴² CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*.

⁴³ SARS-CoV-2 is the technical name of the virus that causes COVID-19 disease.

⁴⁴ FDA, "Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency," March 16, 2020, <https://www.fda.gov/media/135659/download>.

FFCRA Section 6001 created a requirement for most private health insurance plans to cover specified COVID-19 testing and testing-related items and services.⁴⁵ The coverage must be provided without consumer cost-sharing, including deductibles, copayments, or coinsurance. This coverage requirement applies to the specified items and services that are furnished during the COVID-19 public health emergency described in FFCRA.⁴⁶ The provision did not address the reimbursement amount that a provider must receive from a health plan for furnishing COVID-19 testing.

In private health insurance, the amount paid for covered items and services is generally contingent upon whether a consumer's health plan has negotiated with a provider to enter into a contract.⁴⁷ The contract between the health plan and the provider generally specifies the total amount that a provider may receive for furnishing particular items or services to that health plan's enrollees. A provider that enters into a contract with a health plan is considered to be part of the health plan's network, otherwise referred to as being in-network.

A provider that does not enter into a contract with a health plan is considered out-of-network and as such there is no negotiated rate between the provider and the health plan. In situations involving services provided by an out-of-network provider, the amount that a provider will receive from a health plan depends on whether the health plan covers out-of-network services. In situations where health plans *do not cover* out-of-network services, the health plan will not pay any amount to a provider for services provided to an enrollee of the health plan. In situations where plans *do cover* out-of-network services, as there is no negotiated rate between health plans and out-of-network providers, health plans will use their own methodologies for calculating how much they will pay out-of-network providers for services.

Provision

Section 3202 establishes a methodology for determining the amount that a health plan must reimburse a provider for the COVID-19 testing, and testing-related items and services that are required to be covered under FFCRA Section 6001 (as amended).⁴⁸ If a health plan had a negotiated rate with a provider prior to the declaration of the COVID-19 public health emergency declared under PHSA Section 319, then the health plan must apply that negotiated rate throughout the period of the COVID-19 public health emergency.⁴⁹ If a health plan did not have a negotiated rate with a provider prior to the emergency declaration, then the health plan must either reimburse the provider an amount that equals the cash price for the COVID-19 testing, as listed on the provider's public website, or the health plan and provider may negotiate a rate that is less than the cash price.

During the period of the COVID-19 public health emergency, providers of COVID-19 diagnostic testing must make public the cash price for the COVID-19 test on the provider's public website.

⁴⁵ For information on the types of plans subject to the coverage requirement and this payment requirement, see "See Section 6001. Coverage of Testing for COVID-19" in CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*. The definition of covered testing and related services in FFCRA Sec. 6001 was amended by the CARES Act. See "Section 3201. Coverage of Diagnostic Testing for COVID-19."

⁴⁶ See ""Section 319" Public Health Emergency".

⁴⁷ For an overview of private health insurance billing, see the section "Private Health Insurance Billing Overview" in CRS Report R46116, *Surprise Billing in Private Health Insurance: Overview and Federal Policy Considerations*.

⁴⁸ See footnote 44.

⁴⁹ See ""Section 319" Public Health Emergency".

The Secretary may impose a civil monetary penalty on a provider of COVID-19 diagnostic testing that is not in compliance with the requirement to post the cash price for the COVID-19 testing and has not completed a corrective action plan to comply with the requirement. The amount of the civil monetary penalty may not exceed \$300 per day that the violation is ongoing.

Section 3203. Rapid Coverage of Preventive Services and Vaccines for Coronavirus

Background

PHSA Section 2713 and accompanying regulations⁵⁰ require most private health insurance plans to cover, without cost-sharing,⁵¹ specified types of clinical preventive services. These include any preventive service recommended with an A or B rating by the United States Preventive Services Task Force (USPSTF),⁵² or any immunization with a recommendation by the Advisory Committee on Immunization Practices (ACIP),⁵³ adopted by CDC, for routine use for a given individual. These coverage requirements apply no sooner than one year after a recommendation is published.⁵⁴

Requirements of Section 2713 apply to individual health insurance coverage and to small- and large-group plans, whether fully insured or self-insured.⁵⁵ The requirements do not apply to grandfathered individual or group plans, or to short-term, limited duration insurance (STLDI).⁵⁶ By regulation, plans are generally not required to cover preventive services furnished out-of-network. Cost-sharing for office visits associated with a furnished preventive service may or may not be allowed, as specified in regulation.⁵⁷

Provision

Section 3203 requires specified plans—the same types of plans as those subject to PHSA Section 2713—to cover a COVID-19 vaccine and potentially other COVID-19 preventive services, as recommended by ACIP or USPSTF, respectively.⁵⁸ This coverage must be provided without cost-sharing. Section 3203 also applies an expedited effective date for coverage of 15 business days

⁵⁰ Section 2713 was added to the Public Health Service (PHSA) and incorporated into the Employee Retirement Income Security Act (ERISA) and Internal Revenue Code (IRC) by the Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as amended). Regulations are at 29 C.F.R. 2590.715-2713, 26 C.F.R. 54.9815-2713, and 45 C.F.R. 147.130.

⁵¹ In general, private health insurance cost-sharing includes deductibles, coinsurance, and copayments. A *deductible* is the amount an insured consumer pays for covered health care services before coverage begins (with exceptions, such as the preventive services specified in this provision). *Coinurance* is the share of costs, figured in percentage form, an insured consumer pays for a health service. *Co-payment* is the fixed dollar amount an insured consumer pays for a health service.

⁵² U.S. Preventive Services Task Force (USPSTF), <https://uspreventiveservicestaskforce.org/uspstf/>.

⁵³ Advisory Committee on Immunization Practices (ACIP), <https://www.cdc.gov/vaccines/acip/index.html>.

⁵⁴ Per 45 C.F.R. 147.130(b), such coverage is required “for plan years (in the individual market, policy years) that begin on or after the date that is one year after the date the recommendation or guideline is issued.”

⁵⁵ For more information about types of private health insurance plans, see CRS Report R45146, *Federal Requirements on Private Health Insurance Plans*.

⁵⁶ For more information about grandfathered plans and short-term, limited duration insurance (STLDI), see CRS Report R46003, *Applicability of Federal Requirements to Selected Health Coverage Arrangements*.

⁵⁷ In general, whether cost-sharing for office visits is allowed or prohibited depends on whether the preventive service or item was the primary purpose of the visit, and whether the service or item was billed or tracked separately from the office visit. See 45 C.F.R. 147.130(a)(2).

⁵⁸ Cares Act Section 3203 refers to, but does not amend, PHSA Section 2713.

after an applicable ACIP or USPSTF recommendation is published. Otherwise, requirements of Section 3203 mirror existing requirements under PHSA Section 2713.

Subpart B—Support for Health Care Providers

This subpart includes provisions that aim to extend the services available during the COVID-19 period and beyond, particularly for rural or otherwise underserved populations. The subpart includes additional appropriations for health centers that provide care to populations that are underserved or are located in underserved areas. Other provisions relate directly to health care providers; for example, by conferring medical malpractice liability on health professionals who choose to volunteer during the emergency period, by amending program rules for the NHSC program to permit individuals to volunteer during the emergency period, and by clarifying aspects of the USPHS Ready Reserve Corps program. The Ready Reserve Corps is composed of reserve officers serving in other roles who would be subject to intermittent involuntary deployment (“call up”) to bolster the available workforce for public health emergency missions. Finally, the subpart reauthorizes and amends existing programs related to supporting rural health care providers and encouraging the use of telehealth to expand access to care.

Section 3211. Supplemental Awards for Health Centers

Background

The federal health center program, authorized by PHSA Section 330 and administered by the Health Resources and Services Administration (HRSA), provides grants to not-for-profit organizations or state and local government entities to operate outpatient health centers. Participation in the program requires grantees to provide care regardless of a patient’s ability to pay, and grant funding is provided to support this care. These centers are also required to be located in medically underserved areas (MUAs) or to provide care to a population that is designated as underserved.⁵⁹ Health centers are part of the health care safety net, and they have been used as a way to fund safety net providers during prior disasters, when additional funds were appropriated to make awards to existing grantees to respond to an emerging need.⁶⁰ In FY2020, health centers received a combination of discretionary and mandatory funding, which together provided more than \$5.6 billion to support the program.⁶¹ Health centers also received additional funds in P.L. 116-123, Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, the first law to respond to COVID-19. That law provided the program with an additional \$100 million. These funds were awarded via formula to supplement existing health center funding.⁶²

⁵⁹ For more information about these designations, see CRS Report R43937, *Federal Health Centers: An Overview*.

⁶⁰ For example, health centers received additional funding to respond to the Zika virus outbreak. See Table 1 in CRS Report R44460, *Zika Response Funding: Request and Congressional Action*.

⁶¹ For FY2019 and FY2020 funding amounts, see HHS, HRSA, “Justification of Estimates for Congressional Committees, FY2021,” <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2021.pdf>, pp. 17.

⁶² HHS, HRSA, “HHS Awards \$100 Million to Health Centers for COVID-19 Response,” press release, March 24, 2020, <https://www.hhs.gov/about/news/2020/03/24/hhs-awards-100-million-to-health-centers-for-covid-19-response.html>.

Provision

This section appropriates \$1.32 billion in supplemental funding for health centers for FY2020 for the detection of the COVID-19 virus, or prevention, diagnosis, and treatment of COVID-19 illnesses. The section also applies the limits on using these funds for abortion that were included in Further Consolidated Appropriations Act, 2020 (P.L. 116-94), which provided FY2020 appropriations for HHS, among other agencies.⁶³

Section 3212. Telehealth Network and Telehealth Resource Centers Grant Programs

Background

PHSA Section 333(I) authorizes two telehealth programs that were authorized at “such sums as may be necessary” through FY2006. Both programs have been funded since that time, despite the lapsed authorization of appropriation. The programs are administered by HRSA. The first program, authorized in PHSA Section 333I(d)(1), is the Telehealth Network Grant Program (TNGP). This program aims to demonstrate how telehealth technologies can be used through telehealth networks for medically underserved populations who live in rural areas, frontier communities, and MUAs.⁶⁴ Prior to passage of the CARES Act, only nonprofit entities were eligible to apply for TNGP grants; however, prior law permitted both nonprofit and for-profit organizations to participate in the grantees’ telehealth networks. The second program is the Telehealth Resource Centers (TRC) Program. This program aims to coordinate telehealth organizations that serve rural and underserved communities throughout the country, by providing technical assistance to those organizations through national and regional TRCs.⁶⁵ FY2020 appropriations report language provides \$28.5 million to HRSA’s overarching Telehealth Program, which includes both of these programs.⁶⁶

Provision

This section amends PHSA Section 330I to make changes to both the TNGP and the TRC programs. It makes the following changes:

(1) The Telehealth Network Grant Program (TNGP)

Grants. Section 3212 amends PHSA Section 330I by replacing the HRSA Administrator’s Director’s authority to award grants to eligible grantees to demonstrate how telehealth technologies can be used through telehealth networks, with the authority to award grants to evidence-based projects that utilize telehealth technologies through telehealth networks. The purpose of the TNGP now includes improving access to and quality of health care services for the TNGP patient population. Grantees may no longer use TNGP funds to expand health care provider training or for decision-making purposes.

⁶³ Under federal law, federal funds are generally not available to pay for abortions, except in cases of rape, incest, or endangerment of a mother’s life. This restriction is the result of statutory and legislative provisions like the Hyde Amendment, which has been added to the annual appropriations measure for HHS since 1976.

⁶⁴ 42 U.S.C. §254c-14(d)(1).

⁶⁵ 42 U.S.C. §254c-14(d)(2); and CRS Report R46289, *The National Consortium of Telehealth Resource Centers: COVID-19 Assistance*.

⁶⁶ H.Rept. 116-62, p. 327. To learn about HRSA’s other telehealth programs, see HRSA, *FY2021 Justification of Estimates for Appropriations Committees*, pp. 324-328, <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2021.pdf>.

Grant period. Section 3212 allows the HRSA Administrator to extend the period of performance for the TNGP from four years to five years. This section also makes administrative changes to the statutory requirements on telehealth networks, including the nature of entities and composition of telehealth networks. This section removes the statutory requirements that grantees of TNGP be nonprofit entities and that telehealth networks be composed in a certain manner.

Applications. Grant applicants are now required to describe within their applications how the applicants' proposed TNGP projects will, among other things, improve access and quality of the health care services that patients will receive. Prior to passage of the CARES Act, this provision was optional.

Terms, conditions, maximum amount of assistance. Section 3212 removes the statutory requirements that the Secretary has to establish the terms and conditions of the TNGP, as well as the maximum amounts awarded to each TNGP recipient for each fiscal year. This section removes the federal mandate that required the Secretary to publish, through HRSA, a notice of application requirements for the TNGP program for each fiscal year.

Preferences. The Secretary is required to also give preference to eligible entities that develop plans for or establish telehealth networks that provide mental health care services, public health care services, long-term care, home care, preventive care, case management services, or prenatal care for high-risk pregnancies. This section also expands preference to eligible entities that propose projects that promote local and regional connectivity within areas, communities, and populations served. The Secretary, however, may no longer give preference to applicants that demonstrate integration of health care information into TNGP projects.

Distribution of funds. The HRSA Administrator no longer has to ensure that the total amount of funds awarded in a given fiscal year is not less than the total amount awarded for projects in FY2001. The HRSA Administrator must continue to ensure that no less than 50% of funds are awarded to TNGP projects in rural areas.

Use of funds. Grantees no longer have the authority to use TNGP funds to purchase certain equipment. Grantees are prohibited from purchasing computer hardware and software, audio and video equipment, computer network equipment, interactive equipment, and data terminal equipment. However, grantees may continue to purchase equipment that furthers the objectives of the TNGP, such as to expand access to health care services.

Prohibited uses of funds. TNGP grantees are prohibited from using more than 20% of total grant funds to purchase or lease equipment. Under prior law, grantees were allowed to use no more than 40% of total grant funds. Section 3212 also removes the examples of transmission equipment from the list of items that TNGP funds cannot be used to purchase.

Report and regulations. The section requires the Secretary to submit a report, to specified congressional committees, that describes the activities and outcomes of the TNGP, no later than March 27, 2024, and every five years thereafter. The Secretary is no longer required to issue regulations specifying the definition of frontier area.

(2) The Telehealth Resource Centers (TRC) Program

Grants and eligibility. Section 3212 amends PHSA Section 330I by replacing the HRSA Administrator's authority to award grants for projects to demonstrate how telehealth technologies can be used in certain areas and communities, with the authority to award grants to support initiatives that utilize telehealth technologies. The CARES Act removes the program's authority to establish new TRCs, which essentially makes the current TRCs permanent recipients of federal funds under the program and does not allow for other entities to participate as TRCs. The section also permits the HRSA Administrator to extend the period of performance for the TRC program

from four years to five years. Section 3212 removes the statutory requirement that grantees of the TRC program be nonprofit entities.

Terms, conditions, maximum amount of assistance. Section 3212 removes the statutory requirement that the Secretary has to establish the terms and conditions of the TRC program, as well as the maximum amount awarded to each TRC program recipient for each fiscal year. This section no longer requires the Secretary to publish, through HRSA, a notice of application requirements for the TRC program for each fiscal year.

Preferences. The section requires the Secretary to also give preference to eligible entities with successful records in delivering health care services to rural areas, MUAs, and medically underserved populations.

Use of funds. The section specifies that grantees no longer have the authority to use TRC program funds to foster certain telehealth activities. It also prohibits grantees from using funds to foster the use of telehealth technologies to provide health care information. However, grantees may continue to foster the use of telehealth technologies to educate health care providers and consumers in an effective manner.

Report and regulations. The section requires the Secretary to submit a report, to specified congressional committees, on the activities and outcomes of the TRC program, no later than March 27, 2024, and every five years thereafter. (This report need not to be a separate report from that required of the TNGP.) The Secretary is no longer required to issue regulations specifying the definition of frontier area.

Authorization of appropriations. The section authorizes an appropriation of \$29 million for each of FY2021 through FY2025.

Section 3213. Rural Health Care Services Outreach, Rural Health Network Development, and Small Health Care Provider Quality Improvement Grant Programs

Background

PHSA Section 330A authorizes three grant programs supporting rural health care providers: the rural health care services outreach grants, the rural health network development grants, and the small health care provider quality improvement grants. These programs are administered by HRSA's Federal Office of Rural Health Policy (FORHP).⁶⁷ In each case, grants are available to nonprofit or governmental health entities for a period of three years. The Rural Health Network Development program also permits additional one-year planning grants. Funds for the program had been authorized at \$45 million annually through FY2012, and required a one-time report to Congress that was required at the end of FY2005. Despite the lapsed authorizations of appropriations, these programs have continued to be funded in recent years. Most recently, the programs received an appropriation of \$79.5 million in FY2020.⁶⁸

Provision

This section makes a number of technical corrections to PHSA Section 330A. It also replaces language related to essential health services to make reference to basic health services, extends the duration of Rural Health Care Service Outreach grants and Rural Health Network

⁶⁷ HHS, HRSA, "Rural Community Programs," <https://www.hrsa.gov/rural-health/community/index.html>.

⁶⁸ HHS, HRSA "Justification of Estimates for Congressional Committees, FY2021," <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2021.pdf>, p. 20.

Development grants from three to five years, and expands eligibility for the programs to any rural health entity (prior eligibility was limited to rural public or nonprofit health entities). The section also eliminates the one-year planning grants from the Rural Health Network Development program and extends the grant period of the Small Health Care Quality Improvement grants from three to five years. Finally, the section requires a report, to be delivered to specified congressional committees, on these grant programs, not later than four years after enactment and every five years thereafter, and authorizes an appropriation of \$79.5 million for each of FY2020 through FY2025. No additional funding for FY2020 is appropriated in this provision.

Section 3214. United States Public Health Service Modernization

Background

The USPHS Commissioned Corps is a branch of the U.S. uniformed services, but it is not one of the armed services.⁶⁹ The Corps is based in HHS under the authority of the U.S. Surgeon General (SG). USPHS-commissioned officers are physicians, nurses, pharmacists, engineers, and other public health professionals who serve in federal agencies, or as detailees to state or international agencies, to support a variety of public health activities. ACA (the Patient Protection and Affordable Care Act, P.L. 111-148, as amended), Section 5210, authorized a USPHS Ready Reserve Corps—reserve officers serving in other roles who would be subject to intermittent involuntary deployment (“call up”) to bolster the available workforce public health emergency missions.⁷⁰ HHS had not received an appropriation for this purpose and had not established a Ready Reserve Corps. It has been reported that the ACA authority did not fully authorize this action, and legislation (S. 2629, the United States Public Health Service Modernization Act of 2019) was introduced to address this.⁷¹

Provision

Section 3214 enacts the language of S. 2629, making several technical and substantive amendments to PHSA Title II to clarify provisions regarding deployment readiness, retirement, compensation, and other matters as they would affect the Ready Reserve Corps.⁷²

Section 3215. Limitation on Liability for Volunteer Health Care Professionals During COVID-19 Emergency Response

Background

In 1997, Congress enacted the Volunteer Protection Act of 1997 (VPA; P.L. 105-19).⁷³ This act provides that a volunteer at a nonprofit organization or governmental entity is not liable for the

⁶⁹ 10 U.S.C. §101. The Commissioned Corps of the U.S. Public Health Service is authorized in PHSA Secs. 201-224 (42 U.S.C. §§202-233). For more information see HHS, USPHS Commissioned Corps, <http://www.usphs.gov/default.aspx>.

⁷⁰ See “Sec. 5210. USPHS Ready Reserve Corps” in CRS Report R41278, *Public Health, Workforce, Quality, and Related Provisions in ACA: Summary and Timeline*.

⁷¹ Scott Maucione, “Public Health Service Gets Congressional Attention for Ready Reserve Corps,” *Federal News Network*, November 4, 2019, <https://federalnewsnetwork.com/workforce/2019/11/public-health-service-gets-congressional-attention-for-ready-reserve-corps/>.

⁷² In addition, the CARES Act provides about \$27 billion in emergency supplemental appropriations to the HHS Secretary, through the Public Health and Social Services Emergency Fund, for numerous stated purposes, including “enhancements to the U.S. Commissioned Corps.”

⁷³ Codified at 42 U.S.C. §§ 14501-14505.

harm he or she causes by an act (or an act of omission) on behalf of the organization, provided the following: (1) the volunteer was, among other things, properly licensed, certified, or authorized for the activities in a state, if applicable; (2) the volunteer was acting within the scope of his or her responsibilities in the organization at the time of the act (or act of omission); and (3) the harm was not caused by “willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious, flagrant indifference to the rights or safety of the individual harmed by the volunteer.”⁷⁴ The law does not convey liability protections in certain instances (e.g., when misconduct is a criminal act or when the defendant acted under the influence of drugs or alcohol),⁷⁵ and the law specifies how it interacts with relevant state law.⁷⁶ This law was not specific to health professionals in a volunteer capacity but, rather, covered all types of volunteers.

Provision

This section limits the medical malpractice liability of health professionals who volunteer during the COVID-19 emergency. Specifically, it limits the liability under federal and state law for any harm caused by an act or omission while providing health services during the emergency, provided that the health services are within the scope of the health professional’s license registration, or certification, and that the health professional acted in good faith. The section specifies that health professionals do not have liability protections in situations where harm was caused by “willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious flagrant indifference to the rights or safety of the individual harmed by the health care professional,” or when services were provided by a health professional who was under the influence of drugs or alcohol. The section specifies that it preempts state or local laws that are inconsistent with this section, unless those laws provide great liability protections, and specifies that the liability protections are in addition to those provided under the VPA. Finally, the section defines relevant terms and specifies that this provision is effective at enactment and will remain in effect for the length of the public health emergency declared by the Secretary under PHSA Section 319, declared by the Secretary on January 30, 2020.

Section 3216. Flexibility for Members of National Health Service Corps During Emergency Period

Background

The federal government supports a number of health workforce programs administered by HRSA. Among the largest of these programs is the NHSC, which provides scholarships and loan repayment to health care providers in exchange for a two-year or more service commitment in a health professional shortage area (HPSA).⁷⁷ The program is authorized in PHSA Sections 332-338I. PHSA Section 333 specifies the types of health care facilities and the conditions they must meet to receive NHSC personnel. Generally, these are outpatient health facilities in HPSAs.⁷⁸

⁷⁴ *Id.* §14503(a).

⁷⁵ *Id.* §14503(g).

⁷⁶ *Id.* §14502(a) (preempting state laws to the extent of inconsistency with the Volunteer Protection Act (VPA), but not preempting state laws that provide greater liability protections for volunteers).

⁷⁷ CRS Report R44970, *The National Health Service Corps*. For more information about health professional shortage areas (HPSAs), see CRS Infographic IG10015, *Health Professional Shortage Areas (HPSAs)*.

⁷⁸ Certain inpatient facilities are permitted, such as critical access hospitals and Indian Health Service (IHS) facilities.

Provision

This section specifies that for the duration of the public health emergency declared under PHSA Section 319 for the COVID-19 response, the Secretary may waive the requirements in PHSA Section 333 in order to assign NHSC members to voluntarily provide health services to respond to the emergency. The provision allows NHSC members to volunteer services for the number of hours that the Secretary determines appropriate. The provision further specifies that NHSC members must be assigned voluntarily, that the assignment site must be in reasonable proximity to the NHSC corps member's original practice site, and that these hours are to count toward fulfilling their NHSC service commitment.

Subpart C—Miscellaneous Provisions

Section 3221. Confidentiality and Disclosure of Records Relating to Substance Use Disorder

Background

Generally, the privacy of health information is governed by the HIPAA (Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, as amended) Privacy Rule, which establishes requirements for covered entities' (health care plans, providers, and clearinghouses) and their business associates' use and disclosure of protected health information (PHI). All health information is generally treated similarly under the HIPAA Privacy Rule, with certain exceptions in place relating to the use and disclosure of psychotherapy notes. In contrast, stricter federal privacy requirements at PHSA Section 543—requirements promulgated in and commonly known as the “Part 2” rule—apply to individually identifiable patient information received or acquired by federally assisted substance use disorder programs.⁷⁹ Specifically, the Part 2 rule governs any information that would identify a patient as having or having had a substance use disorder, and that is obtained or maintained by a federally assisted substance use disorder program for the purpose of treating a substance use disorder, making a diagnosis for that treatment, or making a referral for that treatment.⁸⁰ Part 2 requirements apply to an individual or entity (other than a general medical facility) that is federally assisted and provides—and holds itself out as providing—diagnosis, treatment, or referral for treatment of substance use disorders.⁸¹ “Federally assisted programs” include programs that are carried out in whole or in part by the federal government or supported by federal funds.

The Part 2 rule strictly regulates the disclosure and redisclosure of patient identifying information held by Part 2 programs. The rule allows disclosure of this information only either (1) with written patient consent or (2) pursuant to exceptions in statute or regulation (e.g., for a medical emergency, for research). A general authorization for the release of medical information does not satisfy the rule's requirement for written consent, although a general designation in consent is allowed in cases where a class of participants may receive and redisclose amongst themselves Part 2 information if there exists a treatment relationship.⁸² Further, the rule strictly prohibits the subsequent *redisclosure* of information received from a Part 2 program without consent from the patient, and a notification clearly prohibiting this redisclosure by the receiving entity travels with

⁷⁹ 42 U.S.C. §290dd-2; 42 C.F.R. Part 2.

⁸⁰ 42 C.F.R. §2.12(a).

⁸¹ 42 C.F.R. §2.12(b).

⁸² 42 C.F.R. §2.31(a)(4)(iii)(3).

any disclosed Part 2 information. Under PHSA Section 543(f), any person who violates any provision of the section or any regulation issued pursuant to the section shall be fined in accordance with Title 18 of the *U.S. Code*.⁸³

Provision

Section 3221 amends PHSA Section 543 to allow for, pursuant to written consent, the use or disclosure of covered records by a covered entity, business associate, or a Part 2 program for purposes of treatment, payment, and health care operations as permitted by the HIPAA Privacy Rule. In addition, the section allows information disclosed pursuant to this exception to be subsequently redisclosed in accordance with the HIPAA Privacy Rule. It further allows the disclosure of deidentified records to public health authorities, without written consent, if the information meets the deidentification standards in the HIPAA Privacy Rule.⁸⁴

Section 3221 applies the penalties under SSA Sections 1176 and 1177 for violations of PHSA Section 543, as specified. It also prohibits discrimination against an individual on the basis of information received pursuant to an inadvertent or intentional disclosure of covered records, or information contained in covered records, in multiple instances (e.g., employment, access to courts). The section applies the HIPAA breach notification requirements to a program or activity under PHSA Section 543 in case of a breach of records.⁸⁵ Section 3221 requires the Secretary to revise regulations as necessary such that changes in the section apply with respect to uses and disclosures of covered records occurring on or after the date that is 12 months after enactment. It also requires the Secretary, not later than one year after enactment and in consultation with appropriate legal, clinical, privacy, and civil rights experts, to update the notice of privacy practices requirement in the HIPAA Privacy Rule⁸⁶ to require covered entities and entities creating or maintaining covered records to provide notice, in plain language, of privacy practices regarding those records. The section also establishes that nothing in the act shall be construed to limit (1) the right of an individual to request a restriction on the use or disclosure of a record under PHSA Section 543 for purposes of treatment, payment, or health care operations, and (2) the choice of a covered entity to obtain consent to use or disclose a covered record for purposes of treatment, health care operations, or payment.

Section 3222. Nutrition Services

Background

The OAA (Older Americans Act, P.L. 89-73, as amended; 42 U.S.C. §§ 3001 et seq.) Nutrition Services Program provides grants to states and U.S. territories under Title III of the act to support congregate nutrition services (i.e., meals served at group sites such as senior centers, community centers, schools, churches, and senior housing complexes) and home-delivered nutrition programs for individuals aged 60 and older.⁸⁷ The Nutrition Services Program is designed to address problems of food insecurity, promote socialization, and promote the health and well-being of older persons through nutrition and nutrition-related services. The program is administered by the Administration for Community Living (ACL) under HHS. States and territories receive separate funding allotments for each program based on a statutory funding formula. Under OAA, states

⁸³ 42 U.S.C. §290dd-2(f).

⁸⁴ 45 C.F.R. §164.514(b).

⁸⁵ 45 C.F.R. 164 Part D.

⁸⁶ 45 C.F.R. §164.520.

⁸⁷ For more information, see CRS In Focus IF10633, *Older Americans Act: Nutrition Services Program*.

and U.S. territories have authority to transfer up to 40% of their allotments between congregate and home-delivered nutrition services and can request waivers to transfer up to 10% of additional funding between these programs. In addition, OAA provides states authority to transfer up to 30% of program funding from the Supportive Services Program to the Nutrition Services Program.⁸⁸

Nutrition services providers are required to offer at least one meal per day, five or more days per week (except in rural areas, where the provision of meals may be less frequent).⁸⁹ The meals must comply with the Dietary Guidelines for Americans published by the Secretary of HHS and the Secretary of Agriculture. Providers must serve meals that meet specified minimum amounts for the daily recommended dietary reference intakes (DRIs) established by the Food and Nutrition Board of the National Academies of Sciences, Engineering, and Medicine based on the number of meals served by the project each day.⁹⁰ With respect to home-delivered nutrition programs, individuals aged 60 or older and their spouses (regardless of age) may participate in the home-delivered nutrition program. Persons aged 60 or over who are frail, homebound by reason of illness or disability, or otherwise isolated, are also prioritized for OAA Title III services.⁹¹ Services may be available to individuals under age 60 with disabilities if they reside at home with the older individual.⁹² Service eligibility is determined by the states and local Area Agencies on Aging (AAA); however, according to the ACL, entities may waive any eligibility requirements they have established for home-delivered meals in response to the COVID-19 pandemic.⁹³

Provision

During any portion of the COVID-19 public health emergency declared under PHS Act Section 319, the section sets forth additional transfer authority between OAA nutrition programs, clarifies participant requirements for home-delivered meals, and authorizes the Assistant Secretary for Aging to waive certain dietary requirements for nutrition services. Specifically, the HHS Secretary is required to allow a state agency or an AAA to transfer up to 100% of the funds appropriated and received for congregate and home-delivered nutrition between these two programs, for such use as the state or area considers appropriate to meet service needs without prior approval. For purposes of state agencies' determining the delivery of nutrition services, the provision requires the same meaning to be given to individuals who are unable to obtain nutrition because they are practicing social distancing due to the emergency as is given to an individual who is homebound because of illness. And, to facilitate implementation of nutrition services programs, the Assistant Secretary is authorized to waive compliance with the Dietary Guidelines for Americans and the specified minimum amounts for the daily recommended DRI requirements.

⁸⁸ On March 13, 2020, the President declared that the ongoing COVID-19 pandemic is of sufficient severity and magnitude to warrant an emergency determination under §501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("Stafford Act"; 42 U.S.C. 5121-5207). The emergency exists nationwide. Under the declaration, states, U.S. territories, and tribes may consider requests for a declaration of a "major disaster" under Section 401(a) of the Stafford Act. A major disaster declaration under the Stafford Act triggers disaster relief authority in the Older Americans Act (OAA) should a state (including a U.S. territory) or tribe (OAA Title VI grantee) request and receive such declaration. Specifically, OAA Section 310 provides authority for states to use any portion of funding made available under any and all sections of the act for disaster relief provided to older individuals. For further information, see Agency for Community Living (ACL) guidance issued March 16, 2020, at https://acl.gov/sites/default/files/common/OAADisasterRelief_2020-03-16.pdf.

⁸⁹ 42 U.S.C. §3030e-f.

⁹⁰ 42 U.S.C. §3030g-21.

⁹¹ 45 C.F.R. §1321.69.

⁹² 42 U.S.C. §3030g-21.

⁹³ ACL, "Information for the Aging and Disability Networks, Grant and Program Guidance, Older Americans Act Programs," <https://acl.gov/COVID-19>.

The provision defines the terms “Assistant Secretary,” “Secretary,” “State agency,” and “area agency on aging” to have the same meanings as under OAA Section 102.

Section 3223. Continuity of Service and Opportunities for Participants in Community Service Activities Under Title V of the Older Americans Act

Background

OAA Title V establishes the Community Service Employment for Older Americans program (CSEOA), sometimes referred to as the Senior Community Service Employment Program (SCSEP). CSEOA promotes part-time employment opportunities in community service activities for unemployed low-income persons aged 55 and older and who have poor employment prospects.⁹⁴ The Title V program is administered by the Department of Labor’s (DOL’s) Employment and Training Administration. DOL allocates Title V funds for grants based on a statutory funding formula to state agencies in all 50 states, the District of Columbia, Puerto Rico, and the U.S. territories, and to national organizations. Program participants work part-time in community service jobs, including employment at schools, libraries, social service organizations, and senior-serving organizations. Program participants earn the higher of minimum wage or the typical wage for the job in which they are employed. An individual may typically participate in the program for a cumulative total of no more than 48 months.⁹⁵

Provision

Due to the effects of the COVID-19 public health emergency declared under PHS Section 319, this section specifies additional flexibility for the Secretary of Labor with respect to administration and implementation of the CSEOA program. Specifically, it authorizes the Secretary to allow individuals participating in OAA Title V projects as of March 1, 2020, to extend their participation for a period that exceeds 48 months in the aggregate, as determined by the Secretary. It authorizes the Secretary to increase the average participation cap for grantees of 27 months for eligible individuals to a cap the Secretary determines is appropriate. And it authorizes the Secretary to increase the amount available to pay the authorized administrative costs for a project, which is currently 13.5% of the grant amount, to not exceed 20% of the grant amount, if the Secretary determines that such increase is necessary to adequately respond to additional administrative needs.

Section 3224. Guidance on Protected Health Information

Background

⁹⁴ For more information, see CRS Report R45626, *Older Americans Act: Senior Community Service Employment Program*.

⁹⁵ 42 U.S.C. §3056.

The HIPAA Privacy Rule governs covered entities' (health care plans, providers, and clearinghouses)⁹⁶ and their business associates' use and disclosure of PHI.⁹⁷ In addition, it establishes strong individual rights of access to an individual's own PHI. PHI is defined as individually identifiable health information created or received by a covered entity that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium.⁹⁸ The rule sets forth multiple situations in which covered entities may permissibly use or disclose PHI *without* written authorization, while generally all other uses and disclosures of PHI (i.e., those that are not expressly permitted under the rule) require an individual's prior written authorization. Broadly, covered entities may share PHI between and among themselves for the purposes of treatment, payment, or health care operations, with few restrictions and, specifically, without the individual's authorization.⁹⁹ The Privacy Rule also recognizes that PHI may be useful or necessary in circumstances besides health care treatment and payment for a given individual or general health care operations, or entirely unrelated to health care or the health care system. For this reason, the rule lists a number of "national priority purposes" for which covered entities may disclose PHI *without* an individual's authorization or opportunity to agree or object.¹⁰⁰ Examples of these include disclosures for public health activities, health oversight, and pursuant to a requirement in law (e.g., state law).

In response to the COVID-19 pandemic, the Office of Civil Rights (OCR)/HHS has issued guidance relating to the disclosure of PHI to first responders and law enforcement, as well as on telemedicine and the HIPAA Privacy Rule. OCR has also released several notifications of exercise of enforcement discretion during the COVID-19 public health emergency, specifically with respect to use and disclosure of PHI by business associates (BAs); the operation of Community-Based Testing Sites during the COVID-19 public health emergency; and the provision of care using telehealth.¹⁰¹ In addition, under authorities in SSA Section 1135 and the Project Bioshield Act (P.L. 108-276), the Secretary has the authority to waive sanctions and penalties for certain HIPAA Privacy Rule violations during certain emergency periods. These have been waived. The specific HIPAA Privacy Rule requirements for which penalties may be waived are as follows: (1) the requirement to distribute a notice of privacy practices (45 C.F.R. §164.520); (2) the patient's right to request certain privacy restrictions (45 C.F.R. §164.522(a)); (3) the patient's right to request confidential communications (45 C.F.R. §164.522(b)); (4) the requirement to honor a request to opt out of a facility directory (45 C.F.R. §164.510(a)); and (5) the requirement to obtain agreement to share information with family and friends involved in a patient's care (45 C.F.R. §164.510(b)). These waivers apply only (1) in the emergency area identified in the public health emergency declaration and for the duration of the emergency, (2) to

⁹⁶ A health care clearinghouse is defined in the Rule as: "a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and 'value-added' networks and switches, that does either of the following functions: (1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction; [or] (2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity." [45 C.F.R. §160.103]

⁹⁷ 45 C.F.R. 164 Subparts A and E.

⁹⁸ 45 C.F.R. §160.103.

⁹⁹ 45 C.F.R. §164.506.

¹⁰⁰ 45 C.F.R. §164.512.

¹⁰¹ HHS, "HIPAA, Civil Rights, and COVID-19," <https://www.hhs.gov/hipaa/for-professionals/special-topics/hipaa-covid19/index.html>.

those hospitals that have a disaster plan; and (3) for the first 72 hours after the hospital's plan has been initiated.¹⁰²

Provision

Section 3224 requires the Secretary, not later than 180 days after enactment, to issue guidance on the sharing of patients' PHI (as defined at 45 C.F.R. §106.103) during emergency declarations and determinations, with respect to COVID-19, pursuant to PHSA Section 319, Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), and the National Emergencies Act. The section requires the guidance to address compliance with the HIPAA Privacy Rule and applicable policies, including any policies that may come into effect during these emergencies.

Section 3225. Reauthorization of Healthy Start Program

Background

The Healthy Start Program (Healthy Start), which is authorized in PHSA Section 330H and administered by HRSA, is a competitive grant program.¹⁰³ The program enables eligible public or private entities, community-based organizations, faith-based organizations, and Indian or tribal organizations to propose and administer innovative, community-based ways to decrease U.S. infant mortality rates (IMRs), improve perinatal and maternal health outcomes, and reduce ethnic and racial health disparities in perinatal health. (*Infant mortality* refers to the death of an infant before his or her first birthday. An *infant mortality rate* refers to the comparison of the number of infant deaths against 1,000 live births in a given year.)¹⁰⁴ Healthy Start participants consist of women, men, infants, children, and involved parties such as family members. The program requires participants to reside in communities with IMRs that are at least 1.5 times greater than the U.S. IMR and/or have high rates of adverse perinatal outcomes such as preterm births and maternal deaths.¹⁰⁵ The program's authorization of appropriations, which expired in 2013, was "the amount authorized for the preceding fiscal year increased by the percentage increase in the Consumer Price Index (CPI) for all urban consumers for such year."¹⁰⁶

Provision

Purpose and considerations in making grants. Section 3225 amends PHSA Section 330H by expanding the Healthy Start project areas to those with increasing IMRs that are above the U.S. IMR. Section 3225 removes the mandate that required applicants to include consumers of project services as participants in community-based consortiums. The Secretary instead must require applicants to include state substance abuse agencies, participants, and former participants of project areas as participants in community-based consortiums.

The Secretary, when considering grant awards, is required to consider factors that contribute to infant mortality, including poor birth outcomes (e.g., low birthweight and preterm birth) and

¹⁰² HHS, "March 2020: COVID-19 and HIPAA Bulletin: Limited Waiver of HIPAA Sanctions and Penalties During a Nationwide Public Health Emergency," <https://www.hhs.gov/sites/default/files/hipaa-and-covid-19-limited-hipaa-waiver-bulletin-508.pdf>.

¹⁰³ 42 U.S.C. §254c-8; and HRSA, *Healthy Start*, <https://mchb.hrsa.gov/maternal-child-health-initiatives/healthy-start>.

¹⁰⁴ CDC, *Reproductive Health: Infant Mortality*, <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/infantmortality.htm>.

¹⁰⁵ HRSA, *Healthy Start Initiative: Eliminating Disparities in Perinatal Health*, Notice of Funding Opportunity, October 16, 2018, p. 1, <https://www.hrsa.gov/grants/find-funding/hrsa-19-049>.

¹⁰⁶ 42 U.S.C. §254c-8.

social determinants of health. In addition, the Secretary must consider factors such as applicants' collaboration with the local community in developing Healthy Start projects and applicants' use and collection of data demonstrating the program's effectiveness in decreasing IMRs and improving perinatal outcomes.

Coordination. Section 3225 makes conforming changes and moves the current language in subsection (c) to a new paragraph (1) and adds a new paragraph (2), under subsection (c). The new paragraph (2) requires the Secretary to ensure the Healthy Start program coordinates with similar programs and activities administered by HHS that aim to reduce IMRs and improve infant and perinatal health outcomes.

Funding. The section authorizes an appropriation of \$125.5 million for each of FY2021-FY2025, eliminates the CPI requirement, and authorizes the Secretary to reserve 1% of appropriated funds to evaluate Healthy Start projects. Section 3225 expands the Secretary's use of the reserved funds to evaluate information related to, among other things, progress made toward meeting program metrics or health outcomes on reducing IMRs, improving perinatal outcomes, and diminishing health disparities.

GAO report. Section 3225 makes conforming changes and adds a new subsection (f). The new subsection requires the Government Accountability Office (GAO) to conduct an independent evaluation of Healthy Start and to submit a report to appropriate congressional committees, no later than March 27, 2024. The section specifies that the evaluation must include a determination of whether Healthy Start projects have been effective in reducing the health disparity in health care outcomes between the general population group and racial and minority population groups, where applicable and appropriate. The report must also contain a review, an assessment, and recommendations on, among other topics, HRSA's allocation of funding to urban and rural areas and progress towards meeting the evaluation criteria for programs that increase and decrease IMRs, improve and adversely affect perinatal outcomes, and affect disparities in infant mortality and perinatal health outcomes.

Section 3226. Importance of the Blood Supply

Background

The nation's blood supply is largely managed by a network of independent blood centers and the American Red Cross, with some oversight from HHS.¹⁰⁷ These organizations collect blood product donations (e.g., whole blood, platelets) from individuals through scheduled appointments, walk-in appointments, and blood drives.

The COVID-19 pandemic poses significant challenges for the United States' blood supply. Mitigation strategies to prevent the spread of COVID-19, such as closures of schools and workplaces, have led to blood drive cancellations, resulting in a critical blood supply shortage. In addition, individuals are reluctant to schedule blood donations while advised to social distance from others.¹⁰⁸

Provision

This section requires the Secretary to carry out a national campaign to improve awareness of, and support outreach to the public and health care providers about, the importance and safety of blood

¹⁰⁷ For more information on independent blood centers, see <https://americasblood.org/about/>. For more information on the American Red Cross, see <https://www.redcross.org/give-blood.html>.

¹⁰⁸ For more information, see CRS Insight IN11238, *Coronavirus Disease 2019 (COVID-19) Poses Challenges for the U.S. Blood Supply*.

donation and the need for donations for the blood supply. The section requires the Secretary to consult with heads of relevant federal agencies (including FDA, CDC, and National Institutes of Health [NIH]), accrediting bodies, and representative organizations to carry out the campaign. In addition, the Secretary is authorized to enter into contracts with public or private nonprofit entities to carry out the campaign.

The section requires the Secretary to submit a report to specified congressional committees, not later than two years from enactment that (1) describes the activities carried out, (2) describes trends in blood supply donations, and (3) evaluates the impact of the public awareness campaign.

Part III—Innovation

This part adds two new authorities to the broad body of law that provides incentives for medical product research and development.¹⁰⁹

Section 3301. Removing the Cap on OTA During Public Health Emergencies

Background

The Biomedical Advanced Research and Development Authority (BARDA) supports the clinical research and development, regulatory approval, and procurement of new MCMs (e.g., vaccines, treatments, and diagnostics) planned for use in public health emergencies. In addition to grants, contracts, and cooperative agreements, the PHSA permits BARDA to enter into “other transactions,” which are exempt from many statutory provisions and procurement regulations. In February 2020, BARDA announced it was using its other transaction authority (OTA) to expand existing relationships with private partners to speed the development of COVID-19 countermeasures.¹¹⁰ In general, such transactions above \$100 million require a written determination “by the Assistant Secretary for Financial Resources, that the use of such authority is essential to promoting the success of the project.”¹¹¹

Provision

Section 3301 amends PHSA Section 319L in a number of ways that appear to be somewhat ambiguous, but the intent seems to be to waive the requirement for a written determination for transactions above \$100 million during a public health emergency declared under PHSA Section 319. Transactions made under this provision would not be terminated solely due to the expiration of the public health emergency. The Secretary is required to report the use of this provision to specified congressional committees after the public health emergency ends.

Section 3302. Priority Zoonotic Animal Drugs

Background

¹⁰⁹ See, for example, CRS In Focus IF11379, *Medical Product Innovation and Regulation: Benefits and Risks*; and HHS Biomedical Advanced Research and Development Authority (BARDA), “BARDA’s Rapidly-Expanding COVID-19 Medical Countermeasure Portfolio,” <https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx>.

¹¹⁰ HHS, *Press Release*, “HHS, Janssen Collaborate to Develop Coronavirus Therapeutics,” February 18, 2020; and HHS, *Press Release*, “HHS, Regeneron Collaborate to Develop 2019-nCoV Treatment,” February 4, 2020.

¹¹¹ 42 U.S.C. 247d-7e(c)(5)(ii)(II).

A zoonotic disease is an infectious disease that is transmissible between humans and nonhuman animals. Many emerging infections that have caused significant outbreaks among humans, are believed to have arisen from animal-to-human transmission. Drugs to treat animals are evaluated for approval by FDA. An animal origin for the COVID-19 virus is considered likely but unproven.¹¹²

Provision

Section 3302 adds a new Section 512A to the FFDCFA regarding Priority Zoonotic Animal Drugs. It requires the Secretary, upon an applying drug sponsor's request, to expedite the development and review of a new animal drug "if preliminary clinical evidence indicates that the new animal drug, alone or in combination with 1 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 request may be made upon, or any time after, the opening of an investigational new animal drug file or filing of an application for approval, and the Secretary shall act on such request within 60 days. Actions that may be used to expedite review include expanded consultations and guidance regarding novel designs or drug development tools to make clinical trials more efficient.

Part IV – Health Care Workforce

PHSA Title VII authorizes a number of programs to support the health workforce. These include scholarships, loans, and academic programs that seek to diversify the workforce, train primary care providers, and increase the number of geriatric health care providers, among other things. PHSA Title VIII authorizes similar programs to support the nursing workforce.

Many of Title VII and Title VIII programs were most recently reauthorized in Title V of the ACA, which made program changes, added new programs, and generally provided authorizations of appropriations through either FY2013 or FY2014. Although authorizations of appropriations for most Title VII and Title VIII have lapsed, a number of these programs have continued to receive appropriations through HRSA's Bureau of the Health Care Workforce.¹¹³ These programs have also been considered for reauthorization in the 116th Congress, where bills would typically provide a five-year authorization of appropriations at the amounts provided in the most recent fiscal year. For example, S. 2997, Title VII Health Care Workforce Reauthorization Act of 2019,¹¹⁴ would have reauthorized a number of Title VII programs for five years, and would have authorized funding at FY2019 funding levels. Much of S. 2997 was included in Sections 3401-3403 of the CARES Act, generally with funding amounts reflective of FY2020 appropriations and with a five-year authorization that begins in FY2021. Similarly, S. 1399, Title VIII Nursing Workforce Reauthorization Act of 2019,¹¹⁵ would have reauthorized a number of Title VIII

¹¹² See "Are animals responsible for COVID-19 in people?" in World Organization for Animal Health (known by its French acronym, OIE), "Questions and Answers on the 2019 Coronavirus Disease (COVID-19)," April 20, 2020, <https://www.oie.int/scientific-expertise/specific-information-and-recommendations/questions-and-answers-on-2019novel-coronavirus/>. OIE is the intergovernmental organization responsible for analyzing and disseminating information related to animal disease control. See also CRS In Focus IF11494, *Wildlife Trade, COVID-19, and Other Zoonotic Diseases*.

¹¹³ For a description of the most recent reauthorization, see CRS Report R41278, *Public Health, Workforce, Quality, and Related Provisions in ACA: Summary and Timeline*. For FY2019 and FY2020 funding amounts, see HHS, HRSA, "Justification of Estimates for Congressional Committees, FY2021," <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2021.pdf>, pp. 17-18.

¹¹⁴ See version of S. 2997, as reported to the Senate on December 17, 2019.

¹¹⁵ See version of S. 1399, as reported to the Senate on November 5, 2019.

programs for five years, and would have authorized funding at FY2019 funding levels. Much of what was included in S. 1399 was enacted in Section 3404 of the CARES Act, with funding amounts reflective of FY2020 appropriations and with a five-year authorization that begins in FY2021.

Section 3401. Reauthorization of Health Professions Workforce Programs

Background

PHSA Title VII authorizes a number of programs to support the health workforce. Though authorizations of appropriations for most Title VII programs have lapsed, several programs have received appropriations in recent years.¹¹⁶ The relevant Title VII programs (with their FY2020 appropriation level, if appropriate) are summarized below. The summary also notes other relevant PHSA Title VII advisory groups amended by this section.

Centers of Excellence (Section 736) supports centers that seek to recruit, retain, and train underrepresented minorities in the health professions. The program received an appropriation of \$23.711 million in FY2020.

Health Professions Training for Diversity (Section 740) authorizes appropriations for a number of diversity-related training programs. Subsection (a) authorizes appropriations for scholarships for disadvantaged students (PHSA §737), which received an appropriation of \$51.47 million in FY2020; subsection (b) authorizes appropriations for loan repayment and fellowships for minority health professional faculty (PHSA §738), which received an appropriation of \$1.19 million in FY2020; subsection (c) authorizes appropriations for the Health Careers Opportunity Program (PHSA §739), which provides grants for programs that provide health career training to individuals from disadvantaged backgrounds. This program received an appropriation of \$15 million in FY2020, and subsection (d) required a report on diversity in the health professions that was due not later than six months after enactment.¹¹⁷

Primary Care Training and Enhancement (Section 747) authorizes grant programs to support primary care medicine and physician assistant training. The program received an appropriation of \$48.925 million in FY2020.

Training in General, Pediatric, and Public Health Dentistry (PHSA Section 748) authorizes grants to support dentists and dental hygienist training. The program received an appropriation of \$28 million in FY2020.¹¹⁸

Advisory Committee on Training in Primary Care Medicine and Dentistry (Section 749) authorizes the advisory committee that provides oversight over PHSA Section 747 and Section 748 programs. Authorizations of appropriations for those programs are contained in their respective authorizing provisions. Section 749 was renumbered in the ACA, but its language was not amended at that time.

¹¹⁶ For FY2019 and FY2020 funding amounts, see HHS, HRSA, “Justification of Estimates for Congressional Committees, FY2021,” <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2021.pdf>, pp. 17-18.

¹¹⁷ This section was not amended in the ACA as such, the section was enacted in November 1998, so the original report was due in 1999 (42 U.S.C. § 293(d)(d)).

¹¹⁸ Amounts obtained from the HRSA Operating plan and have been rounded to the nearest million; see HHS, HRSA, “FY2020 Operating Plan,” <https://www.hrsa.gov/about/budget/operating-plan.html>.

Area Health Education Centers (Section 751) authorizes grants for centers at medical or nursing schools that provide training for students from underserved backgrounds or in underserved (often rural) areas. This program received \$41.25 million in FY2020.

Quentin N. Burdick Program for Rural Interdisciplinary Training (Section 754) provided grants for interdisciplinary rural-focused health workforce training projects. This program has not been funded in the past decade and does not have a current authorization of appropriations.

Allied Health and Other Disciplines (Section 755) authorizes grants to support allied health professionals. This program has not been funded in recent years.

Health Workforce Information and Analysis (Section 761) established HRSA's National Center for Health Workforce Analysis and authorizes grant programs to support state, local, and longitudinal workforce analyses. This program received an appropriation of \$5.663 million in FY2020.

The Council on Graduate Medical Education (COGME; Section 762) analyzes and reports to relevant congressional committees on issues related to the physician workforce, training, and the financing of training. The committee is authorized in Section 762, which lays out the committee membership and its reporting requirements. The section also specifies that the committee was to sunset in 2003; however, language in appropriations laws have waived this sunset date.¹¹⁹

Public Health Training Centers (Section 766) authorizes grants at public health schools to train public health professionals in health promotion and preventive medicine, among other things. This program receives its authorizations of appropriation in PHS Section 770(a).

Authorization of Appropriations (Section 770) authorizes appropriations for the group of public health workforce programs authorized in PHS Sections 765-770. Public health workforce programs received an appropriation of \$17 million in FY2020.

Pediatric Subspecialty Loan Repayment Program (Section 775) authorizes loan repayment to specific pediatric subspecialists (including behavioral health specialists) in exchange for a service requirement in underserved areas. This program was created in the ACA but has never been funded or implemented.

Provision

This section extends authorizations of appropriations for a number of sections in PHS Title VII. In each case, appropriations are authorized for each of FY2021-FY2025. The section reauthorizes the health workforce diversity programs as follows:

- \$23.711 million for PHS Section 736,
- \$51.470 million PHS Section 740(a),
- \$1.19 million for PHS Section 740(b), and
- \$15 million for PHS Section 740(c).

The section also amends the date of a report on diversity in the health professions required in PHS Section 740(d) to require that the report is due to the appropriate congressional committees not later than September 30, 2025, and every five years thereafter.

The section also amends and extends the authorizations of appropriations for a number of programs related to primary care medical and dental training, as specified below.

¹¹⁹ For FY2020, this was included in Title II of Division A of P.L. 116-94.

- The section amends PHSA Section 747, which authorizes training programs for primary care physicians and physician assistants. The section makes the following changes: (1) removes reference to demonstration projects in grants related to innovative care models; (2) amends granting priorities to permit the Secretary to give preference to qualified applicants that train residents in rural areas, including for Tribes or Tribal Organizations that are located in rural areas; (3) changes references from “substance-related disorders” to “substance use disorders;”¹²⁰ and (4) authorizes an appropriation of \$48.294 million annually for each of FY2021-FY2025.
- The section amends PHSA Section 748, which authorizes training programs for general, pediatric, and public health dentists and dental hygienists; it changes references from “substance-related disorders” to “substance use disorders” and authorizes an appropriation of \$28.531 million for each of FY2021-FY2025.
- The section amends PHSA Section 749(d), which authorizes the Advisory Committee on Training in Primary Care Medicine and Dentistry, to update references to congressional committees to reflect the current committee names.
- The section amends PHSA Section 751, which authorizes the Area Health Education Center program, to authorize an appropriation of \$41.25 million for each of FY2021-FY2025.
- The section amends PHSA Section 754, which authorizes the Quentin N. Burdick Program for Rural Interdisciplinary Training, to revise language related to using grant funds by replacing “new and innovate” with “innovative or evidence-based.”
- The section amends in PHSA Section 755, which authorizes grants for training in Allied Health and Other Disciplines to replace language related to the elderly with reference to “geriatric populations or for maternal and child health.”
- The section amends PHSA Section 761, which authorized Health Workforce Information and Analysis, to authorize to be appropriated \$5.663 million annually for each of FY2021-FY2025.
- The section amends PHSA Section 762 (COGME) to update references to congressional committees to reflect the current committee names; change language from the Health Care Financing Administration to CMS; make conforming changes; add the HRSA Administrator to the council; delete language related to reports required at COGME’s outset and the council’s termination; and add new reporting requirement dates. Specifically, it requires a report to be delivered to specified congressional committees not later than September 30, 2023, and not less than every five years thereafter.
- The section amends PHSA Section 766 (Public Health Training Centers) to delete language related to Healthy People 2000 and to add language related to rural areas.
- The section amends PHSA Section 770 (Authorization of Appropriations), which authorizes appropriations for Public Health Workforce Programs, to authorize \$17 million to be appropriated for each of FY2021-FY2025.

¹²⁰ CARES Act Section 3401, and other sections in the law, replace references to substance abuse with “substance use disorders” to reflect contemporary terminology used in the field and align language in the law with the most current version of the *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)*.

- The section amends PHSA Section 775 (Loan Repayment for Pediatric Subspecialists) to authorize such sums as may be necessary for each of FY2021-FY2025.

Section 3402. Health Workforce Coordination

Background

HRSA administers a number of health workforce programs through its Bureau of Health Workforce. A number of these programs also have advisory committees that advise HRSA and Congress about specific programs (e.g., the Advisory Committee on Training in Primary Care Medicine and Dentistry provides oversight of programs authorized in Sections 747 and 748 related to primary care medicine and dental training).¹²¹ Each of these advisory groups has a specific charge or scope, and their work is generally not coordinated. For example, although COGME evaluates graduate medical education (GME) policy, the bulk of GME funding is from CMS, while the relevant advisory group is administered through HRSA. Experts have recommended the need for more coordinated GME and overall health workforce policy as a way to better focus federal health workforce investments across the federal government.¹²²

Provision

This section requires the Secretary, in consultation with the Advisory Committee on Training in Primary Care Medicine and Dentistry and the COGME, to develop a comprehensive plan that coordinates HHS's health care workforce development programs. The plan must include certain specified elements such as performance measures, as specified; gap analyses and plans to rectify these gaps; and barriers to implementing strategies to rectify the identified gaps. It also requires the Secretary to coordinate with other federal agencies and departments that administer relevant education and training programs. The purpose of such coordination is to evaluate whether these programs are meeting U.S. health workforce needs and identify opportunities to improve information collected to better inform program improvements. Finally, the section requires the Secretary to submit a report describing the comprehensive health workforce plan and its implementation to specified congressional committees no later than two years after enactment.

Section 3403. Education and Training Relating to Geriatrics

Background

PHSA Section 753 authorizes a number of geriatric workforce programs. Separately, PHSA Section 865 authorizes similar geriatric workforce programs focused on nurses, because nurses are generally not eligible for programs in Title VII. Beginning in FY2015, HRSA opted to consolidate and administer these geriatric workforce programs together and has since supported two training programs: the Geriatrics Workforce Enhancement Program (GWEP) and the Geriatrics Academic Career Awards (GACA).¹²³ GWEP provides grants to create training programs that focus on training inter-professional teams to increase geriatric competence among

¹²¹ For information on HRSA advisory committees, see HHS, HRSA, "Federal Advisory Committees," <https://www.hrsa.gov/advisory-committees/index.html>.

¹²² See discussion in CRS Report R44376, *Federal Support for Graduate Medical Education: An Overview*. See also discussion of Sec. 5101 in CRS Report R41278, *Public Health, Workforce, Quality, and Related Provisions in ACA: Summary and Timeline*.

¹²³ HHS, HRSA, "Justification of Estimates for Congressional Committees, FY2015," pp. 136-143 and pp. 188-191.

primary care and other types of health care providers.¹²⁴ GACA makes awards to institutions on behalf of junior (non-tenured) faculty to support the career development of academic geriatricians in medicine, pharmacy, nursing, social work, and other health professions. The expectation is that GACA award recipients will provide inter-professional clinical training and become leaders in academic geriatrics.

PHSA Section 753 was most recently reauthorized in the ACA, which added a number of new subsections within the section that authorized new geriatric training programs. These new programs were never implemented. Appropriations were authorized through FY2014, with the exception of the Geriatric Career Incentive Award program, which had been authorized through FY2013.¹²⁵ Despite the lapsed authorization of appropriations, these programs have been funded in recent years; most recently they received \$40.737 million in FY2020.¹²⁶

Provision

This section replaces PHSA Section 753 with a new PHSA Section 753, “Education and Training Related to Geriatrics.” The new section codifies two existing geriatric workforce training programs: (1) GWEP and (2) GACA. It deletes existing unfunded geriatric training programs.

The section, in new subsection (a) requires the Secretary to award grants, contracts, or cooperative agreements to specified health professional schools, including schools of allied health, nursing schools, and programs that focus on geriatric education, to establish GWEPs. It specifies the GWEP requirements that include health trainee support, and an emphasis on patient and family engagement and primary care integration. The section also specifies the activities that GWEP programs are authorized to provide, including specific types of training and Alzheimer’s disease education. The section specifies that GWEP grants may not be awarded for more than five years; that applicants must submit an application, as specified; and that the Secretary is required to use certain awarding priorities but may also take into account specified awarding considerations. Finally, with regard to the GWEP program, the section specifies grantee reporting requirements, requires the Secretary to report to specified congressional committees not later than four years after the enactment of Title VII Health Care Workforce Reauthorization Act of 2019 and every five years thereafter, and requires that the report be made publicly available.¹²⁷

New PHSA Section 753(b) establishes the GACA grant program where grants are awarded to eligible entities to support their geriatric careers. The section defines the entities eligible for GACA awards, including nursing schools and the health professionals who are eligible to receive support. The section also specifies that academics must be junior non-tenured faculty at the time the award is made, but that they remain eligible for the award if they receive tenure during the award period. The section specifies the application requirements and the assurances regarding service requirements that the application must contain. It specifies that, when making awards, the Secretary is required to ensure a geographical distribution among award recipients, including among rural MUAs. The section also specifies that grants must be a minimum of \$75,000 in

¹²⁴ HHS, HRSA, “Justification of Estimates for Congressional Committees, FY2015,” <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2021.pdf>, p.122.

¹²⁵ For a description of the most recent reauthorization, see CRS Report R41278, *Public Health, Workforce, Quality, and Related Provisions in ACA: Summary and Timeline*.

¹²⁶ For FY2019 and FY2020 funding amounts, see HHS, HRSA, “Justification of Estimates for Congressional Committees, FY2021,” <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2021.pdf>, p.18.

¹²⁷ The reference to the *Title VII Health Care Workforce Reauthorization Act of 2019* appears to be a drafting error; however, this provision was included, with changes to the authorization date and amounts, in S. 2997, *Title VII Health Care Workforce Reauthorization Act of 2019*. See version of S. 2997, as reported to the Senate on December 17, 2019.

FY2021, to increase annually by the CPI thereafter; that award periods may not exceed five years; and the service requirement that awardees must fulfill as a condition of receiving an award.

Finally, for both GWEP and GACA, the section waives certain awarding preferences that otherwise apply to Title VII grants, and it authorizes to be appropriated \$40.737 million for each of FY2021-FY2025.

Section 3404. Nursing Workforce Development

Background

PHSA Title VIII authorizes a number of nursing workforce programs. Part A provides general provisions of the title, including definitions and entities eligible for the grants made available under the title. Part B authorizes grant programs to support advance practice nurses, including nurse practitioners, nurse anesthetists, and nurse midwives. Part C authorizes grant programs that seek to increase nursing workforce diversity, and Part D authorizes grant programs that aim to strengthen the nursing workforce and improve nursing practice. This effort includes programs that seek to expand the nursing career ladder whereby individuals in lower skilled health professions receive training and education to advance in the nursing field (e.g., from a nursing assistant to a registered nurse). Finally, Part E establishes the nursing student loan program. These programs were most recently reauthorized in the ACA, with authorizations of appropriations through FY2013 or FY2014.¹²⁸ Despite the lapsed authorization, these programs have been funded in recent years. Specifically, in FY2020, they received an appropriation of \$260 million.¹²⁹

Provision

This section reauthorizes programs in PHSA Title VIII in subsection (a), while subsection (b) requires a GAO report on nursing loan programs.

General Provisions. Subsection (a) makes the following changes to Title VIII. It adds nurse-managed health clinics to the definition of entities eligible for grants authorized in Title VIII; adds new language to applications (in Section 802), to use of funds (in Section 803), and to provisions that are generally applicable to Title VIII (Section 806). Specifically, the subsection adds new language that grants should be awarded to address national nursing needs, as specified; to require new information from grantees; and to add new language requiring a biennial report that includes certain specified elements to be delivered not later than September 30, 2020, to specified congressional committees. The subsection also makes a number of changes to Section 811 (grants for advance education nursing grants) to replace language that references master’s level nurses to graduate level nurses, to change language referencing clinical nurse leaders to nurse administrators, and to add that clinical nurse specialist programs, as specified, are eligible for grants under this section.

Nurse Education, Quality, and Retention Grants. The subsection amends Section 831 to rename the section “Nurse Education, Quality, and Retention Grants.” It also amends the description of practice priority groups and retention priority areas within the nursing career ladder by adding language, that among other things, specifies that grants help individuals, including health aides or community health practitioners certified under the IHS Community Health Aide Program, enter the nursing career ladder. It adds language to Section 831 specifying that grants

¹²⁸ For a description of the most recent reauthorization, see CRS Report R41278, *Public Health, Workforce, Quality, and Related Provisions in ACA: Summary and Timeline*.

¹²⁹ For FY2019 and FY2020 funding amounts, see HHS, HRSA, “Justification of Estimates for Congressional Committees, FY2021,” <https://www.hrsa.gov/site/fault/files/hrsa/about/budget/budget-justification-fy2021.pdf>, p. 18.

may be used to develop and implement fellowship and residency programs and to encourage the mentoring and development of nursing specialties. It also deletes subsection (e), referring to grant awards preferences in prior years, and (h), which had authorized appropriations from FY2010-FY2014, and renumbers the subsection accordingly. The subsection also amends the reporting requirements in Section 831 to require the Secretary to submit a report on the grants in this section as part of a larger report required under Section 806, and expands the entities eligible for grants under this section to add, in addition to nursing schools, health care facilities, Federally Qualified Health Centers (FQHCs), nurse-managed health clinics, and a partnership of such a school and facility.

Deletions. The subsection deletes PHSA Section 831A (Nurse Retention Grants), because grants for this purpose are now included in the amended PHSA Section 831. It then amends PHSA Section 846 (Loan Repayment and Scholarship Program) to permit individuals to fulfill their service commitment and for-profit health facilities, to make language gender neutral, and to remove the sections authorization of appropriation and make reference to an amount allocated under PHSA Section 871(b). The section also deletes the separate authorization of appropriations from PHSA Section 846A (Nurse Faculty Loans) and Section 847 (Eligible Individual Student Loan Repayment); adds language referencing clinical nurse specialists to PHSA Section 851 (National Advisory Council on Nurse Education and Practice); amends the committees that the council is required to report to update to current committee names; and amends language related to amounts available to fund the council’s activities. The section also deletes PHSA Section 861 (Public Service Announcements) and PHSA Section 862 (State and Local Public Service Announcements).

Appropriation Changes. Finally, the subsection amends Section 871, which authorizes appropriations for the title to authorize \$137.837 million for each of FY2021-FY2025 to carry out Parts B, C, and D of Title VIII and to authorize \$117.135 million for each of FY2021-FY2025 to carry out Part E (Student Loan Funds).

Subsection (b) of the provision requires a GAO report that evaluates nurse loan repayment programs, as specified, to be delivered to specified congressional committees, no later than 18 months after enactment.

Subtitle D—Finance Committee

Subtitle D makes a series of changes in the Medicare and Medicaid programs in response to the COVID-19 public health emergency declared by the Secretary. The Medicare provisions increase certain payments to providers, including hospitals; expand the use of allowable telehealth services; make any potential COVID-19 vaccine available under Medicare Part B without cost-sharing; and relax certain program requirements to make it easier for Medicare patients to obtain certain services. The provisions also address cost-sharing to states for Medicaid services.

Section 3701. Exemption for Telehealth Services

Background

A health savings account (HSA) is a tax-advantaged account that individuals can use to pay for unreimbursed medical expenses (e.g., deductibles, co-payments, coinsurance, and services not covered by insurance).¹³⁰

¹³⁰ For more information on health savings accounts (HSAs), see CRS Report R45277, *Health Savings Accounts (HSAs)*.

Individuals are eligible to establish and contribute to an HSA if they have coverage under an HSA-qualified high-deductible health plan (HDHP), do not have disqualifying coverage, and cannot be claimed as a dependent on another person's tax return.

To be considered an HSA-qualified HDHP, a health plan must meet several criteria: (1) it must have a deductible above a certain minimum level, (2) it must limit out-of-pocket expenditures for covered benefits to no more than a certain maximum level, and (3) it can cover only preventive care services before the deductible is met.

For example, if a health plan satisfies the first two of the aforementioned criteria and provides coverage for preventive care services and prescription drugs before the deductible is met, that health plan would not be considered an HSA-qualified HDHP because it provides prescription drug benefits before the deductible is met.

Disqualifying coverage is generally considered any other health coverage that is not an HSA-qualified HDHP or that provides coverage for any benefit that is covered under their HSA-qualified HDHP.

Provision

Section 3701 amends Internal Revenue Code (IRC) Section 223(c) for plan years beginning on or before December 31, 2021, to allow HSA-qualified HDHPs to provide "telehealth and other remote care services" before the deductible is met and still be considered an HSA-qualified HDHP.

For plan years beginning on or before December 31, 2021, Section 3701 provides that telehealth and other remote care would not be considered disqualifying coverage that would prevent an otherwise eligible individual from being considered HSA-eligible.

These provisions were effective upon the date of enactment (i.e., March 27, 2020).

Section 3702. Inclusion of Certain Over-The-Counter Medical Products as Qualified Medical Expenses

Background

There are four categories of health-related tax-advantaged accounts/arrangements: HSAs, Archer medical savings accounts (Archer MSAs), flexible spending arrangements (FSAs), and health reimbursement arrangements (HRAs). Distributions from HSAs and Archer MSAs and reimbursements from FSAs and HRAs that are used to pay for *qualified medical expenses* are not taxed.

Each account/arrangement category has a different set of medical expenses that would be considered a qualified medical expense, but all accounts/arrangements generally consider, at a minimum, the following as qualified medical expenses: the costs of diagnosis, cure, mitigation, treatment, or prevention of disease and the costs for treatments affecting any part of the body; the amounts paid for transportation to receive medical care; and qualified long-term care services.

Most recently, OTC medicines and drugs (other than insulin) were not considered a qualified medical expense for any account/arrangement category unless an individual received a corresponding prescription for each non-prescribed expense.

Provision

Section 3702 amends Sections 106, 220(d)(2)(A), and 223(d)(2) of the IRC to allow OTC medicines and drugs (without a prescription) and menstrual care products to be considered

qualified medical expenses for HSAs, Archer MSAs, FSAs, and HRAs. This change in the definition of qualified medical expenses applies to amounts paid or expenses incurred after December 31, 2019.

Section 3703. Increasing Medicare Telehealth Flexibilities During Emergency Period

Background

Medicare coverage under Part B (fee-for-service) for telehealth services is defined under SSA Section 1834(m), which places certain conditions on such care, including who can furnish and be paid for the service, where the patient is located (the originating site), where the physician is located (the distant site), and the types of services that are covered. Recent legislation has modified some of the conditions under which telehealth services may be furnished under Medicare. The Coronavirus Preparedness and Response Supplemental Appropriations Act (P.L. 116-123) Division B, Section 102, added certain Medicare telehealth restrictions to the list of applicable conditions for which the Secretary could temporarily waive or modify program requirements or regulations during the COVID-19 emergency. The provision also defined a qualified telehealth provider, requiring a prior relationship within the past three years between the patient and the provider under Medicare. Subsequently, FFCRA Division F, Section 6010, expanded the definition of a qualified provider to include those who had provider-patient relationships within the past three years outside of Medicare.

Provision

Section 3703 removes the list of telehealth restrictions the Secretary was allowed to waive under P.L. 116-123 and broadens the Secretary's authority to temporarily waive any of the SSA Section 1834(m) telehealth requirements. The provision also removes the definition of a "qualified provider" for telehealth services during the COVID-19 emergency period pursuant to SSA Section 1135. The provision strikes the specific subsection added under P.L. 116-123 related to telephone use, such that the waiver authority applies more broadly to include "a telehealth service [...] furnished in any emergency area (or portion of such an area) during any portion of any emergency period to an individual." In addition, removing the "qualified provider" definition eliminates the requirement of a prior relationship between the patient and the provider for telehealth services to be delivered and covered under the COVID-19 emergency declaration.

Section 3704. Enhancing Medicare Telehealth Services for Federally Qualified Health Centers and Rural Health Clinics During Emergency Period

Background

Under current law, FQHCs and rural health clinics (RHCs) are allowed to be originating sites for covered telehealth services (sites where a patient is located) but are not allowed to be distant sites, where physicians may provide telehealth services to eligible patients at other locations (originating sites). Generally, both FQHC and RHCs are not paid under the Medicare physician fee schedule (MPFS). Rather, FQHCs are paid through an FQHC-specific prospective payment system (PPS), while RHCs are reimbursed as an all-inclusive rate for the services they provide.

Provision

Section 3704 allows FQHCs and RHCs to serve as distant sites for the furnishing of telehealth services to telehealth-eligible individuals during the emergency period. The Secretary is required

to develop and implement, through program instruction or otherwise, payment methods for this purpose that apply to FQHCs and RHCs serving as a distant sites that furnish telehealth services to eligible telehealth individuals during such an emergency period. Such services are to be paid similar to the national average amount for comparable telehealth services under the MPFS. The costs associated with this care are not to be included when calculating the payments for the FQHC PPS or the RHC all-inclusive rates, under current law.

Section 3705. Temporary Waiver of Requirement for Face-To-Face Visits Between Home Dialysis Patients and Physicians

Background

Medicare is the main source of health care coverage for Americans with end-stage renal disease (ESRD). Individuals with ESRD have substantial and permanent loss of kidney function and require either a regular course of dialysis (a process that removes harmful waste products from an individual's bloodstream) or a kidney transplant to survive. Medicare covers beneficiaries aged 65 and older who have ESRD, as well as qualified individuals with ESRD who are under the age of 65.¹³¹

Medicare ESRD benefits include thrice-weekly dialysis treatment and coverage for kidney transplants. CMS pays physicians, typically nephrologists, and other practitioners a monthly per-patient rate for most dialysis-related services. Physicians and practitioners managing ESRD patients who perform home-based dialysis are paid a single monthly rate based on the ESRD beneficiary's age. A physician or practitioner is required to have at least one face-to-face visit with a home dialysis patient each month.¹³²

As part of the Bipartisan Budget Act of 2018 (BBA 2018; P.L. 115-123), Congress expanded the use of telehealth services for ESRD patients undergoing home dialysis. Starting in 2019, ESRD beneficiaries who use home dialysis have been allowed to receive monthly face-to-face clinical assessments via telehealth services, so long as the beneficiaries receive a face-to-face assessment without the use of telehealth (1) at least monthly for the initial three months of home dialysis, and (2) after the initial three months, at least once every three consecutive months.

Provision

Section 3705 amends SSA Section 1881(b)(3)(B) to allow the Secretary to waive the requirement that to receive telehealth services, a Medicare ESRD beneficiary undergoing home dialysis receive a face-to-face clinical assessment from a practitioner monthly during the initial three months of home dialysis and once every three months thereafter. The requirement may be waived for the period that the COVID-19 emergency is in effect.

Section 3706. Use of Telehealth to Conduct Face-To-Face Encounter Prior to Recertification of Eligibility for Hospice Care During Emergency Period

Background

The Medicare hospice benefit provides coverage for certain services provided to Medicare beneficiaries with a life expectancy of six months or less. Such services must be rendered by

¹³¹ Social Security Amendments of 1972; P.L. 92-603.

¹³² CRS Report R45290, *Medicare Coverage of End-Stage Renal Disease (ESRD)*.

Medicare-certified hospices, which are either public agencies or private organizations primarily engaged in providing hospice services.

Although beneficiaries who elect hospice care may disenroll from the hospice benefit at any time, the benefit is administratively structured by “periods”: specifically, two 90-day periods and an unlimited number of subsequent 60-day periods. For hospice care to be covered under Medicare, an initial certification of a terminal illness must be obtained by the hospice at the beginning of the first 90-day period of care. The initial certification requires signed declarative statements attesting to the presence of a terminal illness by the hospice physician and the beneficiary’s attending physician, if the individual has designated one. For each subsequent period of hospice care, recertification of the beneficiary’s terminal illness is required only by the hospice physician. Since the beginning of 2011, part of the recertification process to determine continued eligibility has included a mandatory face-to-face encounter with the beneficiary by the hospice physician or nurse practitioner.

Provision

Section 3706 amends SSA Section 1814(a)(7)(D)(i) to provide that, as determined appropriate by the Secretary, a hospice physician or nurse practitioner may conduct a face-to-face encounter for continued eligibility purposes via telehealth during a period that the COVID-19 emergency is in effect.

Section 3707. Encouraging Use of Telecommunications Systems for Home Health Services Furnished During Emergency Period

Background

Medicare covers visits by participating home health agencies for beneficiaries who (1) are confined to home and (2) need either skilled nursing care on an intermittent basis, physical therapy, or speech language therapy. As required by SSA Section 1895, home health agencies are paid for services under a home health PPS based on 30-day episodes of care. Generally, the home health PPS consists of a nationwide payment amount that is subject to adjustments for the expected care needs of a beneficiary (i.e., case-mix) and differences in local wages. Further payment adjustments are made in certain situations, including a low-utilization payment adjustment (LUPA) for episodes of care with few home visits.¹³³

Under SSA Section 1895, home health agencies are not precluded from adopting telemedicine or other technologies, but such services are not permitted to serve as a substitute for visits paid under the home health PPS. Accordingly, federal regulations define a home health visit as an episode of personal contact. As such, telemedicine services are not accounted for in the home health PPS, nor do providers receive direct payment for telemedicine services generally.

Although there is no direct payment for home health services provided through remote technologies, regulations in 42 C.F.R. Part 409.46 designate remote patient monitoring as a service with costs that may be reported as administrative if remote patient monitoring is used to augment the care planning process. Remote patient monitoring is defined in regulations as the collection of patient health information that is digitally stored or transmitted by the patient and/or caregiver to the home health agency. CMS allows home health agencies to include the costs of remote patient monitoring as an allowable administrative cost.

¹³³ CRS Report R40425, *Medicare Primer*.

Provision

Section 3707 requires the Secretary to consider how HHS can encourage the use of telemedicine by home health agencies with respect to home health services provided to Medicare beneficiaries during the period that the COVID-19 emergency is in effect. Specifically, the Secretary is required to consider ways to encourage the use of telecommunications systems, including for remote patient monitoring, and other communications or monitoring services. Use of new technologies must be consistent with the plan of care for beneficiaries. As part of this consideration, the Secretary may clarify guidance and conduct outreach, as appropriate.

Section 3708. Improving Care Planning for Medicare Home Health Services

Background

Medicare covers certain home health services under both Parts A and B.¹³⁴ Special eligibility requirements and benefit limits exist for home health services furnished under Part A to beneficiaries who are enrolled in both Parts A and B. For such beneficiaries, Part A pays for only “postinstitutional” home health services, provided for up to 100 visits during a “spell of illness,” which is a period that extends 14 days after a discharge from a skilled nursing facility or a hospital following a minimum stay of three consecutive days. Part B covers any medically necessary home health services that exceed the 100-visit limit, as well as medically necessary home health services that do not qualify as “postinstitutional.”

For beneficiaries enrolled in only Part A or Part B, the requirements described above do not apply. Part A or Part B, as applicable, covers all medically necessary episodes of home health care without a visit limit, regardless of whether the episode of care follows a hospitalization. Whether a beneficiary is enrolled in Part A only, Part B only, or in both, the scope of the Medicare home health benefit is the same. Medicare’s payments to home health agencies are calculated using the same methods, and beneficiaries have no cost-sharing.

As required under SSA Sections 1814 and 1835 (for Parts A and Part B, respectively), for a beneficiary to receive home health services under Medicare, certain eligibility requirements must be certified by a physician, including a face-to-face encounter performed by a physician or a specified medical professional working in collaboration with, or under the supervision of, the physician, as applicable. For a beneficiary to be eligible for coverage, the physician certifies that home health services are required because the beneficiary, under the care of the physician, is (1) confined to the home and (2) in need of either skilled nursing care on an intermittent basis, physical therapy, or speech language therapy. After this eligibility is established, the eligibility period may be continued for homebound beneficiaries with a certified continuing need for occupational therapy services.

A physician is prohibited from certifying home health eligibility if he or she has a significant ownership interest in, or a significant financial or contractual relationship with, the home health agency in which the services are to be provided. These conditions are delineated in federal regulations and include an authorized exception for instances in which there is a solitary community home health agency.

BBA 2018, Section 51002, amended SSA Sections 1814 and 1835 to expand the scope of supporting documentation the Secretary may use to document Medicare eligibility for home health services. Under the BBA changes, in addition to using a physician’s medical record or a

¹³⁴ For more information on the Medicare program, including the services covered under each part, see CRS Report R40425, *Medicare Primer*.

record compiled by an acute/post-acute facility, the Secretary may also use a home health agency's medical record as appropriate to the case involved.

Provision

Section 3708 amends SSA Section 1814(a)(2)(C) and Section 1835(a)(2)(A) to allow, no later than six months after enactment, a nurse practitioner, clinical nurse specialist, or physician assistant to certify the eligibility requirements for Medicare home health services under Parts A and B, respectively. Section 3708 further allows a nurse practitioner, clinical nurse specialist, or physician assistant to conduct the required face-to-face encounter that is part of the certification process.

Section 3708 also amends SSA Sections 1814 and 1835 to prohibit such professionals with a significant financial stake in a home health agency from certifying beneficiary eligibility when that agency is the entity providing the necessary services. However, the same exemption exists as the one pertaining to certifying physicians: the prohibition is waived if the servicing entity is the sole community home health agency. Further, Section 3708 conforms to language in the BBA 2018 to allow the Secretary to use a home health agency's medical record, in addition to a medical record compiled by medical professionals with certification authority, to document eligibility as appropriate to a specific case.

Section 3708 also amends SSA Sections 1861 and 1895 to ensure that the general definitions of home health services, coverage, and payment system encompass and conform with current statutory language referencing the medical professionals to whom certification authority is extended. In addition, amendments made under Section 3708 are applied under SSA Title XIX (Medicaid) in the same manner and to the same extent such requirements apply to Medicare under SSA Title XVIII or regulations promulgated thereunder.

No later than six months after enactment, the Secretary is required to implement regulations relevant to application of the amendments. If necessary, the Secretary must produce an interim final rule to comply with the required six-month effective date.

Section 3709. Adjustment of Sequestration

Background

The Budget Control Act of 2011 (BCA; P.L. 112-25) provided for increases in the debt limit and established procedures designed to reduce the federal budget deficit, including the creation of the Joint Select Committee on Deficit Reduction. The failure of the Joint Committee to propose deficit reduction legislation that was subsequently enacted into law by its mandated deadline triggered automatic spending reductions, including the "sequestration" (i.e., across-the-board reductions) of mandatory spending in FY2013 through FY2021. Subsequent legislation extended the sequestration of mandatory spending through FY2029. Medicare benefits are funded through mandatory spending and are subject to reductions under such sequestration.¹³⁵

Section 256(d) of the Balanced Budget and Emergency Deficit Control Act of 1985 (BBEDCA; P.L. 99-177) contains special rules for the Medicare program in the event of a sequestration. Among other things, it specifies that for Medicare, sequestration is to begin the month after the annual sequestration order has been issued and to continue for one calendar year. Subsequent sequestration orders begin the first month after the previous order ends. Therefore, as the initial

¹³⁵ For additional information, see CRS Report R45106, *Medicare and Budget Sequestration*.

sequestration order was issued March 1, 2013, Medicare sequestration began April 1, 2013, and was (most recently) scheduled to continue through March 31, 2030.

Under a BCA mandatory sequestration order, Medicare benefit payments cannot be reduced by more than 2%. Since April 1, 2013, Medicare benefit-related payments, which include payments to health care providers, Medicare Advantage (MA), and Part D plans, have been subject to 2% reductions.

Provision

This provision waives the application of sequestration to the Medicare program for the period May 1, 2020, through December 31, 2020.

This provision also extends the sequestration of mandatory spending for an additional year, through FY2030. (For Medicare, this means that sequestration will continue through March 31, 2031.)

Section 3710. Medicare Hospital Inpatient Prospective Payment System Add-On Payment for COVID-19 Patients During Emergency Period

Background

Medicare pays most acute care hospitals under the inpatient prospective payment system (IPPS).¹³⁶ The IPPS payment is a predetermined, fixed amount for most services provided to a Medicare beneficiary during an inpatient hospital stay. The bundled, fixed, per-discharge portion of the IPPS is referred to as the IPPS base amount. The total IPPS payment is the base amount, adjusted by a number of factors. These adjustments generally include such things as the geographic location of the hospital, the complexity of the patient's condition, and a hospital's teaching status, among others. One of the adjustments is a payment weight associated with the Medicare severity-diagnosis related group (MS-DRG) to which a patient is assigned. This weight reflects the average cost of patients in a specific MS-DRG relative to the average cost across all MS-DRGs due to differences in the severity of patients' conditions. In FY2020, there are 759 MS-DRGs (i.e., codes). The MS-DRG weights are recalibrated annually, generally effective October 1 of each year. The recalibrations are done in a budget-neutral manner.

Provision

Section 3710 amends SSA Section 1886(d)(4)(C) to require the Secretary to increase the MS-DRG weight that would otherwise apply for a COVID-19-related Medicare discharge by 20% during the COVID-19 emergency period. IPPS payment increases associated with this provision are not to be included in applying budget neutrality. The Secretary is not required to use notice and comment to implement this provision; it may be done through program instruction or otherwise. A state that has a Section 1115A waiver of all or part of SSA Section 1886 to test alternative payment and delivery models through the Center for Medicare & Medicaid Innovation is not precluded from implementing a similar payment adjustment.¹³⁷

Section 3711. Increasing Access to Post-Acute Care During Emergency Period

Background

¹³⁶ See CRS Report R40425, *Medicare Primer*.

¹³⁷ 42 U.S.C. §1315a(d)(1).

Medicare pays for intensive inpatient rehabilitation services—physical, occupational, or speech therapy that is generally required after illness, injury or surgery—under the Inpatient Rehabilitation Facility (IRF) prospective payment system (IRF PPS). The IRF PPS payment is a predetermined, fixed amount per discharge. To receive the IRF PPS payment, the rehabilitation hospital, or a rehabilitation unit within another provider type, must meet IRF requirements specified in regulation. Medicare covers IRF services for patients who, among other requirements, can reasonably be expected to actively participate in, and benefit from, intensive rehabilitation therapy. Intensive rehabilitation therapy is specified in regulation as occurring either 3 hours a day at least five days per week, or 15 hours within a consecutive seven-day period.

Medicare also pays for extended periods of inpatient hospital care for chronic critical illness under the long-term care hospital inpatient prospective payment system (LTCH PPS). The LTCH PPS payment is a predetermined, fixed amount per discharge, and it is generally greater than the IPPS amount. Specifically, LTCHs are paid under the LTCH PPS if a Medicare beneficiary either (1) had a prior three-day intensive-care-unit stay at a hospital paid under the IPPS immediately preceding the LTCH stay, or (2) is assigned to an LTCH PPS case-mix group that is based on the receipt of ventilator services for at least 96 hours, and had a prior hospital stay at a hospital paid under the IPPS immediately preceding the LTCH stay. LTCH discharges occurring in FY2020, and subsequent fiscal years that do not meet the aforementioned criteria are paid a site-neutral payment rate similar to the IPPS amount. Also, an LTCH must have no more than 50% of its Medicare discharges paid at the site-neutral rate to continue to receive the LTCH PPS payment amount for LTCH-eligible cases.

Provision

Section 3711(a) waives the Medicare IRF rule that patients must reasonably be expected to participate in, and benefit from, at least 15 hours of therapy per week, during the COVID-19 emergency period. Section 3711(b) waives the site-neutral payment requirement for COVID-19-related LTCH discharges so that all these discharges will be paid under the LTCH PPS, and it waives the 50% requirement during the COVID-19 emergency period.

Section 3712. Revising Payment Rates for Durable Medical Equipment Under the Medicare Program Through Duration of Emergency Period

Background

Medicare Part B covers a wide variety of medical equipment and devices under the heading of durable medical equipment (DME),¹³⁸ or prosthetics and orthotics (PO)¹³⁹ if the products are medically necessary and prescribed by a physician. Examples of DME include hospital beds, blood glucose monitors, and ventilators.¹⁴⁰ Prosthetics and orthotics include artificial limbs and back and knee braces. The DMEPOS benefit also includes related supplies (S), such as drugs and biologics that are necessary for the effective use of a product.

¹³⁸ Durable medical equipment (DME) is equipment that (1) can withstand repeated use, (2) has an expected life of at least three years (effective for items classified as DME after January 1, 2012), (3) is used primarily to serve a medical purpose, (4) is not generally useful in the absence of an illness or injury, and (5) is appropriate for use in the home.

¹³⁹ Prosthetics (P) are items that replace all or part of a body organ or its function. Orthotics (O) are braces that support a weak or deformed body member, such as leg or back braces.

¹⁴⁰ The Medicare DME benefit applies to equipment that is to be used in the home. Generally, equipment that is to be used during a hospital inpatient stay is paid under Part A.

Except in competitive bidding areas,¹⁴¹ Medicare pays for most DMEPOS based on fee schedules, which are statutory formulas for determining prices of items. Medicare pays 80% of the lower of a supplier's charge for an item or a fee schedule amount. A beneficiary is responsible for the remaining 20%. In general, fee schedule amounts are updated each year, by inflation and a measure of economy-wide productivity.

In addition, since 2016, Medicare fee schedule rates that apply outside of competitive bidding areas for certain DMEPOS¹⁴² have been reduced based on price information collected from the competitive bidding program. (Prices for DMEPOS under competitive bidding are generally lower than the fee schedule rates.) The fee schedule reductions were phased in during 2016, meaning that during that year, 50% of the Medicare payment rate was based on the unadjusted (higher) fee schedule amount, and 50% was based on the (lower) rate fully adjusted with information from competitive bidding. The phase-in was complete by January 2017, at which time fee schedules were based entirely on the adjustment with information from competitive bidding. In response to concerns that the adjusted rates were too low, the Secretary, in June 2018, again applied a phase-in methodology *for rural and noncontiguous areas*, meaning that in these areas the fee schedule was no longer fully adjusted by competitive bidding data, but instead went back to a 50/50 blend of rates based on both (higher) unadjusted fee schedule rates and (lower) rates fully adjusted by competitive bidding information.¹⁴³

As such, two different fee schedules apply to DMEPOS products outside of competitive bidding areas, depending on an area's rural/urban designation and whether an area is part of the contiguous United States. First, in rural or noncontiguous areas, the fee schedule is a 50/50 blend: 50% from the unadjusted fee schedule and 50% from the fee schedule adjusted to account for lower price information from competitive bidding (i.e., the phase-in methodology). Second, in areas that are not rural or noncontiguous (i.e., nonrural and contiguous), the fee schedules are fully adjusted by information from the competitive bidding program. In both cases, CMS regulations specify that this methodology applies from June 1, 2018, through December 31, 2020.

Provision

Section 3712 of the CARES Act extends the 50/50 blended DMEPOS payment rate provided in rural or noncontiguous areas through the duration of the COVID-19 emergency period, if the emergency period lasts longer than December 31, 2020.

Section 3712 also increases the DMEPOS payment rate for items provided in areas other than rural areas and noncontiguous areas for the duration of the COVID-19 emergency period. Items and services furnished in these areas on or after the date that is 30 days after the enactment of the CARES Act (i.e., April 26, 2020) would be reimbursed under a fee schedule that is equal to a 75/25 blend, where 75% of the fee schedule is fully adjusted by competitive bidding rates, and 25% is based on unadjusted (higher) fee schedule amounts.¹⁴⁴

¹⁴¹ The Medicare Modernization Act (MMA, P.L. 108-173) required the Secretary to establish a Competitive Acquisition Program for certain DMEPOS in specified areas. Instead of paying for medical equipment based on a fee schedule established by law, payment for items in competitive bidding areas was based on supplier bids. The program started in 9 metropolitan areas in January 2011 and had expanded to 130 competitive bidding areas in 2018. However, the program was suspended to redesign and implement a new program methodology, which is slated to apply to Medicare rates paid beginning January 1, 2021.

¹⁴² Not all DMEPOS are subject to competitive bidding, and as a result, the fee schedule amounts for noncompetitively bid items cannot be reduced based on competitive bidding.

¹⁴³ The noncontiguous areas are Alaska, Hawaii, and the territories.

¹⁴⁴ The provision indicates that the Secretary is required to apply the regulations at 42 C.F.R. 414.210(g)(9)(iv), which

Section 3713. Coverage of the COVID-19 Vaccine Under Part B of the Medicare Program Without Any Cost-Sharing

Background

Medicare Part B specifically covers the following vaccines: influenza virus (flu), pneumococcal pneumonia (pneumonia), hepatitis B virus (HBV) for beneficiaries at high or intermediate risk, and other vaccines directly related to treatment of an injury or direct exposure to a disease or condition.¹⁴⁵ Otherwise, Medicare Part B does not cover preventive vaccines.¹⁴⁶ If a vaccine is provided by a Medicare-participating practitioner, there is no cost-sharing for Medicare beneficiaries for the flu, HBV, or pneumonia vaccine ingredient or the vaccine administration. However, Medicare Part B cost-sharing applies (20% of the Medicare approved amount plus an annual deductible) for vaccines administered to treat an injury or direct exposure to a disease or condition.

Medicare Part C (MA) plans generally are required to cover the same services as original Medicare, Parts A and B. As a result, MA plans are required to cover, without beneficiary cost-sharing, the flu, HBV, and pneumonia vaccines. MA plans may cover without beneficiary cost-sharing vaccines directly related to treatment of an injury or direct exposure to a disease or condition and other vaccines. MA enrollee cost-sharing for vaccines not covered by Medicare Part B may vary depending on the plan and the vaccine, because they may be covered as supplemental benefits.

Provision

Section 3713 amended SSA Section 1861(s)(10)(A) and SSA Section 1852(a)(1)(B) to require Medicare Part B and MA plans to cover a COVID-19 vaccine and its administration without beneficiary cost-sharing, including waiving applicable annual deductibles. This section was effective upon enactment (i.e., March 27, 2020) and is applicable to a COVID-19 vaccine on the date it is licensed by FDA. The Secretary is authorized to implement Section 3713 through program instructions or otherwise.

Section 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

Background

Medicare Part D is a voluntary outpatient prescription drug benefit. Enrollees purchase Part D prescription drug plans from private insurers, known as plan sponsors. To participate in the Part D

refers to payment phase-in methodology for nonrural and contiguous areas from June 1, 2018, through December 31, 2020 (i.e., the 100% phase-in), as if it were instead a reference to “dates of service from March 6, 2020, through the remainder of the duration of the emergency period.” However, it is unclear what the March 6, 2020 date refers to.

¹⁴⁵ For example, an anti-rabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenin sera, or immune globulin vaccination would be covered if beneficiaries were exposed to the condition or as a result of an injury. However, without an injury or direct exposure, preventive vaccinations against diseases such as smallpox, polio, and diphtheria are not covered under Medicare Part B. When a vaccine is not covered under Part B, related charges, such as a charge for administering the vaccine, also are not covered.

¹⁴⁶ Prescription drug plans that participate in Medicare’s voluntary outpatient prescription drug benefit under Part D are required to cover all commercially available vaccines except those already covered by Medicare Part B, if the vaccines are reasonable and necessary to prevent illness.

program, plan sponsors must meet a series of requirements, including (1) providing an adequate formulary, or list of covered drugs, and (2) providing a sufficient network of contracted pharmacies that dispense prescriptions for set reimbursement. Federal law also requires that Part D sponsors provide enrollees with “adequate emergency access” to needed drugs.¹⁴⁷ Under longstanding CMS guidance, plan sponsors have some latitude in deciding how to comply with the emergency access provisions.¹⁴⁸ In general, however, CMS expects plan sponsors to limit pharmacy edits (i.e., dispensing restrictions) that prevent enrollees from seeking early prescription refills in the case of a federally declared disaster or a public health emergency that is reasonably expected to disrupt access.¹⁴⁹

In a March 10, 2020, memo to Part D sponsors, CMS reiterated its emergency access guidelines and outlined options for responding to the COVID-19 emergency.¹⁵⁰ In the memo, CMS specified actions that Part D sponsors may or must take:

- Sponsors may relax “refill-too-soon” edits on prescriptions if circumstances are reasonably expected to result in a disruption in access. Sponsors have discretion regarding how to relax the edits, so long as enrollees have access to Part D drugs at the point-of-sale (i.e., a retail pharmacy). Sponsors may allow an enrollee to obtain the maximum extended-day supply available under his or her plan, if the prescription is requested and available.
- Sponsors must ensure that an enrollee has adequate access to covered drugs at a pharmacy located out of the enrollee’s regular pharmacy network. The requirement would apply in cases where an enrollee could not reasonably be expected to obtain the drugs at a network pharmacy. Enrollees would still be responsible for required cost-sharing and possible additional charges (i.e., the out-of-network pharmacy’s usual and customary charge for the drugs).¹⁵¹
- Sponsors may relax plan-imposed policies that could discourage certain types of prescription delivery, such as mail or home delivery, if a disaster or emergency makes it difficult for enrollees to get to a retail pharmacy, or when enrollees are prohibited from going to a retail pharmacy (such as in a quarantine situation).
- Sponsors may waive requirements that enrollees receive prior authorization before filling a prescription for drugs used to treat or prevent COVID-19, if or

¹⁴⁷ (SSA 1860D-4(b)(1)(C)(iii))

¹⁴⁸ Center for Medicare & Medicaid Services (CMS), *Medicare Prescription Drug Benefit Manual*, Chapter 5, “Benefits and Beneficiary Protection,” Section 50.12, Rev. September 20, 2011, at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf. In 2014, CMS proposed more uniform requirements regarding emergency access but did not finalize a proposed rule on the topic. CMS, “42 CFR Parts 417, 422, 423, et al. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Final Rule,” *Federal Register*, May 23, 2014, p. 29939.

¹⁴⁹ In 2014, CMS proposed more uniform requirements regarding emergency access but did not finalize a proposed rule on the topic. CMS, “42 CFR Parts 417, 422, 423, et al. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Final Rule,” *Federal Register*, May 23, 2014, p. 29939.

¹⁵⁰ CMS, Memo to Medicare Advantage Organizations, Part D Sponsors, and Medicare-Medicaid Plans, “Information Related to Coronavirus Disease 2019 - COVID-19,” March 10, 2020, <https://www.cms.gov/files/document/hpms-memo-covid-information-plans.pdf>.

¹⁵¹ Consistent with 42 C.F.R. 423.124(a).

when such drugs are identified. Any plan waivers would be provided to enrollees uniformly.

Part D plan sponsors also operate drug management programs for beneficiaries deemed to be at risk of misusing or abusing frequently abused drugs. Sponsors may place additional controls on pharmacy dispensing to such individuals, including placing limits on the number of providers allowed to write prescriptions for at-risk enrollees and limiting the number of pharmacies allowed to dispense drugs to such enrollees. Under CMS regulations, at-risk enrollees must have reasonable access to prescriptions in case of natural disasters or similar situations.¹⁵²

Provision

Section 3714 amends SSA 1860D–4(b) to require Part D sponsors to provide extended dispensing to enrollees during the COVID-19 emergency period. Under the provision, Part D sponsors must allow an enrollee to have access to up to a 90-day fill or refill of a prescription. Plan sponsors cannot deny such prescriptions based on existing plan cost and utilization management requirements that limit dispensing of particular drugs, except for restrictions based on drug safety. The Secretary may implement the provision by program instruction or otherwise.

Section 3715. Providing Home and Community-Based Services in Acute Care Hospitals

Background

Medicaid home and community-based services (HCBS) include coverage of specific benefits such as case management, personal care, homemaker, respite care, and adult day health care, among other services. Medicaid HCBS are authorized under the Medicaid state plan, which is the contract a state makes with the federal government to administer its Medicaid program, subject to CMS approval.¹⁵³ These HCBS state plan authorities include optional services that states may choose to provide under the SSA Section 1915(i) HCBS State Plan Option, the SSA Section 1915(k) Community First Choice State Plan Option, and SSA Section 1915(j) Self-Directed Personal Care Assistance Services. Medicaid HCBS are also authorized through waiver programs that permit states to disregard certain Medicaid requirements under the state plan in the provision of waiver services, also subject to CMS approval. Medicaid HCBS waiver authorities include SSA Section 1915(c) HCBS waivers, SSA Section 1915(d) HCBS waivers for the elderly,¹⁵⁴ and SSA Section 1115 research and demonstration waivers.

SSA Section 1902(h) states that nothing in Title XIX (Medicaid) should be construed as authorizing the Secretary to limit the amount of payment that may be made under a Medicaid state plan for home and community care.¹⁵⁵

Provision

Section 3715 amends SSA Section 1902(h) by adding a new paragraph (1) to specify that the limit on the amount of payment under a Medicaid state plan for home and community care applies to

¹⁵² 42 C.F.R. 423.153(f) (11) and (12).

¹⁵³ For more information about Medicaid coverage of home and community-based services, see CRS Report R43328, *Medicaid Coverage of Long-Term Services and Supports*.

¹⁵⁴ According to CMS, no state has elected to use this waiver authority. CMS, “Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Setting Requirements for Community First Choice; Proposed Rule,” 77 *Federal Register* 26367, May 3, 2012.

¹⁵⁵ 42 U.S.C. §1396a.

certain statutory authorities for providing Medicaid HCBS under state plan services authorized under SSA Section 1915(i), Section 1915(j), and Section 1915(k), as well as waiver authorities under Section 1915(c), Section 1915(d), and Section 1115.

The provision adds a new paragraph (2), which states that nothing in SSA Titles XI (General Provisions), XVIII (Medicare), or XIX (Medicaid) shall be construed as prohibiting receipt of any care or services specified in paragraph (1) in an acute care hospital that are identified in an individual's person-centered service plan (or comparable plan of care); provided to meet needs of the individual that are not met through the provision of hospital services; not a substitute for services that the hospital is obligated to provide through its conditions of participation or under federal or state law, or under another applicable requirement; and designed to ensure smooth transitions between acute care settings and home and community-based settings, and to preserve the individual's functional abilities.

Section 3716. Clarification Regarding Uninsured Individuals

Background

FFCRA Section 6004 permits state Medicaid programs to extend time-limited COVID-19 testing (as specified under that law's new Medicaid mandatory service category) without cost-sharing to uninsured individuals. For the purposes of this provision, FFCRA Section 6004 defines uninsured individuals as those who are not Medicaid eligible under one of Medicaid's mandatory eligibility pathways (e.g., the poverty-related pregnant women and child pathways, or the ACA Medicaid expansion pathway),¹⁵⁶ and are not enrolled in (1) a federal health program (e.g., Medicare, Medicaid, CHIP, or TRICARE); (2) a specified type of private health insurance plan (e.g., individual health insurance coverage, group health insurance coverage, or a group health plan); or (3) an FEHBP. FFCRA provides a 100% federal medical assistance percentage (FMAP or federal matching rate) for medical assistance and administrative costs associated with uninsured individuals who are eligible for Medicaid under this provision.

Provision

Section 3716 of the CARES Act amends the definition of uninsured individuals under FFCRA Section 6004 for the purposes of determining Medicaid eligibility for the state plan option to allow for time-limited COVID-19 testing (as specified under the new Medicaid mandatory service category) without cost-sharing. Under the CARES Act, uninsured individuals will also include those (1) who would be eligible for Medicaid via the ACA Medicaid expansion pathway in states that have not adopted this eligibility pathway (i.e., non-ACA Medicaid expansion states), and (2) certain specified Medicaid enrollees who, by virtue of their Medicaid eligibility pathway, are entitled to limited Medicaid benefits, including

- low-income tuberculosis-infected individuals who are entitled to services related to the tuberculosis infection,
- women needing treatment for breast or cervical cancer,
- individuals eligible only for family planning services and supplies,

¹⁵⁶ For more information on Medicaid eligibility, see CRS Report R43357, *Medicaid: An Overview*.

- individuals eligible through the Medically Needy pathway¹⁵⁷ whose coverage does not meet minimum essential health coverage,¹⁵⁸ and
- certain low-income pregnant woman who are entitled to limited pregnancy-related services.

Section 3717. Clarification Regarding Coverage of COVID-19 Testing Products

Background

FFCRA Section 6004 added FDA-approved tests and testing-related state plan services for the COVID-19 virus without cost-sharing, as defined in Section 6004 to the list of Medicaid mandatory services under traditional Medicaid benefits. States and territories are required to offer services under this new mandatory benefit for the period beginning March 18, 2020, through the duration of the public health emergency, as declared by the Secretary pursuant to PHSA Section 319. During the specified public health emergency period, Section 6004 of FFCRA also permits state Medicaid programs to extend FDA-approved COVID-19 testing (and testing-related state plan services) to uninsured individuals without cost-sharing, as defined in Section 6004 and requires CHIP programs to cover FDA-approved COVID-19 testing and the administration of such testing without cost-sharing for CHIP enrollees.

Section 6004 also amended SSA Section 1905(a)(3) to define applicable tests to include IVDs, as defined in FDA regulation, that detect SARS-CoV-2¹⁵⁹ or diagnose COVID-19 and that had received either 510(k) clearance, premarket approval, authorization pursuant to de novo classification, or emergency use authorization (EUA) for marketing.

Provision

The CARES Act modifies the definition of COVID-19 tests covered under Medicaid and CHIP for the specified public health emergency period. Specifically, Section 3717 amends SSA Section 1905(a)(3)(B), as added by FFCRA Section 6004, to remove language requiring FDA approval, clearance, or authorization for covered tests. Under this modified definition, tests are defined simply as IVDs, as defined in FDA regulation, that detect SARS-CoV-2 or diagnose COVID-19. IVDs are defined in FDA regulation as a specific subset of devices that include “reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions ... in order to cure, mitigate, treat, or prevent disease ... [s]uch products are intended for use in the collection, preparation, and examination of specimens taken from the human body.”¹⁶⁰

¹⁵⁷ Medically needy individuals (e.g., children, pregnant women, aged, blind, or disabled) are individuals who are otherwise eligible for Medicaid but who have incomes too high to qualify and spend down their income on medical care. For this medically needy subgroup, states may offer a more restrictive benefit package than is available to other enrollees.

¹⁵⁸ For more information on the CMS criteria used to evaluate if a given state’s medically needy coverage meets the minimum essential health coverage standard, see CMS, *Dear State Health Official, Dear State Medicaid Director*, SHO# 14-002, Re: Minimum Essential Coverage, November 7, 2014, <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/downloads/SHO-14-002.pdf>. For more general information on minimum essential coverage under Medicaid, see <https://www.medicaid.gov/medicaid/eligibility/minimum-essential-coverage/index.html>.

¹⁵⁹ SARS-CoV-2 is the technical name of the virus that causes COVID-19 disease.

¹⁶⁰ 21 C.F.R. §809.3(a).

Section 3718. Amendments Relating to Reporting Requirements With Respect to Clinical Diagnostic Laboratory Tests

Background

Outpatient clinical laboratory services are paid under the Medicare Clinical Laboratory Fee Schedule (CLFS). Previously, CLFS payment rates were based on historical laboratory charges. The Protecting Access to Medicare Act (PAMA, P.L. 113-93) established a new method for determining clinical laboratory payments beginning in 2018, with Medicare CLFS payment rates based on reported private insurance payment amounts.

Per PAMA, CMS was to collect data from clinical laboratories (aside from advanced diagnostic laboratory tests, for which PAMA also altered payment, coding, and coverage) about private payer payment rates beginning in 2016. The new payment system was to be phased in from 2017 through 2022; during the phase-in period, payment could not be reduced, compared with the amount of the payment in the preceding year, by more than a statutorily specified limit. For each year 2017-2019, the CLFS payment reduction limit was to be 10%, and for each year 2020-2022, the payment reduction limit was to be 15%. Beginning in 2018, CMS set CLFS rates based on the weighted median of private payer rates for each laboratory service, collected from applicable laboratories. These CLFS payment rates are national and do not vary based on geography.

Section 105 of the Further Consolidated Appropriations Act of 2020 (P.L. 116-94) modified the schedule for implementing the new CLFS payment system and reporting requirements. A period during which there would be no reporting required from diagnostic laboratories was established, from January 1, 2020, through December 31, 2020. The first required reporting period would begin January 1, 2021, and end March 31, 2021, with subsequent reporting periods required every three years thereafter. The phase-in schedule was modified so that the payment reduction limit was to be 10% for each year from 2017 through 2020, with the limit to be 15% from 2021 through 2023.

Provision

Section 3718 further delays the reporting requirements under the new CLFS payment methodology and makes additional revisions to the payment reduction limits during the phase-in schedule. The provision would extend the initial period during which no reporting is required from the period beginning January 1, 2021, through December 31, 2021, with the first required reporting period to begin on January 1, 2022, and end March 31, 2022. Subsequent required reporting periods would occur every three years thereafter. For 2021, there would be no payment reduction (i.e., 0% limit) during the phase-in of the private payer rate implementation schedule; the payment reduction limit would be 15% for 2022 through 2024, when the private payer rate is to be fully implemented.

Section 3719. Expansion of the Medicare Hospital Accelerated Payment Program During the COVID-19 Public Health Emergency

Background

SSA Section 1815 permits the Secretary to make accelerated payments to an IPPS hospital and to a Puerto Rico IPPS hospital that experiences significant cash flow problems.¹⁶¹ Cash flow problems must arise out of one or more of the following: (1) a delay in Medicare payments, (2)

¹⁶¹ 42 U.S.C. §1395g(e)(3).

exceptional situations beyond a hospital’s control that result in delayed billing, or (3) highly exceptional situations where the Secretary deems an accelerated payment is appropriate. The amount of the accelerated payment may not exceed 70% of the estimated unbilled charges or unpaid bills (less deductibles and coinsurance). An accelerated payment must be paid-in-full within 90 days after such payment is made. If an accelerated payment is not paid in full within 90 days, CMS is authorized to withhold Medicare payments until the accelerated payment is repaid. Accelerated payments must be requested by a hospital, and those requests are reviewed and approved by the appropriate CMS regional office.

Provision

Section 3719 amends SSA Section 1815 to expand eligibility for accelerated payments to Critical Access Hospitals (CAHs), pediatric hospitals, and IPPS-exempt cancer hospitals located in one of the 50 states or the District of Columbia, during the COVID-19 emergency period.¹⁶² The expansion of accelerated payments made under this provision is subject to appropriate safeguards against fraud, waste, and abuse. In addition, upon the request of a hospital that is eligible for accelerated payment under this provision, the Secretary may implement the following amendments during the designated public health emergency period: make accelerated payments on a periodic or lump sum basis; increase payments by an amount up to 100% of the estimated unbilled charges or unpaid bills or 125% for CAHs; and specify that the accelerated payments can cover up to a six-month period of unbilled charges or unpaid bills. The Secretary is required to extend the recoupment period up to 120 days upon request of the hospital. Also upon request, a hospital is allowed no less than 12 months from the date of the first accelerated payment to pay in full any outstanding balance. The Secretary may implement this provision through program instruction or otherwise.

Section 3720. Delaying Requirements for Enhanced FMAP to Enable State Legislation Necessary for Compliance

Background

Medicaid is jointly financed by the federal government and the states. The federal government’s share of a state’s expenditures for most Medicaid services is called the FMAP rate, which varies by state and is designed so that the federal government pays a larger portion of Medicaid costs in states with lower per capita incomes relative to the national average (and vice versa for states with higher per capita incomes).¹⁶³ Exceptions to the regular FMAP rate have been made for certain states, situations, populations, providers, and services.

In the past, two temporary FMAP exceptions were available to provide states with fiscal relief due to recessions. They were provided through the Jobs and Growth Tax Relief Reconciliation Act of 2003 (P.L. 108-27) and the American Recovery and Reinvestment Act of 2009 (P.L. 111-5). To be eligible for both of these temporary FMAP increases, states had to abide by some requirements. These requirements varied in the two FMAP increases, but for both increases, states were required to maintain Medicaid “eligibility standards, methodologies, and procedures” and to ensure that local governments did not pay a larger percentage of the state’s nonfederal Medicaid expenditures than would have been required otherwise.

¹⁶² 42 U.S.C. §1395x(mm) for Critical Access Hospitals (CAHs); 42 U.S.C. §1395ww(d)(1)(B)(3) for pediatric hospitals; and 42 U.S.C. §1395ww(d)(1)(B)(v) for PPS-exempt cancer hospitals.

¹⁶³ For more information about the federal medical assistance percentage, see CRS Report R43847, *Medicaid’s Federal Medical Assistance Percentage (FMAP)*.

Section 6008 of FFCRA provides an increase to the FMAP rate for all states, the District of Columbia, and the territories of 6.2 percentage points for each calendar quarter occurring during the period beginning on the first day of the public health emergency period (i.e., January 1, 2020) and ending on the last day of the calendar quarter in which the last day of the public health emergency period ends.

States, the District of Columbia, and the territories will not receive this FMAP rate increase if (1) the Medicaid “eligibility standards, methodologies, or procedures” are more restrictive than what was in effect on January 1, 2020;¹⁶⁴ (2) the amount of premiums imposed by the state exceeds the amount as of January 1, 2020; (3) eligibility is not maintained for individuals enrolled in Medicaid on the date of FFCRA enactment (i.e., March 18, 2020) or for individuals who enroll during the public health emergency period through the end of the month in which the public health emergency period ends (unless the individual requests a voluntary termination of eligibility or the individual ceases to be a resident of the state); or (4) the state does not provide coverage (without the imposition of cost-sharing) for any testing services and treatments for COVID-19 (including vaccines, specialized equipment, and therapies).

Section 6008 of FFCRA also modifies SSA Section 1905(cc) to add another condition for the FMAP rate increase. Specifically, states, the District of Columbia, and the territories cannot require local governments to fund a larger percentage of the state’s nonfederal Medicaid expenditures for the Medicaid state plan or Medicaid disproportionate share hospital payments than what was required on March 11, 2020.

Provision

Section 3720 of the CARES Act amends Section 6008 of FFCRA to delay the application of the requirement that a state cannot receive the increased FMAP rate if the amount of premiums imposed by the state is higher than the amount imposed as of January 1, 2020. Specifically, the application of the premium requirement is delayed for 30 days after March 18, 2020 (i.e., the date of enactment for FFCRA). Effectively, a state will be eligible for the FFCRA FMAP increase through April 17, 2020, if the amount of premiums imposed by the state exceeds the amount imposed as of January 1, 2020, as long as the premiums were in effect on the date of enactment for FFCRA. In order to receive the FMAP increase, a state still needs to be in compliance with all of the other requirements listed in FFCRA.

Subtitle F—Over-the-Counter Drugs

Part I—OTC Drug Review

Background

FDA regulates the safety and effectiveness of nonprescription or OTC drugs sold in the United States. Examples of OTC drugs include hand sanitizer, sunscreen, and certain analgesics. To market an OTC drug, a company may follow one of two pathways. First, a company may submit an NDA to FDA for approval. Second, a company may use the OTC drug monograph process. A monograph establishes conditions—active ingredient(s) and related conditions (e.g., dosage level,

¹⁶⁴ A similar provision was in place prior to FFCRA for Medicaid and the State Children’s Health Insurance Program (CHIP) children. Under Social Security Act (SSA) Section 1902(gg)(2) and SSA Section 2105(d)(3), states are required to maintain the Medicaid and CHIP eligibility standards, methodologies, and procedures for children in place on the date of enactment of the ACA, through FY2027. The penalty to states for not complying with either the Medicaid or the CHIP maintenance of effort requirements for children would be the loss of all federal Medicaid funds.

combination of active ingredients, labeled indications, warnings and adequate directions for use)—under which an OTC drug in a given therapeutic category (e.g., sunscreen, antacid) is considered generally recognized as safe and effective (GRASE) for use. If an OTC drug product complies with a monograph, it does not need FDA approval of its NDA prior to marketing. Prior to enactment of the CARES Act, monographs were established and amended through rulemaking. FDA assesses monograph compliance as part of its inspection process.¹⁶⁵

The OTC drug monograph program—established in 1972—was intended to provide an efficient mechanism through which OTC drugs could be marketed without individual FDA evaluation and approval. However, the program has been met with several challenges. For example, some monographs remain unfinalized, so there are OTC drugs on the market without final safety and effectiveness determinations. There are also perceived limitations to the industry’s ability to propose innovations to currently marketed OTC drugs without submitting an NDA, and FDA has stated that it has limited resources to support OTC monograph activities.¹⁶⁶

Section 3851. Regulation of Certain Nonprescription Drugs that Are Marketed Without an Approved Drug Application

Provision

Section 3851 establishes a new FDCA Section 505G, which replaces the current OTC drug monograph rulemaking process with the administrative order process—a less burdensome alternative. This new process allows FDA, on its own initiative or upon request, to issue an administrative order (rather than a rule) determining that a drug, or class or combination of drugs, is GRASE or not GRASE. Certain monograph changes (e.g., new active ingredient, new indication) that are industry-requested and subject to a final administrative order are eligible for 18 months of marketing exclusivity. New FDCA Section 505G, among other things, also (1) requires that certain OTC drugs be marketed only pursuant to FDA approval via an NDA; (2) creates an expedited process for the issuance of administrative orders in certain circumstances (i.e., public health hazard, safety labeling changes); (3) provides for circumstances under which minor changes in dosage form can be made without a new administrative order; (4) requires FDA to publish on its website information related to final interim and administrative orders, develop guidance, and establish meeting procedures; and (5) requires GAO to conduct a study on the impact of the 18-month marketing exclusivity period for certain eligible OTC drugs.

Section 3852. Misbranding

Section 3852 amends FDCA Section 502 to deem a drug misbranded if it is an OTC monograph drug that is subject to new FDCA Section 505G, is not the subject of an approved NDA or ANDA, and does not comply with the requirements in FDCA Section 505G. This provision also deems a drug misbranded if it is “manufactured, prepared, propagated, compounded, or processed” in a facility for which OTC monograph user fees have not been paid.

¹⁶⁵ For additional information, see CRS In Focus IF10463, *Regulation of Over-the-Counter (OTC) Drugs*.

¹⁶⁶ Testimony from Janet Woodcock, M.D., on Modernizing FDA’s Regulation of Over-The-Counter Drugs before House Committee on Energy and Commerce, September 13, 2017, <https://www.fda.gov/news-events/congressional-testimony/modernizing-fdas-regulation-over-counter-drugs>.

Section 3853. Drugs Excluded from the Over-The-Counter Drug Review

Section 3853 states that nothing in this act (or the amendments made by it) applies to any OTC drug excluded by FDA from the OTC Drug Review in accordance with the statement set out at 37 FR 9466 published on May 11, 1972.

Section 3854. Treatment of Sunscreen Innovation Act

Background

Some industry stakeholders and members of Congress perceived FDA to be delaying consumer access to new sunscreens that were not originally included in the OTC Drug Review, and in November 2014, the Sunscreen Innovation Act (SIA; P.L. 113-195) was enacted. The SIA—codified in FDCA Chapter V Subchapter I—created a new pathway for establishing whether certain OTC sunscreen active ingredients (i.e., those marketed in the United States after 1972 or those without any U.S. marketing experience) are GRASE. The SIA requires FDA to make GRASE determinations in the form of administrative orders (first proposed orders and then final orders) rather than through rulemaking, among other things.¹⁶⁷ FDA has not yet approved any submissions for new sunscreen through the SIA process, requesting that sponsors submit additional safety and effectiveness data.

Provision

Section 3854 allows the sponsor of an OTC sunscreen active ingredient that is subject to a proposed sunscreen order under the SIA to elect to transition into the review process under new FDCA Section 505G. The sponsor must notify FDA of such decision within 180 days of enactment, as specified. Otherwise, the order must continue to be reviewed under the SIA. Final sunscreen orders issued under the SIA are deemed final administrative orders under FDCA Section 505G. Certain final sunscreen orders issued under new FDCA Section 505G are eligible for 18 months of marketing exclusivity. Section 3854(b)(4) adds new FDCA Section 586H, which sunsets FDCA Chapter V Subchapter I (added by the SIA) at the end of FY2022.

Section 3855. Annual Update to Congress on Appropriate Pediatric Indication for Certain OTC Cough and Cold Drugs

Background

Between 2004 and 2005, more than 1,500 children under two years of age were treated in U.S. emergency departments for adverse events associated with cough and cold medications.¹⁶⁸ Concerns also arose regarding the use of these products in children under six years of age.¹⁶⁹ In October 2007, FDA convened the Joint Meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee “to discuss the safety and efficacy of [OTC] cough and cold products marketed for pediatric use.”¹⁷⁰ The committees determined that the

¹⁶⁷ FDA, Guidance for Industry, “Sunscreen Innovation Act: Section 586C(c) Advisory Committee Process,” October 2016, <https://www.fda.gov/media/94237/download>.

¹⁶⁸ FDA, “Use Caution When Giving Cough and Cold Products to Kids,” <https://www.fda.gov/drugs/special-features/use-caution-when-giving-cough-and-cold-products-kids>.

¹⁶⁹ Citizen Petition to FDA from the Baltimore City Health Department et al., March 1, 2007, Docket ID FDA-2007-P-0050-0023.

¹⁷⁰ FDA, Center for Drug Evaluation and Research (CDER), “Joint meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee,” Agenda, October 18 and 19, 2007, <http://wayback.archive-it.org/>

available published studies did not demonstrate that OTC monograph cough and cold products marketed for pediatric use were effective in children and recommended additional studies and labeling changes.¹⁷¹ To date, FDA has not amended the monograph for these products in 21 C.F.R. Part 341 to reflect the committee recommendations. Absent rulemaking, FDA has issued several consumer updates warning of potential harms associated with the use of certain cough and cold drug products in children. Manufacturers voluntarily removed OTC infant cough and cold products intended for children under two years of age and voluntarily updated product labeling to include the warning “do not use in children under 4 years of age.”¹⁷² However, such labeling changes are not required by FDA under the cough and cold monograph, and in order for FDA to require such labeling for these products, the agency would have to amend the monograph.

Provision

Section 3855 requires that, not later than one year after enactment and annually thereafter until FDA completes its evaluation, the Secretary submits to the Senate HELP and House Energy and Commerce committees a letter describing FDA’s progress in (1) evaluating the cough and cold monograph under 21 C.F.R. Part 341 with respect to children under age six and (2) as appropriate, revising the monograph to address children under age six, through the administrative order process under new FFDCA Section 505G(b).

Part II—User Fees

Section 3862. Fees Relating to Over-The-Counter Drugs

Background

Historically, OTC drug monograph activities have been funded solely by discretionary appropriations from the General Fund of the Treasury. This funding method is in contrast to FDA’s prescription drug activities, which are funded by a combination of discretionary appropriations and industry-paid user fees. This is because in 1992, the Prescription Drug User Fee Act (PDUFA) gave FDA the authority to collect fees from the pharmaceutical industry and use the revenue to support “the process for the review of human drug applications.”¹⁷³ PDUFA connected the user fees to performance goals that were negotiated between FDA and industry. The five-year PDUFA authority has been renewed on five subsequent occasions, and user fee authorities have been added for medical devices, animal drugs, tobacco products, and other FDA-regulated products and activities. These fee authorities—codified in FFDCA Chapter VII, Subchapter C—allow the Secretary, acting through the FDA Commissioner, to assess, collect, and spend user fees paid from regulated entities for specified FDA activities.

Provision

Section 3862 creates in FFDCA Chapter VII, a new Part 10—“Fees Relating to Over-The-Counter Drugs”—and the following new FFDCA sections: Section 744L (“Definitions”), Section 744M (“Authority to Assess and Use OTC Monograph Fees”), and Section 744N

7993/20170404050512/https://www.fda.gov/ohrms/dockets/ac/07/agenda/2007-4323a1-Final.pdf.

¹⁷¹ Meeting minutes, Joint Meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee October 18-19, 2007, <http://wayback.archive-it.org/7993/20170404050526/https://www.fda.gov/ohrms/dockets/ac/07/minutes/2007-4323m1-Final.pdf>.

¹⁷² FDA, “Use Caution When Giving Cough and Cold Products to Kids,” <https://www.fda.gov/drugs/special-features/use-caution-when-giving-cough-and-cold-products-kids>.

¹⁷³ P.L. 102-571.

(“Reauthorization; Reporting Requirements”). New FFDCa Section 744M establishes a legal framework for the Secretary, beginning with FY2021, to assess and collect facility fees and monograph order request fees to support FDA’s OTC monograph drug activities (e.g., review of order requests, inspections). Fees may be collected and spent only to the extent and in the amount provided in advance in appropriations acts (with an exception for the first year of the program), may remain available until expended, and may be transferred as specified for monograph drug activities only. This user fee program is authorized through FY2025. New FFDCa Section 744N requires the Secretary to submit annual performance and fiscal reports on user fee collection and spending to the Senate HELP and House Energy and Commerce committees. The performance and fiscal reports must be made publicly available on FDA’s website. New FFDCa Section 744N also specifies the process for reauthorization of the user fee program, requiring the Secretary to consult with stakeholders on recommendations for future monograph activities and to transmit the recommendations to Congress no later than January 15, 2025.

Appendix. Health Provisions in Title III of the CARES Act: Implementation Dates, Reporting Requirements, and Deadlines

The table below includes relevant provisions (listed in order number) that include an effective date, a required report, or an explicit sunset date. The table does not include every provision described in this report, nor does it include required internal reports (i.e., reports required by grantees); it includes only reports that must be made public or be delivered to Congress. This CRS report reflects the CARES Act at enactment and will not be track actions pursuant to these deadlines, nor will this report be updated.

Table A-1. Title III CARES Act Provisions with Implementation Dates, Reporting Requirements, and Deadlines

Provision Number	Title	Brief Description	Effective Date/Reporting Deadlines
Section 3101	National Academies Report on America’s Medical Product Supply Chain Security	Requires the Secretary to enter into an agreement with NASEM to examine and report on the security of the U.S. medical product supply chain.	Not later than 60 days after enactment (i.e., by May 26, 2020).
Section 3112	Additional Manufacturer Reporting Requirements In Response to Drug Shortages	Requires the Secretary to transmit to CMS a report regarding the drugs on the current drug shortage list.	Not later than 180 days after enactment (i.e., by September 23, 2020) and every 90 days thereafter, including Section 3111 amendments) effective 180 days after enactment (i.e., by September 23, 2020).
Section 3212	Telehealth Network and Telehealth Resource Centers Grant Programs	Requires the Secretary to submit a report, to specified congressional committees, on the activities and outcomes of the Telehealth Network Grant Program and the Telehealth Resource Centers Program.	Not later than four years after enactment (i.e., by March 27, 2024) and every five years thereafter.
Section 3213	Rural Health Care Services Outreach, Rural Health Network Development, and Small Health Care Provider Quality Improvement Grant Programs	Requires the Secretary to submit a report, to specified congressional committees, on the activities and outcomes of the specified rural health related grant programs.	Not later than four years after enactment (i.e., by March 27, 2024) and every five years thereafter.
Section 3215	Limitation on Liability for Volunteer Health Care Professionals During COVID-19 Emergency Response	Section confers medical malpractice liability on health professionals who volunteer during the emergency period.	Liability coverage is effective at enactment (i.e., March 27, 2020), through the duration of the public health emergency, when the coverage protections sunset.
Section 3221	Confidentiality and Disclosure of Records Relating to Substance Use Disorder	Requires the Secretary to revise regulations as necessary to better align the HIPAA Privacy Rule requirements with those for substance use disorder records under PHSA Section 543 to facilitate improved patient care and care coordination.	Changes apply to use and disclosures of covered records occurring on or after the date that is 12 months after enactment (i.e., by March 27, 2021).

Provision Number	Title	Brief Description	Effective Date/Reporting Deadlines
Section 3221	Confidentiality and Disclosure of Records Relating to Substance Use Disorder	Requires the Secretary, in consultation with specified experts, to update the notice of privacy practices requirement in the HIPAA Privacy Rule to require covered entities and entities creating or maintaining covered records to provide notice, in plain language, of privacy practices regarding those records.	Not later than one year after enactment (i.e., by March 27, 2021).
Section 3224	Guidance on Protected Health Information	Requires the Secretary to issue guidance with respect to sharing patients' protected health information during the COVID-19 public health emergency, and specifically clarifying compliance with HIPAA Privacy Rule requirements and related policies.	Not later than 180 days after enactment (i.e., by September 23, 2020).
Section 3225	Reauthorization of Healthy Start Program	Requires GAO to conduct an independent evaluation of the Healthy Start program and to submit a report to specified congressional committees that contains a review, an assessment, and recommendations on a number of specified topics regarding the Healthy Start Program and the allocation of funding provided under the program.	Not later than four years after enactment (i.e., by March 27, 2024).
Section 3226	Importance of the Blood Supply	Requires the Secretary to submit a report to specified congressional committees that (1) describes the awareness activities carried out under this section, (2) describes trends in blood supply donations, and (3) evaluates the impact of the public awareness campaign.	Not later than two years after enactment (i.e., by March 27, 2022).

Provision Number	Title	Brief Description	Effective Date/Reporting Deadlines
Section 3301	Removing the Cap on OTA During Public Health Emergencies	Requires the Secretary to submit a report to specified congressional committees on use of this other transaction authority including the reasons for using it and any outcomes, benefits, and risks associated with its use.	After the expiration of the public health emergency (which began January 31, 2020).
Section 3401	Reauthorization of Health Professions Workforce Programs	Requires the Secretary to report to specified congressional committees on certain specified elements related to health workforce diversity programs that provide scholarships, loans, and educational assistance.	Not later than September 30, 2023, and not less than every five years thereafter.
Section 3402	Health Workforce Coordination	Requires the Secretary, in consultation with specified entities, to develop a comprehensive plan to coordinate HHS's health care workforce development programs.	Not later than one year after enactment (i.e., by March 27, 2021).
Section 3402	Health Workforce Coordination	Requires the Secretary to report to specified congressional committees about the implementation of the HHS's plan to coordinate its health care workforce development programs.	Not later than two years after enactment (i.e., by March 27, 2022).
Section 3403	Education and Training Relating to Geriatrics	Requires the Secretary to submit a report to specified congressional committees that describes certain specified elements of funded geriatric workforce programs.	Not later than four years after enactment of the Title VII Health Care Workforce Reauthorization Act of 2019 and every five years thereafter. ^a
Section 3404	Nursing Workforce Development	Requires the Secretary to submit a report to specified congressional committees on nursing workforce program improvements.	Not later than September 30, 2020, and biennially thereafter.

Provision Number	Title	Brief Description	Effective Date/Reporting Deadlines
Section 3404	Nursing Workforce Development	Requires a GAO report delivered to certain specified congressional committees that evaluates nursing workforce loan repayment programs.	Not later than 18 months after enactment (i.e., by September 27, 2021).
Section 3701	Exemption for Telehealth Services	Amends the IRC, applicable for plan years beginning on or before December 31, 2021, to allow health savings account (HSA)-qualified high-deductible health plans to provide “telehealth and other remote care service” benefits before the deductible is met.	Effective upon enactment (i.e., March 27, 2020).
Section 3701	Exemption for Telehealth Services	Amends the IRC, for plan years beginning on or before December 31, 2021, to provide that telehealth and other remote care would not be considered disqualifying coverage that would prevent an otherwise eligible individual from being considered HSA-eligible.	Effective upon enactment (i.e., March 27, 2020).
Section 3702	Inclusion of Certain Over-The-Counter Medical Products as Qualified Medical Expenses	Amends the IRC to allow OTC over-the-counter medicines and drugs (without a prescription) and menstrual care products to be considered qualified medical expenses for HSAs, Archer medical savings accounts, flexible spending arrangements, and health reimbursement arrangements.	<i>Distributions from savings accounts:</i> Applied to amounts paid after December 31, 2019. <i>Reimbursements:</i> Applied to expenses incurred after December 31, 2019.
Section 3708	Improving Care Planning for Medicare Home Health Services	Amends the SSA to allow a nurse practitioner, clinical nurse specialist, or physician assistant to certify the eligibility requirements for Medicare home health services under Parts A and B.	Effective no later than six months after enactment (i.e., by September 27, 2020).

Provision Number	Title	Brief Description	Effective Date/Reporting Deadlines
Section 3712	Revising Payment Rates for Durable Medical Equipment Under the Medicare Program through Duration of Emergency Period	Requires the Secretary to increase the Medicare payments for certain durable medical equipment, prosthetics, orthotics and supplies provided in areas that are not rural, and are contiguous.	Effective from the date that is 30 days after the enactment of the CARES Act (i.e., April 26, 2020) through the end of the emergency period.
Section 3713	Coverage of the COVID-19 Vaccine Under Part B of the Medicare Program Without Any Cost-Sharing	Medicare Part B and MA are required to cover a COVID-19 vaccine and its administration without beneficiary cost-sharing or application of the annual Part B deductible.	Effective upon enactment (i.e., March 27, 2020) and applicable to a COVID-19 vaccine on the date it receives FDA approval.
Section 3716	Clarification Regarding Uninsured Individuals	Amends the definition of uninsured individuals for the purposes of determining Medicaid eligibility for the state plan option to allow for time-limited COVID-19 testing without cost-sharing.	Effective during any portion of the public health emergency period defined in section 1135(g)(1)(B) of the act beginning on or after March 18, 2020.
Section 3717	Clarification Regarding Coverage of COVID-19 Testing Products	Modifies the definition of COVID-19 tests covered under Medicaid and CHIP for the specified public health emergency period to include IVDs, as defined in FDA regulation, which detect SARS-CoV-2 or diagnose COVID-19.	Effective during any portion of the public health emergency period defined in section 1135(g)(1)(B) of the act beginning on or after March 18, 2020.
Section 3718	Amendments Relating to Reporting Requirements with Respect to Clinical Diagnostic Laboratory Tests	Delays reporting requirements and phase-in schedule changes to the Medicare Clinical Laboratory Fee Schedule.	Delays reporting requirements by one year (initial reporting to begin January 1, 2022 and end March 31, 2022.) [Implementation schedule modified, with no payment reductions for 2021 and 15% limit on reductions in 2022 through 2024.]
Section 3851	Regulation of Certain Nonprescription Drugs that are Marketed Without an Approved Drug Application	Requires GAO to submit to Congress a study on the 18-month exclusivity period established by this act, including the impact of such exclusivity on consumer access to OTC drugs and other specified information.	Not later than four years after enactment (i.e., by March 27, 2024).

Provision Number	Title	Brief Description	Effective Date/Reporting Deadlines
Section 3854	Treatment of the Sunscreen Innovation Act (SIA)	Sunset FFDCA Chapter V Subchapter I “Nonprescription Sunscreen and Other Active Ingredients” (established by the SIA).	Sunset at the end of FY2022.
Section 3854	Treatment of the Sunscreen Innovation Act	Requires the Secretary to amend and revise the final administrative order concerning OTC sunscreen (currently under 21 C.F.R. Part 352). If the revised sunscreen order does not include certain information (e.g., effective SPF levels), then the Secretary must submit to Congress a report with the rationale for not including it and a plan to compile the necessary information.	Not later than 18 months after enactment (i.e., by September 27, 2021) and issued by the Secretary at least one year prior to the effective date of the revised order. No specified date for the report.
Section 3855	Annual Update to Congress on Appropriate Pediatric Indication for Certain OTC Cough and Cold Drugs	Requires the Secretary to submit to Congress a letter describing FDA’s progress in evaluating the cough and cold monograph under 21 C.F.R. Part 341 with respect to children under age six and, as appropriate, revising the monograph to address this age group.	Annually, beginning not later than one year after enactment (i.e., by March 27, 2021), until FDA completes its evaluation.
Section 3862	Fees Relating to Over-The-Counter Drugs	Requires the Secretary to establish OTC monograph drug facility fees for FY2021 and subsequent years and to publish fee revenue, facility fees, and OTC monograph order request fees in the <i>Federal Register</i> .	For FY2021, not later than the second Monday in May 2020 (i.e., by May 11, 2020) and for every subsequent fiscal year after September 30, 2021, not later than the second Monday in March that precedes such fiscal year.

Source: Table prepared by the Congressional Research Service (CRS) based on statutory language contained in Title III of the CARES Act (P.L. 116-136).

Notes: CARES Act=Coronavirus Aid, Relief, and Economic Security Act; C.F.R.=Code of Federal Regulations; CMS = Centers for Medicare and Medicaid Services; FDA=Food and Drug Administration; FFDCA= Federal Food, Drug, and Cosmetic Act; FY=Fiscal Year; GAO=Government Accountability Office; HHS = Department of Health and Human Services; HIPAA= Health Insurance Portability and Accountability Act; HSA=Health Savings Account; IRC=Internal Revenue Code; MA=Medicare Advantage; NASEM=National Academies of Science, Engineering, and Medicine; OTA=Other Transaction Authority; OTC=Over-The-Counter; Secretary=Secretary of the Department of Health and Human Services (HHS); SIA=Sunscreen Innovation Act; SSA=Social Security Act.

- a. The reference to the Title VII Health Care Workforce Reauthorization Act of 2019 appears to be a drafting error. However, this provision was included, with changes to the authorization date and amounts, in the Title VII Health Care Workforce Reauthorization Act of 2019. See version of S. 2997, as reported to the Senate on December 17, 2019.

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