



MEMORANDUM

July 13, 2021

To: Subcommittee on Health Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Subcommittee Markup of 19 Health Bills

On Thursday, July 15, 2021, at 11 a.m. (EDT) in the John D. Dingell Room, 2123 of the Rayburn House Office Building, and via Cisco Webex online video Conferencing, the Subcommittee on Health will hold a markup of the following 19 bills:

H.R. 4369, the “National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act”; **H.R. 654**, the “Drug-Free Communities Pandemic Relief Act”; **H.R. 2051**, the “Methamphetamine Response Act of 2021”; **H.R. 2379**, the “State Opioid Response Grant Authorization Act of 2021”; **H.R. 2364**, the “Synthetic Opioid Danger Awareness Act”; **H.R. 2355**, the “Opioid Prescription Verification Act of 2021”; **H.R. 2503**, the “Social Determinants Accelerator Act of 2021”; **H.R. 4026**, the “Social Determinants of Health Data Analysis Act of 2021”; **H.R. 3743**, the “Supporting the Foundation for the National Institutes of Health and the Reagan-Udall Foundation for the Food and Drug Administration Act”; **H.R. 550**, the “Immunization Infrastructure Modernization Act”; **H.R. 1550**, the “Promoting Resources to Expand Vaccination, Education and New Treatments for HPV Cancers Act of 2021” or the “PREVENT HPV Cancers Act of 2021”; **H.R. 951**, the “Maternal Vaccination Act”; **H.R. 925**, the “Data to Save Moms Act”; **H.R. 4387**, the “Maternal Health Quality Improvement Act of 2021”; **H.R. 3742**, the “Vaccine Information for Nursing Facility Operators” or the “Vaccine INFO Act”; **H.R. 1978**, the “Protecting Seniors Through Immunization Act of 2021”; **H.R. 2347**, the “Strengthening the Vaccines for Children Act of 2021”; **H.R. 3894**, the “Collecting and Analyzing Resources Integral and Necessary for Guidance for Social Determinants Act of 2021” or the “CARING for Social Determinants Act of 2021”; and **H.R. 4406**, the “Supporting Medicaid in the U.S. Territories Act.”

I. H.R. 4369, THE “NATIONAL CENTERS OF EXCELLENCE IN CONTINUOUS PHARMACEUTICAL MANUFACTURING ACT”

H.R. 4369, the “National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act”, introduced by Chairman Pallone (D-NJ) and Rep. Guthrie (R-KY), would amend the 21st Century Cures Act to direct the Food and Drug Administration (FDA) to designate National Centers of Excellence in Continuous Pharmaceutical Manufacturing (NCEs). NCEs would work with FDA and industry to craft a national framework for continuous manufacturing implementation, including supporting additional research and development of this technology, workforce development, standardization, and collaborating with manufacturers to

support adoption of continuous manufacturing. The bill authorizes \$80 million to be appropriated for NCEs each year from fiscal year (FY) 2021 through FY 2025.

An amendment in the nature of a substitute (AINS) is expected to be offered to expand the NCEs to include advanced manufacturing, to ensure NCEs implement research infrastructure to support accelerating drug development to respond to emerging medical threats or drug shortages, increase the authorization level, and make technical changes.

II. H.R. 654, THE “DRUG-FREE COMMUNITIES PANDEMIC RELIEF ACT”

H.R. 654, the “Drug-Free Communities Pandemic Relief Act”, was introduced by Reps. Joyce (R-OH) and Kilmer (D-WA). This bill would allow the Drug-Free Communities program to waive a grantee’s matching requirement during the COVID-19 pandemic if they are unable to meet the match.

III. H.R. 2051, THE “METHAMPHETAMINE RESPONSE ACT OF 2021”

H.R. 2051, the “Methamphetamine Response Act of 2021”, was introduced by Reps. Peters (D-CA) and Curtis (R-UT). This bill would designate methamphetamine as an emerging threat and requires the Office of National Drug Control Policy (ONDCP) to develop a national plan to prevent methamphetamine addiction from becoming a crisis.

IV. H.R. 2379, THE “STATE OPIOID RESPONSE GRANT AUTHORIZATION ACT OF 2021”

H.R. 2379, the “State Opioid Response Grant Authorization Act of 2021”, was introduced by Reps. Trone (D-MD) and Sherrill (D-NJ). This bill would authorize the State Opioid Response Grant program and would harmonize the uses of these grants with the opioid funding provided under the 21st Century Cures Act.

An AINS is expected to be offered that will provide transparency around awarded grants; require the U.S. Government Accountability Office (GAO) to assess how grant funding is allocated to states, state perspectives on funding levels, and how grant funding is awarded under similar programs; and make technical changes.

V. H.R. 2364, THE “SYNTHETIC OPIOID DANGER AWARENESS ACT”

H.R. 2364, the “Synthetic Opioid Danger Awareness Act” was introduced by Reps. Kim (D-NJ) and Pappas (D-NH). This legislation requires the Centers for Disease Control and Prevention (CDC) to implement a public education campaign related to synthetic opioids, including fentanyl and its analogues. In addition, the National Institute for Occupational Safety and Health would be required to publish a training guide and webinar for first responders and other individuals related to exposures to synthetic opioids.

An AINS is expected to be offered which makes technical changes to the education and training on synthetic opioids.

VI. H.R. 2355, THE “OPIOID PRESCRIPTION VERIFICATION ACT OF 2021”

H.R. 2355, the “Opioid Prescription Verification Act of 2021”, was introduced by Reps. Davis (R-IL), Bilirakis (R-FL), and Wagner (R-MO). This bill directs federal agencies to develop, disseminate, and periodically update training materials for pharmacists on verifying the identity of individuals picking up a prescription for a controlled substance. It also creates a preference for grants awarded to states by CDC for evidence-based overdose prevention activities to states that utilize prescription drug monitoring programs (PDMPs), require pharmacists to confirm the identity of individuals retrieving prescriptions for schedule II, III, or IV controlled substances via state-approved photo identification, and require entry of information about the purchase of such prescriptions into the State’s PDMPs including the quantity dispensed, the name of the patient, the name of the ultimate user, the name of the individual picking up the prescription if different, and the date filled.

An AINS is expected to be offered that would amend the identity verification requirements in the bill as well as encourage awards to states which utilize electronic prescribing systems for prescriptions.

VII. H.R. 2503, THE “SOCIAL DETERMINANTS ACCELERATOR ACT OF 2021”

H.R. 2503, the “Social Determinants Accelerator Act of 2021”, introduced by Rep. Bustos (D-IL) and 22 original cosponsors, directs the Secretary of Health and Human Services (HHS) in coordination with the Centers for Medicare and Medicaid Services (CMS) to establish an interagency council on social determinants of health to improve the coordination of federal programs and funding. I would also provide grants to State, local, and Tribal health agencies to create and implement social determinants accelerator plans that are designed to advance the health and well-being of individuals at-risk for poor health outcomes secondary to adverse social determinants of health.

An AINS is expected to be offered that would amend the Social Determinants Accelerator Council established in the legislation, make technical changes to the grant award programs to states, among other changes.

VIII. H.R. 4026, THE “SOCIAL DETERMINANTS OF HEALTH DATA ANALYSIS ACT OF 2021”

H.R. 4026, the “Social Determinants of Health Data Analysis Act of 2021”, introduced by Reps. Burgess (R-TX) and Blunt Rochester (D-DE), requires the Comptroller General of the United States to submit to Congress within two years of enactment a report on the actions taken by the Secretary of HHS to address social determinants of health. The report shall include: an analysis of how data collection undertaken by HHS complies with Federal and state privacy laws and regulations, a description of any coordination by HHS with other relevant Federal, State, and local agencies, an identification of any potential for duplication or any barriers, and recommendations on how to foster public-private partnerships and leverage the private sector to address social determinants of health.

IX. H.R. 3743, THE “SUPPORTING THE FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH AND THE REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION ACT”

H.R. 3743, the “Supporting the Foundation for the National Institutes of Health and the Reagan-Udall Foundation for the Food and Drug Administration Act”, introduced by Reps. Hudson (R-NC) and Eshoo (D-CA), would authorize the National Institutes of Health (NIH) and FDA to increase transfer authority for funding to their supporting foundations, the Foundation for the National Institutes of Health (FNIH) and the Reagan-Udall Foundation for the Food and Drug Administration.

X. H.R. 550, THE “IMMUNIZATION INFRASTRUCTURE MODERNIZATION ACT”

H.R. 550, the “Immunization Infrastructure Modernization Act”, introduced by Reps. Kuster (D-NH) and Bucshon (R-IN), would authorize \$400 million for grants to expand, enhance, and improve immunization information systems administered by health departments and used by health care providers. This bill directs HHS to develop a strategy to improve immunization information systems, designate data and technology standards for the systems, and award grants to health departments and government organizations to improve their immunization systems based on the developed standards. It also requires HHS to report to the Committee one year after enactment on the barriers to public health authorities on implementing interoperable immunization information systems, the exchange of information, or reporting, as well as the barriers to establish effective networks to support immunization reporting and monitoring and an assessment of immunization coverage and access including any disparities or gaps.

XI. H.R. 1550, THE “PROMOTING RESOURCES TO EXPAND VACCINATION, EDUCATION AND NEW TREATMENTS FOR HPV CANCERS ACT OF 2021” OR THE “PREVENT HPV CANCERS ACT OF 2021”

H.R. 1550, the “PREVENT HPV Cancers Act of 2021”, introduced by Reps. Castor (D-FL) and Schrier (D-WA), would create a national CDC public awareness campaign targeted to communities with the lowest HPV vaccination rates, with the goal of increasing vaccinations and preventing HPV-associated cancers. This bill would also provide funding to enhance HPV cancer research at the National Cancer Institute, improve state immunization information systems, and expand CDC’s Cervical Cancer Early Detection initiative.

An AINS is expected to be offered to streamline the public awareness provisions of H.R. 1550 with Johanna’s Law,¹ an existing CDC program aimed at increasing awareness of HPV and gynecologic cancers, while reauthorizing and modernizing the program to cover all HPV-associated cancers.

¹ 42 U.S.C. 247b-17(d).

XII. H.R. 951, THE “MATERNAL VACCINATION ACT”

H.R. 951, the “Maternal Vaccination Act”, introduced by Rep. Sewell (D-AL) and 44 original cosponsors, would require CDC to carry out a national campaign to increase awareness of maternal vaccinations for pregnant and postpartum individuals and their children and to increase maternal vaccination rates with a focus on communities with historically high rates of unvaccinated individuals. The bill authorizes \$2 million for each year from FY 2022 through 2026.

An AINS is expected to be offered to streamline provisions of H.R. 951 with existing immunization programs signed into law as part of the 2021 Consolidated Appropriations Act.²

XIII. H.R. 925, THE “DATA TO SAVE MOMS ACT”

H.R. 925, the “Data to Save Moms Act”, introduced by Rep. Davids (D-KS) and 34 original cosponsors, expands data collection and research on maternal morbidity and mortality among minority populations through additional funding for maternal mortality review committees (MMRCs) in order to promote representative community engagement and develop initiatives to conduct outreach and community engagement efforts on the work of MMRCs. Additionally, H.R. 925 requires the Secretary of HHS to consult with relevant stakeholders to review existing maternal health data collection processes and measures and make recommendations on ways to improve such processes and measures. The legislation also requires the Indian Health Service (IHS) to conduct a comprehensive study on maternal mortality and severe maternal morbidity in the populations of American Indian and Alaska Native individuals and report to Congress on its findings. Finally, the legislation also establishes a grant program to award grants to research centers, health professions schools and programs, and other entities at minority-serving institutions to study specific aspects of the maternal health crisis among pregnant and postpartum individuals from racial and ethnic minority groups.

An AINS is expected to make technical and conforming changes based on technical assistance feedback. The AINS also makes changes to Section 4 and Section 5 to revise the parameters of these provisions.

XIV. H.R. 4387, THE “MATERNAL HEALTH QUALITY IMPROVEMENT ACT OF 2021”

H.R. 4387, the “Maternal Health Quality Improvement Act of 2021”, introduced by Reps. Kelly (D-IL), Bucshon, Adams (D-NC), Burgess, Hayes (D-CT), and Latta (R-OH), amends the Public Health Service Act to authorize grant funding to identify, develop, or disseminate best practices to improve maternal health quality and outcomes and eliminate preventable maternal mortality and severe maternal morbidity. The bill also establishes a grant program to award funding to accredited health professional schools for the training of health care professionals in order improve the provision of maternal health care with respect to perceptions and biases that may affect care.

² Pub. L. No. 116-260.

Additionally, H.R. 4387 authorizes a competitive grant program to support perinatal quality collaboratives to improve perinatal care and health outcomes for pregnant and postpartum women and their infants. The bill also permits the Secretary of HHS to award grants to States, Indian Tribes, and Tribal organizations to deliver integrated health care services to pregnant and postpartum women. Finally, the legislation also includes provisions to improve rural maternal and obstetric care, including data collection and care networks, as well as telehealth resources and training.

XV. H.R. 3742, THE “VACCINE INFORMATION FOR NURSING FACILITY OPERATORS” OR THE “VACCINE INFO ACT”

H.R. 3742, the “Vaccine INFO Act”, introduced by Reps. Bilirakis and Rice (D-NY), would require the Secretary of HHS to issue revised regulations requiring dissemination of information to staff on all vaccines recommended by ACIP for health care personnel, including information on the benefits and potential side effects of receiving the vaccines and where they may receive the vaccines.

XVI. H.R. 1978, THE “PROTECTING SENIORS THROUGH IMMUNIZATION ACT OF 2021”

H.R. 1978, the “Protecting Seniors Through Immunization Act of 2021”, introduced by Reps. Kuster and Bucshon, would ensure that all Medicare Part D covered vaccines recommended by ACIP have no beneficiary cost-sharing, including no application of a deductible, no application of coinsurance, or no application of the initial coverage limit or out-of-pocket threshold. The bill would also require additional information to be shared regarding vaccines for seniors as part of the Medicare & You handbook and would require CDC, in collaboration with CMS, to conduct a study on the uptake of vaccines among the Medicare beneficiary population.

An AINS is expected to be offered to incorporate technical assistance.

XVII. H.R. 2347, THE “STRENGTHENING THE VACCINES FOR CHILDREN ACT OF 2021”

H.R. 2347, the “Strengthening the Vaccines for Children Act of 2021”, introduced by Reps. Schrier, Butterfield (D-NC), McKinley (R-WV), and Joyce, would enhance the Vaccines for Children Program, which provides ACIP-recommended vaccines to low-income children. These enhancements include extending eligibility to children enrolled in CHIP, making changes to ensure adequate payment for multi-component vaccines, temporarily increasing provider rates to the Medicare level, and providing an FMAP increase, among other programmatic changes. The bill would also require the CDC to publicly report information related to demographic data of those vaccinated under the program, and require a GAO study on the analysis of the effects of the bill’s provisions on vaccination rates and provider participation.

An AINS is expected to be offered.

XVIII. H.R. 3894, THE “COLLECTING AND ANALYZING RESOURCES INTEGRAL AND NECESSARY FOR GUIDANCE FOR SOCIAL DETERMINANTS ACT OF 2021” OR THE “CARING FOR SOCIAL DETERMINANTS ACT OF 2021”

H.R. 3894, the “CARING for Social Determinants Act of 2021”, introduced by Reps. Blunt Rochester and Bilirakis, requires the Secretary of HHS to provide guidance and technical assistance to states on how to address social determinants of health through Medicaid and CHIP. It requires that the guidance be updated every three years.

XIX. H.R. 4406, THE “SUPPORTING MEDICAID IN THE U.S. TERRITORIES ACT”

H.R. 4406, the “Supporting Medicaid in the U.S. Territories Act,” introduced by Reps. Soto (D-FL) and Bilirakis, and five original co-sponsors, would provide five years of enhanced Medicaid funding for Puerto Rico, and eight years of enhanced Medicaid funding for the U.S. Virgin Islands, American Samoa, the Commonwealth of the Northern Mariana Islands, and Guam. It would extend the current enhanced federal medical assistance percentage for each territories for the length of the time of the increased funding. It would also make certain programmatic improvements to the Puerto Rico Medicaid program, including requiring increased provider payment rates, strengthening program integrity, and improving contracting practices.