Brownstein

Division H, Title II – Department of Health and Human Services

Health Resources and Services Administration (HRSA)

- $9.7 billion in FY 2023; an increase of $852 million over FY 2022 enacted levels.
    - Provides $322 million for Community Health Centers and Ryan White programs to increase investments in communities and support PrEP services to protect people at highest risk for getting HIV; and
    - $55 million, an increase of $26 million, for State Maternal Health Innovation Grants to expand grants for maternal care services, workforce needs and postpartum care services.

Centers for Disease Control and Prevention (CDC)

- $9.2 billion in FY 2023; an increase of $760 million over FY 2022 enacted levels.
    - $108 million, an increase of $25 million above FY 2022, to expand support for Safe Motherhood/Infant Health;
    - $220 million in the Domestic HIV/AIDS Prevention and Research programs to develop and deploy innovative data management solutions, increase access to PrEP, and better detect and respond to HIV clusters;
    - $505 million for opioid overdose surveillance and prevention;
    - $350 million in flexible funding for public health infrastructure and capacity;
    - $750 million for emerging and zoonotic infectious diseases, of which $197 million is for the antibiotic resistance initiative;
    - $1.4 billion for chronic disease prevention and health promotion, with $58.4 million going toward nutrition, physical activity and obesity;
    - $38.5 million going toward Alzheimer's disease;
    - $155.1 million going toward heart disease and stroke; and
    - $155.1 million going toward diabetes.

National Institutes of Health (NIH)

- $47.5 billion in FY 2023; an increase of $2.5 billion over FY 2022 enacted levels. This includes:
    - $226 million for Alzheimer's disease and related dementias;
    - $45 million for research related to opioids, methamphetamines and pain;
    - $88 million to address health disparities;
    - $40 million to address cybersecurity threats; and
    - $60 million to support the second phase of the BRAIN initiative.

Substance Abuse and Mental Health Services Administration (SAMHSA)

- $7.5 billion in FY 2023; an increase of $970 million over FY 2022 enacted levels. This includes:
    - $4 billion for substance abuse treatment programs;
    - $7 million for the Behavioral Health Crisis and 988 Coordinating Office; and
    - $17.5 million for Project AWARE to support efforts in high-crime, high-poverty areas.

Agency for Healthcare Research and Quality (AHRQ)

- $373 million in FY 2023; an increase of $23 million over FY 2022 enacted levels. This includes:
    - $10 million to study long COVID; and
    - $20 million to fund research, testing and solutions to avoid diagnostic error.

Centers for Medicare and Medicaid Services (CMS)

- $1.1 trillion in mandatory and discretionary spending in FY 2023; an increase of $90 billion over FY 2022 enacted levels. This includes:
    - $35 million for the Senior Medicare Patrol to fight waste, fraud and abuse;
    - Directs CMS to provide feedback on providing appropriate relief for struggling hospitals in rural and underserved communities; and
    - Directs CMS, in collaboration with CDC, to develop new or identify existing hospital quality measures for adult and pediatric sepsis that could be implemented.

Administration for Children and Families (ACF)

- $50 billion in FY 2023; an increase of $1.7 billion over FY 2022 enacted levels**.** This includes:
    - $4 billion for the Low-Income Home Energy Assistance program; and
    - $5 million for the National Human Trafficking Hotline.

Administration for Community Living

- $2.6 billion in FY 2023; an increase $219 million over FY 2022 enacted levels. This includes:
    - $8.5 million to the Holocaust Survivor's Assistance program;
    - $2 million for a direct care workforce demonstration project to identify and reduce barriers to entry for a diverse and high-quality direct care workforce; and
    - $15 million for the nationwide Adult Protective Services formula grant program.

Office of the Secretary

- $6.9 billion in FY 2023; an increase of $1.1 billion over FY 2022 enacted levels. This includes:
    - $1.5 billion for the Advanced Research Projects for Health (ARPA-H);
    - $950 million, an increase of $200 million over FY 2022, for the Biomedical Advanced Research and Development Authority (BARDA); and
    - $965 million, an increase of $120 million over FY 2022, for the Strategic National Stockpile (SNS).

Division FF, Health and Human Services

TITLE I—RESTORING HOPE FOR MENTAL HEALTH AND WELL-BEING

Subtitle A—Mental Health and Crisis Care Needs

CHAPTER 1—CRISIS CARE SERVICES AND 9–8–8 IMPLEMENTATION

Sec. 1101. Behavioral Health Crisis Coordinating Office.

- Requires the Secretary to establish an office to coordinate work relating to behavioral health crises care across the SAMHSA, the CMS, the HRSA and external stakeholders.
- Requires the office to convene federal, state, tribal, local and private partners; launch and manage federal workgroups charged with making recommendations regarding issues related to mental health and substance abuse disorder crises; and support technical assistance, data analysis and evaluation functions in order to assist in developing crisis care systems.
- Appropriates $5 million annually for FY 2023 through 2027 to carry out this section.
- **Impact:** Creates a behavioral health crisis coordinating office to coordinate the work of the private and public sectors related to mental health and substance abuse disorder crises.

Sec. 1102. Crisis Response Continuum of Care.

- Requires the Assistant Secretary for Mental Health and Substance Use to facilitate the identification and publication of best practices for a crises response continuum of care related to mental health and substance abuse disorders.
- The best practices must be published no later than one year after the date of enactment of the bill, and after three years, the best practices must include any updates.
- **Impact:** Requires the Secretary to identify and publish best practices for a crises response continuum of care.

Sec. 1103. Suicide Prevention Lifeline Improvement.

- Requires an awareness initiative and ongoing outreach to the public regarding the suicide prevention lifeline program.
- Requires the Secretary to develop, implement and make public a plan no later than one year after the date of enactment to ensure high quality of the lifeline.
- Requires the Secretary to carry out a pilot program to research, analyze and employ various technologies and platforms of communication for suicide prevention.
- Appropriates $101.62 million annually for FY 2023 through 2027 to carry out this section.
- **Impact:** Increases awareness of the suicide prevention lifeline through an awareness initiative and ongoing outreach to the public.

CHAPTER 2—INTO THE LIGHT FOR MATERNAL MENTAL HEALTH AND SUBSTANCE USE DISORDERS

Sec. 1111. Screening and Treatment for Maternal Mental Health and Substance Use Disorders.

- Allows women who are postpartum to receive screening and treatment for maternal mental health and substance use disorders.

- Appropriates $24 million annually for FY 2023 through 2027 to carry out this section.
- **Impact:** Expands access to screening and treatment for maternal mental health and substance use disorders.

Sec. 1112. Maternal Mental Health Hotline.

- Requires the Secretary to maintain a national maternal mental health hotline to provide emotional support, information, brief intervention and mental health and substance use disorder resources to pregnant and postpartum women at risk of, or affected by, maternal mental health and substance use disorders.
- Appropriates $10 million annually for FY 2023 through 2027 to carry out this section.
- **Impact:** Creates a national maternal mental health hotline.

Sec. 1113. Task Force on Maternal Mental Health.

- Establishes the Task Force on Maternal Mental Health for the purposes of identifying, evaluating and making recommendations to coordinate and improve federal activities related to address maternal mental health conditions.
- The Task Force must consist of federal and non-federal members.
- The Task Force will exist until Sept. 30, 2027.
- **Impact:** Creates a Task Force for the purpose of improving maternal mental health conditions.

Sec. 1114. Residential Treatment Program for Pregnant and Postpartum Women Pilot Program Reauthorization.

- Provides technical changes to section 508(r) of the Public Health Service Act.

CHAPTER 3—REACHING IMPROVED MENTAL HEALTH OUTCOMES FOR PATIENTS

Sec. 1121. Innovation for Mental Health.

- Appropriates $10 million annually for FY 2023 through 2027 to the National Mental Health and Substance Use Policy Laboratory.
- Establishes the Interdepartmental Serious Mental Illness Coordinating Committee to submit a report to Congress that includes a summary of advances in serious mental illness and serious emotional disturbance research; an evaluation of the effect that federal programs have on the public's health; and specific recommendations for actions that agencies can take to better coordinate the administration of mental health services.
- The committee will exist until Sept. 30, 2027.
- **Impact:** Improves mental health services by providing funding for the National Mental Health and Substance Use Policy Laboratory and creating the Serious Mental Illness Coordinating Committee.

Sec. 1122. Crisis Care Coordination.

- Establishes a pilot program where the Secretary will award competitive grants to states, localities, territories, Indian tribes, and tribal organizations to create a new, or enhance existing, mobile crisis response teams that divert the response for mental health and substance use disorder crises for law enforcement to mobile crisis teams.
- The mobile crisis team is a team of individuals that is available to respond to individuals in mental health and substance use disorder crises and provide immediate stabilization.
- The Secretary must prioritize applications that account for the specific needs of the communities to be served.
- Appropriates $10 million annually for FY 2023 through 2027 to carry out this section.
- Appropriates $24.96 million annually for FY 2023 through 2027 for mental health awareness training grants.
- Appropriates $30 million annually for FY 2023 through 2027 for adult suicide prevention.
- **Impact:** Creates a new mobile crisis team and provides funding for existing crisis care programs.

Sec. 1123. Treatment of Serious Mental Illness.

- Appropriates $9 million annually for FY 2023 through 2027 for the assertive community treatment grant program.
- Appropriates $22 million annually for FY 2023 through 2027 for assisted outpatient treatment.
- **Impact:** Provides funding for existing programs that treat serious mental illness.

Sec. 1124. Study on the Costs of Serious Mental Illness.

- Requires the Secretary, in consultation with the Assistant Secretary for Mental Health and Substance Use, the Assistant Secretary for Planning and Evaluation, the Attorney General of the United States, the Secretary of Labor and the Secretary of Housing and Urban Development, to conduct a study on the direct and indirect costs of serious mental illness with respect to nongovernmental entities and the federal government, state, local and tribal governments.
- The study must include the costs to the health care system for health services, homelessness, structured residential facilities and other supportive housing for residential and custodial care services, law enforcement encounters, mental illness on employment, family members and caregivers, and any other relevant programs.
- A report containing the results of the study must be submitted to Congress no later than two years after the enactment of this bill.
- **Impact:** Creates a method of studying the impact of serious mental illness on society as a whole.

CHAPTER 4—ANNA WESTIN LEGACY

Sec. 1131. Maintaining Education and Training on Eating Disorders.

- Requires the Secretary to maintain, by competitive grant or contract, a Center of Excellence for Eating Disorders to improve the identification of interventions for and treatment of eating disorders in a manner that is developmentally, culturally and linguistically appropriate.
- Appropriates $1 million annually for FY 2023 through 2027 to carry out this section.
- **Impact:** Creates the Center of Excellence for Eating Disorders to improve the treatment for eating disorders.

CHAPTER 5—COMMUNITY MENTAL HEALTH SERVICES BLOCK GRANT REAUTHORIZATION

Sec. 1141. Reauthorization of Block Grants for Community Mental Health Services.

- Appropriates $857.57 million annually for FY 2023 through 2027 for Community Mental Health Services Block Grant Reauthorization.
- **Impact:** Reauthorizes the Community Mental Health Services Block Grant

CHAPTER 6—PEER-SUPPORTED MENTAL HEALTH SERVICES

Sec. 1151. Peer-Supported Mental Health Services.

- Requires the Secretary to award grants to eligible entities to enable such entities to develop, expand and enhance access to mental health peer-delivered services.
- Grants should be used to develop, expand and enhance national, statewide or community-focused programs, including virtual peer-support services and technology-related capabilities.
- The Secretary should give special consideration to the unique needs of rural areas in awarding grants.
- Appropriates $13 million annually for FY 2023 through 2027 to carry out this section.
- **Impact:** Builds out the network for mental health peer-delivered services.

Subtitle B—Substance Use Disorder Prevention, Treatment, and Recovery Services

CHAPTER 1—NATIVE BEHAVIORAL HEALTH RESOURCES

Sec. 1201. Behavioral Health and Substance Use Disorder Resources for Native Americans.

- Requires that the Secretary, in consultation with the director of the Indian Health Service (as appropriate), must award funds to eligible entities to provide services for the prevention of, treatment of and recovery from mental health and substance use disorders among American Indians, Alaska Natives and Native Hawaiians.
- Appropriates $80 million annually for FY 2023 through 2027 to carry out this section.
- **Impact:** Creates a grant program to address mental health and substance use disorders among American Indians, Alaska Natives and Native Hawaiians.

CHAPTER 2—SUMMER BARROW PREVENTION, TREATMENT, AND RECOVERY

Sec. 1211. Grants for the Benefit of Homeless Individuals.

- Provides technical changes to Section 506(e) of the Public Health Service Act.

Sec. 1212. Priority Substance Use Disorder Treatment Needs of Regional and National Significance.

- Appropriates $521.5 million annually for FY 2023 through 2027 for Section 509 of the Public Health Service Act.
- **Impact:** Increases funding for priority substance use disorder treatment needs.

Sec. 1213. Evidence-Based Prescription Opioid and Heroin Treatment and Interventions Demonstration.

- Provides technical changes to Section 514B of the Public Health Service Act.

Sec. 1214. Priority Substance Use Disorder Prevention Needs of Regional and National Significance.

- Appropriates $218.2 million annually for FY 2023 through 2027 for Section 516 of the Public Health Service Act.
- **Impact:** Increases funding for priority substance use disorder prevention needs.

Sec. 1215. Sober Truth on Preventing (STOP) Underage Drinking Reauthorization.

- Requires the Secretary, in collaboration with the federal official, to continue to support and enhance the efforts of the Interagency Coordinating Committee that began operating in 2004, focusing on underage drinking.
- The committee must guide policy and program development across the federal government with respect to underage drinking.
- Appropriates $2.5 million annually for FY 2023 through 2027.
- Requires the Assistant Secretary for Mental Health and Substance Use, in consultation with the director of the Office of National Drug Control Policy, to award enhancement grants, not to exceed $60,000 per year or four years, to eligible entities to design, implement, evaluate and disseminate comprehensive strategies to maximize the effectiveness of communitywide approaches to preventing and reducing underage drinking.
- Appropriates $11.5 million annually for FY 2023 through 2027 for the enhancement grants.
- Requires the Secretary to provide grants to one or more entities representing pediatric providers and other related health professionals with demonstrated ability to increase the effective practices to reduce the prevalence or alcohol use among individuals under the age of 21, including college students.
- Appropriates $3 million annually for FY 2023 through 2027 for the grants.
- **Impact:** Funding to carry out several programs aimed at preventing underage drinking.

Sec. 1216. Grants for Jail Diversion Programs.

- Appropriates $14 million annually for FY 2023 through 2027 for grants for jail diversion programs.
- **Impact:** Increases funding to provide grants for jail diversion programs.

Sec. 1217. Formula Grants to States.

- Provides technical changes to Section 521 of the Public Health Service Act.

Sec. 1218. Projects for Assistance in Transition from Homelessness.

- Provides technical changes to Section 535(a) of the Public Health Service Act.

Sec. 1219. Grants for Reducing Overdose Deaths.

- Allows a state, territory, locality or Indian tribe or tribal organization or tribal organization to receive a grant for reducing overdose deaths.
- Permits an eligible entity to award subgrants to a federally qualified health center, an opioid treatment program, any practitioner dispensing narcotic drugs or any nonprofit organization that the Secretary deems appropriate.
- **Impact:** Provides grants to reduce overdose deaths.

Subtitle C—Access to Mental Health Care and Coverage

CHAPTER 1—IMPROVING UPTAKE AND PATIENT ACCESS TO INTEGRATED CARE SERVICES

Sec. 1301. Improving Uptake and Patient Access to Integrated Care Services.

- Expands the list of eligible entities and updates requirements to receive up to $2 million in grants and cooperative agreements to improve integrated care for physical and behavioral health care. An award must be used to:
    - Promote full integration and collaboration in clinical practices between physical and behavioral health care;
    - Support the improvement of integrated care models for physical and behavioral health care to improve overall wellness and physical health status;
    - Promote the implementation and improvement of bidirectional integrated care services, including evidence-based screening, assessment, diagnosis, prevention, treatment and recovery services for mental and substance use disorders, and co-occurring physical health conditions and chronic diseases; and
    - Support the implementation of integrated care through hiring staff, contracting psychiatric consultants and behavioral health care managers, and upgrading software and other resources needed to establish a patient registry. No more than 10% may be used for administrative purposes.
- Requires an annual report to Congress, starting within 18 months of enactment, on the uptake of integrated care models.
- Authorizes $60 million annually through FY 2027.
- **Impact:** Expands the scope of grants to improve integrated care services.

CHAPTER 2—HELPING ENABLE ACCESS TO LIFESAVING SERVICES

Sec. 1311. Reauthorization and Provision of Certain Programs to Strengthen the Health Care Workforce.

- Reauthorizes mental and behavioral health education and training grants through FY2 027.
- Expands a training demonstration program to include counselors and nurses in pediatric settings. Also authorizes $31.7 million annually through FY 2027.
- **Impact:** Ensures grants to educate and train behavioral health care workers, including for pediatric care, continue for an additional five years. Also increases funding by $21.7 million each year.

Sec. 1312. Reauthorization of Minority Fellowship Program.

- Reauthorizes the Minority Fellowship Program to help provide culturally competent mental health and substance use disorder care and provides $25 million annually through FY 2027.
- **Impact:** Increases funding for the Minority Fellowship Program by $12.3 million each year.

CHAPTER 3—ELIMINATING THE OPT-OUT FOR NONFEDERAL GOVERNMENTAL HEALTH PLANS

Sec. 1321. Eliminating the Opt-Out for Nonfederal Governmental Health Plans.

- Prohibits new treatment limitations and prohibits renewing treatment limitations that would expire within 180 days.
- **Impact:** Eliminates the opt-out for non-federal governmental health plans for mental health parity requirements.

CHAPTER 4—MENTAL HEALTH AND SUBSTANCE USE DISORDER PARITY IMPLEMENTATION

Sec. 1331. Grants to Support Mental Health and Substance Use Disorder Parity Implementation.

- Provides grants for states to ensure compliance with the mental health and substance use disorder parity provisions.
- Authorizes $10 million annually through FY 2027.
- **Impact:** Provides resources for states to enforce parity requirements for mental health and substance use disorder services.

Subtitle D—Children and Youth

CHAPTER 1—SUPPORTING CHILDREN'S MENTAL HEALTH CARE ACCESS

Sec. 1401. Technical Assistance for School-Based Health Centers.

- Provides technical assistance, either through grants or contracts, to support school-based health centers' mental health and substance use disorder services. Such

assistance may include help with program operations and implementing evidence-based best practices.
- **Impact:** Ensures school-based health centers have technical resources in addition to service grants.

Sec. 1402. Infant and Early Childhood Mental Health Promotion, Intervention, and Treatment.
- Adds technical assistance for grants awarded to develop, maintain or enhance infant and early childhood mental health promotion, intervention and treatment programs.
- Authorizes $50 million annually through FY 2027 for this grant program.
- **Impact:** Increases funding for infant and early childhood mental health promotion, intervention and treatment grants by $30 million each year.

Sec. 1403. Co-Occurring Chronic Conditions and Mental Health in Youth Study.
- Directs HHS to complete a study within one year on the rates of suicidal behaviors among children and adolescents with chronic illnesses, including substance use disorders, autoimmune disorders and heritable blood disorders.
- Requires HHS to submit a report to Congress on the results of the above study, including recommendations for early intervention services, best practices to support youth emotional and mental health needs, and strategies to lower the rates of suicidal behaviors in children and adolescents.
- **Impact:** The study and report will provide data to demonstrate links between mental health and co-occurring chronic conditions.

Sec. 1404. Best Practices for Behavioral and Mental Health Intervention Teams.
- Requires HHS to submit a report to Congress identifying best practices related to using behavioral and mental health intervention teams.
- Stipulates that the report should consider the following:
    - How behavioral and mental health intervention teams might operate effectively while protecting the rights and privacy of individuals;
    - How such teams identify and support students exhibiting behaviors interfering with learning or posing a risk of harm to self or others;
    - How such teams access evidence-based professional development;
    - How such teams ensure they are composed of trained, diverse stakeholders with expertise in child and youth development, behavioral and mental health, and disability; and
    - How such teams can help mitigate inappropriate referral to mental health services or law enforcement by implementing evidence-based interventions that meet student needs.
- **Impact:** The required report will help inform future policymaking on the use of behavioral and mental health intervention teams in school settings.

CHAPTER 2—CONTINUING SYSTEMS OF CARE FOR CHILDREN

Sec. 1411. Comprehensive Community Mental Health Services for Children with Serious Emotional Disturbances.

- Authorizes $125 million annually for comprehensive community mental health services for children with serious emotional disturbances through FY 2027.
- **Impact:** Increases funding for comprehensive community mental health services for children with serious emotional disturbances by $6 million each year.

Sec. 1412. Substance Use Disorder Treatment and Early Intervention Services for Children and Adolescents.

- Provides a five-year reauthorization for grants to provide:
    - Early identification and services for children, adolescents and young adults who are at risk of substance use disorders;
    - Substance use disorder treatment services for children, adolescents and young adults, including those co-occurring mental illness and substance use disorders; and
    - Assistance to pregnant women and parenting women with substance use disorders, in obtaining treatment services, linking mothers to community resources to support independent family lives, and staying in recovery so that children are in safe, stable home environments and receive appropriate health care services.
- **Impact:** Ensures a continuation of resources for substance use disorder treatment and early intervention services for children and adolescents.

CHAPTER 3—GARRETT LEE SMITH MEMORIAL REAUTHORIZATION

Sec. 1421. Suicide Prevention Technical Assistance Center.

- Requires an annual report on the activities of the research, training and technical assistance resource center regarding the prevention of suicide among all ages.
- Authorizes $9 million annually through FY 2027.
- **Impact:** Increases funding for the suicide prevention technical assistance center by $3 million each year.

Sec. 1422. Youth Suicide Early Intervention and Prevention Strategies.

- Expands eligibility for grants to create and implement statewide and tribal youth suicide early intervention and prevention strategies to include pediatric health programs.
- Requires a report to Congress by the end of 2025 analyzing the use of the grants for suicide prevention.
- Authorizes $40 million annually through FY 2027.
- **Impact:** Increases funding for statewide and tribal youth suicide early intervention and prevention by $10 million each year.

Sec. 1423. Mental Health and Substance Use Disorder Services for Students in Higher Education.

- Reauthorizes grants to higher education institutions to enhance services for students with mental health or substance use disorders.

- Authorizes $7 million annually through FY 2027.
- **Impact:** Clarifies wording around the use of grant funds and maintains the previous amount of funding for another five years.

Sec. 1424. Mental and Behavioral Health Outreach and Education at Institutions of Higher Education.

- Reauthorizes a national public education campaign focused on mental and behavioral health at institutions of higher education.
- Authorizes $1 million annually through FY 2027.
- **Impact:** Maintains resources for outreach and education around mental health services available at higher education institutions.

CHAPTER 4—MEDIA AND MENTAL HEALTH

Sec. 1431. Study on the Effects of Smartphone and Social Media Use on Adolescents.

- Directs HHS to study adolescent smartphone and social media use and its effect on emotional, behavioral and physical health and development within five years of enactment.
- **Impact:** The required study will help inform future policymaking on the effects of smartphone and social media use on adolescents' mental and physical health.

Sec. 1432. Research on the Health and Development Effects of Media and Related Technology on Infants, Children and Adolescents.

- Directs HHS to research the health and developmental effects of exposure to, and use of, social media, applications, websites, television, motion pictures, artificial intelligence, mobile devices, computers, video games, virtual and augmented reality, and other internet or broadcasted content, networks or platforms for infants, children and adolescents.
- Suggested topics for the required research include:
    - Effects on cognitive development, such as language development or learning abilities;
    - Effects on physical health, such as sleeping and eating routines, diet and exercise; and
    - Effects on mental health, such as self-awareness, social awareness, relationship skills, decision-making, violence, bullying, privacy and mental disorders.
- Requires a report to Congress within two years of enactment on the progress made in improving data and expanding research on the health and developmental effects of media.
- **Impact:** The required research and report will help inform future policymaking on the effects of a wide range of media on the health and development of infants, children and adolescents.

Subtitle E—Miscellaneous Provisions

Sec. 1501. Limitations on Authority.

- Prevents the Secretary from allocating funding or requiring award recipients to prioritize, dedicate or allocate funding without consideration of the incidence, prevalence or determinants of mental health or substance use issues, unless such allocation or requirement is consistent with statute, regulation or other federal law, in carrying out any program of the Substance Abuse and Mental Health Services Administration.
- **Impact:** Requires the consideration mental health or substance use issues in carrying out Substance Abuse and Mental Health Services Administration programs.

TITLE II—PREPARING FOR AND RESPONDING TO EXISTING VIRUSES, EMERGING NEW THREATS, AND PANDEMICS

Subtitle A—Strengthening Federal and State Preparedness

CHAPTER 1—FEDERAL LEADERSHIP AND ACCOUNTABILITY

Sec. 2101. Appointment and Authority of the Director of the Centers for Disease Control and Prevention.

- Requires Senate confirmation of the CDC Director and establishes specific functions of the director.
- Requires an agencywide strategic plan to be developed every four years that describes CDC's priorities and objectives, the capabilities that need to be developed to achieve these objectives, and how CDC will leverage strategic communications, external partnerships and coordination with other agencies.
- Requires the CDC Director to appear annually before the Senate HELP and House Energy and Commerce committees unless this requirement is waived by the chair.
- **Impact:** Requires Senate confirmation of the CDC Director and adds additional reporting and oversight measures for the CDC.

Sec. 2102. Advisory Committee to the Director of the Centers for Disease Control and Prevention.

- Directs the Secretary to establish an advisory committee to the CDC Director on policy and strategy enabling the agency to fulfill its mission.
- **Impact:** Provides for composition and duties of the new advisory committee to the CDC Director.

Sec. 2103. Public Health and Medical Preparedness and Response Coordination.

- Provides additional authority for the Secretary of HHS to coordinate with, and request support from, other departments and agencies in leading the federal public health and medical response to a public health emergency.
- Clarifies ASPR's role and responsibilities in public health and medical preparedness and response activities.
- Requires national- and state-level full-scale exercises every four years to identify and address gaps in preparedness and response, including the ability of SNS to

appropriately support the response to a large-scale, long-term public health emergency.
- Requires the ASPR to appear annually before the Senate HELP and House Energy and Commerce committees unless this requirement is waived by the chair.
- Requires HHS to submit an annual report to Congress on the state of public health preparedness.
- **Impact:** Provides measures to facilitate better coordination among state and federal public health emergency responses.

Sec. 2104. Office of Pandemic Preparedness and Response Policy.
- Establishes an Office of Pandemic Preparedness and Response Policy within the president's Executive Office to advise on policy related to pandemic preparedness and other biological threats that may impact national security.
- **Impact:** Provides duties and roles within the new Executive Office of Pandemic Preparedness and Response Policy.

CHAPTER 2—STATE AND LOCAL READINESS

Sec. 2111. Improving State and Local Public Health Security.
- Requires the CDC Public Health Emergency Preparedness (PHEP) recipients to provide technical assistance to agencies and other entities in which there is an increased risk of infectious disease outbreaks, such as residential care facilities and group homes, in order to improve preparedness and response.
- **Impact:** Updates PHEP cooperative agreements to ensure coordination between health departments and other state agencies to improve preparedness and response planning.

Sec. 2112. Supporting Access to Mental Health and Substance Use Disorder Services during Public Health Emergencies.
- Requires the SAMHSA Strategic Plan and Biennial Report to Congress to include the agency's activities to support continued access to mental health and substance use disorder services during public health emergencies.
- Requires the assistant secretary to submit a report to Congress, based on feedback from SAMHSA's advisory councils, describing steps SAMHSA can take to: (1) improve the provision of mental health and substance use disorder services as part of the medical response to a public health emergency, and (2) improve the provision of such services during public health emergencies.
- **Impact:** Directs the SAMHSA to support continued access to mental health and substance use disorder services during public health emergencies.

Sec. 2113. Trauma Care Reauthorization.
- Reauthorizes two grant programs to improve the provision of trauma care, including in rural areas, by increasing coordination and situational awareness within emergency medical and trauma systems and identifying and disseminating best practices.

- Directs ASPR to support the improvement and coordination of emergency medical services and trauma care during a public health emergency, which may include issuing guidance for patient movement and triage and disseminating best practices and related information.
- **Impact:** Reauthorizes grant funding for trauma care programs intended to increase coordination among emergency systems.

Sec. 2114. Assessment of Containment and Mitigation of Infectious Diseases.

- Requires a GAO report on state and territorial preparedness and response plans to mitigate the spread of COVID-19 and technical assistance provided by the federal government to support such mitigation efforts over the course of the pandemic.
- **Impact:** Requires GAO to report on containment and mitigation effects by the government for COVID-19.

Sec. 2115. Consideration of Unique Challenges in Noncontiguous States and Territories.

- Directs the HHS Secretary to conduct quarterly meetings or consultations with noncontiguous states and territories.
- **Impact:** Provides measures directing HHS to better address unique public health challenges faced specifically by noncontiguous states and territories.

Subtitle B—Improving Public Health Preparedness and Response Capacity

CHAPTER 1—IMPROVING PUBLIC HEALTH EMERGENCY RESPONSES

Sec. 2201. Addressing Factors Related to Improving Health Outcomes.

- Authorizes $35 million annually for FY 2023 through 2027 for grants to identify or facilitate the development of best practices to support improved health outcomes by addressing social determinants of health; provide technical assistance, training and evaluation assistance to health departments; or establish or operate regional centers to develop, evaluate and disseminate effective strategies to address social determinants of health.
- Requires the Secretary to submit a report to Congress on activities funded.
- Requires a GAO study on the outcomes and effectiveness of this program and coordination with related HHS programs within four years of enactment.
- **Impact:** Authorizes a grant program to support evidence-based or evidence-informed projects seeking to reduce health disparities and improve health outcomes by increasing capacity to address social determinants of health within communities.

CHAPTER 2—IMPROVING STATE, LOCAL, AND TRIBAL PUBLIC HEALTH DATA

Sec. 2211. Modernizing State, Local and Tribal Biosurveillance Capabilities and Infectious Disease Data.

- Clarifies the Secretary's public health situational awareness authority to include modernizing applicable existing public health data systems and networks within HHS to reflect technological advancements.

- Updates the strategy and implementation plan to improve collaboration among federal departments, implement lessons learned from previous public health emergencies and identify steps the Secretary will take to further develop and integrate infectious disease detection, support rapid and accurate reporting of laboratory test results during a public health emergency, and improve coordination with public health officials, clinical laboratories and other entities with expertise in public health surveillance.
- Clarifies that an existing authority allowing the Secretary to award grants to states to establish or operate state or regional situational awareness systems should be carried out by the CDC Director.
- **Impact:** Provides funding to support updating HHS biosurveillance capabilities to improve public health situational awareness.

Sec. 2212. Genomic Sequencing, Analytics and Public Health Surveillance of Pathogens.

- Requires the Secretary to issue guidance to support collaboration related to genomic sequencing of pathogens.
- Directs the CDC Director, in consultation with the director of the NIH and heads of other departments and agencies, to strengthen and expand activities related to advanced molecular detection and genomic sequencing of pathogens, including the use of genomic sequencing technologies to inform surveillance activities, enhancing the sequencing and analytics capabilities of the public health workforce, and continuing partnerships with public and private entities for these activities.
- Allows the CDC to award grants, contracts or cooperative agreements to entities with expertise in genomic sequencing for public health purposes.
- Requires the Secretary to establish Centers of Excellence to support innovation in pathogen genomics and molecular epidemiology.
- **Impact:** Directs for increased federal investments and cross-agency coordination of genomic sequencing efforts.

Sec. 2213. Supporting State, Local and Tribal Public Health Data.

- Amends public health data systems modernization provisions in current law by directing the CDC Director to disseminate public health data standards within two years of enactment to improve the exchange of public health data and reporting to public health data systems.
- Directs ONC to conduct a study on the use of electronic data standards to order and report laboratory test results.
- Directs the Secretary to work with public health departments to improve the access, exchange and use of public health data by updating existing data, and entering into new, memoranda of understanding or data use agreements with relevant federal agencies and other public and private entities.
- **Impact:** Requires annual disclosures of statutory health data standards and directs HHS to review and improve the availability of public health data and information sharing between health systems.

Sec. 2214. Epidemic Forecasting and Outbreak Analytics.

- Authorizes the CDC Director to continue activities related to the development of capabilities for the analysis, modeling and forecasting of public health emergencies and infectious disease outbreaks, including by leveraging the capabilities of public and private entities.
- Requires the Secretary to issue an annual report on these activities for the next four years
- **Impact:** Directs the CDC Director to continue agency efforts to develop enhanced prediction, monitoring and response practices for infectious disease outbreaks.

Sec. 2215. Public Health Data Transparency.

- Requires the Secretary to issue a report assessing practices, objectives and associated progress and challenges from CDC efforts to collect and disseminate public health data related to public health emergencies.
- Requires the CDC to submit a plan on efforts to Congress within 180 days of enactment.
- **Impact:** Provides additional reporting requirements on CDC efforts to improve public health data quality.

Sec. 2216. GAO Report on Public Health Preparedness, Response and Recovery Data Capabilities.

- Requires GAO to issue a report on HHS efforts to ensure that public health preparedness, response and recovery data capabilities related to pandemic and other biological threats are not unnecessarily duplicative, overlapping or fragmented.
- GAO will provide recommendations to Congress on how to streamline data collection, reduce duplication and improve information-sharing across programs.
- **Impact:** Requires reporting to weed out redundant programs and prioritize efficiency across federal pandemic preparedness resources.

CHAPTER 3—REVITALIZING THE PUBLIC HEALTH WORKFORCE

Sec. 2221. Improving Recruitment and Retention of the Frontline Public Health Workforce.

- Authorizes $100 million annually for FY 2023 through 2025 for the Public Health Workforce Loan Repayment Program.
- Requires GAO to conduct an evaluation of the public health workforce addressing gaps in positions that may be required during a public health emergency and efforts to improve hiring.
- **Impact:** Reauthorizes the program providing loan repayment in exchange for individuals providing public health services in a state, territorial, tribal or local public health department.

Sec. 2222. Awards to Support Community Health Workers and Community Health.

- Authorizes $50 million annually for FY 2023 through 2027 to support community health workers.
- Directs funds be used to recruit, hire, and train community health workers; support community health workers in providing education and outreach in their communities; address social determinants of health and eliminate health disparities; and to educate community members.
- Requires GAO to submit a report to Congress on the outcomes and effectiveness of the program, as well as coordination with programs operated by HRSA.
- **Impact:** Reauthorizes a community health worker program intended to promote healthy behaviors and outcomes in medically underserved communities through the use of community health workers.

Sec. 2223. Improving Public Health Emergency Response Capacity.

- Allows the Secretary to directly appoint individuals to preparedness and response positions within HHS during periods where there is a declared public health emergency.
- Requires an annual report to Congress and a GAO study on the use of this authority.
- **Impact:** Provides hiring flexibilities to improve HHS' ability to quickly mount an initial response to a public health emergency.

Sec. 2224. Increasing Educational Opportunities for Allied Health Professions.

- Expands the Quentin Burdick Program for Rural Interdisciplinary Training under the Public Health Service Act to create educational opportunities in physical therapy, occupational therapy, respiratory therapy, audiology and speech-language pathology professions.
- **Impact:** Provides additional funding to expand educational opportunities in allied health professions for individuals from disadvantaged backgrounds or underrepresented communities.

Sec. 2225. Public Health Service Corps Annual and Sick Leave.

- Provides Public Health Service Corps officers with 120 days of annual leave.
- **Impact:** Increases the amount of annual paid leave available to Public Health Service Corps officers.

Sec. 2227. Continuing Educational Support for Health Professionals Serving in Rural and Underserved Communities.

- Authorizes grant funding to increase access to accredited continuing medical education for primary care physicians and health care providers at community health centers or rural health clinics for FY 2023 through 2025.
- Directs that eligible entities prioritize funding for primary care providers who are seeking additional education in specialty fields such as infectious disease, endocrinology, pediatrics, mental health and substance use disorders, pain management and geriatrics.

- **Impact:** Reauthorizes grant funding under the Public Health Service Act to expand medical education opportunities within community health centers or rural health clinics, with a focus on specialty practice.

CHAPTER 4—ENHANCING PUBLIC HEALTH PREPAREDNESS AND RESPONSE

Sec. 2231. Centers for Public Health Preparedness and Response.

- Authorizes funding for institutes of higher education to establish a network of Centers for Public Health Preparedness and Response.
- The allocated funding may be used to translate research findings or strategies into evidence-based practices to inform preparedness and response to public health emergencies; improve awareness of these practices and other relevant information among health care and public health professionals and the public; expand activities, such as through partnerships, to improve public health preparedness and response; and provide technical assistance and expertise to health departments as appropriate.
- **Impact:** Reauthorizes funding for public health institutions to collaborate within other government departments, facilities and coalitions to better coordinate efforts to improve public health preparedness.

Sec. 2232. Vaccine Distribution Plans.

- Clarifies that existing authorities of the Secretary to track the initial distribution of federally purchased vaccines to inform decision-makers during an influenza pandemic also apply to other pandemics.
- **Impact:** Bolster's HHS authority to track the distribution of pandemic-related vaccines.

Sec. 2233. Coordination and Collaboration Regarding Blood Supply.

- Directs the HHS Secretary to ensure coordination and collaboration between relevant federal departments, agencies and private stakeholders related to the safety and availability of the blood supply.
- **Impact:** Provides for increased federal oversight generally of the availability of the blood supply across HHS offices and other agencies.

Sec. 2234. Supporting Laboratory Capacity and International Collaboration to Address Antimicrobial Resistance.

- Directs the CDC Director to maintain a network of antibiotic resistance laboratory sites across the U.S. to identify, monitor and study the emergence of antimicrobial-resistant pathogens.
- **Impact:** Provides funding for a network of CDC-supported laboratories, using existing laboratory capacity, to ensure the maintenance of appropriate capabilities to detect and respond to antimicrobial-resistant pathogens.

Sec. 2235. One Health Framework.

- Directs the CDC, in collaboration the secretaries of Agriculture and the Interior, to develop a One Health framework to address zoonotic diseases and advance public health preparedness.
- Requires the Secretary to report to Congress within one year of enactment.
- **Impact:** Revitalizes federal efforts to address zoonotic diseases of concern.

Sec. 2236. Supporting Children during Public Health Emergencies.

- Requires the National Advisory Committee on Children and Disasters to provide advice and consultation with respect to continuity of care and education for all children and supporting parents and caregivers during an all-hazards emergency.
- **Impact:** Adds measures directing for increased attention on continuity of behavioral care for children during national emergencies.

Subtitle C – Accelerating Research and Countermeasure Discovery

CHAPTER 1—FOSTERING RESEARCH AND DEVELOPMENT AND IMPROVING COORDINATION

Sec. 2301. Research Centers for Pathogens of Pandemic Concern.

- Requires the National Institute of Allergy and Infectious Diseases (NIAID), in collaboration with ASPR and the BARDA, to establish or continue a multidisciplinary research program to advance discovery and preclinical development of medical products for priority virus families and other viral pathogens.
- NIH shall award grants to public or private entities to provide support for the research centers. Priority shall be given to applicants with existing frameworks and partnerships.
- **Impact:** A new research center at NIH will be established to advance research for pathogens of pandemic concern.

Sec. 2302. Improving Medical Countermeasure Research Coordination.

- Requires NIH to consult with ASPR, BARDA, the CDC and other federal agencies regarding research needs to advance medical countermeasures. This would apply to any biological agent or toxin that may cause a public health emergency, or other research needs relating to emerging public health threats.
- **Impact:** Requires NIH to collaborate with other federal agencies regarding research needs to advance medical countermeasures.

Sec. 2303. Accessing Specimen Samples and Diagnostic Tests.

- No later than one year after enactment, HHS is required to make public policies and procedures related to public and private entities accessing specimens of pathogens to support research and development of medical countermeasures.
- Requires HHS to issue guidance on methods for requesting samples and considerations for sample availability.
- Allows HHS to contract with public and private entities to improve the rapid development and availability of diagnostic tests.

- **Impact:** HHS is required to implement policies for public and private entities to access specimens of pathogens to support future research and development of medical countermeasures and diagnostic tests.

Sec. 2304. National Academies of Sciences, Engineering, and Medicine Study on Natural Immunity in Relation to the COVID-19 Pandemic.

- Not later than 45 days after enactment, HHS shall seek to enter into a contract with the National Academies of Sciences, Engineering, and Medicine to conduct a study related to the current scientific evidence on the durability of immunity to COVID-19. A report shall be submitted to Congress no later than 18 months after enactment.
- **Impact:** The National Academies will conduct a study on the immunity related to COVID-19.

CHAPTER 2—IMPROVING BIOSAFETY AND BIOSECURITY

Sec. 2311. Improving Control and Oversight of Select Biological Agents and Toxins.

- Reauthorizes the Federal Select Agents Program to ensure appropriate training of personnel working with or around select agents and those with administrative or oversight responsibilities related to Select Agent Program-registered facilities.
- Amends reporting requirements to Congress regarding theft or loss of select agents from federal laboratories.
- **Impact:** Reauthorizes the Federal Select Agents Program and amends reporting requirements to Congress when select agents are lost or stolen from federal laboratories.

Sec. 2312. Strategy for Federal High-Containment Laboratories.

- No later than one year after enactment, the director of the Office of Science and Technology Policy (OSTP) to establish a strategy for the management, maintenance and oversight of federally owned laboratory facilities operating a Biosafety Level 3 or 4.
- **Impact:** OSTP is required to establish a strategy for the oversight of federally owned high-containment laboratories.

Sec. 2313. National Science Advisory Board for Biosecurity.

- Codifies the National Science Advisory Board for Biosecurity (NSAAB) to provide technical advice and recommendations to relevant federal agencies related to biosafety and biosecurity.
- **Impact:** The NSAAB is codified to improve the safety and security of biomedical research.

Sec. 2314. Research to Improve Biosafety.

- Directs HHS to conduct or support research to improve the safe conduct of biomedical research involving pathogens of pandemic potential or biological agents or toxins.

- Requires HHS to submit a report to Congress not later than five years after enactment on any research conducted or supported under this section, any relevant findings, and any steps HHS is taking to disseminate such findings to support the reduction of risks associated with such research.
- **Impact:** HHS is required to take steps to improve biomedical research of pathogens with pandemic potential.

Sec. 2315. Federally Funded Research with Enhanced Pathogens of Pandemic Potential.

- Directs OSTP to review existing federal policies, not later than one year of enactment, on research proposed for federal funding that may be reasonably anticipated to involve the creation, transfer or use of pathogens of pandemic potential. OSTP is also required to establish a federal policy for the consistent review and oversight of such research and update such policy every four years.
- Requires the policy to include:
    - A clear scope for the consistent identification of proposals subject to the policy;
    - Measures to appropriately enhance the transparency and public availability of information related to such research; and
    - Consistent procedures across departments and agencies to identify such research, including research that may not have initially been subject to the policy but may have produced unanticipated results, and monitor such research through the duration of the project period, including work performed by any subrecipients of an award.
- **Impact:** Directs OSTP to review existing policies on federally funded research for pathogens of pandemic potential.

CHAPTER 3—PREVENTING UNDUE FOREIGN INFLUENCE IN BIOMEDICAL RESEARCH

Sec. 2321. Foreign Talent Recruitment Programs.

- Requires NIH extramural researchers to disclose participation in foreign talent programs, which includes providing to NIH copies of all grants, contracts, or other agreements related to their participation in such programs.
- **Impact:** NIH researchers will be required to disclose participation in foreign talent recruitment programs.

Sec. 2322. Securing Identifiable, Sensitive Information and Addressing Other National Security Risks Related to Research.

- Requires HHS to consult with national security experts to ensure that HHS biomedical research involving human genomic information appropriately considers the national security risks.
- Requires HHS to develop a risk framework for assessing and managing national security risks and develop and implement controls related to the risk framework to ensure appropriate data access and involve individuals with national security expertise in the evaluation of certain data access requests.

- Directs the Secretary to update human genomic data access and sharing policies related to human genomic data based on emerging national security threats.
- **Impact:** Requires HHS to develop a framework to ensure that research involving genomic information considers national security risks.

Sec. 2323. Duties of the Director.

- Requires the NIH Director to consult with the HHS Office of National Security (ONS), the HHS Assistant Secretary for Preparedness and Response and other relevant agencies regarding HHS biomedical research that may be relevant to national security matters.
- Requires the NIH Director to ensure that recipients of NIH awards and related entities adhere to appropriate technology practices to secure identifiable, sensitive information.
- **Impact:** Clarifies additional duties of the NIH Director to consider the national security impact of biomedical research.

Sec. 2324. Protecting America's Biomedical Research Enterprise.

- Requires the HHS Secretary to consult with the National Security Advisor, the Director of National Intelligence, the Director of the FBI and the heads of other relevant agencies, research institutions and advocacy groups to: (1) identify ways to improve the protection of intellectual property and other types of sensitive information in biomedical research, (2) develop strategies to address national security threats in biomedical research, including through foreign talent programs, (3) make recommendations to protect proprietary information from potential misuse that may pose national security risks, and (4) develop a framework to identify areas of federally supported biomedical research that are emerging areas of interest for adversaries and may pose national security risks, if subjected to foreign influence.
- **Impact:** Requires the HHS Secretary to regularly review policies made under this section and provide updates as appropriate, as well as submit a report to the president and relevant congressional committees that addresses the findings and recommendations of this section.

Sec. 2325. GAO Study.

- Authorizes GAO to assess the extent to which HHS funds are used for human genomic sequencing services or genetic services provided by entities, or subsidiaries of such entities, organized under the laws of a country or countries of concern, as determined by the Director of National Intelligence or the head of another federal departments and agencies.
- **Impact:** Requires GAO to make recommendations to address any vulnerabilities identified and submit a report to Congress no later than two years after enactment.

Sec. 2326. Report on Progress to Address Undue Foreign Influence.

- Requires the HHS Secretary to submit an annual report to Congress on actions taken to address cases of research misconduct related to foreign influence; document the number of potential cases reported to NIH, cases referred to law

enforcement agencies, and enforcement actions taken; and prevent, address and mitigate research misconduct related to foreign influence.
- **Impact:** Requires HHS to submit a report to Congress on actions to prevent foreign influence on research.

CHAPTER 4—ADVANCED RESEARCH PROJECTS AGENCY – HEALTH

Sec. 2331. Advanced Research Projects Agency – Health.

- Provides additional clarity on how ARPA-H should be structured within NIH. Within ARPA-H, there will be an Office of the Director, not more than eight program offices, and special project offices which the director may establish. Not fewer than two-thirds of the program offices will be exclusively dedicated to research and development activities.
- Outlines the functions and goals of ARPA-H, including to support the discovery of revolutionary advancements in science, the translation of scientific discoveries into health technologies, and the delivery of concepts that demonstrate meaningful clinical application.
- ARPA-H will not be located on the NIH campus. ARPA-H will have offices in not less than three geographic areas.
- Requires several evaluations of ARPA-H by the National Academies and GAO after a period of time.
- No later than one year after enactment, the director of ARPA-H will submit a strategic plan to Congress and update this plan every three years.
- Projects shall be prioritized based on entities that conduct research in the U.S.
- Authorizes $500 million to be appropriated each FY 2024 through 2028.
- **Impact:** Provides additional direction on how ARPA-H should be structured and function.

Subtitle D—Modernizing and Strengthening the Supply Chain for Vital Medical Products

Sec. 2401. Warm Base Manufacturing Capacity for Medical Countermeasures.

- Directs BARDA to support the establishment and maintenance of warm-base domestic manufacturing surge capacity and capabilities so that medical countermeasures can be rapidly manufactured when needed to respond to public health emergencies.
- Improves coordination and communication between private sector partners, BARDA and FDA to ensure that this manufacturing capacity and capabilities are appropriately maintained, follow good manufacturing practices, and any related challenges are identified and addressed.
- Extends the authorization for BARDA's Medical Countermeasure Innovation Partner through FY 2028 to improve BARDA's ability to support investment in innovative medical countermeasures and related technologies.
- **Impact:** Expands BARDA's authority to ensure a warm base for any qualified medical countermeasure, pandemic or epidemic product.

Sec. 2402. Supply Chain Considerations for the Strategic National Stockpile.

- Amends the SNS Annual Threat-Based Review to include an assessment of the supply chains and any vulnerabilities for products that SNS plans to purchase during the period covered by the review.
- **Impact:** Requires consideration of external supply chain disturbances for SNS planning.

Sec. 2403. Strategic National Stockpile Equipment Maintenance.

- Clarifies that, as part of the procedures of the SNS, the Secretary should ensure that items in the stockpile are in working condition so they can be readily deployed when needed.
- **Impact:** Adds provisions to enhance SNS readiness.

Sec. 2404. Improving Transparency and Predictability of Processes of the Strategic National Stockpile.

- Requires the Secretary to issue guidance on how states, territories and tribes can access the SNS and other countermeasures, and factors the Secretary considers when making decisions related to product distribution.
- Requires the Secretary to convene annual meetings with public health officials, the private sector and other stakeholders to share information around the maintenance and use of the SNS and future procurement plans.
- **Impact:** Provides measures intended to enhance transparency for state public health workers regarding the status of SNS distribution.

Sec. 2405. Improving Supply Chain Flexibility for the Strategic National Stockpile.

- Authorizes the Secretary to enter into contracts to enhance surge capacity and supply chain flexibility for supplies intended for the SNS through vendor-managed inventory and warm-base domestic manufacturing capacity arrangements.
- Requires a report to Congress on the use of these authorities.
- **Impact:** Expands ability for HHS to respond to surge supply demands.

Sec. 2406. Reimbursement for Certain Supplies.

- Authorizes the Secretary to sell excess products from the SNS to other entities when the cost of maintaining these products is not appropriate to meet the needs of the SNS and the transfer of these products does not compromise national security.
- Requires a report to Congress after two years on the use of this authority.
- **Impact:** Sets out specific circumstances under which HHS may sell excess supplies within the SNS.

Sec. 2407. Action Reporting on Stockpile Depletion.

- Requires the Secretary to report regularly to Congress on SNS content deployment and replenishment plans during a public health emergency.
- **Impact:** Provides an additional oversight measure on SNS operations.

Sec. 2409. Grants for State Strategic Stockpiles.

- Authorizes a pilot program to support states in establishing, expanding or maintaining stockpiles of medical supplies needed to respond to a public health emergency or disaster.
- Requires HHS to issue guidance to all states within 180 days of enactment on best practices and strategies for maintaining stockpiles, such as the types of products that may be appropriate to maintain in a stockpile, use of vendor-managed inventory arrangements, and purchasing products made in America.
- **Impact:** Provides grant funding for states to implement their own medical supply stockpiles

Sec. 2410. Study on Incentives for Domestic Production of Generic Medicines.

- Directs the Assistant Secretary for Planning and Evaluation to conduct a study on the feasibility, sustainability, potential effectiveness and utility of providing incentives for increased domestic production and capacity of specified generic medicines.
- **Impact:** Directs HHS to report on the potential for incentivized domestic generic drug production during public health emergencies.

Sec. 2411. Increased Manufacturing Capacity for Certain Critical Antibiotic Drugs.

- Authorizes funding for HHS to enter into contracts with independent manufacturers to increase the domestic manufacturing capacity of certain antibiotic drugs with identified supply chain vulnerabilities.
- Eligible manufacturers will be required to submit an application for HHS funding, describing the planned use of funding, subject antibiotic drugs and current supply chain status for the drug as well as how the entity will use advanced or flexible manufacturing in carrying out the contract.
- **Impact:** Expands HHS capabilities to fund private sector manufacturing of specific antibiotics subject to supply chain constraints.

Subtitle E—Enhancing Development and Combating Shortages of Medical Products

Sec. 2511. Ensuring Registration of Foreign Drug and Device Manufacturers.

- Clarifies that all foreign drug and device establishments that manufacture or process drugs or devices intended to be marketed in the U.S. must register with the FDA, including products manufactured at an establishment that are not directly imported into the United States.
- **Impact:** Reinforces registration requirements for foreign drug and device manufacturers.

Sec. 2512. Extending Expiration Dates for Certain Drugs.

- Requires FDA to issue or revise guidance to address recommendations for drug sponsors regarding the submission of stability data in applications and establishing

the longest feasible expiration dates supported by such data, in order to help mitigate or prevent potential drug shortages.
- Requires FDA to issue a report on the number and type of drugs for which the Secretary has requested a labeling change to extend the expiration date and information related to the circumstances of such requests.
- **Impact:** Provides measures to FDA regulation of longer drug expiration periods.

Sec. 2513. Combating Counterfeit Devices.
- Strengthens FDA enforcement authority against, and increases the penalties for, selling counterfeit medical devices, including personal protective equipment, in the U.S.
- **Impact:** Adds consumer protections for the sale of counterfeit medical devices.

Sec. 2514. Preventing Medical Device Shortages.
- Expands the circumstances when shortage notifications are required for medical devices to include circumstances that are likely to lead to a meaningful disruption in the supply of a device, or a shortage of the device or other reasonably substitutable devices.
- **Impact:** Tightens notification requirements regarding medical device shortages.

TITLE III—FOOD AND DRUG ADMINISTRATION

Subtitle A—Reauthorizations

Sec. 3101. Reauthorization of the Critical Path Public-Private Partnership.
- Appropriates $6 million annually for FY 2023 through 2027 to the Critical Path Public-Private Partnership.
- **Impact:** Reauthorizes the Critical Path Public-Private Partnership for five years.

Sec. 3102. Reauthorization of the Best Pharmaceuticals for Children Program.
- Appropriates $25 million annually for FY 2023 through 2027 to the Best Pharmaceuticals for Children Program.
- **Impact:** Reauthorizes the Best Pharmaceuticals for Children Program for five years.

Sec. 3103. Reauthorization of the Humanitarian Device Exemption Incentive.
- Reauthorizes the Humanitarian Device Exemption Incentive from Dec. 24, 2022, through Oct. 1, 2027.
- **Impact:** Reauthorizes the Humanitarian Device Exemption Incentive through Oct. 1, 2027.

Sec. 3104. Reauthorization of the pediatric device consortia program.
- Appropriates $7 million annually for FY 2023 through 2027 to the Pediatric Device Consortia Program.
- **Impact:** Reauthorizes the Pediatric Device Consortia Program for five years.

Sec. 3105. Reauthorization of Provision Pertaining to Drugs Containing Single Enantiomers.

- Reauthorizes the provision pertaining to drugs containing single enantiomers from Dec. 24, 2022, through Oct. 1, 2027.
- **Impact:** Reauthorizes the provision pertaining to drugs containing single enantiomers through Oct. 1, 2027.

Sec. 3106. Reauthorization of Certain Device Inspections.

- Reauthorizes the authority for inspections of certain class II or class III devices by accredited persons from Dec. 24, 2022, through Oct. 1, 2027.
- **Impact:** Reauthorizes certain device inspections through Oct. 1, 2027.

Sec. 3107. Reauthorization of Orphan Drug Grants.

- Appropriates $30 million annually for FY 2023 through 2027 for Orphan Drug Grants.
- **Impact:** Reauthorizes Orphan Drug Grants for five years.

Sec. 3108. Reauthorization of Reporting Requirements Related to Pending Generic Drug Applications and Priority Review Applications.

- Reauthorizes the reporting requirements related to pending generic drug applications and priority review applications from Dec. 24, 2022, through Oct. 1, 2027.
- **Impact:** Reauthorizes the reporting requirements related to pending generic drug applications and priority review applications through Oct. 1, 2027.

Sec. 3109. Reauthorization of Third-Party Review Program.

- Reauthorizes the Third-Party Review Program from Dec. 24, 2022, through Oct. 1, 2027.
- **Impact:** Reauthorizes the Third-Party Review Program through Oct. 1, 2027.

Subtitle B—Drugs and Biologics

CHAPTER 1—RESEARCH, DEVELOPMENT, AND COMPETITION IMPROVEMENTS

Sec. 3201. Prompt Reports of Marketing Status by Holders of Approved Applications for Biological Products.

- Requires all holders of approved Biologics License Applications (BLA) to conduct a one-time report to confirm that their products listed in the Purple Book are still available for sale.
- Requires approved BLA holders to report to the Secretary when withdrawing a product from the market.
- **Impact:** Aims to increase accuracy and transparency of Purple Book listings.

Sec. 3202. Improving the Treatment of Rare Diseases and Conditions.

- Requires the Secretary to submit a publicly available report by Sept. 30, 2026, summarizing FDA's activities relating to designating, approving and licensing drugs used to treat rare diseases.
- Directs the Secretary to publish final guidance related to the 2019 draft guidance on "Rare Diseases: Common Issues in Drug Development."
- Requires the Secretary to enter into a contract with the National Academies of Sciences, Engineering, and Medicine to conduct a study on the processes for evaluating the safety and efficacy of drugs for rare diseases in the United States and the European Union.
- The contract must provide for consultation with relevant stakeholders and for a report not later than two years after entering into the contract on the completion of the study.
- Directs FDA to convene one or more public meetings by Dec. 31, 2023, to solicit input from stakeholders regarding approaches to improving engagement with rare disease condition patients, patient groups and experts.
- Directs the Secretary to establish a public docket to receive written comments in response to the discussion at the public meetings as well as to submit a report no later than 180 days after each public meeting on the approaches discussed at the meeting and related recommendations.
- Requires GAO to submit a report no later than June 23, 2024, assessing the policies, practices and programs at the FDA with respect to the review of drugs intended to treat rare diseases.
- **Impact:** Aims to improve FDA processes relating to the approval of applications for drugs intended to treat rare diseases and conditions.

Sec. 3203. Emerging Technology Program.

- Authorizes the Secretary to establish the Emerging Technology Program at FDA, a collaborative program where industry representatives, academics and others can meet with FDA officials to support the adoption and improve the development of innovative approaches to drug design and manufacturing.
- Authorizes FDA to make grants to carry out the program.
- Requires FDA to issue guidance to facilitate the adoption of and advance the development of innovative approaches to drug product design and manufacturing.
- Not later than four years after enactment, requires a report to Congress regarding allocation of funds and staff utilization in this program.
- **Impact:** Creates the Emerging Technology Program.

Sec. 3204. National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing.

- Allows FDA to solicit requests for designation as National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing.
- Beginning no later than Dec. 23, 2023, directs FDA to designate as National Centers of Excellence not more than five institutions of higher education.
- Sets the eligibility criteria for the designation, which includes institutions of higher education that:

    - Have the physical and technical capabilities for advanced and continuous pharmaceutical manufacturing;
    - Collaborate with other institutions of higher education, nonprofits, pharmaceutical manufacturers and other relevant entities;
    - Have the proven capacity to design, develop and implement new, highly effective technologies for use in advanced and continuous pharmaceutical manufacturing;
    - Have the proven ability to facilitate training of a qualified workforce for advanced and continuous pharmaceutical manufacturing; and
    - Have experience in participating and leading advanced and continuous pharmaceutical manufacturing technology partnerships.
- As a condition for designation, the Secretary requires that institutions of higher education enter into an agreement to:
    - Collaborate directly with the FDA;
    - Share data with the FDA;
    - Develop a strategic plan for an advanced and continuous pharmaceutical manufacturing workforce;
    - Develop a strategic plan for strengthening existing collaborations and developing new ones; and
    - Report annually to the FDA.
- Authorizes the Secretary to award funding through grants and contracts to entities designated as National Centers of Excellence.
- Directs the Secretary to submit an annual report to Congress on the program.
- Authorizes $100 million through FY 2027 to carry out this section.
- **Impact:** Aims to improve collaboration between higher education, government and industry to further develop and implement advanced and continuous manufacturing technology.

Sec. 3205. Public Workshop on Cell Therapies.

- Not later than Dec. 23, 2025, requires FDA to convene a public workshop with relevant stakeholders on best practices on generating scientific data necessary to facilitate development of certain human cell-, tissue-, and cellular-based medical products.
- **Impact:** Directs FDA to hold a public workshop on cell therapies.

Sec. 3206. Clarifications to Exclusivity Provisions for First Interchangeable Biosimilar Biological Products.

- Clarifies FDA's authority to tentatively approve a subsequent interchangeable biosimilar biological product while a first interchangeable product's period of exclusivity is pending.
- Clarifies that multiple interchangeable biosimilar biological products can share a period of first interchangeable exclusivity if they are approved on the same day and otherwise qualify for exclusivity.
- **Impact:** Clarifies the exclusivity period for the first interchangeable biosimilar biological product.

Sec. 3207. GAO Report on Nonprofit Pharmaceutical Organizations.

- No later than Dec. 23, 2024, directs the GAO to prepare a report to Congress on nonprofit pharmaceutical organizations and recommendations to address any challenges to manufacturing or other operations.
- **Impact:** Directs GAO to submit a report to Congress on nonprofit pharmaceutical organizations.

Sec. 3208. Rare Disease Endpoint Advancement Pilot Program.

- Authorizes a Rare Disease Endpoint Advancement Pilot to provide increased interaction with sponsors of rare disease drug development programs to advance the development of efficacy endpoints.
- Directs the Secretary to conduct up to three public workshops to be completed no later than Sept. 30, 2026, to discuss topics relevant to the development of endpoints for rare diseases.
- Requires the Secretary to submit an interim report to Congress on the pilot program no later than Sept. 30, 2026, and a final report by Sept. 30, 2027.
- Directs the Secretary to issue guidance by Sept. 30, 2027, describing best practices and strategies for developing efficacy endpoints.
- Prohibits the Secretary from accepting any new application or request to participate in the program on or after Oct. 1, 2027.
- **Impact:** Creates the Rare Disease Endpoint Advancement Pilot Program.

Sec. 3209. Animal Testing Alternatives.

- Clarifies that drug application sponsors can use alternative testing methods to animal testing in evaluating the safety and effectiveness of human drugs in certain circumstances.
- Alternative methods may include cell-based assays, organ chips and microphysiological systems, sophisticated computer modeling, and other human biology-based test methods.
- Clarifies that sponsors of biosimilar applications can demonstrate biosimilarity to a reference product using alternative testing methods to animal studies.
- **Impact:** Provides alternatives to animal testing for evaluating the safety and effectiveness of human drugs.

Sec. 3210. Modernizing Accelerated Approval.

- Clarifies that real-world evidence that may be used to augment or support appropriate post-approval studies.
- Requires FDA to publish on the FDA website why a study is not appropriate or necessary if FDA does not require that a product approved under accelerated approval conduct a post-approval study.
- Clarifies that the Secretary may specify the conditions for a post-approval study or study, which may include enrollment targets, study protocol, milestones and target date for study completion.
- Clarifies that the Secretary may require post-approval studies to be underway prior to approval.

- Describes expedited procedures for withdrawal of an accelerated approval, including providing the sponsor with due notice and an explanation, opportunity for a meeting, opportunity for written appeal, opportunity for public comment, the publication of a summary of public comments received, and convening and consulting an advisory committee at the sponsor's request.
- Requires that sponsors of drugs approved under accelerated approval submit to the Secretary a report of progress on required post-approval studies every 180 days.
- Requires the Secretary to establish an intra-agency coordinating council within FDA to ensure the consistent and appropriate use of the accelerated approval pathway.
- **Impact:** Aims to modernize the accelerated approval pathway.

Sec. 3211. Antifungal Research and Development.

- Requires the Secretary to issue draft guidance to industry and hold a public workshop to assist entities seeking approval or licensure for antifungal therapies intended to treat and preventative vaccines for coccidioidomycosis, commonly known as Valley Fever.
- Directs the Secretary to finalize the draft guidance no later than 18 months after the close of the public comment period on the draft guidance.
- **Impact:** Aims to assist industry to develop treatments for Valley Fever.

Sec. 3212. Advancing Qualified Infectious Disease Product Innovation.

- Allows for biological products to qualify as Qualified Infectious Disease Product (QIDP) and allows for priority review of innovative biological antifungal such products if such products require clinical data to demonstrate safety or effectiveness.
- Does not extend QIDP exclusivity to biological products.
- **Impact:** Allows for biological products to qualify as QIDP.

Sec. 3213. Advanced Manufacturing Technologies Designation Program.

- No later than Dec. 23, 2023, directs FDA to initiate a program to designate an advanced manufacturing technology.
- A method of manufacturing is eligible for designation if such method incorporates a novel technology or uses an established technology in a novel way that will substantially improve the manufacturing process and maintain equivalent or superior drug quality.
- Designated technologies qualify for expedited application development and review and allow the designated technology application holder, or a person authorized by the application holder, to reference or rely upon data and information in a drug or biologic application about the advanced manufacturing technology in the same context of use.
- Requires FDA to hold a public meeting, issue guidance and report to Congress regarding this program, which sunsets in 2032.
- **Impact:** Creates the Advanced Manufacturing Technologies Designation Program.

CHAPTER 2—TRANSPARENCY, PROGRAM INTEGRITY, AND REGULATORY IMPROVEMENTS

Sec. 3221. Safer Disposal of Opioids.

- Facilitates the disposal of opioids and other drugs with serious risks by allowing FDA to require these drugs be dispensed to patients with safe, in-home disposal systems.
- Clarifies that in-home disposal systems are eligible to be dispensed to patients.
- **Impact:** Allows for the dispensing of in-home disposal systems for opioids.

Sec. 3222. Therapeutic Equivalence Evaluations.

- Requires FDA to make timely therapeutic equivalence evaluations for follow-on drugs approved through the 505(b)(2) pathway that have similar formulations as other approved products.
- Facilitates the availability of lower-cost drugs available for automatic substitution at the pharmacy.
- **Impact:** Requires FDA to make timely therapeutic equivalence evaluations for certain drugs approved through the 505(b)(2) pathway.

Sec. 3223. Public Docket on Proposed Changes to Third-Party Vendors.

- No later than 90 days after enactment, directs the Secretary to solicit comments on factors that generally should be considered when reviewing requests from sponsors of drugs subject to risk evaluation and mitigation strategies to change third-party vendors.
- No later than Dec. 31, 2026, directs GAO to submit a report to Congress on changes in third-party vendors.
- **Impact:** Aims to assess risks of changes to third-party vendors.

Sec. 3224. Enhancing Access to Affordable Medicines.

- Allows FDA to approve generic drugs with different labels than the brand-name versions if:
    - the brand-name drug is subject to an active patent or exclusivity period and a revised label for the brand-name drug is approved within 90 days of the expiration of the patent or exclusivity period;
    - the sponsor of the application agrees to submit revised labeling for the drug that is the subject of the application no later than 60 days after approval of the application; and
    - the labeling revision does not include a change to the warnings section.
- **Impact:** Aims to expedite the generic drug approval process.

Subtitle C—Medical Devices

Sec. 3301. Dual Submission for Certain Devices.

- Allows the sponsor of a device that has been authorized for emergency use to provide a single submission when submitting a request under the De Novo classification pathway.
- **Impact:** Aims to streamline submission for certain devices.

Sec. 3302. Medical Devices Advisory Committee Meetings.

- Requires the Medical Device Advisory Committee to meet at least once a year through 2027 to provide FDA advice on topics related to medical devices in pandemic preparedness and response, including issues related to in vitro diagnostics.
- **Impact:** Requires the Medical Devices Advisory Committee to meet at least once a year on medical devices used in pandemic preparedness and response.

Sec. 3303. GAO Report on Third-Party Review.

- Requires GAO to report on the program for accrediting third-party reviewers for medical devices no later than Sept. 30, 2026.
- **Impact:** Authorizes a GAO report on the third-party review program for medical devices.

Sec. 3304. Certificates to Foreign Governments.

- Allows the Secretary to issue certification to a device if it meets the following criteria: the device is manufactured outside of the United States at an establishment registered under section 510 and has been cleared and approved and is not required to submit a pre-market report.
- **Impact:** Aims to streamline the certification process for foreign-made devices.

Sec. 3305. Ensuring Cybersecurity of Medical Devices.

- Requires manufacturers of cyber devices to develop processes to ensure their devices are secure, have plans to identify and address cybersecurity vulnerabilities, provide a software bill of materials in their labeling, and submit this information to the FDA in premarket submissions.
- Defines cyber devices as devices that have software, connect to the internet or otherwise could be vulnerable to cybersecurity threats.
- Authorizes FDA to deny 510(k) clearance if cybersecurity information is inadequate and to exempt types of devices from these requirements.
- Makes failure to comply a prohibited act.
- Directs the Secretary, in consultation with the Director of CISA, to review and update guidance titled, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," by no later than Dec. 23, 2024, and periodically thereafter.
- No later than June 21, 2023, and at least annually thereafter, directs the FDA to update its website with public information regarding improving cybersecurity devices.
- Directs the GAO to submit a report identify challenges in cybersecurity for devices by Dec. 23, 2024.
- **Impact:** Aims to improve cybersecurity of medical devices.

Sec. 3306. Bans of Devices for One or More Intended Uses.

- Clarifies that FDA is authorized to ban a particular use of a medical device.
- **Impact:** Enables FDA to ban a particular use of a medical device.

Sec. 3307. Third Party Data Transparency.

- To the extent the Secretary relies on any data, analysis or other information or findings provided by third-party entities, directs the Secretary to request access to the datasets, methods and other components underlying the analysis or findings.
- No later than Sept. 30, 2023, and biennially thereafter, directs the Secretary to submit to Congress a report on the number of post-market device signals communications issued by the Secretary, the sources of data for such signals and how such signals were revised or resolved.
- **Impact:** Aims to increase transparency within the use of data from third parties.

Sec. 3308. Predetermined Change Control Plans for Devices.

- Does not require a supplemental application for a change to a device as long as the change is consistent with the predetermined change control plan.
- Allows the Secretary to approve a predetermined change control plan that describes planned changes that may be made to the device as long as the device remains safe and effective without any change.
- **Impact:** Authorizes the Secretary to approve predetermined change control plans.

Sec. 3309. Small Business Fee Waiver.

- Beginning Oct. 1, 2024, directs the Secretary to waive the device fee for small businesses that reported $1 million or less of gross receipts or sales in its most recent federal income tax return for a taxable year, including the returns of all its affiliates.
- **Impact:** Waives the device fee for small businesses.

Subtitle D—Infant Formula

Sec. 3401. Protecting Infants and Improving Formula Supply.

- Defines "critical food" as infant formula or a medical food.
- Directs the Secretary to establish an Office of Critical Foods within the Center for Food Safety and Applied Nutrition and appoint a director of the office, which is responsible for oversight, coordination and facilitation of activities related to critical foods.
- Directs the Secretary to waive the 90-day premarket submission requirement for infant formula and instead apply a 30-day premarket submission requirement.
- Directs the Secretary to submit a report to Congress by Dec. 23, 2023, regarding the number of premarket submissions for new infant formula.
- Requires the Secretary to publish on the HHS website information on how to identify appropriate substitutes for infant formula products in shortage.
- Directs the Secretary to participate in meeting with other countries to discuss methods and approaches to harmonizing regulatory requirements for infant formula and allows the Secretary to enter into such agreements with other countries.
- Directs the Secretary to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine by Feb. 21, 2023, to examine and report on challenges in supply, market competition and regulation of infant formula in the United States.

- Requires the Secretary to notify Congress of a recall of infant formula within 24 hours.
- Requires the Secretary to submit a report to Congress each year by March 30 on infant formula submissions, inspections, compliance and manufacturers.
- Directs the manufacturer of a recalled infant formula to submit certain information to the Secretary following such recall.
- Requires the Secretary to submit a report to Congress on the domestic supply of infant formula.
- Directs the FDA to provide a list of corrective actions following an inspection of an infant formula manufacturing facility impacted by a recall. Also directs the FDA to prioritize inspection and reinspection of such facilities to help mitigate a shortage.
- Directs the Secretary to conduct annual inspections of infant formula manufacturing facilities in accordance with a risk-based approach.
- Requires the Secretary, in consultation with the Secretary of Agriculture and other relevant agency heads, to develop a national strategy on infant formula by March 23, 2023.
- Requires a manufacturer of a critical food to notify the Secretary of a permanent discontinuance or an interruption in manufacturing that could lead to a meaningful disruption in the supply of such a food.
- Directs the Secretary to distribute appropriate information on the shortage within five calendar days of receiving the notification.
- Requires each manufacturer of a critical food to develop, maintain, and implement a redundancy risk management plan.
- Allows the Secretary to waive requirements under this section during a shortage of specialty infant formula.
- Allows individuals to import a three-month supply of infant formula for personal use within the 90-day period following enactment from Canada, any country in the European Union or any other country determined by the Secretary.
- Requires health care providers to report to the FDA adverse events related to imported infant formula.

Subtitle E—Cosmetics

Sec. 3502. Amendments to Cosmetic Requirements.

- Provides definitions for the terms adverse event, cosmetic product, facility, responsible person, and serious adverse event.
- Requires responsible persons to submit reports of serious adverse events to FDA no later than 15 days after receiving the report.
- Requires responsible persons to maintain records related to each report of an adverse event for a period of six years and authorizes FDA to have access to such records during an inspection.
- Provides that FDA may request a complete list of ingredients in specific fragrances or flavors in a cosmetic product if FDA has reasonable grounds to believe that an ingredient or combination of ingredients has caused a serious adverse event.
- Requires FDA to establish good manufacturing practice regulations. Such regulations shall be, to the extent practicable and appropriate, consistent with

national and international standards, and may allow FDA to inspect records necessary to demonstrate compliance with good manufacturing practice regulations during an inspection.

- Requires FDA, in establishing good manufacturing practice regulations, to take into account the size and scope of businesses engaged in the manufacture of cosmetics, the public health risks of such cosmetics, and provide sufficient flexibility to be practicable for all sizes and types of manufacturing facilities subject to the regulations.
- Requires FDA to issue proposed regulations on good manufacturing practice no later than two years after enactment and issue final regulations no later than three years after enactment.
- Requires persons that own or operate a manufacturing facility for cosmetic products to register each facility.
- Requires registrants to renew registrations biennially, and otherwise notify FDA within 60 days of any changes to information registrants are required to submit as part of registration.
- Requires FDA to provide for an abbreviated registration renewal process for persons that own or operate facilities that have not been required to submit any changes since the time of the last registration.
- Imposes requirements for the format and contents of registration.
- Requires responsible persons to submit a product listing for each cosmetic product.
- Requires responsible persons to submit product listings not later than one year after the date of enactment or, for a product first marketed after the date of enactment, within 120 days of marketing the product.
- Provides for an abbreviated renewal process for product listings for which there have been no changes since the previous listing.
- Imposes requirements for the contents of a listing, including the manufacturing facility registration number, a list of ingredients in the cosmetic product, and the product listing number.
- Provides that a single listing submission for a cosmetic product may include multiple cosmetic products with identical formulations or formulations that differ only with respect to colors, fragrances, flavors, or quantity of contents.
- Requires responsible persons to submit any updates to a product listing annually.
- Requires FDA to issue facility registration and product listing numbers at the time of initial registration or listing and clarifies that facility registration numbers shall be considered confidential commercial information.
- Provides that FDA may suspend the registration of a facility if FDA determines that a cosmetic product manufactured by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans and FDA has a reasonable belief that other products manufactured by the facility may be similarly affected.
- Requires responsible persons to ensure, and maintain records supporting, that there is adequate substantiation of safety for cosmetic products.
- Provides that, for purposes of determining whether a product is safe, FDA may consider, as appropriate and available, the cumulative or other relevant exposure to the cosmetic product or any ingredient in the product.

- Exempts coal-tar hair dye from the safety substantiation requirements, and instead relies on the current provisions in Section 601 of the Federal Food, Drug, and Cosmetic Act for such products. Responsible persons for coal-tar hair dyes must maintain records related to the safety of such products.
- Requires cosmetic product labels to include contact information through which the responsible person can receive adverse event reports.
- Requires responsible persons to identify on the label of a cosmetic product each fragrance allergen in such product.
- Requires FDA to determine by regulation the substances that are fragrance allergens, with a proposed regulation to be issued not later than one year after enactment, and a final rule issued not later than 180 days after the close of the public comment period for the proposed regulation, which takes into consideration international, state and local requirements for allergen disclosure, including requirements in the European Union.
- Requires certain labeling for cosmetic products that are intended to be used only by licensed professionals to bear a label that the product shall be administered or used only by licensed professionals and includes the same information on its label that is required of cosmetics products intended for consumers.
- Authorizes FDA to access and copy certain records related to a cosmetic product, including safety substantiation records, if FDA has a reasonable belief that a cosmetic product, including an ingredient in such cosmetic product, is likely to be adulterated such that the use or exposure to the product presents a threat of serious adverse health consequences or death to humans.
- Provides appropriate protections for trade secret or confidential information as part of the access to such records.
- Provides FDA the authority to order a recall of a cosmetic product if FDA determines that there is a reasonable probability that a cosmetic is adulterated or misbranded and the use or exposure to the cosmetic will cause serious adverse health consequences or death.
- Provides certain exemptions for small businesses with average gross annual sales for the previous three-year period if less than $1 million.
- Exempts products and facilities that are also subject to the drug and device chapters of the Federal Food, Drug, and Cosmetic Act, such as over-the-counter drugs and devices, from requirements under the Modernization of Cosmetics Regulation Act of 2022, except for certain labeling requirements.
- Provides that no state or political subdivision of a state may establish or continue in effect any requirement for cosmetics that is different from or in addition to any requirement in Chapter VI of the Federal Food, Drug, and Cosmetic Act with respect to registration and product listing, good manufacturing practice, recordkeeping, recalls, adverse event report, or safety substantiation.
- Clarifies that the Modernization of Cosmetics Regulation Act of 2022 does not preempt any state laws other than those laws that are expressly preempted.
- Clarifies that the language in the Modernization of Cosmetics Regulation Act of 2022 does not preempt any state from prohibiting the use or limiting the amount of an ingredient in a cosmetic product and does not preempt any current requirement for reporting certain cosmetic ingredients to states.

- Provides that the Modernization of Cosmetics Regulation Act of 2022, nor any other requirement shall be construed to modify, preempt or displace any actions for damages or the liability of any person under the law of any state, whether statutory or based in common law.
- Clarifies that the preemption and savings language in the Modernization of Cosmetics Regulation Act of 2022 do not affect the provisions under section 752 of the Federal Food, Drug, and Cosmetic Act (preemption for labeling or packaging of cosmetics).
- New enforcement provisions become effective one year after enactment of the Modernization of Cosmetics Regulation Act of 2022.
- Provides that failure to register or submit listing information, refusal or failure to follow a recall order, and failure to comply with adverse event reporting requirements are prohibited acts under the Federal Food, Drug, and Cosmetic Act.
- Provides that cosmetic products are adulterated if they are manufactured under conditions that do not meet good manufacturing practice regulations or do not have adequate substantiation for safety.
- Provides that cosmetic products are misbranded if they are not in compliance with labeling requirements contained in the Modernization of Cosmetics Regulation Act of 2022.
- Makes conforming edits to Section 704 of the Federal Food, Drug, and Cosmetic Act to provide that FDA inspections shall extend to records and information, such as safety substantiation information, when the applicable standard is met.
- Requires FDA to promulgate proposed regulations to establish testing methods for detecting and identifying asbestos in talc-containing cosmetic products not later than one year after the date of enactment of the Modernization of Cosmetics Regulation Act of 2022, and to issue final regulations not later than 180 days after the date on which the public comment period on the proposed regulations closes.
- Requires FDA to assess the use of perfluoroalkyl and polyfluoralkyl substances (PFAS) in cosmetic products and the scientific evidence regarding the safety of their use in cosmetics products, including any risks associated with their use.
- Provides that FDA can, as appropriate, consult with the National Center for Toxicological Research, in conducting the assessment.
- Requires FDA to publish on the FDA website a report summarizing the assessment not later than three years after enactment of the FDA Safety and Landmark Advancements Act.
- Establishes the sense of the Congress that animal testing should not be used for the purposes of safety testing on cosmetic products and should be phased out with certain exceptions.
- In order to carry out the Modernization of Cosmetics Regulation Act of 2022, FY year 2025 through 2027.
- **Impact:** Amends Chapter VI of the Federal Food, Drug, and Cosmetic Act to include new provisions for cosmetic products.

Subtitle F—Cross-Cutting Provisions

CHAPTER 1—CLINICAL TRIAL DIVERSITY AND MODERNIZATION

Sec. 3601. Diversity Action Plans for Clinical Studies.

- Requires a sponsor for a clinical investigation of a new drug that is a phase 3 study or certain devices to submit a diversity action plan that includes the sponsor's goals for enrollment in the clinical trial or trials involved, the sponsor's rationale for such goals and an explanation for how the sponsor intends to meet such goals.
- **Impact:** Requires sponsors of certain drugs and devices to submit a diversity action plan.

Sec. 3602. Guidance on Diversity Action Plans for Clinical Studies.

- Requires FDA to issue new draft guidance or update existing draft guidance on the format and content of diversity action plans within 12 months of enactment, and to finalize such guidance no later than nine months after closing the comment period of such draft guidance.
- **Impact:** Directs FDA to issue guidance on diversity action plans.

Sec. 3603. Public Workshops to Enhance Clinical Study Diversity.

- Requires FDA, in consultation with drug sponsors, medical device manufacturers, patients and other stakeholders, not later than Dec. 23, 2023, to convene one or more public workshops to solicit input from stakeholders on increasing the enrollment of historically underrepresented populations in clinical trials.
- Directs the Secretary to establish a 60-day public comment period following each public workshop and issue a report on the topics discussed at the workshops.
- **Impact:** Directs FDA to hold public workshops on clinical trial diversity.

Sec. 3604. Annual Summary Report on Progress to Increase Diversity in Clinical Studies.

- Requires FDA, not later than two years after enactment and annually thereafter, to submit to Congress and publish on the public website of FDA, a report that summarizes information related to the diversity action plans.
- Notes that nothing in this section shall be construed to authorize FDA to disclose any information that is a trade secret or confidential.
- **Impact:** Creates an annual FDA report on diversity action plans.

Sec. 3605. Public Meeting on Clinical Study Flexibilities Initiated in Response to COVID–19 Pandemic.

- Requires FDA, not later than 180 days after the date on which the COVID-19 public health emergency period ends, to convene a public meeting to discuss recommendations provided during the COVID-19 public health emergency to mitigate disruption of clinical trials.
- Such meeting shall discuss incorporating certain clinical trial disruption mitigation recommendations into current or additional guidance to improve clinical trial access and enrollment of diverse patient populations.
- **Impact:** Directs FDA to hold a public meeting on recommendations provided during the COVID-19 public health emergency to mitigate disruption of clinical trials.

Sec. 3606. Decentralized Clinical Studies.

- Requires FDA, not later than one year after the enactment, to issue draft guidance that addresses considerations for decentralized clinical trials, including regarding the engagement, enrollment and retention of a meaningfully diverse clinical population, with respect to race, ethnicity, age, gender and geographic location, when appropriate.
- Requires FDA to finalize this guidance no later than one year after the public comment period for the draft guidance ends.
- **Impact:** Directs FDA to issue guidance on decentralized clinical studies.

Sec. 3607. Modernizing Clinical Trials.

- Directs the Secretary to issue or revise draft guidance within one year of enactment regarding the appropriate use of digital health technologies in clinical trials to help improve recruitment for, retention in, participation in and data collection during clinical trials, and provide for novel clinical trial designs utilizing such technology for purposes of supporting the development of and review of applications for, drugs and devices.
- Requires the Secretary to finalize this guidance no later than 18 months after the public comment period for the draft guidance ends.
- Directs the Secretary to issue or revise draft guidance within one year of enactment on the use of seamless, concurrent and other innovative clinical trial designs to support the expedited development and review of applications for drugs.
- Requires the Secretary to finalize this guidance no later than 18 months after the public comment period for the draft guidance ends.
- Directs the Secretary to work with foreign regulators as appropriate to facilitate international harmonization of the regulation and the use of decentralized clinical trials, digital technology in clinical trials, and seamless, concurrent and other adaptive or innovative clinical trial designs.
- **Impact:** Directs FDA to issue guidance to modernize clinical trials.

CHAPTER 2—INSPECTIONS

Sec. 3611. Device Inspections.

- Directs the Secretary to issue or update guidance within one year of enactment describing circumstances in which the Secretary intends to issue requests for records or other information in advance of or in lieu of an inspection.
- Requires the Secretary to finalize this guidance no later than one year after the public comment period for the draft guidance ends.
- **Impact:** Directs the Secretary to issue guidance regarding record requests in advance of in lieu of an inspection.

Sec. 3612. Bioresearch Monitoring Inspections.

- Codifies and clarifies FDA authority to inspect clinical study sites, also known as bioresearch monitoring inspections.

- Requires FDA to review its processes and practices applicable to such inspections in the United States and in foreign countries, evaluate whether updates are needed to facilitate consistency, and issue guidance describing the conduct of such inspections.
- **Impact:** Authorizes FDA to conduct bioresearch monitoring inspections.

Sec. 3613. Improving Food and Drug Administration Inspections.

- Allows FDA to consider the compliance history of establishments in a country or region as a factor when establishing a schedule for risk-based inspections.
- Allows the Secretary to use any records or other information collected for the purposes of or in lieu of an inspection to satisfy requirements that may pertain to a preapproval or risk-based surveillance inspection, and to resolve deficiencies found in such inspections, if applicable and appropriate.
- Allows the recognition of foreign government inspections as sufficient for preapproval inspections if the Secretary has entered into an agreement with that foreign government.
- Requires a periodic review of whether additional arrangements with foreign governments are appropriate.
- Beginning no later than four years after enactment and every four years thereafter, directs the Secretary to submit a report to Congress describing the periodic review of arrangements with foreign governments.
- **Impact:** Aims to enhance FDA inspection tools.

Sec. 3614. GAO Report on Inspections of Foreign Establishments Manufacturing Drugs.

- Requires the GAO to submit a report to Congress by June 23, 2024, on FDA inspections of foreign establishments manufacturing drugs.
- **Impact:** Authorizes a GAO report on FDA inspections of foreign establishments manufacturing drugs.

Sec. 3615. Unannounced Foreign Facility Inspections Pilot Program.

- Requires FDA to conduct a pilot program in which FDA increases the conduct of unannounced surveillance inspections of foreign drug establishments and evaluates the differences between such domestic and foreign establishments, including the impact of announcing such inspections.
- Directs FDA to post a report on the FDA website no later than 180 days following the completion of the pilot program of its findings and recommendations.
- **Impact:** Creates the Unannounced Foreign Facility Inspections Pilot Program at the FDA.

Sec. 3616. Enhancing Coordination and Transparency on Inspections.

- Directs the Secretary to ensure timely and effective internal coordination among FDA field investigators and staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program regarding the reviews of inspection reports and any feedback or corrective actions.

- Updates reporting requirements with respect to communication between field investigators and staff, including on procedures for enabling and ensuring such communication.
- **Impact:** Aims to improve communication at the FDA as it relates to inspections.

Sec. 3617. Enhancing Transparency of Drug Facility Inspection Timelines.

- Requires FDA to publicly post, not later than 120 days after the end of each FY, information related to inspections of facilities, including inspections that are necessary for approval of a drug or device.
- Such information shall include the median time following a request from FDA staff reviewing an application to the beginning of an inspection, as well as the median time from the sending of a warning letter, issuance of an import alert or holding of a regulatory meeting to resolution of the actions indicated to address the conditions or practices observed during an inspection.
- **Impact:** Aims to improve transparency of drug facility inspection timelines.

CHAPTER 3—MISCELLANEOUS

Sec. 3621. Regulation of Certain Products as Drugs.

- Deems all contrast agents, radioactive drugs and over-the-counter monograph drugs to be drugs and not medical devices.
- **Impact:** Defines certain products as drugs, not medical devices.

Sec. 3622. Women's Health Research Roadmap.

- By Dec. 23, 2024, directs FDA's Office of Women's Health to review and update as appropriate the 2015 Women's Health Research Roadmap and to brief Congress on the review and any resulting updates.
- **Impact:** Directs FDA to review and update its Women's Health Research Roadmap, issued in December 2015.

Sec. 3623. Strategic Workforce Plan and Report.

- Requires the Secretary to develop and implement a strategic workforce plan that includes strategic goals and priorities for recruiting, hiring, training, developing and retaining a qualified workforce, and establishes metrics and milestones for measuring progress in achieving those goals and priorities.
- Directs the Secretary to publish this plan by Sept. 30, 2023, and at least every four years thereafter.
- Directs each FDA center to develop and update their own strategic plans informed by the agencywide FDA plan.
- **Impact:** Directs the FDA to develop a strategic workforce plan.

Sec. 3624. Enhancing Food and Drug Administration Hiring Authority for Scientific, Technical and Professional Personnel.

- Enhances existing flexibilities and authorities for FDA to simplify and expedite the process for hiring individuals to scientific, technical and professional positions,

including personnel who work on the regulation of food, in addition to personnel who work on medical products.
- **Impact:** Aims to enable the FDA to recruit and retain outstanding, highly qualified individuals for these positions.

Sec. 3625. Facilities Management.
- Preserves Section 905 of the FDA Reauthorization Act (FDARA) by clarifying that FDA use of budget authority for costs excluded under Section 905 (e.g., for furniture and fixtures) can count toward meeting the spending trigger amount for user fees for the PDUFA, GDUFA, MDUFA and BsUFA programs.
- This provision starts in FY 2024.
- **Impact:** Clarifies that costs of furniture and fixtures can count toward meeting the spending trigger amount for user fees for the PDUFA, GDUFA, MDUFA and BsUFA programs.

Sec. 3626. User Fee Program Transparency and Accountability.
- Strengthens the reporting requirements for the user fee programs to ensure greater accountability and transparency with respect to the FDA's commitments.
- Requires FDA, with regulated industry, to provide regular updates to Congress regarding user fee negotiations, and to publish the minutes from user fee negotiations within 30 days.
- **Impact:** Strengthens the reporting requirements for the user fee programs.

Sec. 3627. Improving Information Technology Systems of the Food and Drug Administration.
- Directs the Secretary to develop a coordinated information technology strategic plan to modernize the FDA's information technology systems.
- Directs the Secretary to publish this plan by Sept. 30, 2023, and at least every four years thereafter.
- Directs the GAO to submit to Congress by Sept. 30, 2026, a report assessing the implementation of the FDA Strategic Information Technology Plan.
- **Impact:** Directs the FDA to develop a strategic plan to improve its information technology systems.

Sec. 3628. Reporting on Mailroom and Office of the Executive Secretariat of the Food and Drug Administration.
- Directs the Secretary to submit to Congress by March 23, 2023, information related to policies, procedures and activities of the FDA mailroom.
- Directs the Secretary to report to Congress on new or revised policies of the FDA mailroom no later than the end of each FY for each 2023 and 2024.
- Directs the GAO to submit to Congress 18 months after enactment a report assessing the policies and practices of the FDA with respect to the receipt, tracking, managing and prioritization of correspondence.
- **Impact:** Authorizes various reports on the activities and policies of the FDA mailroom.

Sec. 3629. Facilitating the Use of Real-World Evidence.

- Requires FDA to issue guidance addressing the use of real-world evidence and real-world data, including that obtained for drugs and devices authorized for emergency use during the COVID-19 public health emergency, to support drug and device approvals and clearances.
- Requires FDA to report to Congress regarding the number of applications submitted for which an emergency use authorization was previously granted and, of such applications, how many included real-world evidence and whether such evidence was sufficient to support a regulatory decision.
- **Impact:** Directs FDA to issue guidance on the use of real-world evidence.

Sec. 3630. Facilitating Exchange of Product Information Prior to Approval.

- Provides that no drug or device shall be considered misbranded as a result of the provision of information regarding investigational drugs or devices or uses to payors, formulary committees or other similar entities under specified conditions.
- Requires the information to include a clear statement that the drug or device it discusses has not been approved, and that the safety and efficacy of the drug or device has not been established.
- Additional required disclosures include information about studies the drug or device is undergoing, how the studies relate to the overall plan for the development of the drug or device, and whether an application for the drug or device has been submitted to FDA and when such submission is planned.
- **Impact:** Aims to facilitate the exchange of product information prior to approval of a drug or device.

Sec. 3631. Streamlining Blood Donor Input.

- Exempts from Paperwork Reduction Act requirements FDA information collections to solicit information from blood donors and potential blood donors to inform recommendations regarding blood donation.
- **Impact:** Aims to streamline blood donor input.

TITLE IV – MEDICARE PROVISIONS

Subtitle A – Medicare Extenders

Sec. 4101. Extension of Increased Inpatient Hospital Payment Adjustment for Certain Low-Volume Hospitals.

- Extends the Medicare increased inpatient hospital payment adjustments for certain low-volume hospitals for two years through 2024.
- **Impact:** Ensures that inpatient hospital payment adjustments for low-volume hospitals, which were set to expire in December 2022, are extended for a period of two years.

Sec. 4102. Extension of the Medicare-Dependent Hospital Program.

- Extends the Medicare-dependent hospital program for two years through 2024.

- **Impact:** Ensures that the Medicare-dependent hospital program, which was set to expire in December 2022, is extended for a period of two years.

Sec. 4103. Extension of Add-On Payments for Ambulance Services.

- Extends add-on payments for ground ambulance services under the Medicare Fee Schedule for two years through 2024.
- **Impact:** Ensures that add-on payments for ground ambulance services under the Medicare Fee Schedule are extended for a period of two years through 2024.

Subtitle B – Other Expiring Medicare Provisions

Sec. 4111. Extending Incentive Payments for Participation in Eligible Alternative Payment Models.

- Provides a one year extension of the bonus(es) for Alternative Payment Model (APM) providers.
- Lowers the APM bonus from 5% to 3.5%.
- Extends the current freeze on qualification thresholds with respect to participation in the APM bonus program for one additional year.
- **Impact:** Extends the APM payment incentives, with a reduction in the bonus from 5% to 3.5%.

Sec. 4112. Extension of Support for Physicians and Other Professionals in Adjusting to Medicare Payment Changes.

- Addresses expected reductions to Medicare reimbursement for physician services by increasing the Medicare conversion factor by 2.5% and 1.25% for 2023 and 2024, respectively.
- **Impact:** Reduces the physician fee schedule reduction that was set to take effect.

Sec. 4113. Advancing Telehealth Beyond COVID-19.

- Extends and/or expands COVID-19 telehealth flexibilities under Medicare for an additional two years through Dec. 31, 2024, including:
    - Removing geographic requirements and expanding the concept of originating site to include the site at which the patient is located, including the patient's home;
    - Expanding the scope of eligible practitioners to furnish telehealth services to include occupational therapist, physical therapist, speech-language pathologist and audiologist services, among certain others;
    - Extending the authority for rural health clinics and federally qualified health centers to furnish telehealth services;
    - Delaying the six-month in-person requirement for mental health services furnished through telehealth, including the in-person requirements for rural health clinics and federally qualified health centers;
    - Extending Medicare's coverage and payment for audio-only telehealth services; and
    - Extending the use of telehealth services to conduct face-to-face, in-person encounters prior to recertifications of eligibility for hospice care.

- Requires the HHS Secretary to conduct a study using medical record review on program integrity related to such telehealth services. The study shall focus on the duration of telehealth services furnished, the types of telehealth services furnished and the impact of the telehealth services furnished on future utilization of health care services by Medicare beneficiaries.
- Requires the HHS Secretary to submit an initial report of the study no later than Oct. 1, 2024, to the Senate Finance Committee, House Committee on Energy and Commerce and the House Committee on Ways and Means. A final report is due no later than April 1, 2026.
- **Impact:** Extends COVID-19 telehealth flexibilities under Medicare for an additional two years through Dec. 31, 2024.

Sec. 4114. Revised Phase-In of Medicare Clinical Laboratory Test Payment Changes.

- Delays currently pending data-reporting periods and payment reductions for the Clinical Laboratory Fee Schedule under the Protecting Access to Medicare Act (PAMA) by one year.
- **Impact:** Ensures that the applicable data-reporting period and payment reductions for the Clinical Laboratory Fee Schedule under PAMA are delayed for one year.

Subtitle C – Medicare Mental Health Provisions

Sec. 4121. Coverage of Marriage and Family Therapist Services and Mental Health Counselor Services under Part B of the Medicare Program.

- Effective Jan. 1, 2024, marriage and family therapist services and mental health counselor services providers are eligible to receive payment from Medicare for providing certain covered mental health services to Medicare beneficiaries.
- Adds relevant definitions to the applicable statute for marriage and family therapist services; marriage and family therapist; mental health counselor services; and mental health counselor.
- Excludes marriage and family therapist services and mental health counselor services from the skilled nursing facility prospective payment system and includes marriage and family therapists and mental health counselors s as practitioners for assignment of claims.
- Includes marriage and family therapist services and mental health counselor services within coverage provided under certain settings, including rural health clinics and federally qualified health centers and certain covered hospice programs.
- **Impact:** Expands the range of services covered under Medicare Part B to include certain covered marriage, family therapist and mental health counselor services

Sec. 4122. Additional Residency Positions.

- Allocates 200 new Medicare-funded graduate medical education (GME) slots, of which at least 50% are specifically allocated for psychiatry and psychiatry subspecialties.

- The HHS Secretary must notify hospitals of the increase in residency positions and number of positions distributed to an applicable hospital pursuant to this provision by Jan. 31 of the FY.
- The HHS Secretary is required to distribute no less than 10% of the aggregate number of residency positions distributed pursuant to this provision to specified categories of hospitals, including, among others, hospitals located in a rural area; hospitals in which the reference resident level of the hospital is greater than the otherwise applicable resident limit; hospitals in states with new medical schools that have achieved certain specified requirements or accreditations or additional locations and branch campuses subject to such requirements; and hospitals that serve areas designated as health professional shortage areas.
- No hospital may receive more than 10 additional full-time equivalent residency positions under this provision.
- There is prohibition on the distribution of such new positions to hospitals without an increase agreement with an applicable hospital.
- **Impact:** Expands the number of residency positions hospitals can offer to ensure additional opportunities for medical students and increased opportunities to maximize patient care.

Sec. 4123. Improving Mobile Crisis Care in Medicare.

- Effective as of Jan. 1, 2024, a 50% payment increase in the Medicare Physician Fee Schedule payment rates for crisis psychotherapy services shall be applied when furnished by a mobile unit.
- No later than Jan. 1, 2024, the HHS Secretary must use existing communications mechanisms to provide education and outreach to stakeholders with respect to the ability of health professionals to bill for psychotherapy for crisis services under the Medicare Physician Fee Schedule.
- No later than Jan. 1, 2024, the HHS Secretary must convene stakeholders and experts for an open door forum or other appropriate forum to discuss current Medicare program coverage and payment policies for services that can be furnished to provide care to a Medicare beneficiary who is experiencing a mental or behavioral health crisis.
- No later than Jan. 1, 2024, the HHS Secretary must use existing communications mechanisms to provide education and outreach to providers of services, physicians and practitioners with respect to the ability of auxiliary personnel in the furnishing of psychotherapy for crisis services billed under the Medicare Physician Fee Schedule and behavioral health integration services.
- **Impact:** Incentivizes additional coverage of psychotherapy services under Medicare by both patients and practitioners. Ensures a focus toward increased education and outreach so that such services are utilized by beneficiaries effectively.

Sec. 4124. Ensuring Adequate Coverage of Outpatient Mental Health Services under the Medicare Program.

- Effective as of Jan. 1, 2024, the partial hospitalization benefit under Medicare is revised to include coverage of intensive outpatient services.

- **Impact:** Ensures intensive outpatient services in the mental health space are covered under Medicare's partial hospitalization benefit.

Sec. 4125. Improvements to Medicare Prospective Payment System for Psychiatric Hospitals and Psychiatric Units.

- The HHS Secretary must collect data and information to revise payments under the Inpatient Psychiatric Facilities Prospective Payment System for psychiatric hospitals and psychiatric units. The HHS Secretary must begin to collect such data by not later than Oct. 1, 2023.
- For rate year 2025 (and for any subsequent rate year, as determined by the HHS Secretary), the HHS Secretary must, by regulation, implement revisions to the methodology for determining the payment rates under the Inpatient Psychiatric Facilities Prospective Payment System for psychiatric hospitals and psychiatric units.
- Starting in calendar year 2028, and each subsequent rate year, each psychiatric hospital and psychiatric unit must submit to the HHS Secretary certain standardized patient assessment data and other related data.
- **Impact:** Ensures that standardized patient assessment and other quality factors-related data will be collected and taken into account as more mental health-related services are covered under Medicare.

Sec. 4126. Exception for Physician Wellness Programs.

- Exempts certain bona fide mental health or behavioral health improvement or maintenance programs offered to a physician by an entity from the statutory prohibition (Section 1877(e) of the Social Security Act (42 U.S.C. 1395nn(e))) against physicians referring Medicare patients for certain designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship so long as certain requirements related to the substance of the program, written compliance thereof and other similar requirements are satisfied.
- Similarly exempts certain bona fide mental health or behavioral health improvement or maintenance programs from the anti-kickback statute set forth at Section 1128B(b)(3) of the Social Security Act (423 U.S.C. 1320a–7b(b)(3))) so long as similar requirements are satisfied.
- **Impact:** Ensures that mental health or behavioral health improvement or maintenance programs can be broadly utilized by beneficiaries and practitioners without implicating anti-referral or kickback statutes.

Sec. 4127. Consideration of Safe Harbor under the Anti-Kickback Statute for Certain Contingency Management Interventions.

- No later than one year after the date of enactment of this provision, the HHS Inspector General must conduct a review on whether to establish a safe harbor for evidence-based contingency management incentives and the parameters for such a safe harbor.
- No later than two years after the date of enactment of this provision, the HHS Secretary and HHS Inspector General must submit to Congress recommendations,

including based on the safe harbor review, for improving access to evidence-based contingency management interventions while ensuring quality of care, ensuring fidelity to evidence-based practices, and including strong program integrity safeguards that prevent increased waste, fraud and abuse and prevent medically unnecessary or inappropriate items or services reimbursed in whole or in part by a federal health care program.

- **Impact:** Allows the HHS Inspector General and HHS Secretary to explore the means and parameters for a potential safe harbor for evidence-based contingency management incentives, while also ensuring a report for the same is provided to Congress for potential future congressional action on this subject.

Sec. 4128. Provider Outreach and Reporting on Certain Behavioral Health Integration Services.

- The HHS Secretary is required to conduct outreach to physicians and appropriate non-physician practitioners participating under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) with respect to behavioral health integration services described by any of HCPCS codes 99492 through 99494 or 99484 (or any successor codes). This outreach must include a comprehensive, one-time education initiative to inform such physicians and practitioners of the inclusion of such services as a covered benefit under the Medicare program, including describing the requirements to bill for such codes and the requirements for beneficiary eligibility for such services.
- No later than one year after the date of completion of the education initiatives described above, the HHS Secretary must submit a report to the House Committee on Energy and Commerce and Committee on Ways and Means and the Senate Finance Committee regarding such outreach efforts.
- No later than 18 months after the date of completion of the education initiatives described above, the HHS Secretary must submit a report to the House Committee on Energy and Commerce and Committee on Ways and Means and the Senate Finance Committee regarding the number of Medicare beneficiaries who, during the preceding year, were furnished such services, and for which, payment was made under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).
- **Impact:** Ensures that HHS is required to engage in educational and outreach efforts related to behavioral and mental health services to applicable physicians, practitioners and beneficiaries, while also ensuring a report for the same is provided to Congress for potential future congressional action on this subject.

Sec. 4129. Outreach and Reporting on Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs.

- The HHS Secretary must conduct outreach to physicians and appropriate non-physician practitioners participating under the Medicare program under title XVIII of the Social Security Act (42 17 U.S.C. 1395 et seq.) with respect to opioid use disorder treatment services furnished by an opioid treatment program. This outreach must include a comprehensive, one-time education initiative to inform such physicians and practitioners of the inclusion of such services as a covered

benefit under the Medicare program, including describing the requirements for billing and requirements for beneficiary eligibility for such services.
- The HHS Secretary must also conduct outreach to Medicare beneficiaries with respect to opioid use disorder treatment services furnished by an opioid treatment program, including a comprehensive, one-time education initiative informing such beneficiaries about the eligibility requirements to receive such services.
- Not later than one year after the date of the completion of the education initiatives described above, the HHS Secretary must submit a report to the House Committee on Energy and Commerce and Committee on Ways and Means and the Senate Finance Committee regarding such outreach efforts.
- No later than 18 months after the date of completion of the education initiatives described above, the HHS Secretary must submit a report to the House Committee on Energy and Commerce and Committee on Ways and Means and the Senate Finance Committee regarding the number of Medicare beneficiaries who, during the preceding year, were furnished opioid use disorder treatment services by an opioid treatment program, for which, payment was made under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).
- **Impact:** Ensures that HHS is required to engage in educational and outreach efforts related to opioid disorder treatment services to applicable physicians, practitioners and beneficiaries, while also ensuring a report for the same is provided to Congress for potential future congressional action on this subject.

Sec. 4130. GAO Study and Report Comparing Coverage of Mental Health and Substance Use Disorder Benefits and Non-Mental Health and Substance Use Disorder Benefits.

- The Comptroller General of the United States must conduct a study that compares the mental health and substance use disorder benefits offered by Medicare Advantage plans with benefits offered by Medicare Advantage Plans and the mental health and substance disorder benefits under the original Medicare fee-for-service program under parts A and B.
- No later than 30 months after the date of enactment of the omnibus bill, the Comptroller General must submit to Congress a report on the study described above.
- **Impact:** Ensures that there is further attention paid to a comparison of the mental health benefits and substance use disorder benefits offered by Medicare Advantage plans with similar benefits offered under other Medicare plans, while also ensuring a report for the same is provided to Congress for potential future congressional action on this subject.

Subtitle D – Other Medicare Provisions

Sec. 4131. Temporary Inclusion of Authorized Oral Antiviral Drugs as Covered Part D Drug.

- Includes certain oral antiviral drugs (dispensed following a prescription) authorized under Section 564 of the Federal Food, Drug, and Cosmetic Act within Medicare Part D coverage until Dec., 31, 2024.

- **Impact:** Ensures that certain authorized oral antiviral drugs are covered under Medicare Part D through 2024.

Sec. 4132. Restoration of CBO Access to Certain Part D Payment Data.

- Authorizes the Congressional Budget Office (CBO) to have access to certain Medicare Part D payment data, including, but not limited to, rebate and direct and indirect remuneration (DIR) data, for the purposes of analysis of such programs.
- **Impact:** Ensures that the CBO can use certain payment data from Medicare Part D as part of its data collection and analysis efforts.

Sec. 4133. Medicare Coverage of Certain Lymphedema Compression Treatment Items.

- Adds certain lymphedema compression treatment items as items and services covered under Medicare.
- Adds certain lymphedema compression treatment items into the payment framework under Medicare. Specifically, the amount paid for these items shall be equal to 80% of the lesser of the actual charge or the amount determined under the payment basis set forth at Section 1834(z) of the Social Security Act, which provides the HHS Secretary with the statutory authority to determine an appropriate payment basis for these items.
- **Impact:** Adds certain lymphedema compression treatment items as covered items/services under Medicare.

Sec. 4134. Permanent In-Home Benefit for IVIG Services.

- Added a permanent benefit under Medicare coverage for items and services furnished on or after Jan. 1, 2024, related to the in-home administration of intravenous immune globulin (IVIG).
- Adds these items and services to the payment framework under Medicare whereby the HHS Secretary is directed to provide for a separate bundled payment to an applicable supplier for all items and services related to the administration of intravenous immune globulin to an applicable patient in his or her home.
- Authorizes and appropriates $4.3 million for the payment of items and services provider under the demonstration project established by the Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 (42 U.S.C. 1395(l) note).
- **Impact:** Adds a permanent benefit for in-home IVIG services to patients under Medicare.

Sec. 4135. Access to Non-Opioid Treatments for Pain Relief.

- Provides for a separate Medicare payment from 2025 to 2027 for certain non-opioid treatments for pain relief previously covered under the payment framework applicable to the Outpatient Prospective Payment Systems (OPPS).
- This payment is capped at 18% of the estimated average payment under OPPS for the applicable surgery(ies) or other service with which the applicable non-opioid is used and furnished to a patient.

- Provides for a similar separate Medicare payment from 2025 to 2027 for certain non-opioid treatments for pain relief in connection with surgical services furnished via ambulatory surgical centers.
- No later than Jan. 1, 2028, the HHS Secretary must provide a report to Congress that, among other things, identifies limitations, gaps, barriers to access or deficits in Medicare coverage or reimbursement for restorative therapies, behavioral approaches and complementary and integrative health services that are identified in the Pain Management Best Practices Inter-Agency Task Force Report and that have demonstrated the ability to replace or reduce opioid consumption, as well as recommends actions to address such limitations, gaps, barriers to access or deficits.
- **Impact:** Ensures that non-opioid treatments for pain relief are afforded a separate Medicare payment, subject to the conditions described above.

Sec. 4136. Technical Amendments to Medicare Separate Payment for Disposable Negative Pressure Wound Therapy Devices.

- Establishes an adjustment to the payment framework applicable to disposable negative pressure wound therapy devices by applying the supply price for the purpose of calculating the applicable services' relative value under the applicable fee schedule. This adjustment will take into account the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending in June of the previous year.
- The separate payment amount calculated under this provision exempts certain nursing and therapy services.
- **Impact:** Ensures that a payment adjustment is applied for certain disposable negative pressure wound therapy devices in light of current and recent economic conditions, among other factors.

Sec. 4137. Extension of Certain Home Health Rural Add-On Payments.

- Extends 1% add-on payments for rural health home agencies for one additional year through 2023.
- **Impact:** Ensures that add-on payments for rural health home agencies continue through 2023.

Sec. 4138. Remedying Election Revocations Relating to Administration of COVID-19 Vaccines.

- Provides that individuals who elect to receive services in religious nonmedical health institutions may receive COVID-19 vaccines under Medicare.
- Clarifies that (i) an individual's receipt of a COVID-19 vaccine does not revoke his or her election to receive services in religious nonmedical health institutions and (ii) an individual whose election was revoked due to the receipt of a COVID-19 vaccine prior to the date of enactment of the omnibus bill is permitted to reelect to receive services in religious nonmedical health institutions under Medicare.
- **Impact:** Ensures that individuals who elect to receive services in religious nonmedical health institutions may receive COVID-19 vaccines under Medicare, and

that their election to receive services in such institutions under Medicare is not adversely impacted by receipt of COVID-19 vaccine(s).

Sec. 4139. Payment Rates for Durable Medical Equipment under the Medicare Program.

- Requires the HHS Secretary to apply the transition rule set forth under section 414.210(g)(9)(v) of title 42 of the Code of Federal Regulations to all durable medical equipment items and services furnished in areas other than rural or noncontiguous areas through the remainder of the duration of the Public Health Emergency (PHE) or Dec. 31, 2023, whichever is later.
- Prohibits the HHS Secretary from implementing the transition rule set forth under section 414.210(g)(9)(vi) of title 42 of the Code of Federal Regulations until the date immediately following the last day of the PHE or Jan. 1, 2024, whichever is later.
- **Impact:** Ensures that transition rules for payment of certain durable medical equipment set to go in effect in the near future are delayed until the later of the end of the PHE or through 2023, as applicable.

Sec. 4140. Extending Acute Hospital Care at Home Waivers and Flexibilities.

- Extends waivers and telehealth flexibilities to hospitals and other eligible entities for acute hospital care pursuant to the Acute Hospital Care at Home initiative for two years until Dec. 31, 2024.
- The HHS Secretary must conduct a study to, among other things, analyze and compare the quality of care finished to individuals in the inpatient setting and through the Acute Hospital Care at Home initiative based on various factors, including costs incurred, health outcomes, hospital mortality rates, length of stay and other factors.
- No later than Sept. 30, 2024, the HHS Secretary must post on the CMS website a report on the foregoing study.
- Appropriates $5 million to CMS for FY 2023 for carrying out the study and preparing the report.
- **Impact:** Ensures telehealth flexibilities and related waivers are provided to hospitals and other eligible entities participating or seeking to participate in the Acute Hospital Care at Home initiative, so long as they satisfy certain conditions.

Sec. 4141. Extension of Pass-Through Status under the Medicare Program for Certain Devices Impacted by COVID-19.

- Extends pass-through status for certain medical devices impacted by COVID-19 whose pass-through status will expire on Dec. 31, 2022, for a period of one year.
- During this one-year extension of pass-through status, the HHS Secretary is not permitted to remove the packaged cost of such device from the payment amount for a covered OPD (outpatient department) service with which it is packaged.
- **Impact:** Ensures pass-through status for certain eligible medical devices is sustained for one additional year.

Sec. 4142. Increasing Transparency for Home Health Payments under the Medicare Program.

- With respect to HHS' proposed rulemaking regarding one or more permanent increases or decreases to the standard prospective payment amount for applicable years on a prospective basis to offset increases or decreases in estimated aggregate expenditures for home health services (as set forth under 42 U.S.C. 1395fff(b)(3)(D)), the HHS Secretary, as part of any notice and comment period, is required to make publicly available certain data showing CMS' simulation of 60-day episodes under the home health prospective payment system in effect prior to the Patient Driven Groupings Model using data from 30-day periods paid under such model as well as a description of behavioral changes as a result of implementation of adjustments and other related statutory requirements that occurred in 2020 through 2026, among other things.
- No later than 90 days after the date of enactment of this provision, the HHS Secretary must use an open door forum or other forum to receive input from home health stakeholders and interested parties on Medicare home health payment rate development.
- At least 30 days before the above-referenced forum, the HHS Secretary must make publicly available via the CMS website the data noted above with respect to the home health prospective payment system rate for calendar year 2023 as finalized in the final rule entitled "Medicare Program; Calendar Year 2023 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Program Requirements; Home Health Value-Based Purchasing Expanded Model Requirements; and Home Infusion Therapy Services Requirements" published in the *Federal Register* on Nov. 4, 2022 (87 Fed. Reg. 66790).
- **Impact:** Ensures that certain data related to the home health payments under Medicare are made publicly available, including in connection with recent and forthcoming notice and comment periods and related proposed rulemaking.

Sec. 4143. Waiver of Cap on Annual Payments for Nursing and Allied Health Education Payments.

- Waives the annual cap(s) on payments for nursing and allied health education made during the time periods of 2010 to 2019.
- Ensures that HHS must not take into account any increases in the total amount of additional payment amounts for nursing and allied health education when determining payments for direct graduate medical education.
- $3 million is appropriated to CMS for FY 2023 to carry out the terms of this section.
- **Impact:** Retroactively ensures that annual caps on payments for nursing and allied health education from 2010–2019 are not applied.

Subtitle E – Health Care Tax Provisions

Sec. 4151. Extension of Safe Harbor for Absence of Deductible for Telehealth.

- Extends the flexibility to exempt telehealth services from the deductible in high-deductible plans coupled with a health savings account through 2024.

- **Impact:** Ensures that beneficiaries with these type of high deductible plans are able to continue to access telehealth services before their annual deductible is met.

Subtitle F – Offsets

Sec. 4161. Reduction of Medicare Improvement Fund.

- Reduces balances in the Medicare Improvement Fund by approximately $7 billion.
- **Impact:** This reduction helps offset the costs of the extensions and other amendments to Medicare policies set forth in the omnibus bill.

Sec. 4162. Extension of Adjustment to Calculation of Hospice Cap Amount under Medicare.

- Extends by one year (i.e., through 2032) the use of a hospice payment update percentage by hospice providers for the annual update to the hospice aggregate cap.
- **Impact:** Ensures that the hospice payment update percentage for hospice providers will be extended one additional year.

Sec. 4163. Medicare Direct Spending Reductions.

- Extends sequestration for the first six months of FY 2032 as an offset to the omnibus bill's cost.
- Lowers the sequestration percentages to 2% and 3% for FY 2030 and FY 2031, respectively.
- **Impact:** Extends sequestration as an offset for other costs set forth in the legislation.

TITLE V – MEDICAID AND CHIP PROVISIONS

Subtitle A – Territories

Sec. 5101. Medicaid Adjustments for the Territories.

- Revises allotments for Puerto Rico for FY23 and each subsequent year to the following:
    - $3.275 billion for FY 2023
    - $3.325 billion for FY 2024
    - $3.475 billion for FY 2025
    - $3.645 billion for FY 2026
    - $3.825 billion for FY 2027
    - For FY 2028, the sum of the amount that would have been provided under this subsection for Puerto Rico had the amount provided under this subsection for each of FY 2020–2027 been equal to the following:
        - For FY 2020, the sum of the amount provided for Puerto Rico for FY 2019, increased by the percentage increase in the medical care component of the Consumer Price Index (CPI) for all urban consumers

for the 12-month period ending in March preceding the beginning of the FY, rounded to the nearest $100,000.
        - For each of FY 2021-2027, the sum of the amount provided for the preceding FY, increased in accordance with the percentage increased described above.
    - For FY 2029 and each subsequent FY, the sum of the amount specified for the preceding FY, increased by the percentage increase in the medical care component of the CPI for all urban consumers for the 12-month period ending in March preceding the beginning of the FY, rounded to the nearest $100,000.
- Adds an additional $300 million increase for Puerto Rico for FY 2023 and each subsequent FY through FY 2027, if certified by the Secretary based on the reimbursement floor imposed by Puerto Rico's state plan for physician services covered under the Medicare Part B fee schedule.
- Extends increased FMAPs from expiring on Dec. 23, 2022, to expiring on Sept. 30, 2027.
- Requires Puerto Rico to implement an asset verification program by Jan. 1, 2026.
- Requires the Secretary to pay each eligible territory an amount equal to 100% of the qualifying system improvement expenditures incurred on or after Oct. 1, 2023.
- Requires each territory to submit to the Secretary of HHS a four-year strategic plan outlining the territory's goals related to workforce development, financing, systems implementation and operation, and program integrity with respect to the territory's Medicaid program, and to submit an analysis of the territory's achievements or progress toward achieving such goals no later than Sept. 30, 2027.
- **Impact:** Revises Medicaid payments to the territories at increasing rates beginning in FY 2023, and imposes additional quality and accountability measures for such increased funding.

Subtitle B – Medicaid and CHIP Coverage

Sec. 5111. Funding Extension of the Children's Health Insurance Program and Related Provisions.

- Extends funding for the Children's Health Insurance Program (CHIP) through FY 2029, as opposed to FY 2027.
- Provides $15 million for each of FY 2028 and FY 2029 for the Pediatric Quality Measures Program.
- Extends the Assurance of Eligibility Standards for Children from running through Sept. 30, 2027, to running through Sept. 30, 2029.
- Extends the Qualifying States Option through 2029, as opposed to 2027.
- Extends the Outreach and Enrollment Program through 2029, as opposed to 2027, and funds the program at $48 million through 2027, and at $40 million for the period of FY 2028 and FY 2029.
- Extends the Child Enrollment Contingency Fund and additional CHIP-related provisions through 2029.
- **Impact:** Extends funding for CHIP and related policies for a minimum of two additional years.

Sec. 5112. Continuous Eligibility for Children under Medicaid and CHIP.

- Provides for one year of continuous eligibility for individuals under age 19 who are eligible for benefits under a state plan or waiver of such state plan.
- Makes an exception such that a targeted low-income child enrolled under the state child health plan or waiver may be transferred to the Medicaid program under title XIX for the remaining duration of the 12-month continuous eligibility period, if the child becomes eligible for full benefits under title XIX during such period, effective on the first day of the first fiscal quarter that begins on or after the date that is one year after enactment of this act.
- **Impact:** Ensures one year of continuous eligibility for children enrolled in Medicaid and CHIP.

Sec. 5113. Modifications to Postpartum Coverage under Medicaid and CHIP.

- Strikes "during the 5-year period" to extend coverage for pregnant and postpartum women beyond the five-year period beginning on the first day of the first FY quarter that began one year after the date of the enactment of the American Rescue Plan Act (ARPA).
- **Impact:** Removes the time frame imposed by the ARPA to extend postpartum coverage under Medicaid and CHIP.

Sec. 5114. Extension of Money Follows the Person Rebalancing Demonstration.

- Extends the Money Follows the Person Rebalancing Demonstration and funds it at $450 million annually for FY 2024 through FY 2027.
- Appropriates $5 million for technical assistance for FY 2023 and each subsequent three-year period through FY 2029.
- Requires unexpended funds to be rescinded at the end of the fourth succeeding FY and added to the appropriation for the fifth succeeding FY.
- **Impact:** Provides additional funding to extend the Money Follows the Person Rebalancing Demonstration.

Sec. 5115. Extension of Medicaid Protections Against Spousal Impoverishment for Recipients of Home and Community-Based Services.

- Extends Medicaid Protections Against Spousal Impoverishment for Recipients of Home and Community-Based Services through Sept. 30, 2027.
- **Impact:** Pushes the end date for such protections from Sept. 30, 2023, to Sept. 30, 2027.

Subtitle C – Medicaid and CHIP Mental Health

Sec. 5121. Medicaid and CHIP Requirements for Health Screenings, Referrals, and Case Management Services for Eligible Juveniles in Public Institutions.

- Requires states put a plan in place in the case of an eligible juvenile who is within 30 days of scheduled release from a public institution following adjudication. The plan must provide for the following:

    - In the 30 days prior to release, or not later than one week after release, any screening or diagnostic service that meets reasonable standards or is deemed medically necessary; and
    - In the 30 days prior to release, and for at least 30 days following release, targeted case management services.
- Provides that a state shall not terminate eligibility for CHIP for a targeted low-income child because the child is an inmate of a public institution, but may suspend coverage during the period the child is such an inmate. Prior to the child's release, the state shall conduct a redetermination of eligibility, and if the child continues to meet eligibility requirements, the state shall restore CHIP coverage upon release. The state shall also process any application for CHIP submitted by, or on behalf of, the eligible child upon release.
- Amendments made by this section apply beginning on the first day of the first calendar quarter that begins on or after the date that is 24 months after the act's enactment.
- **Impact:** Outlines requirements for health screenings, referrals and case management services for Medicaid- and CHIP-eligible juveniles in public institutions, including juvenile inmates.

Sec. 5122. Removal of Limitations on Federal Financial Participation for Inmates Who Are Eligible Juveniles Pending Disposition of Charges.

- Removes limitations on Medicaid and CHIP participation for eligible juveniles while inmates of a public institution, pending disposition of charges with respect to such individuals.
- Amendments made by this section apply beginning on the first day of the first calendar quarter that begins on or after the date that is 24 months after the act's enactment and apply to items and services furnished for periods beginning on or after such date.
- **Impact:** Removes limitations on federal financial participation in Medicaid and CHIP for eligible juvenile inmates pending disposition of charges.

Sec. 5123. Requiring Accurate, Updated and Searchable Provider Directories.

- Requires each managed care organization, prepaid inpatient health plan, prepaid ambulatory health plan and, when appropriate, primary care case management entity with a state contract, to publish and regularly update on a public website a searchable directory of network providers that includes:
    - The name of the provider;
    - The specialty of the provider;
    - The address at which the provider provides services;
    - The telephone number of the provider; and
    - Information regarding the provider's cultural and linguistic capabilities, whether the provider is accepting new patients, whether the provider's office or facility has accommodations for individuals with physical disabilities, the website of the provider, whether the provider offers covered services via telehealth, and other relevant information.

- Provides that in the case of a state plan that provides medical assistance on a fee-for-service basis or through a primary care case-management system, the state shall publish and update on at least a quarterly basis on the public website of the administering state agency, a searchable directory of the providers that, in addition to other requirements the Secretary may specify, includes:
    - The name of the provider;
    - The specialty of the provider;
    - The address at which the provider provides services;
    - The telephone number of the provider;
    - Information regarding the provider's cultural and linguistic capabilities;
    - Whether the provider is accepting as new patients individuals who receive medical assistance under this title;
    - Whether the provider's office or facility has accommodations for individuals with physical disabilities;
    - The website of such provider;
    - Whether the provider offers covered services via telehealth; and
    - Other relevant information.
- Amendments made by this section take effect on July 1, 2025.
- **Impact:** Outlines requirements for managed care organizations and health plans to make publicly available and regularly update their provider directories with specified information.

Sec. 5124. Supporting Access to a Continuum of Crisis Response Services under Medicaid and CHIP.

- Requires that the HHS Secretary, in coordination with the CMS Administrator and the Assistant Secretary for Mental Health and Substance Use, issue guidance to states regarding Medicaid and CHIP that includes the following:
    - Provides recommendations for an effective continuum of crisis response services;
    - Outlines the federal authorities through which states may finance and enhance the availability of crisis response services across each state of the continuum of crisis response services;
    - Addresses how states may support the ongoing implementation of crisis services hotlines, and how Medicaid administrative funding and the Medicaid Information Technology Architecture 3.0 framework, may be used to establish or enhance regional or statewide crisis call centers that coordinate in real time;
    - Identifies how states under Medicaid and CHIP may support access to crisis response services that are responsive to the needs of children, youth and families;
    - Identifies policies and practices to meet the need for crisis response services with respect to differing patient populations;
    - Identifies policies and practices to promote evidence-based suicide risk screenings and assessments;
    - Identifies strategies to facilitate timely provision of crisis response services;

    - Describes best practices for coordinating Medicaid and CHIP funding with other payors and sources of federal funding for mental health and substance use disorder crisis response services, and best practices for Medicaid and CHIP financing when the continuum of crisis response services serves individuals regardless of payor;
    - Describes best practices for establishing effective connections with follow-on mental health and substance use disorder services, as well as with social services and supports;
    - Describes best practices for coordinating and financing a continuum of crisis response services through Medicaid managed care organizations, prepaid inpatient health plans, prepaid ambulatory health plans, and fee-for-service delivery systems; and
    - Identifies strategies and best practices for measuring and monitoring utilization of, and outcomes related to, crisis response services.
- Requires establishment of a technical assistance center to help states design, implement or enhance a continuum of crisis response services for children, youth and adults.
- Requires development and maintenance of a publicly available compendium of best practices for the successful operation of a continuum of crisis response services.
- Appropriates $8 million to carry out the above subsections.
- **Impact:** Requires guidance be issued to states to support access to and operation of a continuum of crisis responses services under Medicaid and CHIP.

Subtitle D – Transitioning from Medicaid FMAP Increase Requirements

Sec. 5131. Transitioning from Medicaid FMAP Increase Requirements.

- Adjusts the ending of the temporary Federal Medical Assistance Percentages (FMAP) increase from the last day of the calendar quarter in which to last day of the emergency period occurs to Dec. 31, 2023, and changes the 6.2 percentage points increase to "the applicable number of percentage points for the quarter."
- Defines the applicable number of percentage points for a calendar quarter as 6.2 percentage points for each calendar quarter that ends on March 31, 2023; 5 percentage points for the calendar quarter that begins on April 1, 2023, and ends on June 30, 2023; 2.5 percentage points for the calendar quarter that begins on July 1, 2023 and ends on Sept. 30, 2023; and 1.5 percentage points for the calendar quarter that begins on Oct. 1, 2023, and ends on Dec. 31, 2023.
- Provides conditions for states to impose the outlined FMAP increase during the transition period, as well as guidance for when a state does not qualify for said increase.
- Outlines requirements for reporting, enforcement and corrective action if a state does not satisfy set requirements.
- Amendments made by this section take effect on April 1, 2023.
- **Impact:** Makes changes to the temporary FMAP increase to ease the transition from 6.2 percentage points to the level set prior to implementation of the Families First Coronavirus response Act.

Subtitle E – Medicaid Improvement Fund

Sec. 5141. Medicaid Improvement Fund.

- Extends funding from FY 2025, at $0, to FY 2028 and thereafter, at $7 billion.
- **Impact:** Provides $7 billion in funding for the Medicaid Improvement Fund for FY 2028 and thereafter.

TITLE VI – HUMAN SERVICES

Sec. 6101. Jackie Walorski Maternal and Child Home Visiting Reauthorization Act of 2022.

- Requires the Secretary to establish and operate a website accessible to the public that includes annually updated and easy-to-understand information on outcomes achieved by state or territory Maternal, Infant, and Early Childhood Home Visiting (MIECHV) programs. The Secretary may operate the website directly or via grants or contracts.
    - The reported outcomes must be related to statutory benchmarks including improved maternal and newborn health; prevention of child injuries, child abuse, and neglect or maltreatment, and reduction of emergency department visits; improvement in school readiness and achievement; reduction in crime or domestic violence; improvement in family economic self-sufficiency; or improvements in the coordination and referrals for other community resources and supports.
    - The dashboard must convey outcomes for states and territories using a template that includes a profile for each entity showing outcome indicators and how they compare to the benchmarks established for those outcomes; information on the outcome indicators and requisite outcome levels for each entity; information on the evidence-based home visiting model(s) used by the entity and specific participant outcomes the model is intended to affect; the most recently available information reported in the report on performance improvement; an electronic link to the state needs assessment; and information regarding any penalty or other corrective action taken by the Secretary against an entity and, if the entity is operating under a corrective action plan, detailed information about the plan and progress toward improvement.
- Provides five years of funding for MIECHV and explains how federal base and matching funds are calculated and allocated to states, territories and nonprofit entities operating programs on behalf of states and requires those entities to meet maintenance of effort (MOE) requirements.
    - Starting in FY 2023, and each year through FY 2027, every eligible entity qualifies for a federal base grant, which is calculated in FY 2023 and remains the same in subsequent years. If the eligible entity changes during the 2023–2027 period, the new eligible entity for that state or territory receives the same base grant as the previous entity established FY 2023.

    - The federal base grant amount is calculated by first reducing the amount available for base grants to account for reserved amounts and any required sequester, then allocating the remainder according through a formula.
    - Starting in FY 2024, and each year through FY 2027, federal matching grant funds are made available to every eligible entity up to a specified allocation if the entity complies with statutory conditions.
    - The federal matching grant amount is calculated by first reducing the amount available for matching grants to account for reserved funding amounts and any required sequester, then allocating the remainder through a formula. Minimum matching grant allocation amounts are $776,000 for FY 2024, $1 million for FY 2025, $1.5 million for FY 2026, and $2 million for FY 2027.
    - In order to draw down its full allotment of federal matching grant funds, an entity must provide non-federal funds above their MOE requirement such that 25%of the total spending consists of non-federal funds. Eligible entities may draw down a proportionate share of federal matching funds up to their full allotment. The non-federal funds must be used to support home visiting that meets the MIECHV requirements related to individual and family outcomes, evidence, and providing targeted, intensive services. Any unobligated federal matching funds in a FY may be redistributed to eligible entities willing to provide the required non-federal match.
- Reserves funds for purposes other than state/territory grants. The reservation percentages are applied equally to the total available base grant and matching grant funds provided for each FY. The reservations are:
    - 6% of total funding for grants to Indian tribes, tribal organizations or urban Indian organizations;
    - 2% for technical assistance to states, tribes and territories;
    - 2% for workforce support, retention and case management; and
    - 3% for HHS costs related to administering the program, research and evaluation activities.
- Provides five years of funding for MIECHV at the following levels:
    - FY 2023: $500 million for base grants
    - FY 2024: $500 million for base grants and $50 million for matching grants
    - FY 2025: $500 million for base grants and $100 million for matching grants
    - FY 2026: $500 million for base grants and $150 million for matching grants
    - FY 2027: $500 million for base grants and $300 million for matching grants
- Clarifies that any home visiting program funded under this section must provide or support targeted, intensive services to families determined to be at risk, to prevent diversion of funds from the program's core purpose.
- Limits states, territories and administering nonprofits to using no more than 10% of their federal funding for administrative costs; provides a narrow exception authority to the Secretary and makes conforming changes.
- Requires the Secretary to report to Congress no later than Dec. 31, 2023, and each subsequent year, on the grants funded in the previous year. The report must include:
    - Information for all states and territories on the outcomes achieved and how they compare to applicable statutory benchmarks;
    - Information regarding technical assistance provided to grantees;

    - Information on the demographic makeup of families served;
    - Information that states, territories and nonprofits report in their demonstration of improvement report to HHS, in the years in which that information is available;
    - Information on the estimated share of the eligible population receiving home visiting from MIECHV;
    - A description of the service delivery models funded in each state or territory and the share of grants used for each model;
    - A description of non-federal funds used to meet match requirements;
    - Information on uses of funds reserved for workforce support, retention and case management;
    - Information relating to tribal home visiting programs; and
    - A list of data elements that HHS requires eligible entities to report, and the purpose and use of each element.
- Requires the Secretary to reduce the administrative burden of MIECHV data reporting and compliance with federal rules in a way that focuses more resources on families, while maintaining accountability. The Secretary must include findings from the process in the report to Congress described in the prior section and implement the findings within two years after the report.
- Authorizes the use of virtual home visits and adds restrictions to their use. Includes a general requirement that service delivery models must include at least one in-person visit a year to qualify for federal funding. Entities that wish to provide limited virtual visits must provide the Secretary with:
    - A description of limitations or constraints on virtual home visits;
    - An assurance that virtual visits are implemented as a model enhancement or that the Secretary has identified the home visit as part of an effective model or model adaptation, based on an evidence of effectiveness review; and
    - An assurance that at least one in-person home visit shall be conducted each year, except during public health emergencies.
- Requires that training provided to home visitors providing virtual visits be equivalent to training for in-person visits, defines certain terms used in the section, and requires the Secretary to provide technical assistance to eligible entities to ensure compliance.
- Makes all provisions except the virtual visit rules effective Oct. 1, 2022; makes virtual home visit provisions effective Oct. 1, 2023.
- **Impact:** Reauthorizes the MIECHV program for five years, increases funding for services that aid new parents and their children from pregnancy through kindergarten with in-home support, and updates the program to better measure and improve outcomes for families, promote state accountability and ensure additional MIECHV funding reaches families in poverty.

Sec. 6102. Extension of Temporary Assistance for Needy Families Program.

- Extends funding for the Temporary Assistance for Needy Families (TANF) Program through Sept. 30, 2023, at the FY22 level.
- **Impact:** Level funds TANF for FY23.

Sec. 6103. One-Year Extension of Child and Family Services Programs.

- Extends child and family services programs for one year, through 2023.
- **Impact:** Extends provisions within child and family services programs beyond 2022 and 2021 to 2023, respectively.