# Consolidated Appropriations Act, 2023

## *Section-by-Section Summary*

## 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*

**Section 1101. Behavioral Health Crisis Coordinating Office.**
Section 1101 codifies the Behavioral Health Crisis Coordinating Office within the Substance Abuse and Mental Health Services Administration (SAMHSA) to convene partners and provide technical assistance to enhance access to crisis care.

**Section 1102. Crisis response continuum of care.**
Section 1102 requires the Secretary of Health and Human Services (HHS) to facilitate the publication of best practices for a crisis response continuum of care not later than one year after the date of enactment for use by health care providers, crisis services administrators, and crisis services providers; and, three years later, to facilitate the identification of any updates of such best practices, as appropriate. Directs the Government Accountability Office (GAO) to assess the extent to which relevant programs related to mental health and substance use disorder crises utilize best practices and recommendations identified under this section and submit its findings to Congress within three years.

**Section 1103. Suicide Prevention Lifeline Improvement.**
Section 1103 reauthorizes and expands the National Suicide Prevention Lifeline Program. It strengthens agreements, as appropriate, to facilitate the transmission of epidemiological data from the program to the Centers for Disease Control and Prevention (CDC) and ensure relevant analyses are made available to state and local agencies. It also requires the Secretary of HHS, acting through the Assistant Secretary for Mental Health and Substance Use, to implement a pilot program focused on innovative technologies for suicide prevention. The section also directs HHS to develop, implement, and complete a study on the goals and objectives of its plan and submit a report of its findings to Congress, and requires a GAO study of the program.

## *Chapter 2 – Into the Light for Maternal Mental Health and Substance Use Disorders*

**Section 1111. Screening and treatment for maternal mental health and substance use disorders.**
Section 1111 reauthorizes section 317L-1 of the Public Health Service Act (PHSA) to award grants to states, Tribes, and Tribal organizations to establish, improve, or maintain maternal mental health and substance use disorder programs for pregnant or postpartum women.

**Section 1112. Maternal mental health hotline.**
Section 1112 establishes a national hotline to provide information and resources for pregnant and postpartum women at risk of, or affected by, maternal mental health and substance use disorders.

**Section 1113. Task force on maternal mental health.**
Section 1113 establishes a task force to make recommendations to coordinate and improve federal activities related to maternal mental health conditions.

**Section 1114. Residential treatment program for pregnant and postpartum women pilot program reauthorization.**
Section 1114 extends the residential treatment pilot program for pregnant and postpartum women.

## *Chapter 3 – Reaching Improved Mental Health Outcomes for Patients*

**Section 1121. Innovation for mental health.**
Section 1121 reauthorizes the National Mental Health and Substance Abuse Policy Laboratory and requires a GAO report on the Policy Lab's activities. It also reauthorizes the Interdepartmental Serious Mental Illness Coordinating Committee, and reauthorizes the Priority Mental Health Needs of Regions of National Significance (PRNS).

**Section 1122. Crisis care coordination.**
Section 1122 establishes the Mental Health Crisis Response Partnership pilot program to allow for mobile crisis response teams. It also reauthorizes the Mental Health Awareness Training (MHAT) Grant program, and expands access to technical assistance for MHAT grantees. The section also reauthorizes and improves Adult Suicide Prevention program.

**Section 1123. Treatment of serious mental illness.**
Section 1123 reauthorizes the Assertive Community Treatment Grant. It requires a related report to Congress by the end of fiscal year (FY) 2026. It also reauthorizes the Assisted Outpatient Treatment Grant Program and directs GAO to examine the efficacy of the program compared to other community-based outpatient treatment programs and services and submit a report to respective Committees of jurisdiction within three years of enactment.

**Section 1124. Study on the costs of serious mental illness.**
Section 1124 requires a study to determine the true costs of untreated serious mental illness on families, health care systems, public housing, and law enforcement in America.

### *Chapter 4 – Anna Westin Legacy*

**Section 1131. Maintaining education and training on eating disorders.**
Section 1131 authorizes the SAMHSA National Center of Excellence for Eating Disorders to award competitive subgrants or subcontracts to develop and provide training and technical assistance for primary and mental health providers and other paraprofessionals and relevant individuals. It also authorizes the center to collaborate and coordinate with SAMHSA, CDC, and the Health Resources and Services Administration (HRSA) on the identification, treatment, and ongoing support of individuals with eating disorders.

### *Chapter 5 – Community Mental Health Service Block Grant Reauthorization*

**Section 1141. Reauthorization of block grants for community mental health services.**
Section 1141 reauthorizes the Community Mental Health Services Block Grants for states, territories, Tribes, and Tribal organizations to support community mental health services for adults with serious mental illness and children with serious emotional disturbance, and to support the collection of performance and outcome data. It requires five percent of the funds to be used for crisis-care services.

### *Chapter 6 – Peer-Supported Mental Health Services*

**Section 1151. Peer-Supported Mental Health Services.**
Section 1151 authorizes grants for consumer-run nonprofit organizations, Tribes and Tribal organizations, Urban Indian organizations, or Tribal consortia to provide peer-supported mental health services, including virtual peer support.

## 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.**
Section 1201 authorizes resources to provide services for the prevention of, treatment of, and recovery from mental health and substance use disorders for American Indians, Alaska Natives, and Native Hawaiians.

### *Chapter 2 – Summer Barrow Prevention, Treatment, and Recovery*

**Section 1211. Grants for the benefit of homeless individuals.**
Section 1211 reauthorizes the Formula Grants for the Benefit of Homeless Individuals program.

**Section 1212. Priority substance use disorder treatment needs of regional and national significance.**
Section 1212 reauthorizes the Substance Use Disorder Treatment Programs of Regional and National Significance (PRNS) program.

**Section 1213. Evidence-based prescription opioid and heroin treatment and interventions demonstration.**
Section 1213 reauthorizes Prescription Opioid and Heroin Treatment and Interventions Demonstration Grants.

**Section 1214. Priority substance use disorder prevention needs of regional and national significance.**
Section 1214 reauthorizes Substance Use Disorder Prevention PRNS.

**Section 1215. Sober Truth on Preventing (STOP) Underage Drinking Reauthorization.**
Section 1215 reauthorizes underage drinking prevention programs at SAMHSA, including the Community-based Coalition Enhancement Grants to Prevent Underage Drinking, a National Media Campaign to Prevent Underage Drinking, and grants to Organizations Representing Pediatric Providers and Other Related Health Professionals. It also authorizes a National Academies of Sciences, Engineering, and Medicine review and report to Congress.

**Section 1216. Grants for jail diversion programs.**
Section 1216 reauthorizes the Grants for Jail Diversion Program.

**Section 1217. Formula grants to States.**
Section 1217 extends the Secretary's authority to allocate funds for Projects for Assistance in Transition from Homelessness formula grants to states.

**Section 1218. Projects for Assistance in Transition from Homelessness.**
Section 1218 reauthorizes the Projects for Assistance in Transition from Homelessness Program.

**Section 1219. Grants for reducing overdose deaths.**
Section 1219 reauthorizes the Grants for Reducing Overdose Deaths program, including supporting the development of strategic opioid crisis response plans.

**Section 1220. Opioid overdose reversal medication access and education grant programs.**
Section 1220 reauthorizes the Opioid Overdose Reversal Medication Access, Education, and Co-prescribing Grants.

**Section 1221. Emergency department alternatives to opioids.**
Section 1221 reauthorizes Emergency Department Alternatives to Opioids Demonstration Grants.

## *Chapter 3 – Excellence in Recovery Housing*

**Section 1231. Clarifying the role of SAMHSA in promoting the availability of high-quality recovery housing.**
Section 1231 requires the Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, to collaborate with federal agencies and relevant stakeholders to promote the

availability of high-quality recovery housing and services for individuals with substance use disorders.

**Section 1232. Developing guidelines for States to promote the availability of high-quality recovery housing.**
Section 1232 requires the Secretary to develop and periodically update consensus-based best practices for operating, and promoting the availability of, high-quality recovery housing.

**Section 1233. Coordination of Federal activities to promote the availability of recovery housing.**
Section 1233 requires the Secretary, acting through the Assistant Secretary for Mental Health and Substance Use and the Secretary of Housing and Urban Development, to convene an interagency working group and report to Congress on its activities to increase federal collaboration and coordination, develop a long-term plan to support state, Tribal, and local efforts to operate recovery housing consistent with best practices, and coordinate fair housing practices and data collection on the quality of recovery housing.

**Section 1234. National Academies of Sciences, Engineering, and Medicine study and report.**
Section 1234 requires a National Academies of Sciences, Engineering, and Medicine study on the quality and effectiveness of recovery housing, including recommendations to promote the availability of recovery housing.

**Section 1235. Grants for states to promote the availability of recovery housing and services.**
Section 1235 permits SAMHSA to provide grants to states, Tribes, and territories for technical assistance to promote and maintain recovery housing according to best practices and to develop related state promotion plans.

**Section 1236. Funding.**
Section 1236 authorizes $5 million for recovery housing activities for the period of FY 2023 through FY 2027.

**Section 1237. Technical correction.**
Section 1237 makes technical conforming corrections to the Public Health Services Act.

## *Chapter 4 – Substance Use Prevention, Treatment, and Recovery Services Block Grant*

**Section 1241. Eliminating stigmatizing language relating to substance use.**
Section 1241 replaces "substance abuse" with "substance use," including renaming SAMHSA's Substance Abuse Prevention and Treatment Block Grant as the "Substance Use Prevention, Treatment, and Recovery Services Block Grant."

**Section 1242. Authorized activities.**
Section 1242 adds "provide recovery support services" as an authorized activity.

**Section 1243. State plan requirements.**
Section 1243 requires that states' plans describe the recovery support service activities supported by block grant funds, including number of individuals served, target populations, workforce capacity (including with respect to prevention, treatment, and recovery), priority needs, and the amount of funds allocated to recovery support services disaggregated by type of activity.

**Section 1244. Updating certain language relating to Tribes.**
Section 1244 updates the statutory language with regard to Tribes and Tribal organizations.

**Section 1245. Block grants for substance use prevention, treatment, and recovery services.**
Section 1245 reauthorizes the Substance Use Prevention, Treatment, and Recovery Services Block Grant to provide states and Tribes with funding to plan, carry out, and evaluate substance use disorder prevention, treatment, and recovery support services for individuals, families, and communities impacted by substance use disorders.

**Section 1246. Requirement of reports and audits by states.**
Section 1246 requires states' reports to include the amount of funds provided to each grant recipient from the previous fiscal year.

**Section 1247. Study on assessment for use of state resources.**
Section 1247 requires the Secretary to conduct a study on strategies to assess community needs with respect to prevention, treatment, or recovery support services, which shall, where feasible and appropriate, include estimates for resources to provide such services.

## *Chapter 5 – Timely Treatment for Opioid Use Disorder*

**Section 1251. Study on exemptions for treatment of opioid use disorder through opioid treatment programs during the COVID–19 public health emergency.**
Section 1251 requires the Assistant Secretary for Mental Health and Substance Use to conduct a study and report within 180 days on the impacts of treatment flexibilities allowed during the pandemic.

**Section 1252. Changes to federal opioid treatment standards.**
Section 1252 allows certain Drug Enforcement Administration (DEA) registrants to operate one or more mobile units to dispense medications for opioid use disorder without separate registrations for each mobile unit. It also requires HHS to issue regulations eliminating the requirement that an individual have an opioid use disorder for at least one year before being admitted for treatment by an opioid treatment program.

## *Chapter 6 – Additional Provisions Relating to Addiction Treatment*

**Section 1261. Prohibition.**
Section 1261 prohibits funds authorized or amended by this title from being used to purchase, procure, or distribute pipes or cylindrical objects intended to be used to smoke or inhale illegal

scheduled substances.

**Section 1262. Eliminating additional requirements for dispensing narcotic drugs in schedule III, IV, and V for maintenance or detoxification treatment.**
Section 1262 eliminates a requirement for health care practitioners registered to dispense controlled substances to apply for a separate waiver through the DEA to dispense buprenorphine for opioid use disorder maintenance or detoxification treatment, known as the X Waiver

**Section 1263. Requiring prescribers of controlled substances to complete training.**
Section 1263 requires health care providers, as a condition of receiving or renewing a DEA registration to prescribe controlled substances, to meet a one-time eight-hour training requirement on identifying and treating patients with substance use disorders.

**Section 1264. Increase in number of days before which certain controlled substances must be administered.**
Section 1264 increases the time limit for health care providers to hold long-acting injectable (LAI) buprenorphine before administration to a patient, if received through a specialty pharmacy, from 14 to 45 days.

### *Chapter 7 – Opioid Crisis Response*

**Section 1271. Opioid prescription verification.**
Section 1271 requires the development and dissemination of training materials for pharmacists who may decline to fill a prescription, under certain circumstances. It allows the CDC to prioritize jurisdictions with a high burden of drug overdoses or drug overdose deaths when awarding grants to prevent overdoses of controlled substances.

**Section 1272. Synthetic opioid and emerging drug misuse danger awareness.**
Section 1272 requires HHS to conduct a public education campaign on synthetic opioids (including fentanyl and its analogues) and other emerging drug misuse issues, disseminate information about synthetic opioids to health care providers, and develop a training guide and webinar for first responders and other individuals at high risk of exposure to synthetic opioids that details measures to prevent exposure.

**Section 1273. Grant program for State and Tribal response to opioid use disorders.**
Section 1273 authorizes the State Opioid Response (SOR) Grants and Tribal Opioid Response (TOR) Grants.

## Subtitle C – Access to Mental Health Care and Coverage

### *Chapter 1 – Improving Uptake and Patient Access to Integrated Care Services*

**Section 1301. Improving uptake and patient access to integrated care services.**
Section 1301 reauthorizes a SAMHSA program to increase uptake and access to integrated care services. States receiving funds through the program that partner with primary care practices

may use funds to implement evidence-based or evidence-informed integrated models of care, including the psychiatric collaborative care model (CoCM). Depending on the availability of appropriations, allocates ten percent of such funds to support primary care practices implementing CoCM.

### *Chapter 2 – Helping Enable Access to Lifesaving Services*

**Section 1311. Reauthorization and provision of certain programs to strengthen the health care workforce.**
Section 1311 reauthorizes the Behavioral Health Workforce Education and Training (BHWET) Program, which updates advanced degree references for occupational therapists, and emphasizes support for children and adolescents that have experienced trauma. This section also reauthorizes HRSA's Training Demonstration Program related to graduate fellowship training opportunities, updates eligibility to include nurses and counselors, and places emphasis on trauma-informed care and pediatric populations.

**Section 1312. Reauthorization of minority fellowship program.**
Section 1312 reauthorizes SAMHSA's Minority Fellowship Program supporting individuals pursuing masters or doctoral degrees in various fields of mental health and substance use disorder counseling.

### *Chapter 3 – Eliminating the Opt-Out for Nonfederal Governmental Health Plans*

**Section 1321. Eliminating the opt-out for nonfederal governmental health plans.**
Section 1321 requires self-funded, non-federal governmental health plans to comply with mental health parity requirements beginning six months after the date of enactment or longer contingent on the terms of the plan agreement.

### *Chapter 4 – Mental Health and Substance Use Disorder Parity Implementation*

**Section 1331. Grants to support mental health and substance use disorder parity implementation.**
Section 1331 authorizes grants to states to enforce and ensure compliance with mental health parity requirements.

## Subtitle D – Children and Youth

### *Chapter 1 – Supporting Children's Mental Health Care Access*

**Section 1401. Technical assistance for school-based health centers.**
Section 1401 requires the Secretary of HHS to provide technical assistance to school-based health centers (SBHC) through private, nonprofit entities with demonstrated expertise related to SBHCs. This technical assistance shall support SBHCs in providing services to improve physical and mental health.

**Section 1402. Infant and early childhood mental health promotion, intervention, and treatment.**
Section 1402 reauthorizes SAMHSA's Infant and Early Childhood Mental Health Grant program and allows the Secretary of HHS to provide technical assistance for grantees.

**Section 1403. Co-occurring chronic conditions and mental health in youth study.**
Section 1403 requires HHS to study rates of suicidal behaviors among children and adolescents with chronic illnesses, including substance use disorders, autoimmune disorders, and heritable blood disorders. It also requires HHS to submit a report to Congress on findings and recommendations, including addressing related demographic disparities.

**Section 1404. Best practices for behavioral and mental health intervention teams.**
Section 1404 requires HHS to develop and submit a report to congressional committees of jurisdiction that identifies best practices related to using behavioral and mental health intervention teams in educational settings.

## *Chapter 2 – Continuing Systems of Care for Children*

**Section 1411. Comprehensive Community Mental Health Services for Children with Serious Emotional Disturbances.**
Section 1411 reauthorizes the Comprehensive Community Mental Health Services for Children with Serious Emotional Disturbances Grants.

**Section 1412. Substance Use Disorder Treatment and Early Intervention Services for Children and Adolescents.**
Section 1412 reauthorizes the Enhancement and Expansion of Treatment and Recovery Services for Adolescents, Transitional Aged Youth, and their Families (Youth and Family TREE) Grants.

## *Chapter 3 – Garrett Lee Smith Memorial Reauthorization*

**Section 1421. Suicide prevention technical assistance center.**
Section 1421 reauthorizes the Suicide Prevention Resource Center.

**Section 1422. Youth suicide early intervention and prevention strategies.**
Section 1422 reauthorizes the State and Tribal Youth Suicide Prevention and Early Intervention Grants Program.

**Section 1423. Mental health and substance use disorder services for students in higher education.**
Section 1423 reauthorizes the Mental Health Youth Suicide Prevention Campus Grants.

**Section 1424. Mental and behavioral health outreach and education at institutions of higher education.**
Section 1424 reauthorizes and renames the Mental and Behavioral Health Public Outreach and

Education at Institutions of Higher Education program and specifies that representatives from minority-serving institutions and community colleges be included within the program's working group.

### *Chapter 4 – Media and Mental Health*

**Section 1431. Study on the effects of smartphone and social media use on adolescents.**
Section 1431 directs the Secretary of HHS to, as appropriate, conduct or support research on smartphone and social media use by adolescents and the effects of such use on their health and development, including any disparities in mental health outcomes of rural, minority, or other underserved populations.

**Section 1432. Research on the health and development effects of media and related technology on infants, children, and adolescents.**
Section 1432 requires the National Institutes of Health (NIH) to fund conduct or support research regarding the effects of media on infants, children, and adolescents. Such research must, as appropriate, examine the impacts of multimedia (e.g., social media, television, video games) on cognitive, physical, and social development.

## Subtitle E – Miscellaneous Provisions

**Section 1501. Limitations on authority.**
Section 1501 limits the authority of the Secretary of HHS, in carrying out any SAMHSA program authorized or amended by this title from allocating funding, or requiring award recipients to prioritize, dedicate, or allocate funding, without consideration of the incidence, prevalence, or determinations of mental health or substance use issues, unless such allocation or requirement is consistent with statute, regulation, or other federal law.

# 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*

**Section 2101. Appointment and authority of the Director of the Centers for Disease Control and Prevention.**
Section 2101 requires Senate confirmation of the Director of the CDC beginning on January 20, 2025, and establishes specific functions of the Director. It also requires an agency-wide 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.

**Section 2102. Advisory Committee to the Director of the Centers for Disease Control and Prevention.**
Section 2102 requires the CDC Director to establish or maintain an advisory committee within the CDC to advise the Director on policy and strategies that enable the agency to fulfill its mission, which may include informing strategic planning and advising on prioritization and performance metrics. The advisory committee shall consist of up to 15 non-federal members in relevant fields of expertise, of which 12 shall be appointed by the Director from relevant health disciplines and three shall be appointed by the Secretary from the general public, such as individuals with expertise in public policy, public relations, or economics.

**Section 2103. Public health and medical preparedness and response coordination.**
Section 2103 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 and includes a GAO study on the use of existing authorities for related interagency agreements. It also clarifies the role and responsibilities of the Assistant Secretary for Preparedness and Response in public health and medical preparedness and response activities. The section requires national- and state-level full-scale exercises every five years to identify and address gaps in preparedness and response, including the ability of the Strategic National Stockpile (SNS) to appropriately support the response to a large-scale, long-term public health emergency. Finally, the section requires HHS to submit an annual report to Congress on the state of public health preparedness.

**Section 2104. Office of Pandemic Preparedness and Response Policy.**
Section 2104 establishes an Office of Pandemic Preparedness and Response Policy within the Executive Office of the President, led by a Director appointed by the President, to advise on pandemic preparedness and response policy and to support coordination and communication within the federal government related to preparedness and response. It also establishes an Industry Liaison within the Office to work with affected industries during responses. The section requires the Director to develop a Preparedness Outlook Report every five years on situations and conditions that warrant significant attention related to preparedness and response including opportunities and challenges related to medical countermeasures. It also requires the Director to conduct a review of existing federal policies to identify gaps and inefficiencies related to preparedness and response and submit to Congress a report, which shall be updated every two years, describing the findings of the review, current and emerging threats, federal roles and responsibilities, and any plans and associated barriers to address such findings.

## *Chapter 2 – State and Local Readiness*

**Section 2111. Improving State and local public health security.**
Section 2111 updates the Public Health Emergency Preparedness (PHEP) cooperative agreements to ensure coordination between health departments and other state agencies to improve preparedness and response planning. It also requires 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.

**Section 2112. Supporting access to mental health and substance use disorder services during public health emergencies.**
Section 2112 directs SAMHSA to support continued access to mental health and substance use disorder services during public health emergencies. It requires SAMHSA's 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, including for at-risk individuals. It also 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. The section also requires GAO to report on SAMHSA's work during the COVID-19 pandemic.

**Section 2113. Trauma care reauthorization.**
Section 2113 reauthorizes 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. It directs the Administration for Strategic Preparedness and Response (ASPR) to support the improvement and coordination of emergency medical services and trauma care during a public health emergency, which may include issuing guidance to support patient movement and triage and disseminating best practices and related information.

**Section 2114. Assessment of containment and mitigation of infectious diseases.**
Section 2114 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.

**Section 2115. Consideration of unique challenges in noncontiguous states and territories.**
Section 2115 requires the Secretary of HHS to conduct quarterly meetings, as applicable, with noncontiguous states and territories during public health emergencies impacting such jurisdictions to help address any associated unique public health challenges.

## Subtitle B – Improving Public Health Preparedness and Response Capacity

### *Chapter 1 –Improving Public Health Emergency Responses*

**Section 2201. Addressing factors related to improving health outcomes.**
Section 2201 authorizes a grant program to support evidence-based or evidence-informed projects to improve health outcomes by improving the capacity of grant recipients to address factors that contribute to negative health outcomes in communities. It requires the Secretary to submit a report to Congress on activities funded, and requires a GAO study on the outcomes and effectiveness of this program and coordination with related HHS programs.

## *Chapter 2 – Improving State, Local, and Tribal Public Health Data*

**Section 2211. Modernizing State, local, and Tribal biosurveillance capabilities and infectious disease data.**
Section 2211 improves collaboration among federal departments, implements lessons learned from previous public health emergencies, and identifies steps the Secretary will take to further develop and integrate infectious disease detection, support rapid, accurate, and secure sharing 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.

**Section 2212. Genomic sequencing, analytics, and public health surveillance of pathogens.**
Section 2212 requires the Secretary to issue guidance to support collaboration related to genomic sequencing of pathogens. It directs the CDC Director, in consultation with the Director of 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 better anticipate and prepare for pathogen mutations, enhancing the sequencing and analytics capabilities of the public health workforce, and continuing partnerships with public and private entities for these activities. It also codifies Centers of Excellence to support innovation in pathogen genomics and molecular epidemiology.

**Section 2213. Supporting State, local, and Tribal public health data.**
Section 2213 directs the Secretary to help states, localities, territories, and Tribes better leverage public health data that is deidentified as applicable to support public health responses, such as by improving data use agreements between relevant federal agencies and other public and private entities. It also authorizes a program to develop best practices to improve the quality and completeness of demographic data to support public health responses.

**Section 2214. Epidemic forecasting and outbreak analytics.**
Section 2214 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. It also requires the Secretary to issue an annual report on these activities for the next five years

**Section 2215. Public health data transparency.**
Section 2215 directs HHS to issue a report within one year on current practices and objectives, and associated progress and challenges, related to CDC collection and dissemination of public health data during public health emergencies.

**Section 2216. GAO report on public health preparedness, response, and recovery data capabilities.**
Section 2216 requires a GAO report within 18 months of enactment on the efforts of HHS to ensure that public health data capabilities are not unnecessarily duplicative, overlapping, or fragmented and protect individual privacy.

## *Chapter 3 – Revitalizing the Public Health Workforce*

**Section 2221. Improving recruitment and retention of the frontline public health workforce.**
Section 2221 reauthorizes the Public Health Workforce Loan Repayment Program to provide loan repayment to individuals in exchange for working in a state, Territorial, Tribal, or local public health department. It establishes a Bio-Preparedness Workforce Pilot Program to provide for loan repayment for health professionals with expertise in infectious diseases and emergency preparedness and response activities to ensure an adequate supply of such professionals. It also requires GAO to conduct an evaluation of the public health workforce in the U.S. during the COVID-19 pandemic.

**Section 2222. Awards to support community health workers and community health.**
Section 2222 reauthorizes a community health worker program to promote healthy behaviors and outcomes in medically underserved communities through the use of community health workers. It directs funds to be used to recruit, hire, train, and retain community health workers; support community health workers in providing education and outreach in their communities; and to educate community members. It also 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.

**Section 2223. Improving public health emergency response capacity.**
Section 2223 improves HHS' ability to quickly mount an initial response to a public health emergency by allowing the Secretary to directly appoint up to 500 individuals to preparedness and response positions within HHS. It also requires an annual report to Congress and a GAO study on the use of this authority.

**Section 2224. Increasing educational opportunities for allied health professions.**
Section 2224 provides authority to the HRSA to increase educational opportunities in physical therapy, occupational therapy, respiratory therapy, audiology, and speech-language pathology professions, for individuals from disadvantaged backgrounds or individuals who are underrepresented in such professions.

**Section 2225. Public Health Service Corps annual and sick leave.**
Section 2225 allows for regulations to be updated to authorize accumulated annual leave up to 120 days for any commissioned officer of the Regular Corps or officer of the Ready Reserve Corps on active duty, consistent with the other uniformed services.

**Section 2226. Leadership exchange pilot for public health and medical preparedness and response positions at the Department of Health and Human Services.**
Section 2226 allows the Secretary to establish a voluntary program for mid-level and senior employees that have public health preparedness and response duties to participate in fellowships, interagency details, or placements in federal agencies or health departments for up to two years to support professional development. It requires a report to Congress on the number of individuals who participated, the types of placements in which they participated, an assessment of outcomes, and recommendations related to the continuation of the program.

**Section 2227. Continuing educational support for health professionals serving in rural and underserved communities.**
Section 2227 reauthorizes awards to community health centers and rural health clinics for accredited continuing medical education for their primary care providers. It supports access to specialty care through existing service delivery locations and allows for clinical training components between primary care providers and clinical specialists.

## *Chapter 4 – Enhancing Public Health Preparedness and Response*

**Section 2231. Centers for public health preparedness and response.**
Section 2231 reauthorizes a network of Centers for Public Health Preparedness and Response to: (1) translate research findings or strategies into evidence-based practices to inform preparedness and response to public health emergencies; (2) improve awareness of these practices and other relevant scientific or public health information among health care and public health professionals and the public; (3) expand activities, such as through partnerships, to improve public health preparedness and response; and (4) provide technical assistance and expertise to health departments, as appropriate.

**Section 2232. Vaccine distribution plans.**
Section 2232 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.

**Section 2233. Coordination and collaboration regarding blood supply.**
Section 2233 directs the Secretary of HHS to ensure coordination and collaboration between relevant federal departments and agencies related to the safety and availability of the blood supply.

**Section 2234. Supporting laboratory capacity and international collaboration to address antimicrobial resistance.**
Section 2234 directs the CDC Director to leverage existing CDC-supported laboratory capacity to support the detection of antibiotic resistance and other laboratory activities, including identifying and monitoring the emergence of antimicrobial-resistant pathogens, providing technical assistance to other laboratories when requested, and supporting the diagnosis of pathogens and determining susceptibility of pathogens to treatments. It requires the Secretary to support activities to address antimicrobial resistance internationally, including by supporting research and providing technical assistance related to antimicrobial resistant infection and control activities.

**Section 2235. One Health framework.**
Section 2235 requires the CDC Director, in coordination with other federal departments and agencies, to develop or update a One Health framework to address zoonotic diseases and advance public health preparedness. It requires the CDC Director to coordinate with the Secretaries of Agriculture and Interior to strengthen collaboration regarding One Health activities.

**Section 2236. Supporting children during public health emergencies.**
Section 2236 requires the National Advisory Committee on Children and Disasters to provide advice and consultation on the continuity of care and education for all children, and supporting parents and caregivers, during all-hazards emergencies. It amends the composition of the Advisory Committee to include at least four non-Federal members representing childcare settings, state or local educational agencies, individuals with expertise in children with disabilities, and parents.

## Subtitle C – Accelerating Research and Countermeasure Discovery

### *Chapter 1 – Fostering Research and Development and Improving Coordination*

**Section 2301. Research centers for pathogens of pandemic concern.**
Section 2301 requires the National Institute of Allergy and Infectious Diseases (NIAID), in collaboration with ASPR and Biodefense Advanced Research and Development Authority (BARDA), to establish or continue a multidisciplinary research program with research centers to advance the discovery and preclinical development of antivirals and other medical products to combat priority virus families and other viral pathogens with the significant potential to cause a pandemic.

**Section 2302. Improving medical countermeasure research coordination.**
Section 2302 requires the NIH Director to consult with ASPR, BARDA, CDC, and the heads of other federal agencies and offices regarding research needs to advance medical countermeasures for any agent or toxin that may cause a public health emergency, or other research needs related to emerging public health threats.

**Section 2303. Accessing specimen samples and diagnostic tests.**
Section 2303 requires HHS to make public policies and procedures related to public and private entities accessing specimens of pathogens to support research and development of medical countermeasures, such as tests. It requires the Secretary to issue guidance on methods for requesting samples and additional considerations for sample access and availability. The section also allows HHS to contract with public and private entities to improve the rapid development and availability of diagnostic tests to support immediate public health response activities to more quickly address emerging infectious diseases.

**Section 2304. National Academies of Sciences, Engineering, and Medicine study on natural immunity in relation to the COVID–19 pandemic.**
Section 2304 requires a National Academies study on the current scientific evidence on the durability of immunity to COVID-19, including an assessment of the durability of immunity resulting from SARS–CoV–2 infection, COVID–19 vaccination, or both, as well as a summary of international studies on the subject.

## *Chapter 2 – Improving Biosafety and Biosecurity*

**Section 2311. Improving control and oversight of select biological agents and toxins.**
Section 2311 reauthorizes the HHS provisions of 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. It also enhances reporting requirements to Congress regarding releases, losses, and thefts of select agents from federal laboratories.

**Section 2312. Strategy for Federal high-containment laboratories.**
Section 2312 requires the Director of the Office of Science and Technology Policy (OSTP) to establish a strategy for the maintenance and coordination of Biosafety Level 3 and 4 laboratories that are owned by the federal government or were established through federal funds.

**Section 2313. National Science Advisory Board for Biosecurity.**
Section 2313 codifies the National Science Advisory Board for Biosecurity (NSABB), including ex officio members from other departments, and tasks the NSABB with providing departments and agencies with technical advice, guidance, and recommendations related to biosafety and biosecurity oversight of biomedical research. It allows the NSABB to consider strategies to improve the safety and security of research, including through leveraging new technologies and supporting education and outreach to individuals with respect to safety and security risks associated with such research. It also clarifies that changes made under this section shall not apply until work of the NSABB that is ongoing on the date of enactment is completed to ensure that these changes do not disrupt ongoing activities.

**Section 2314. Research to improve biosafety.**
Section 2314 directs HHS to conduct or support research to improve the safe conduct of biomedical research involving pathogens of pandemic potential or select agents. It requires HHS to submit a report to Congress 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.

**Section 2315. Federally-funded research with enhanced pathogens of pandemic potential.**
Section 2315 directs OSTP to review existing federal policies on research proposed for federal funding that may be reasonably anticipated to involve the creation, transfer, or use of pathogens of pandemic potential, establish or update a federal policy for the consistent review and oversight of such research, and update such policy every four years. It also prohibits HHS funding of certain types of research conducted by foreign entities at facilities in countries of concern until the policy review required by this section is complete.

## *Chapter 3 – Preventing Undue Foreign Influence in Biomedical Research*

**Section 2321. Foreign talent recruitment programs.**
Section 2321 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, consistent with the CHIPS and Science Act of 2022.

**Section 2322. Securing identifiable, sensitive information and addressing other national security risks related to research.**
Section 2322 requires the HHS Secretary to consult with national security experts to ensure that HHS biomedical research involving human genomic information appropriately considers national security risks. It requires the Secretary to develop a risk framework for assessing and managing such 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. It also directs the Secretary to update human genomic data access and sharing policies related to human genomic data based on emerging national security threats and requires a briefing to appropriate congressional committees on the activities carried out under this section.

**Section 2323. Duties of the Director.**
Section 2323 requires the NIH Director to consult with HHS Office of National Security, the HHS Assistant Secretary for Preparedness and Response, and other relevant agencies regarding HHS biomedical research that may be relevant to national security matters. It requires the NIH Director to ensure that recipients of NIH awards and related entities adhere to appropriate technology practices to secure identifiable, sensitive information. It also requires the NIH Director to ensure that recipients of NIH awards are in compliance with the terms and conditions of such award, which may include activities to support awareness of, and compliance with, such terms and conditions by any subrecipients of the award.

**Section 2324. Protecting America's biomedical research enterprise.**
Section 2324 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. It 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.

**Section 2325. GAO Study.**
Section 2325 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. It requires GAO to make recommendations to address any vulnerabilities identified and submit a report to Congress no later than two years after enactment.

**Section 2326. Report on progress to address undue foreign influence.**
Section 2326 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.

### *Chapter 4 – Advanced Research Projects Authority for Health*

**Section 2331. Advanced Research Projects Agency–Health.**
Section 2331 establishes the Advanced Research Projects Agency for Health (ARPA–H) within NIH to accelerate innovation in health and medicine by investing in novel, broadly applicable, high-risk, high-reward research projects. This section requires the President to appoint the Director of ARPA–H, who shall report to the Secretary of HHS. The provision provides a number of authorities and flexibilities related to personnel, hiring, funding mechanisms, facilities, peer review, annual reporting, and evaluations, among other components.

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

**Section 2401. Warm base manufacturing capacity for medical countermeasures.**
Section 2401 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. It improves coordination and communication between private sector partners, BARDA, and the Food and Drug Administration (FDA) to ensure that this manufacturing capacity and capabilities are appropriately maintained, follow good manufacturing practices, and any related challenges are identified and addressed. It amends a previously required GAO report to also consider plans for the sustainment of this manufacturing capacity and how BARDA is assessing the ability of its award recipients to rapidly manufacture medical countermeasures.

**Section 2402. Supply chain considerations for the Strategic National Stockpile.**
Section 2402 amends the Strategic National Stockpile (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.

**Section 2403. Strategic National Stockpile equipment maintenance.**
Section 2403 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.

**Section 2404. Improving transparency and predictability of processes of the Strategic National Stockpile.**
Section n2404 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. It 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.

**Section 2405. Improving supply chain flexibility for the Strategic National Stockpile.**
Section 2405 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. It requires a report to Congress on the use of these authorities.

**Section 2406. Reimbursement for certain supplies.**
Section 2406 authorizes the Secretary to sell excess products from the SNS to other entities when the cost of maintaining these products in the SNS is not appropriate to meet the needs of the SNS and the transfer of these products does not compromise national security. It requires a report to Congress after two years on the use of this authority.

**Section 2407. Action reporting on stockpile depletion.**
Section 2407 requires the Secretary to report regularly to Congress on SNS content deployment and replenishment plans during a public health emergency.

**Section 2408. Provision of medical countermeasures to Indian programs and facilities.**
Section 2408 clarifies that when HHS deploys products to states to respond to a public health emergency, the Secretary should also make these products directly available to Tribes that are affected by the public health emergency.

**Section 2409. Grants for State strategic stockpiles.**
Section 2409 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. It requires HHS to issue guidance to all states within 180 days 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. It also requires a report to Congress and GAO report assessing the impacts of the pilot program and technical assistance provided by HHS to states on stockpiling

**Section 2410. Study on incentives for domestic production of generic medicines.**
Section 2410 directs the HHS Assistant Secretary for Planning and Evaluation to conduct a study on the feasibility and utility of providing incentives for increased domestic production and capacity of specified generic medicines and their active pharmaceutical ingredients, which may include through applicable nonprofit or for-profit entities.

**Section 2411. Increased manufacturing capacity for certain critical antibiotic drugs.**
Section 2411 allows the Secretary of HHS to award new contracts for up to three years after the date of enactment to eligible entities to increase the domestic manufacturing capacity of certain antibiotic drugs with identified supply vulnerabilities, or the active pharmaceutical ingredient or key starting material of such antibiotic drugs. It requires the Secretary to report to Congress no later than two years after enactment on activities supported through this program.

# Subtitle E – Enhancing Development and Combating Shortages of Medical Products

## *Chapter 1 – Development and Review*

**Section 2501. Accelerating countermeasure development and review.**
Section 2501 codifies FDA's successful Coronavirus Treatment Acceleration Program to ensure expedited action for the development and review of countermeasures during future public health emergencies.

**Section 2502. Third party test evaluation during emergencies.**
Section 2502 clarifies FDA's authority to consult with third parties to evaluate and make recommendations with respect to in vitro diagnostic tests offered for use during a public health emergency, which will enable FDA to prioritize its response efforts and surge where needed during future emergencies. It also requires FDA to issue guidance to facilitate such consultations with third parties.

**Section 2503. Platform technologies.**
Section 2503 creates a platform technology designation program to support the development and review of new treatments and countermeasures that use cutting-edge, adaptable platform technologies that can be incorporated or used in more than one drug or biological product. It requires FDA to issue guidance on the implementation of the new designation.

**Section 2504. Increasing EUA decision transparency.**
Section 2504 provides FDA with authority to share more safety and effectiveness information with the public about products authorized for emergency use.

**Section 2505. Improving FDA guidance and communication.**
Section 2505 requires publication of a report identifying best practices across FDA and other applicable agencies for the development, issuance, and use of guidance documents and for communications with product sponsors and other stakeholders, and a plan for implementing such best practices. It requires FDA to publish a report on the agency's best practices for communicating with medical product sponsors and other stakeholders, and a plan for implementing such best practices.

## *Chapter 2 – Mitigating Shortages*

**Section 2511. Ensuring registration of foreign drug and device manufacturers.**
Section 2511 clarifies that all foreign drug and medical device establishments that manufacture or process drugs or medical devices intended to be marketed in the United States must register with FDA, including products manufactured at an establishment that are not directly imported into the United States.

**Section 2512. Extending expiration dates for certain drugs.**
Section 2512 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 scientifically supported by such data, in order to help mitigate or prevent potential drug shortages. It 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.

**Section 2513. Combating counterfeit devices.**
Section 2513 strengthens FDA enforcement authority against, and increases the penalties for, selling counterfeit medical devices, including personal protective equipment, in the United States.

**Section 2514. Preventing medical device shortages.**
Section 2514 clarifies that FDA may receive voluntary notifications of supply disruptions of certain critical medical devices, and requires FDA to issue guidance to facilitate such voluntary notifications.

**Section 2515. Technical corrections.**
Section 2515 includes technical corrections to the CARES Act, and to the Food, Drug, and Cosmetic Act related to the CARES Act.

# TITLE III – FOOD AND DRUG ADMINISTRATION

## Subtitle A – Reauthorizations

**Section 3101. Reauthorization of the critical path public-private partnership.**
Section 3101 reauthorizes the Critical Path Public-Private Partnership.

**Section 3102. Reauthorization of the best pharmaceuticals for children program.**
Section 3102 reauthorizes programs that require the NIH to identify the drugs of highest priority for study in pediatric populations, publish a list of drugs/needs in pediatric therapeutics, and fund studies in the prioritized areas.

**Section 3103. Reauthorization of the humanitarian device exemption incentive.**
Section 3103 reauthorizes the Humanitarian Device Exemption incentive, which exempts the effectiveness requirement for medical devices intended to benefit patients in the treatment or diagnosis of rare diseases through October 1, 2027.

**Section 3104. Reauthorization of the pediatric device consortia program.**
Section 3104 reauthorizes the Pediatric Device Consortia Program, which supports the continued development of medical devices intended specifically for children.

**Section 3105. Reauthorization of provision pertaining to drugs containing single enantiomers.**
Section 3105 reauthorizes the provision that allows drugs containing single enantiomers to be marketed under a different name than the racemic mixture through October 1, 2027, and makes a technical correction.

**Section 3106. Reauthorization of certain device inspections.**
Section 3106 reauthorizes a third-party accreditation program for certain medical device inspections through October 1, 2027.

**Section 3107. Reauthorization of orphan drug grants.**
Section 3107 reauthorizes grants for the development of drugs for rare diseases or conditions. It also allows grants to be used for the development of regulatory science pertaining to chemistry, manufacturing, and controls of individualized medical products to treat rare diseases or conditions.

**Section 3108. Reauthorization of reporting requirements related to pending generic drug applications and priority review applications.**
Section 3108 reauthorizes reporting requirements related to pending generic drug applications and priority review applications through October 1, 2027.

**Section 3109. Reauthorization of third-party review program.**
Section 3109 reauthorizes a third-party accreditation program for the review and classification of certain medical devices through October 1, 2027.

## Subtitle B – Drugs and Biologics

### *Chapter 1 – Research, Development, and Competition Improvements*

**Section 3201. Prompt reports of marketing status by holders of approved applications for biological products.**
Section 3201 aligns certain reporting requirements for biologics with the reporting requirements for drugs by requiring holders of approved biologics license applications to report to FDA when withdrawing a product from the market and requiring holders of approved biologics license applications to submit a one-time report to confirm that their products listed in the Purple Book are still available for sale. It also requires FDA to update the Purple Book for changes related to the status of biologics.

**Section 3202. Improving the treatment of rare diseases and conditions.**
Section 3202 requires FDA to submit a report summarizing its activities relating to designating, approving, and licensing drugs used to treat rare diseases no later than September 30, 2026. It requires FDA to finalize the draft guidance document entitled "Rare Diseases: Common Issues in Drug Development." It also requires the Secretary to enter into a contract with the National Academies of Sciences, Engineering, and Medicine to study processes for evaluating the safety and efficacy of drugs for rare diseases in the United States and the European Union. The section also requires FDA to convene one or more public meetings to solicit input from stakeholders regarding approaches to improving engagement with rare disease condition patients, patient groups, and experts. It also adds the science of small population studies as a topic for consultation with external experts on issues related to the review of drugs for rare diseases. Finally, it requires the GAO to conduct a study on FDA's activities regarding the review of drugs for rare diseases.

**Section 3203. Emerging technology program.**
Section 3203 authorizes the Emerging Technology Program at FDA, a collaborative program wherein 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. It requires FDA to issue guidance regarding requirements related to such approaches and report to Congress regarding allocation of funds and staff utilization in this program.

**Section 3204. National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing.**
Section 3204 authorizes FDA to award grants to institutions of higher education designated as a National Center of Excellence in Advanced and Continuous Pharmaceutical Manufacturing to support the advancement and development of continuous and advanced pharmaceutical manufacturing technologies and practices.

**Section 3205. Public workshop on cell therapies.**
Section 3205 requires FDA to convene a public workshop on best practices on generating scientific data necessary to further facilitate development of certain human cell-, tissue-, and cellular-based medical products, and the latest scientific information about such products.

**Section 3206. Clarifications to exclusivity provisions for first interchangeable biosimilar biological products.**
Section 3206 clarifies FDA's authority to tentatively approve a subsequent interchangeable biosimilar biological product while a first interchangeable product's period of exclusivity is pending. It 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.

**Section 3207. GAO report on nonprofit pharmaceutical organizations.**
Section 3207 requires GAO, not later than two years after the enactment, to submit a report on what is known about nonprofit pharmaceutical organizations, including the impact of such organizations on the development, availability, and cost of prescription drugs, and any challenges to manufacturing or other operations.

**Section 3208. Rare disease endpoint advancement pilot program.**
Section 3208 establishes a rare disease endpoint advancement pilot program to implement procedures to provide increased interaction with sponsors of rare disease drug development programs for purposes of advancing the development of efficacy endpoints for drugs intended to treat rare diseases. It requires FDA to hold public workshops and report to Congress regarding this pilot, which sunsets on October 1, 2027.

**Section 3209. Animal testing alternatives.**
Section 3209 clarifies that drug application sponsors can use alternative testing methods to animal testing in evaluating the safety and effectiveness of human drugs. It clarifies that sponsors of biosimilar applications can demonstrate biosimilarity to a reference product using alternative testing methods to animal studies.

**Section 3210. Modernizing accelerated approval.**
Section 3210 requires FDA to specify conditions for required postapproval studies for drugs approved under accelerated approval, which may include enrollment targets and milestones, including the target date for study completion, by the time the drug is approved. It authorizes FDA to require postapproval studies to be underway at the time of approval or within a specified time period following approval for such drugs, and requires FDA to explain any instances where it does not require such studies. The section clarifies that existing authority to withdraw approvals where sponsors fail to conduct studies with due diligence applies with respect to the approval conditions and streamlines the procedures for withdrawal of approval. To withdraw an accelerated approval, it requires FDA to provide an explanation for the withdrawal, an opportunity for written appeal, a meeting with the Commissioner or their designee, responses to public comment, and, upon request, an advisory committee meeting if there was not previously one on the withdrawal. It also requires more frequent reports on postapproval study progress and lists failure to file reports and conduct accelerated approval postapproval studies with due diligence as a prohibited act. The section also requires FDA to report to Congress on the use of real world evidence to support postapproval studies and issue guidance on novel surrogate endpoints and clinical trial designs. Finally, it requires the Secretary to establish an intra-agency coordinating council within FDA to ensure the consistent and appropriate use of the accelerated approval pathway.

**Section 3211. Antifungal research and development.**
Section 3211 requires the Secretary to issue guidance for industry to assist entities seeking approval or licensure for antifungal therapies intended to treat coccidioidomycosis, commonly known as Valley Fever. It requires FDA to finalize guidance not later than 18 months after the close of the public comment period on the draft guidance and to hold a public workshop to assist entities developing preventative vaccines for fungal infections and Valley Fever.

**Section 3212. Advancing qualified infectious disease product innovation.**
Section 3212 allows a biological product to qualify as a Qualified Infectious Disease Product (QIDP) under Section 505E of the Federal Food, Drug, and Cosmetic Act (FFDCA), which renders it eligible for fast-track designation, and provides for priority review for the first application for an innovative biological antifungal or antibiotic QIDP that requires clinical data to demonstrate safety or effectiveness. This section does not extend QIDP exclusivity to biological products.

**Section 3213. Advanced manufacturing technologies designation program.**
Section 3213 requires FDA to initiate a program for designating methods of manufacturing as advanced manufacturing technologies. A method of manufacturing is eligible for designation if such method both: incorporates a novel technology or uses an established technology in a novel way and 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 holder of such designation, or a person authorized by the designation holder, to reference or rely upon, in a drug or biologic application, data and information about the designated technology for use in manufacturing drugs in the same context of use for which FDA granted the designation. It requires FDA to hold a public meeting, issue guidance, and report to Congress regarding this program, which sunsets on October 1, 2032.

*Chapter 2 – Transparency, Program Integrity, and Regulatory Improvements*

**Section 3221. Safer disposal of opioids.**
Section 3221 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. It also clarifies that in-home disposal systems are eligible to be dispensed to patients.

**Section 3222. Therapeutic equivalence evaluations.**
Section 3222 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. It also facilitates the availability of lower-cost drugs available for automatic substitution at the pharmacy.

**Section 3223. Public docket on proposed changes to third-party vendors.**
Section 3223 requires FDA to provide a public comment period regarding patient access and provider administration when a proposed modification to an approved risk evaluation and mitigation strategy (REMS) related to a change in third-party vendor is reviewed under section 505-1(h) of the FFDCA. This section makes clear that it shall not delay any agency action on any modification to a REMS.

**Section 3224. Enhancing access to affordable medicines.**
Section 3224 provides that a generic drug is eligible for approval notwithstanding differences between its proposed labeling and that of the listed drug due to revisions made to the labeling of the listed drug approved by FDA within 90 days of when the generic application is otherwise eligible for approval. It preserves the provisions requiring that the revisions not be to the "Warnings" section of the labeling. The generic sponsor must submit revised labeling within 60 days of approval, and otherwise meet applicable requirements for approval.

## Subtitle C – Medical Devices

**Section 3301. Dual submission for certain devices.**
Section 3301 provides that sponsors of diagnostic tests that have been deemed to be Clinical Laboratory Improvement Amendments (CLIA)-waived under section 564(m) of the FFDCA as part of a COVID-19 emergency use authorization that submit requests for de novo classification of their test under section 513(f)(2) of the FFDCA may submit such request together with sufficient information to enable FDA to determine whether the test satisfies the criteria for CLIA categorization under section 353(d)(3) of the Public Health Service Act in a single submission.

**Section 3302. Medical Devices Advisory Committee meetings.**
Section 3302 requires the Medical Devices 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.

**Section 3303. GAO report on third-party review.**
Section 3303 requires GAO to report on the program for accredited third-party review of 510(k) premarket notifications for medical devices.

**Section 3304. Certificates to foreign governments.**
Section 3304 clarifies that FDA can issue Certificates to Foreign Governments for medical devices that are manufactured by a device establishment located outside of the United States, if the establishment is registered, the medical device is listed, the device is lawfully marketed and imported or offered for import into the United States.

**Section 3305. Ensuring cybersecurity of medical devices.**
Section 3305 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 FDA in any premarket submissions. It defines cyber devices as devices that have software, connect to the internet, and could be vulnerable to cybersecurity threats. The section authorizes FDA to deny 510(k) clearance if cyber security information is inadequate and to exempt types of devices from these requirements. It makes failure to comply with these requirements a prohibited act.

**Section 3306. Bans of devices for one or more intended uses.**
Section 3306 a]mends section 516 of the FFDCA to make clear that FDA is authorized to ban a medical device intended for a particular use. A ban may apply to devices intended for more than one use, but in a situation where there are devices with the same or similar technological characteristics and different intended uses, FDA may ban one use and not the other.

**Section 3307. Third party data transparency.**
Section 3307 requires FDA to make reasonable efforts to evaluate third-party research on medical devices that is used for regulatory decision-making; and to the extent practicable, provide the manufacturer(s) a summary of such information.

**Section 3308. Predetermined change control plans for devices.**
Section 3308 allows the Secretary to approve a predetermined change control plan submitted in an application or supplement that describes planned changes that may be made to the device if the device remains safe and effective. Allows cleared devices to submit a predetermined change control plan in a notification.

**Section 3309. Small business fee waiver.**
Section 3309 allows certain small businesses, defined as those that reported $1 million or less of gross receipts in its most recent federal income tax return for a taxable year, to qualify for a waiver of the Medical Device User Fee Amendments (MDUFA) annual establishment registration fees, if the Secretary finds that paying such fee represents a financial hardship.

**Section 3401. Protecting infants and improving formula supply.**
Section 3401 provides flexibility to FDA to waive the 90-day premarket submission requirement for infant formula when there is a supply disruption and apply a 30-day premarket submission requirement, which will remain in effect for 90 days beginning on the date that FDA distributes

manufacturer notifications of infant formula shortages. Not later than one year after enactment, the section requires FDA to submit a report to Congress on the timelines related to FDA's review of premarket submissions for infant formula. It requires FDA to publish a list on the FDA website detailing which infant formula products may be appropriate substitutes for infant formula products in shortage that are relied on by individuals with amino-acid and metabolic conditions. It also requires FDA to participate in meetings with representatives from other countries to discuss harmonizing regulatory requirements for infant formula. The section also requires a study by the National Academies of Sciences, Engineering, and Medicine to report on challenges in supply, market competition, and regulation of infant formula in the United States, and any differences from infant formula marketed in the European Union. The section requires FDA to submit an annual report to Congress on infant formula submissions and inspections, to respond to a new submission for infant formula not later than 45 days after receiving such submission, and to review the required nutrients in infant formula every four years. It also requires infant formula manufacturers to submit a report to FDA promptly after the initiation of a recall, including a plan of actions the manufacturer will take to address the recall. It then requires FDA to submit the manufacturer's report to Congress, along with information concerning the current domestic supply of infant formula and, if the recall impacts over 10 percent of the domestic production of infant formula intended for sale in the United States, actions that FDA will take to work with the manufacturer or other manufacturers to increase production. The section requires FDA to ensure timely communication with manufacturers following an inspection and to reinspect facilities in a timely manner. It also requires FDA to conduct annual inspections of each manufacturer of infant formula in accordance with a risk-based approach and ensure coordination among the investigators and Center for Food Safety and Applied Nutrition. It also requires FDA, in consultation with the Secretary of Agriculture, to develop and issue within 90 days of enactment a national strategy on infant formula to increase the resiliency of the infant formula supply chain, protect against future contamination and other potential causes of shortages, and ensure parents and caregivers have access to formula and information they need. The section requires manufacturers of critical foods to notify FDA of a permanent discontinuance in the manufacture or an interruption of the manufacture of such food that is likely to lead to a meaningful disruption in the supply of such food in the United States, and the reason for such discontinuance or interruption, as soon as practicable, but no later than five business days after such discontinuance or such interruption. It requires FDA to distribute information on such meaningful disruption to the Secretary of Agriculture and other appropriate entities. It also requires critical food manufacturers to develop, maintain, and implement, as appropriate, a redundancy risk management plan that identifies and evaluates risks to the supply of critical food for each establishment in which such food is manufactured. The section provides that if a person fails to submit a notification, FDA shall issue a letter to such person informing them of the failure, and then no later than 45 days after issuance of the letter, FDA may post the letter (and, at the request of such person, any response to the letter) on the FDA website.

## Subtitle E – Cosmetics

**Section 3501. Short title.**

Section 3501 establishes the short title for Subtitle E as the "Modernization of Cosmetics Regulation Act of 2022."

**Section 3502. Amendments to cosmetic requirements.**
Section 3502 amends Chapter VI of the Federal Food, Drug, and Cosmetic Act to include new provisions for cosmetic products:

- Sec. 604. Definitions. Provides definitions for the terms adverse event, cosmetic product, facility, responsible person, and serious adverse event.

- Sec. 605. Adverse events. 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 (three years for small businesses), and authorizes FDA to have access to such records during an inspection. Provides that FDA may request a 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.

- Sec. 606. Good manufacturing practice. 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 practices no later than two years after enactment and issue final regulations no later than three years after enactment.

- Sec. 607. Registration and product listing. 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 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 change since the previous listing. Imposes requirements for the contents of 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. The suspension of cosmetics facilities is similar to the current process for food facilities and contains certain guardrails and limitations.

- Sec. 608. Safety substantiation. 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.

- Sec. 609. Labeling. 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, that 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.

- Sec. 610. Records. 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.

- Sec. 611. Mandatory recall. 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.

- Sec. 612. Small businesses. Provides certain exemptions for small businesses with average gross annual sales for the previous three-year period of less than $1 million.

- Sec. 613. Exemptions for certain products and facilities. 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.

- Sec. 614. Preemption. 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, records, 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 state laws or requirements for reporting certain cosmetic ingredients to states. Provides that nothing in the Modernization of Cosmetics Regulation Act of 2022, nor any standard, rule, requirement, or adverse event report, 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), including any exemptions from labeling preemption.

**Section 3503. Enforcement and conforming amendments.**
Section 3503 states that new enforcement provisions become effective one year after enactment of the Modernization of Cosmetics Regulation Act of 2022. The section 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. It provides that cosmetic products are adulterated if they are manufactured under conditions that do not meet good manufacturing practice requirements or do not have adequate substantiation for safety, and are misbranded if they are not in compliance with labeling requirements contained in the Modernization of Cosmetics Regulation Act of 2022.

**Section 3504. Records inspection.**
Section 3504 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.

**Section 3505. Talc-containing cosmetics.**
Section 3505 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.

**Section 3506. PFAS in cosmetics.**
Section 3506 requires FDA to assess the use of perfluoroalkyl and polyfluoroalkyl 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. The section provides that FDA

can, as appropriate, consult with the National Center for Toxicological Research, in conducting the assessment. It also requires FDA to publish on its website a report summarizing the assessment not later than two years after enactment of the Food and Drug Omnibus Reform Act.

**Section 3507. Sense of the Congress on animal testing.**
Section 3507 provides a 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 the exception of appropriate allowances.

**Section 3508. Funding.**
Section 3508 provides for an authorization of appropriations for purposes of conducting the activities under this section and hiring personnel required to carry out this section.

## Subtitle F – Cross-Cutting Provisions

### *Chapter 1 – Clinical Trial Diversity and Modernization*

**Section 3601. Diversity action plans for clinical studies.**
Section 3601 requires sponsors of phase 3 and other pivotal studies of new drugs and sponsors of studies of devices to develop and implement a diversity action plan, subject to certain exceptions. Such plan must include the sponsor's goals for enrollment in the clinical studies, the sponsor's rationale for such goals, and an explanation for how the sponsor intends to meet such goals.

**Section 3602. Guidance on diversity action plans for clinical studies.**
Section 3602 requires FDA to issue new guidance or update existing guidance specifying the form and content of diversity action plans regarding the sponsor's goals for enrollment, disaggregated into certain demographic categories, including regarding the rationale for such goals, and how they will be met.

**Section 3603. Public workshops to enhance clinical study diversity.**
Section 3603 requires FDA, in consultation with drug sponsors, medical device manufacturers, patients, and other stakeholders, not later than one year after enactment, to convene one or more public workshops to solicit input from stakeholders on increasing the enrollment of historically underrepresented populations in clinical studies.

**Section 3604. Annual summary report on progress to increase diversity in clinical studies.**
Section 3604 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 received pursuant to Section 505(z) or 520(g)(9) of the Food, Drug, and Cosmetic Act. The section notes that nothing in this section shall be construed to authorize FDA to disclose any information that is a trade secret or confidential.

**Section 3605. Public meeting on clinical study flexibilities initiated in response to COVID–19 pandemic.**
Section 3605 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 studies. Such meeting shall discuss incorporating certain clinical study disruption mitigation recommendations into current or additional guidance to improve clinical study access and enrollment of diverse patient populations.

**Section 3606. Decentralized clinical studies.**
Section 3606 requires FDA, not later than one year after enactment, to issue draft guidance that addresses considerations for decentralized clinical studies, including regarding the engagement, enrollment, and retention of a meaningfully diverse clinical population with respect to race, ethnicity, age, sex, and geographic location, when appropriate. FDA is required to finalize this guidance no later than one year after the public comment for the draft guidance ends.

**Section 3607. Modernizing clinical trials.**
Section 3607 requires FDA to issue three guidances to modernize and improve clinical trials, including on the use of: (1) Digital health technologies in clinical trials to help improve recruitment, participation, and data collection; (2) Decentralized clinical trials to improve trial participant engagement and advance the use of flexible and novel clinical trial designs; and (3) Seamless, concurrent, and other innovative clinical trial designs to support the expedited development and review of drugs and biological products. It requires FDA to work with foreign regulators with respect to the use of digital health technologies in clinical trials, decentralized clinical trials, seamless, concurrent, and other innovative clinical trial designs.

## *Chapter 2 – Inspections*

**Section 3611. Device inspections.**
Section 3611 clarifies that the scope of FDA inspectional authority extending to all things in a factory, warehouse, establishment, or consulting laboratory applies to such places that manufacture, process, pack, or hold non-restricted devices as well as ones that do so with respect to restricted devices. It extends the requirement for the provision, to FDA, of records requested in advance or in lieu of an inspection to persons that own or operate establishments engaged in the manufacture, preparation, propagation, compounding, or processing of devices. FDA will have to provide a rationale for requesting such records and issue guidance regarding such requests.

**Section 3612. Bioresearch monitoring inspections.**
Section 3612 codifies and clarifies FDA authority to inspect clinical study sites, also known as bioresearch monitoring inspections. It 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.

**Section 3613. Improving Food and Drug Administration inspections.**
Section 3613 provides for FDA consideration of the compliance history of other FDA-regulated establishments in the country or region in which an establishment is located as a factor in establishing a schedule for risk-based inspections. It clarifies that FDA may rely on any records or other information inspected to satisfy requirements that may pertain to a preapproval or risk-based surveillance inspection, or to resolve deficiencies found in such inspections, if applicable and appropriate. It also provides that FDA may enter into agreements with foreign governments to recognize inspections of foreign establishments to facilitate preapproval inspections and requires a periodic assessment of whether additional arrangements with foreign governments are appropriate.

**Section 3614. GAO report on inspections of foreign establishments manufacturing drugs.**
Section 3614 requires GAO to report on inspections conducted by FDA and recognized foreign governments on actions taken to improve inspections of foreign establishments manufacturing drugs.

**Section 3615. Unannounced foreign facility inspections pilot program.**
Section 3615 requires FDA to conduct a pilot program in which FDA increases the conduct of unannounced surveillance inspections of foreign drug establishments, evaluates the differences between such inspections of domestic and foreign establishments, including the impact of announcing inspections, and post a report of its findings and recommendations on the FDA website.

**Section 3616. Enhancing coordination and transparency on inspections.**
Section 3616 advances intra-agency coordination between field investigators and drug shortage staff at FDA. It requires FDA to include additional information in an annual report with respect to FDA domestic and foreign inspections and FDA recognition of foreign government inspections. It also requires FDA to include additional information in an annual report with respect to the timing of inspections and regulatory and enforcement actions. The section harmonizes the timing of the FDA annual reporting requirement on inspections under Section 902 of the Food and Drug Administration Reauthorization Act to align with reporting requirements related to the PDUFA user fee program.

**Section 3617. Enhancing transparency of drug facility inspection timelines.**
Section 3617 amends the information FDA must annually report regarding inspections on its website pursuant to section 902 of the FDA Reauthorization Act of 2017 (FDARA), including by adding to this information the time between a request from FDA and the beginning of an inspection for certain generic drugs, drugs subject to discontinuance reporting, and drugs on the shortage list.

## *Chapter 3 – Miscellaneous*

**Section 3621. Regulation of certain products as drugs.**
Section 3621 deems all contrast agents, radioactive drugs, and over-the-counter monograph drugs to be drugs and not medical devices. It waives application fees for products that are currently medical devices that would be deemed to be drugs.

**Section 3622. Women's Health Research Roadmap.**
Section 3622 requires the FDA Office of Women's Health, not later than two years after enactment, to update the Women's Health Research Roadmap.

**Section 3623. Strategic workforce plan and report.**
Section 3623 requires FDA to develop a strategic workforce plan at least every four years.

**Section 3624. Enhancing Food and Drug Administration hiring authority for scientific, technical, and professional personnel.**
Section 3624 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 and cosmetics, in addition to personnel who work on medical products, to enable the agency to recruit and retain outstanding, highly qualified individuals for these positions.

**Section 3625. Facilities management.**
Section 3625 preserves Section 905 of FDARA by clarifying that FDA use of budget authority for costs excluded under Section 905 (e.g., for furniture and fixtures) can count towards meeting the spending trigger amount for user fees for the Prescription Drug User Fee Amendments (PDUFA), Generic Drug User Fee Amendments (GDUFA), MDUFA, and Biosimilar User Fee Amendments (BsUFA) programs. This provision starts in FY 2024.

**Section 3626. User fee program transparency and accountability.**
Section 3626 strengthens the reporting requirements for the user fee programs to ensure greater accountability and transparency with respect to FDA's commitments. It 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.

**Section 3627. Improving information technology systems of the Food and Drug Administration.**
Section 3627 requires FDA to develop and submit to Congress and post on the FDA website a coordinated information technology strategic plan to modernize the information technology systems of the FDA. It also requires GAO to assess the implementation of such plan.

**Section 3628. Reporting on mailroom and Office of the Executive Secretariat of the Food and Drug Administration.**
Section 3628 requires FDA to submit a report to Congress on policies, procedures, and activities of the mailroom and the Office of the Executive Secretariat of the FDA, the development and implementation of new or revised policies and procedures to monitor and ensure the effective

receipt, tracking, managing, and prioritization of complaints, and the effective receipt of common carrier packages to FDA. It requires annual reporting to Congress on information regarding FDA's handling of common carrier packages and correspondence.
It also requires GAO to conduct a report assessing the policies and practices of the Division of Executive Operations in the Office of the Secretariat with respect to the receipt, tracking, managing, and prioritization of correspondence.

**Section 2629. Facilitating the use of real world evidence.**
Section 2629 requires FDA to issue or revise guidance on the use of real-world data and real-world evidence to support regulatory decision making, including with respect to real-world data and real-world evidence from products authorized for emergency use.

**Section 3630. Facilitating exchange of product information prior to approval.**
Section 3630 provides that no drug or medical device shall be considered misbranded as a result of the provision of information regarding investigational drugs or medical devices or uses to payors, formulary committees, or other similar entities under specified conditions. It requires the information to include a clear statement that the drug or medical device has not been approved and that the safety and efficacy of the drug or medical device has not been established. Additional required disclosures include information about studies the drug or medical device is undergoing, how the studies relate to the overall plan for the development of the drug or medical device, whether an application for the drug or medical device has been submitted to FDA, and if not, when such submission is planned.

**Section 3631. Streamlining blood donor input.**
Section 3631 provides a Paperwork Reduction Act (PRA) exemption for voluntary information that is solicited from blood donors or potential blood donors to support the development of recommendations by the Secretary concerning blood donation.