EXTRANEOUS MATTER

Division O – Extenders and Technical Corrections

Title I – National Cybersecurity Protection System Authorization Extension
Extends the National Cybersecurity Protection System authorization, which expired Dec. 18, 2022, through the end of the fiscal year.

Title II – NDAA Technical Corrections
Sec. 201. Basic Needs Allowance: Fixes a drafting error that would not allow the language to be implemented.

Sec. 202. Military service academy: Exempts the class of 2023/2024 from the NDAA provision requiring athletes at military service academies to fulfill 2 years of military service obligation prior to pursuing a career as a professional athlete.

Title III – Immigration Extensions
Contains standard extensions of four immigration provisions. First, it extends the popular E-Verify program, which allows participating employers to verify the employment status of potential workers. Second, it extends the non-minister religious worker program which provides visas for religious workers who are engaged in a professional or otherwise non-ministerial vocation. Third, it extends the Conrad 30 program for rural healthcare workers, which addresses the lack of doctors in underserved communities. Lastly, it delegates to DHS discretionary authority to issue additional H-2B low-skilled temporary-worker visas beyond the annual statutory cap, as Congress has typically done in recent years.

Title IV – Environment and Public Works Matters
Sec. 401. Establishment of regional authority for the Great Lakes.
Establishes the Great Lakes Authority under subtitle V of Title 40 of the U.S. Code, to support economic and infrastructure development in the watershed of the Great Lakes and the Great Lakes System in certain states. The subtitle establishes commission membership, voting structure, and staffing; outlines conditions for financial assistance; authorizes grants to local development districts; establishes an Inspector General for the commissions; and includes other provisions designed to produce a standard administrative framework.

Sec. 402. Keep America's Refuges Operational Act
Reauthorizes through Fiscal Year 2027 the volunteer services, community partnerships and refuge education programs of the National Wildlife Refuge System.

Sec. 403. Kentucky Highway Renumbering Fix
Makes a technical correction relating to the existing interstate designation for the Louis B. Nunn Cumberland Expressway (Expressway) in Kentucky. Under current law, there is duplicative interstate numbering along the Expressway. This language removes the original designation, which was established in the Intermodal Surface Transportation Efficiency Act of 1991, and maintains the other designation of the Expressway as an interstate spur of I-65.

Sec. 404. Patrick Leahy Lake Champlain Basin Program
Amends Sec. 120 of the Federal Water Pollution Control Act to: (1) reauthorize federal appropriations of $35 million annually for fiscal years 2023 through 2027 for the U.S. Environmental Protection Agency's (EPA) Lake Champlain Basin regional watershed program; and (2) redesignates the program as the "Patrick Leahy Lake Champlain Basin Program."

Sec. 405. Clean School Bus Program Technical Changes.
Makes technical fixes to the Clean School Bus Program created in the Infrastructure Investment and Jobs Act (IIJA, P.L. 117-58, Sec. 71101). This allows public charter schools and third-party school bus providers direct access to funding and provides additional flexibility in the requirement that there be five-year school bus contracts with local educational agencies.

Title V – Safety Enhancements
Sec. 501. Amendments to the Flight Crew Alerting Requirements (737 MAX): Codifies the Aircraft Certification, Safety, and Accountability Act prohibition on FAA issuing a type certificate for a transport category airplane after December 27, 2022, that does not incorporate capabilities of a modern flight crew alerting system.

Provides an exception to this requirement if the application for the type certificate was submitted to the FAA prior to December 27, 2020, the date of enactment of the Aircraft Certification, Safety, and Accountability Act (ACSAA). This is consistent with the original intention of ACSAA provision, Sec. 116(b)(1).

Requires incorporation of additional safety enhancements – synthetic enhanced angle of attack and a means to shut off stall warnings and overspeed alerts – for the entire MAX aircraft fleet. The original equipment manufacturer is responsible for the costs of the safety enhancements retrofit for the operating fleet.

Requires quarterly Congressional briefings by FAA on the status of type certification of the MAX-7 and MAX-10 and implementation of required safety enhancements.

Title VI – Extension of Temporary Order for Fentanyl-Related Substances
Sec. 601. Extends the current categorization of fentanyl-related substances in schedule 1 of the Controlled Substances Act to December 31, 2024. Fentanyl is the leading killer of Americans between the ages of 18-45. A key tool in fighting this deadly opioid is the scheduling of its analogues as controlled substances.

Title VII — Federal Trade Commission Oversight of Horseracing Integrity and Safety Authority
Sec. 701. Makes clear the original intent of the Horseracing Integrity and Safety Act of 2020 (HISA) by clarifying that the Federal Trade Commission has full oversight of the Horseracing Integrity and Safety Authority's rulemaking. This technical correction will also allow HISA to continue providing a safe, uniform alternative to the patchwork of inconsistent state-by-state regulations.

Title VIII—United States Parole Commission Extension
Sec. 801. Extends the authorization of the United States Parole Commission, which makes parole decisions regarding certain federal offenders.

Title IX— Extension of FCC Auction Authority
Sec. 901. Extends the auction authority of the Federal Communications Commission.

Title X—Budgetary Effects
Sec. 1001. Postpones Statutory PAYGO sequestration preventing cuts to Medicare, agriculture, and other programs.

Division P—Electoral Count Reform And Presidential Transition Improvement
Title I – Electoral Count Reform Act (ECRA): Reforms and modernizes the 1887 Electoral Count Act, which governs the joint-session of Congress in which each state's electoral votes are counted pursuant to the Twelfth Amendment.

Title II – Presidential Transition Improvement Act: Amends the Presidential Transition Act by providing clear guidelines for when eligible candidates for President or Vice President may receive federal resources to support their transition into office.

Division Q—Aviation Related Matters

Sec. 101. Advanced air mobility infrastructure pilot program.
Establishes a FAA planning grant program to assist in the preparation and development of infrastructure necessary to support the anticipated deployment of advanced air mobility (AAM) operations. Grants would be awarded to eligible recipients to facilitate the submission of comprehensive AAM infrastructure plans. Eligible grant recipients include states, localities, and Tribal governments, airport sponsors, transit agencies, port authorities, and metropolitan planning organizations.

Sec. 102. Samya Stumo National Air Grant Fellowship Act
Renames the National Air Grant Fellowship Program (Section 131 of the Aircraft Certification, Safety, and Accountability Act – P.L. 116-260) after Samya Rose Stumo, who died in the Ethiopian Airlines Flight 302 crash. The bill also includes a Sense of Congress to commemorate and recognize the lives lost in the Lion Air Flight 610 and Ethiopian Airlines Flight 302 crashes as well as the life of Indonesian diver Syachrul Anto, who died during search and recovery efforts in the aftermath of the Lion Air Flight 610 crash.

Sec. 103. Temporary insurance for air carriers for certain terminated coverage
If a "hostile nuclear detonation" event were to occur, causing existing air carrier insurance policies to be cancelled and air carriers to subsequently ground their fleets in the U.S. and around the world, the war risk proposal would allow the FAA to provide temporary insurance to air carriers for a period not to exceed 90 days. This 90 day time period would give the private insurance market time to respond, issue new commercial war risk insurance, and enable airlines to get their operations back up and running under these circumstances.

Sec. 104. Removal of restriction on veterans concurrently serving in the Offices of Administrator and Deputy Administrator of the Federal Aviation Administration
Eliminates the restriction on veterans serving concurrently in the Offices of Administrator and Deputy Administrator of the Federal Aviation Administration.

Sec. 105. National Aviation Preparedness Plan
Directs DOT, in collaboration with HHS and DHS and other appropriate federal agencies, to develop a national aviation preparedness plan for communicable disease outbreaks. The preparedness plan would be required to prescribe the responsibilities of airports, air carriers, and government entities in responding to future pandemics; improve coordination among aviation stakeholders, and federal and international entities in preparing for future pandemics; and identify appropriate technologies, equipment, protective infrastructure and related policies to better respond to communicable disease outbreaks. GAO would also be directed to review and study the plan and submit their recommendations to congressional committees of jurisdiction.

Sec. 106. Aerospace Supply Chain Resiliency Task Force
Directs the DOT to establish an aerospace supply chain resiliency task force, made up of a holistic group of industry and labor stakeholders, to identify vulnerabilities, assess risks, and recommend solutions to improve the domestic aerospace supply chain. The task force would terminate after issuing a report to the Senate Committee on Commerce, Science, and Transportation and the House Committee on Transportation and Infrastructure no later than one year after the first meeting of the task force.

Sec. 107. Covered Operations Elective Standards
Permits large private jet fractional (time-share) ownership programs to elect to impose an age cap of 70 years for their pilots. This authority to impose a pilot age cap is only extended to large private fractional ownership programs with high-volume operations (those that have performed 75,000 turbojet operations annually in 2019 or any subsequent year).

Division R—No Tiktok On Government Devices
Bans government employees, including officers of the United States, Members of Congress, congressional employees, or officers or employees of a government corporation from downloading or using TikTok and any successor application developed by ByteDance on any device issued by the US government or a government corporation.

Division S—Oceans Related Matters

Title I – Driftnet Modernization and Bycatch Reduction Act – Addresses certain driftnet fishing, in which a gillnet or series of gillnets is placed in the water and allowed to drift with currents and winds for the purpose of entangling fish. This Sec. reduces the size of gillnet mesh to reduce unwanted bycatch.

Title II – Fishery Resource Disasters Improvement Act – Contains the fish disasters legislation passed by the Senate in September 2021, as amended by the House Commission on Natural Resources. Improves the Fishery Resource Disaster Relief program of the National Marine Fisheries Service.

Title III – Alaska Salmon Research Task Force Act – Includes legislation passed by the Senate in December 2022, as amended. This Sec. requires the National Oceanic and Atmospheric Administration to convene an Alaska Salmon Research Task Force to review and report on research needed to better understand salmon migration and declining salmon returns in some regionals of Alaska, and to support sustainable management of salmon.

Title IV – IUU technical corrections – Makes technical corrections to the recently passed National Defense Authorization Act, contained in the Coast Guard Authorization Act, regarding illegal, unreported, and unregulated fishing. The effects of the corrections retain current law.

Division T—Secure 2.0 Act Of 2022

Building on the bipartisan Setting Every Community Up for Retirement Enhancement (SECURE) Act of 2019, the SECURE 2.0 Act of 2022 is the product of four bipartisan bills originating in the tax and labor committees of the House and Senate. SECURE 2.0 increases participation in retirement plans by expanding automatic enrollment features in retirement plans, decreases costs for employers that seek to offer retirement plans for their employees, encourages small businesses to offer retirement plans, and simplifies various rules relating to 401(k), 403(b), and other retirement plans. Also encourages workers to save more and allows retirees to save longer. Finally, the bill provides flexibility for workers who have unexpected emergency expenses.

Division U—Joseph Maxwell Cleland And Robert Joseph Dole Memorial Veterans Benefits And Health Care Improvement Act Of 2022

Title I – Health Care Matters

Title I improves veterans health care by expanding access to care for World War II veterans and improving the research and treatment of prostate cancer. It also improves oversight of health care providers and strengthens accountability for substandard care. Subtitle C improves veteran access to care outside VA and improves accountability for non-VA providers. This title also increases oversight of rural care and telehealth care by VA, improves care for aging veterans, studies effectiveness of VA's Foreign Medical Program, and makes improvements to VA research efforts, including for mental health treatments.

Subtitle A – Access to Care
Subtitle B – Health Care Providers
Subtitle C – Care From Non-Department of Veterans Affairs Providers
Subtitle D – Improvement of Rural Health and Telehealth
Subtitle E – Care for Aging Veterans
Subtitle F – Foreign Medical Program
Subtitle G – Research Matters
Subtitle H – Mental Health Care
Subtitle I – Other Matters

Title II – Benefits Matters

Makes improvements to veterans benefits related to disability compensation, home loan guaranty, the GI Bill, survivors' education assistance, beneficiary travel assistance, and VA's

debt management rules. Provisions in this title improve the clothing allowance VA provides for certain disabled veterans, and improve income considerations for veterans using the VA home loan guaranty. Other provisions improve access to apprenticeships, increase options for transferring GI Bill benefits to dependents, and increase the time veterans have to use education benefits when their education is interrupted by national emergencies. This title also requires several studies of the beneficiary travel benefits VA provides and directs VA to conduct two pilot programs aimed at improving access to care through the use of travel benefits. Subtitle E sets requirements on when and under what circumstances VA can assign a debt to a veteran and provides options for a veteran to request assistance or relief from a debt.

Subtitle A – Benefits Generally
Subtitle B – Education
Subtitle C – GI Bill National Emergency Extended Deadline Act
Subtitle D – Rural Veterans Travel Enhancement
Subtitle E – VA Beneficiary Debt Collection Improvement Act

Title III – Homelessness Matters
Makes improvements to programs serving veterans who are homeless or at risk of being homeless. This title makes it easier for service providers to qualify for grants to serve homeless veterans, expands the grant and per diem program to deliver case management to more veterans and connect them with additional resources, and makes permanent the Homeless Veterans Reintegration Program with the intent to have program providers delivering services in every state. This title also makes improvements to the HUD-VASH program between HUD and VA to better serve homeless veterans, and establishes a pilot program to address the unique needs of veterans with substance use disorders who are also experiencing homelessness.

Title IV – Other Matters
Title IV directs VA to improve its logistics and supply chain resiliency through planning, partnerships with DoD, and regular reporting to Congress. This title also makes improvements to VA's Equal Employment Opportunity program through additional personnel and reporting requirements. The VA Information Technology Reform Act in title IV improves VA's project management, planning, and prioritization functions over its information technology programs and requires VA to more regularly report to Congress in order to increase accountability and improve VA IT performance.

Division V—Strong Veterans Act Of 2022

Title I – Training to Support Veterans' Mental Health
Directs VA to invest in the providers delivering mental health care to veterans. It directs VA to increase its capacity and effectiveness in serving Native American veterans, expands the number of providers serving veterans through Vet Centers, and provides VA additional resources to recruit and retain mental health care providers through scholarships and loan repayment.

Title II – Veterans Crisis Line
Improves the Veterans Crisis Line through training, oversight, and research. This includes external quality reviews of training, performance, and management. It also authorizes resources for additional research into the crisis line's effectiveness and ways to improve the service.

Title III – Outreach to Veterans
Title III improves outreach to veterans in order to increase access and usage of resources for mental health. This includes the designation of a Buddy Check Week to promote peer engagement among veterans, improve outreach to highlight VA's Veteran Justice Outreach Program for veterans involved in the justice system, and gives Native American Tribes access to VA's Governors' Challenge program to help states develop veteran suicide prevention proposals.

Title IV – Mental Health Care Delivery
Title IV improves mental health care delivery by expanding the peer support program, extending Vet Center care to student veterans and certain veterans' surviving family members, and requiring VA to offer specific services if a veteran submits a claim for disability benefits due to a mental health condition.

Title V – Research
Title V directs VA to conduct a number of studies and research projects focused on various aspects of brain health and mental health care delivery. This includes reports on the Veterans Integration to Academic Leadership (VITAL) program and how it serves veterans in higher education, improvement of sleep disorder assessment and care, and studies on inpatient mental health and substance use care within VA. This title also includes three provisions to improve suicide prevention efforts, additional resources for studies on brain health and studies on care in clinical settings and care at home.

Division W—Unleashing American Innovators Act Of 2022
Requires U.S. Patent and Trademark Office (USPTO) satellite offices to include outreach activities targeting underrepresented groups including the economically and geographically underrepresented. Requires the establishment of more USPTO satellite offices and community outreach offices. Mandates a report to Congress on patent pro bono programs.

Division X— Extension Of Authorization For Special Assessment For Domestic Trafficking Victims' Fund
Justice for Victims of Trafficking Act: Reauthorizes $5,000 special assessments (fines) against convicted human traffickers.

Division Y—Contract Act Of 2022
Exempts from a FAA-required reduction in annuity payments air traffic controllers who participates in the Air Traffic Control Contract Program (a public-private partnership for air traffic control services) following mandatory retirement.

Division Z—COVS Act
Requires GSA to transfer certain surplus computers and technology equipment to nonprofit computer refurbishes for repair and eventual distribution to schools (including home schools),

veterans, seniors and other populations in need and to state and local agencies for donation to nonprofit and public entities.

Division AA—Financial Services Matters

Title I—Registration for Index-Linked Annuities Act: Requires the SEC to establish a tailored form for registering the offering of index-linked annuities.

Title II—Masih Alinejad HUNT Act of 2022: Creates an annual reporting requirement to assess the state of human rights inside Iran and authorizes mandatory sanctions on Iranian officials responsible for targeting dissidents and human rights advocates.

Title III—Trading prohibitions: Amends the 2020 legislation and builds on recent PCAOB oversight efforts to increase accountability for foreign companies that refuse to submit to U.S. oversight of their audit firms and further close a loophole that companies based in China have used to avoid such oversight. Foreign companies traded on U.S. stock exchanges will have to comply with accounting transparency requirements in two years instead of three.

Title IV—Anti-Money Laundering Whistleblower Improvement Act: Strengthens an existing anti-money laundering whistleblower program by setting a minimum whistleblower award amount and creating a funding mechanism to pay whistleblowers.

Title V— Small Business Mergers, Acquisitions, Sales, and Brokerage Simplification Act: This provision, which passed the House on suspension, codifies an SEC decision to exempt from SEC and FINRA registration requirements qualifying M&A brokers that facilitate the sale of small private companies.

Title VI— Public and Federally Assisted Housing Fire Safety Act: Requires the installation of hardwired or tamper-resistant, battery-powered smoke alarms in federally assisted housing.

Title VII—Benjamin Berell Ferencz Congressional Gold Medal: Recognizes the last living Nuremberg prosecutor, 102-year-old Benjamin Ferencz, with Congress's highest expression of civilian appreciation.

Title VIII— Congressional Oversight Committee Expiration: Moves up the termination date to mid-2023 for the Congressional Oversight Commission. Created by the CARES Act, this five-member panel oversaw since-discontinued COVID emergency lending programs at the Federal Reserve.

Title IX—Flood Insurance: Extends the National Flood Insurance Program's (NFIP) authorization and borrowing authority through September 30, 2023.

Division BB—Consumer Protection And Commerce

Manufacturing.gov – Requires the Department of Commerce to establish a Sec. of the manufacturing.gov website to serve as the primary hub for information relating to federal manufacturing programs. In addition to serving as the primary hub for this information, the hub

must also (1) provide the contact information for relevant program offices carrying out federal manufacturing programs; (2) provide an avenue for public input and feedback relating to these programs; and (3) host web pages that focus on topics such as trade, workforce development, and small and medium manufacturers.

STURDY Act –Directs the Consumer Product Safety Commission (CPSC) to promulgate a consumer product safety standard for free standing clothing storage units to protect children from tip-over related death or injury. The standard must protect children up to 72 months of age from tip-over related death or injury and be developed in consultation with consumer groups and clothing storage unit manufacturers. If a voluntary standard exists that meets the requirements, the Commission shall adopt such standard. The Sec. also provides a mechanism for revising an adopted voluntary standard.

INFORM Consumers Act – Establishes a national standard, enforced by the Federal Trade Commission (FTC) and State Attorneys General, that requires online platforms that allow for third party sellers of consumer products to verify the identity of high-volume third party sellers, enabling consumers to obtain basic identification and contact information for certain high-volume third party sellers.

Virginia Graeme Baker Pool and Spa Safety Act Reauthorization – Reauthorizes the Virginia Graeme Baker Pool and Spa Safety Act, authorizes $2.5 million for grants to states and Indian tribes to address pool and spa safety, reauthorizes the Consumer Product Safety Commission Education and Awareness Program and authorizes $2.5 million for the agency to inform the public of methods to prevent drowning and entrapment in swimming pools.

RANSOMWARE Act – Requires the FTC to report on cross-border complaints received that involve ransomware or other cyber-related attacks committed by certain foreign individuals, companies, and governments. The report must focus specifically on attacks committed by Russia, China, North Korea, or Iran or individuals or companies that are located in or have ties to those countries.

Travel and Tourism – Includes a Sense of Congress related to travel and tourism, establishes and defines the responsibilities of the position of Assistant Secretary of Commerce for Travel and Tourism to be appointed by the President, requires the Department of Commerce to develop a 10-year strategy with annual goals to boost the industry, establishes the United States Travel and Tourism Advisory Board and establishes the functions of the Board, and requires the Assistant Secretary for travel and tourism to collect and make public aggregate data on domestic travel and tourism trends.

Further requires the Department of Commerce complete a study and issue a report on the effects of the COVID-19 pandemic on the travel and tourism industry, including various segments of the travel and tourism industry, such as domestic, international, leisure, business, convention, meetings, and events.

Division CC—Water Related Matters

Sec. 101. Extension of Authorizations Related to Fish Recovery Programs: Extends the authority and report deadline for the Department of the Interior to implement capital projects for the endangered fish recovery programs of the Upper Colorado and San Juan River basins through FY2024 and adjusts cost ceilings for the programs.

Sec. 102. Colorado River System Conservation Pilot Program: Extends the Bureau of Reclamation's legal authority for the Colorado River System Conservation Pilot Program through FY2024 and clarifies that new water conservation agreements will be eligible for funding under the program.

Sec. 103. Salton Sea Projects: Authorizes the Bureau of Reclamation to provide grants and enter into contracts and cooperative agreements to carry out projects in partnership with Salton Sea stakeholders to mitigate dust impacts; and improve water quality, fish and wildlife habitat, and recreational opportunities.

Sec. 104. Authorization of Sun River Project, Montana: Authorizes the U.S. Bureau of Reclamation to advance hydroelectric power generation at Montana's Sun River Project, consistent with reclamation laws and other requirements.

Sec. 105. Eligibility under the Infrastructure Investment and Jobs Act of Small Water Storage and Groundwater Storage Projects: Changes the eligibility requirements under Bureau of Reclamation's Small Water Storage Program to allow projects larger than 200 acre-feet to be eligible for competitive grant funding.

Division DD—Public Land Management

Sec. 1. Definition of the Secretary. This Sec. defines the term "Secretary" to mean the Secretary of the Interior within the division.

TITLE I – Department of the Interior Provisions

Sec. 101. Pilot Program for Native Plant Species: Establishes a pilot program for native plant species within geographically diverse units of the National Park System and public lands administered by the Bureau of Land Management to promote and increase the use of native plants on Federal lands.

Sec. 102. Reauthorization of the Highlands Conservation Act: Amends the Highlands Conservation Act (Public Law 108-42), to authorize Federal matching funds through fiscal year (FY) 2028, and to update and clarify other provisions of the Act. Congress enacted the Highlands Conservation Act in 2004 to recognize the importance of the water, forest, agricultural, wildlife, recreational, and cultural resources of the Highlands region, which extends from Connecticut through New Jersey, New York, and Pennsylvania. Under the Act, the Secretary of the Interior (through the U.S. Fish and Wildlife Service) is authorized to provide matching funds to help fund land conservation partnership projects.

Sec. 103. Cadastre of Federal Real Property: Requires the Secretary of Agriculture, acting through the Chief of the Forest Service, and Secretary of the Interior to develop and maintain a publicly available cadastre (inventory) of Federal real property under the jurisdiction of the Secretaries.

Sec. 104. Sale or Lease of Land to Federally Recognized Indian Tribes: Authorizes the Department of the Interior to sell or lease public lands to federally recognized Indian Tribes under the Recreation & Public Purposes Act.

TITLE II – Forest Service Provisions

Sec. 201. Administration of the Land Between the Lakes National Recreation Area: Makes several amendments to the management provisions of the Land Between the Lakes (LBL) Protection Act of 1998, including: expanding the role of the LBL Advisory Board, using funds collected by fees for deferred maintenance instead of for general management and salaries, and encouraging the Forest Service to enter into Memorandum of Agreements with state and local governments, including local law enforcement, to clarify jurisdictional matters.

Sec. 202. Hawaii National Forest Study: Requires the Secretary of Agriculture to conduct a study on the establishment of, and the potential land that could be included in, a unit of the National Forest System in the State of Hawaii.

TITLE III – Land Conveyances and Exchanges

Sec. 301. Gilt Edge Mine Conveyance: Transfers approximately 266 acres of National Forest System land within the Gilt Edge Mine Superfund Site to the State of South Dakota. The State owns a portion of land base of the mine site and has an interest in consolidating adjoining Federal and private land within the Superfund site to mitigate acidic rock drainage.

Sec. 302. Conveyances to the University of Alaska: Authorizes the transfer of up to 360,000 acres of land selections made by the State of Alaska to the University of Alaska. The University must manage any land received and income derived under this program in a trust capacity to support higher education.

Sec. 303. Bonneville Shoreline Trail Wilderness Boundary Adjustments: Removes 326 acres certain lands in the State of Utah as components of the National Wilderness Preservation System to allow for expanded uses of the Bonneville Shoreline Trail. Further, the bill designates an equal amount of land—326 acres—for addition to the Mount Olympus Wilderness in Utah.

Sec. 304. Arizona Experiment Station Land Conveyance: Directs the Department of Agriculture, upon request of the Arizona Board of Regents, acting on behalf of the University of Arizona Experiment Station, to convey approximately 13.3 acres of National Forest System land within the Coconino National Forest in Arizona to the university.

Sec. 305. Wind River Administrative Site Conveyance: Directs the Secretary of Agriculture to transfer a 23.4-acre parcel of National Forest System land in the State of Washington to Skamania County, Washington if certain conditions are met.

Sec. 306: Right-of-way Permit for Natural Gas Distribution Main Segment at Valley Forge NHP: Authorizes the Department of the Interior to issue a right-of-way permit for a specified segment of the natural gas distribution pipeline (including all appurtenances used in the operation of such pipeline) within Valley Forge National Historical Park if the pipeline segment is relocated to a proposed realignment of Valley Forge Park Road and North Gulph Road within the park.

TITLE IV – Wild and Scenic River Designations and Studies

Sec. 401. York Wild and Scenic River, Maine: Designates approximately 30.8 miles of the York River in Maine and its tributaries as a recreational component of the National Wild and Scenic Rivers System.

Sec. 402. Housatonic Wild and Scenic River, Connecticut: Designates specified segments of the Housatonic River in Connecticut as components of the National Wild and Scenic Rivers System.

Sec. 403. Little Manatee River Wild and Scenic River Study, Florida: Designates a segment of the Little Manatee River in Florida for study for potential addition to National Wild and Scenic Rivers System.

Sec. 404. Kissimmee River Wild and Scenic River Study, Florida: Designates for a study a restored segment of the Kissimmee River in Florida as a potential addition to the National Wild and Scenic Rivers System.

TITLE V – National Trails System Designations and Studies

Sec. 501. Designation of the Chilkoot National Historic Trail: Designates the Chilkoot National Historic Trail in Alaska as a component of the National Trails System.

Sec. 502. Alaska Long National Scenic Trail Study: Directs the Secretary of the Interior to study feasibility of designating the Alaska Long Trail as a component of the National Trails System.

Sec. 503. Buckeye National Scenic Trail Feasibility Study: Directs the Department of the Interior to study of the feasibility of designating the Buckeye Trail as a National Scenic Trail.

TITLE VI – National Park Service Provisions

Subtitle A – Additions to the National Park System

Sec. 601. New Philadelphia National Historic Site: Establishes the New Philadelphia Historic Site in Illinois as a unit of the National Park System.

Subtitle B – Modifications to Existing Units of the National Park System

Sec. 611. Sunset Crater Volcano National Monument Boundary Adjustment: Modifies the boundary of the Sunset Crater Volcano National Monument in Arizona.

Sec. 612. Rosie the Riveter/World War II Home Front National Historical Park: Expands the Rosie the Riveter/World War II Home Front National Historical Park in California to include the Nystrom Elementary School, the Maritime Building, and other areas as the Department of the Interior deems appropriate.

Sec. 613. Cape Cod National Seashore Advisory Commission: Extends the Cape Cod National Seashore Advisory Commission until September 26, 2029.

Sec. 614. Cane River Creole National Historical Park Boundary Modification: Modifies the boundary of the Cane River Creole National Historical Park in Louisiana.

Sec. 615. Use of Certain Roads Within the Delaware Water Gap National Recreation Area: Extends until September 30, 2026, the use of a federally owned road within the boundaries of the Delaware Water Gap National Recreation Area by certain commercial vehicles that serve local businesses.

Sec. 616. Wilson's Creek National Battlefield Boundary Modification: Expands the boundary of the Wilson's Creek National Battlefield in Missouri.

Sec. 617. Ste. Genevieve National Historical Park Boundary Revision: Makes a minor boundary revision to the Ste. Genevieve National Historical Park in Missouri.

Sec. 618. Conveyance of Certain Federal Land in Maine for Affordable Workforce Housing: This Sec. conveys certain federal land in Bar Harbor, Maine, for affordable workforce housing.

Sec. 619. Designation of Pullman National Historical Park: This Sec. re-designates Pullman National Monument in Illinois as Pullman National Historical Park.

Sec. 620. Palo Alto Battlefield National Historic Park Boundary Addition: Adjusts the boundary of the Palo Alto Battlefield Historical Park in Texas.

Sec. 621. Installation of Plaque Commemorating Slave Rebellion on St. John: Directs the Department of the Interior to install on the Ram Head trail at the peak of the Ram Head in the Virgin Islands National Park on St. John, U.S. Virgin Islands, a suitable plaque to commemorate the slave rebellion that began on St. John on November 23, 1733.

Subtitle C – National Park Service Studies

Sec. 631. Special Resource Study of John P. Parker House: Directs the Department of the Interior to conduct a special resource study of the John P. Parker House in Ripley, Ohio, to evaluate the national significance of the area and determine the suitability and feasibility of designating it as a unit of the National Park System.

Sec. 632. Dearfield, Colorado, Special Resource Study: Directs the Department of the Interior to conduct a special resource study of the Dearfield site in Weld County, Colorado, which was a historically black agricultural settlement founded by Oliver Toussaint Jackson, to evaluate the national significance of the area and determine the suitability and feasibility of designating it as a unit of the National Park System.

Sec. 633. Special Resource Study of Lynching Locations: Directs the Department of the Interior to conduct a special resource study of sites within approximately 100 miles of Memphis, Tennessee, at which lynchings took place, to evaluate the national significance of the area and determine the suitability and feasibility of designating it as a unit of the National Park System.

Sec. 634. Resource Study of the Los Angeles Coastal Area, California: Directs the Department of the Interior to conduct a special resource study of the coastline of Los Angeles, California, to evaluate the national significance of the area and determine the suitability and feasibility of designating it as a unit of the National Park System.

Subtitle D – National Park Service Programs

Sec. 641. Acquisition of Land for Administrative Purposes of Historic Preservation Training Center: Authorizes the National Park Service to acquire land in Frederick County, Maryland, for the Historic Preservation Training Center.

Sec. 642. Waiver of Special Use Permit Application Fee for Veterans' Special Events: Waives the application fee for any application for any special use permit of which the sole purpose is to hold veterans' special event at a war memorial on land administered by National Park Service in the District of Columbia.

Sec. 643. United States African-American Burial Grounds Preservation Program: Directs the Department of the Interior to establish the United States African-American Burial Grounds Preservation Program within the National Park Service.

Sec. 644. Norman Y. Mineta Japanese American Confinement Education Grants: Reauthorizes and increases appropriations for the Japanese American Confinement Sites (JACS) grant program. The JACS grant program supports the preservation of U.S. confinement sites that were used to detain Japanese Americans during World War II. This Sec. also establishes a program within JACS to provide grants to Japanese American nonprofits to educate individuals about the historical significance of these events.

Sec. 645. Japanese American World War II History Network: Directs the Department of the Interior to establish the Japanese American World War II History Network within the National Park Service.

Sec. 646. Authorization of Appropriations for the National Park Foundation: Reauthorizes the National Park Foundation through FY 2030 and raises the annual authorization of appropriations from $5,000,000 to $15,000,000.

TITLE VII – Commemorative Works and National Memorials

Sec. 701. Designation of the Kol Israel Foundation Holocaust Memorial as a National Memorial: Designates the Kol Israel Foundation Holocaust Memorial in Bedford Heights, Ohio, as a national memorial.

Sec. 702. Authorization to Establish Commemorative Work to Commemorate the Commitment and Service Represented by Women Who Worked on the Home Front During World War II: Authorizes the Women Who Worked on the Home Front Foundation to establish a commemorative work on federal land in the District of Columbia in commemoration of women who worked on the home front during World War II.

Sec. 703. Extension of Authority for Establishment of National Liberty Memorial Commemorative Work: Extends through FY 2027 the authority of the National Mall Liberty Fund D.C. to establish a memorial in the District of Columbia to honor slaves and free black persons who served during the American revolution.

Sec. 704. Authorization to Establish Commemorative Work to Commemorate the Heroic Deeds and Sacrifices of Animals and Handlers of Service Animals: Authorizes the National Service Animals Monument Corporation to establish a commemorative work on federal land in the District of Columbia to commemorate the deeds and sacrifices of service animals and their handlers in the United States.

Sec. 705. Authorization to Establish Commemorative Work to Honor Jean Monnet: Authorizes the Government of France to establish a commemorative work on federal land in the District of Columbia to honor the contributions of Jean Monnet, who was instrumental in founding the European Union.

Sec. 706. Designation of El Paso Community Healing Garden National Memorial: Designates the Healing Garden located in El Paso, Texas, as the El Paso Community Healing Garden National Memorial.

Sec. 707. Authorization to Establish Commemorative Work to Commemorate the Enslaved Individuals Who Endured the Middle Passage: Authorizes the Georgetown African American Historic Landmark Project and Tour to establish a commemorative work on federal land in the District of Columbia to commemorate the enslaved individuals, the identities of whom may be known or unknown, who endured the Middle Passage.

Sec. 708. Approval of Commemorative Work to Honor Journalists Who Sacrificed Their Lives in Service to a Free Press: Approves of the location in Area I (as defined by the Commemorative Works Act) of a memorial to commemorate the commitment of the United States to a free press by honoring journalists who sacrificed their lives in service to that cause.

Sec. 709. Authorization of Thomas Paine Commemorative Work: Authorizes the Thomas Paine Memorial Association to establish a commemorative work on federal land in the District of Columbia in honor of the philosopher Thomas Paine.

Sec. 710. Designation of Ukrainian Independence Park: Designates unnamed parcels owned by the National Park Service in the District of Columbia as Ukrainian Independence Park.

TITLE VIII – Miscellaneous

Sec. 801. Long-Term Abandoned Mine Land Reclamation: Allows states receiving Abandoned Mine Land (AML) funding through the Infrastructure Investment and Jobs Act (IIJA) to set aside up to 30% of these funds in an interest-bearing account to address the long-term costs associated with acid mine drainage (AMD), subsidence, and mine fire abatement. States are already able to set aside up to 30% of their regular AML funds in an AMD account, but this authorization was not originally included for AML funds appropriated by IIJA.

Sec.802. Amendment to the Constitution of the State of New Mexico: S.3404 provides the consent of Congress to an amendment to the Constitution of the State of New Mexico.

The proposed amendment would allocate an additional 1.25% in annual distributions from the Land Grant Permanent Fund to New Mexico's early childhood education and public education programs. This increase is estimated to bring in an additional $236 million each year for these education programs. The Land Grant Permanent Fund is funded by royalties generated by developing natural resources on 13 million acres granted to the state.

The New Mexico-Arizona Enabling Act of 1910 enabled New Mexico and Arizona to become states under restrictive conditions on how the two states could use their school lands and the funds derived from them. These conditions are enshrined in each state's constitution, and changes must be approved by state voters and by Congress in order to take effect. On November 8, 2022, New Mexico voters overwhelmingly voted yes on the state constitutional amendment with 70% of the vote.

Division EE—Post Office Designations

Names 25 post offices.

Division FF—Health And Human Services

TITLE I – Restoring Hope for Mental Health and Well-being

Subtitle A – Mental Health and Crisis Care Needs

Chapter 1 – Crisis Care Services and 9-8-8 Implementation

Sec. 1101. 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.

Sec. 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 Sec. and submit its findings to Congress within three years.

Sec. 1103. reauthorizes and expands the National Suicide Prevention Lifeline Program. It requires SAMHSA to develop a plan to ensure the provision of high-quality service and 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 Sec. 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

Sec. 1111. reauthorizes Sec. 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.

Sec. 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.

Sec. 1113. establishes a task force to make recommendations to coordinate and improve federal activities related to maternal mental health conditions.

Sec. 1114. extends the residential treatment pilot program for pregnant and postpartum women.

Chapter 3 – Reaching Improved Mental Health Outcomes for Patients

Sec. 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).

Sec. 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 Sec. also reauthorizes and improves Adult Suicide Prevention program.

Sec. 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.

Sec. 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

Sec. 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

Sec. 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

Sec. 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. 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

Sec. 1211. reauthorizes the Formula Grants for the Benefit of Homeless Individuals program.

Sec. 1212. reauthorizes the Substance Use Disorder Treatment Programs of Regional and National Significance (PRNS) program.

Sec. 1213. reauthorizes Prescription Opioid and Heroin Treatment and Interventions Demonstration Grants.

Sec. 1214. reauthorizes Substance Use Disorder Prevention PRNS.

Sec. 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.

Sec. 1216. reauthorizes the Grants for Jail Diversion Program.

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

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

Sec. 1219. reauthorizes the Grants for Reducing Overdose Deaths program, including supporting the development of strategic opioid crisis response plans.

Sec. 1220. reauthorizes the Opioid Overdose Reversal Medication Access, Education, and Co-prescribing Grants.

Sec. 1221. reauthorizes Emergency Department Alternatives to Opioids Demonstration Grants.

Chapter 3 – Excellence in Recovery Housing

Sec. 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.

Sec. 1232. requires the Secretary to develop and periodically update consensus-based best practices for operating, and promoting the availability of, high-quality recovery housing.

Sec. 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.

Sec. 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.

Sec. 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.

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

Sec. 1237. makes technical conforming corrections to the Public Health Services Act.

Chapter 4 – Substance Use Prevention, Treatment, and Recovery Services Block Grant
Sec. 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."

Sec. 1242. adds "provide recovery support services" as an authorized activity.

Sec. 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.

Sec. 1244. updates the statutory language with regard to Tribes and Tribal organizations.

Sec. 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.

Sec. 1246. requires states' reports to include the amount of funds provided to each grant recipient from the previous fiscal year.

Sec. 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

Sec. 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.

Sec. 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

Sec. 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.

Sec. 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

Sec. 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.

Sec. 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

Sec. 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.

Sec. 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.

Sec. 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

Sec. 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

Sec. 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 Sec. 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.

Sec. 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

Sec. 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

Sec. 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

Sec. 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.

Sec. 1402. reauthorizes SAMHSA's Infant and Early Childhood Mental Health Grant program and allows the Secretary of HHS to provide technical assistance for grantees.

Sec. 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.

Sec. 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

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

Sec. 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

Sec. 1421. reauthorizes the Suicide Prevention Resource Center.

Sec. 1422. reauthorizes the State and Tribal Youth Suicide Prevention and Early Intervention Grants Program.

Sec. 1423. reauthorizes the Mental Health Youth Suicide Prevention Campus Grants.

Sec. 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

Sec. 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.

Sec. 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

Sec. 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

Sec. 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.

Sec. 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.

Sec. 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 Sec. 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 Sec. requires HHS to submit an annual report to Congress on the state of public health preparedness.

Sec. 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 Sec. 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

Sec. 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.

Sec. 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 Sec. also requires GAO to report on SAMHSA's work during the COVID-19 pandemic.

Sec. 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.

Sec. 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.

Sec. 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

Sec. 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

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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

Sec. 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.

Sec. 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

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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

Sec. 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.

Sec. 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.

Sec. 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 Sec. 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.

Sec. 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

Sec. 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.

Sec. 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.

Sec. 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 Sec. 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.

Sec. 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 Sec., any relevant findings, and any steps HHS is taking to disseminate such findings to support the reduction of risks associated with such research.

Sec. 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 Sec. is complete.

Chapter 3 – Preventing Undue Foreign Influence in Biomedical Research

Sec. 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.

Sec. 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 Sec..

Sec. 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.

Sec. 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 Sec. 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 Sec..

Sec. 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.

Sec. 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

Sec. 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 Sec. 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

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 2404. 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.

Sec. 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.

Sec. 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.

Sec. 2407. requires the Secretary to report regularly to Congress on SNS content deployment and replenishment plans during a public health emergency.

Sec. 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.

Sec. 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

Sec. 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.

Sec. 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

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 2504. provides FDA with authority to share more safety and effectiveness information with the public about products authorized for emergency use.

Sec. 2505. Improving FDA guidance and communication.
Sec. 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

Sec. 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.

Sec. 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.

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

Sec. 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.

Sec. 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

Sec. 3101. reauthorizes the Critical Path Public-Private Partnership.

Sec. 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.

Sec. 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.

Sec. 3104. reauthorizes the Pediatric Device Consortia Program, which supports the continued development of medical devices intended specifically for children.

Sec. 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.

Sec. 3106. reauthorizes a third-party accreditation program for certain medical device inspections through October 1, 2027.

Sec. 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.

Sec. 3108. reauthorizes reporting requirements related to pending generic drug applications and priority review applications through October 1, 2027.

Sec. 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

Sec. 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.

Sec. 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 Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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 Sec. 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 Sec. 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.

Sec. 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.

Sec. 3212. allows a biological product to qualify as a Qualified Infectious Disease Product (QIDP) under Sec. 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 Sec. does not extend QIDP exclusivity to biological products.

Sec. 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

Sec. 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.

Sec. 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.

Sec. 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 Sec. 505-1(h) of the FFDCA. This Sec. makes clear that it shall not delay any agency action on any modification to a REMS.

Sec. 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" Sec. 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

Sec. 3301. provides that sponsors of diagnostic tests that have been deemed to be Clinical Laboratory Improvement Amendments (CLIA)-waived under Sec. 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 Sec. 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 Sec. 353(d)(3) of the Public Health Service Act in a single submission.

Sec. 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.

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

Sec. 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.

Sec. 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 Sec. 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.

Sec. 3306. amends Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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 Sec. 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 Sec. 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 Sec. 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 Sec. 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 Sec. 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 Sec. 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

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

Sec. 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 Sec. 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 Sec. 752 of the Federal Food, Drug, and Cosmetic Act (preemption for labeling or packaging of cosmetics), including any exemptions from labeling preemption.

Sec. 3503. states that new enforcement provisions become effective one year after enactment of the Modernization of Cosmetics Regulation Act of 2022. The Sec. 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.

Sec. 3504. makes conforming edits to Sec. 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.

Sec. 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.

Sec. 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 Sec. 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.

Sec. 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.

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

Subtitle F – Cross-Cutting Provisions

Chapter 1 – Clinical Trial Diversity and Modernization

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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 Sec. 505(z) or 520(g)(9) of the Food, Drug, and Cosmetic Act. The Sec. notes that nothing in this Sec. shall be construed to authorize FDA to disclose any information that is a trade secret or confidential.

Sec. 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.

Sec. 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.

Sec. 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

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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 Sec. harmonizes the timing of the FDA annual reporting requirement on inspections under Sec. 902 of the Food and Drug Administration Reauthorization Act to align with reporting requirements related to the PDUFA user fee program.

Sec. 3617. amends the information FDA must annually report regarding inspections on its website pursuant to Sec. 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

Sec. 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.

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

Sec. 3623. requires FDA to develop a strategic workforce plan at least every four years.

Sec. 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.

Sec. 3625. preserves Sec. 905 of FDARA by clarifying that FDA use of budget authority for costs excluded under Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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.

TITLE IV — MEDICARE PROVISIONS

Subtitle A — Medicare Extenders

Sec. 4101. extends the Medicare low-volume hospital payment adjustment for two years through September 30, 2024.

Sec. 4102. extends the Medicare-Dependent Hospital (MDH) program for two years through September 30, 2024.

Sec. 4103. extends a number of add-on payments for ground ambulance services under the Medicare fee schedule through December 31, 2024.

Subtitle B — Other Expiring Medicare Provisions

Sec. 4111. extends incentive payments for participation in advanced alternative payment models (APMs) through 2025. Under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), eligible clinicians who participate in advanced APMs and meet certain payment or patient count thresholds qualify for a 5 percent Medicare Part B incentive payment in payment years 2019 through 2024. This Sec. extends incentive payments through 2025, with a 3.5 percent Medicare Part B incentive payment for services covered in 2025. This Sec. also extends the current freeze on participation thresholds for qualification for the APM bonuses for an additional year.

Sec. 4112. provides additional support for physicians and other health care professionals in adjusting to Medicare payment changes. For services furnished in 2023, this Sec. increases otherwise applicable Medicare Physician Fee Schedule payments by 2.5 percent. For services furnished in 2024, the Sec. provides a 1.25 percent payment increase.

Sec. 4113. extends all of the Medicare telehealth flexibilities that were extended in the Consolidated Appropriations Act, 2022, through December 31, 2024.

Sec. 4114. delays by one year pending payment reductions and data reporting periods for the Clinical Laboratory Fee Schedule under the Protecting Access to Medicare Act.

Subtitle C — Medicare Mental Health Care Provisions

Sec. 4121. establishes Medicare coverage for services provided by marriage and family therapists and licensed professional counselors beginning on January 1, 2024.

Sec. 4122. supports physician workforce development by providing for the distribution of 200 additional Medicare-funded graduate medical education (GME) residency positions. Specifically, this provision dedicates one-half of the total number of positions to psychiatry or psychiatry subspecialty residencies.

Sec. 4123. establishes a 50 percent payment increase in Medicare Physician Fee Schedule payments rates for crisis psychotherapy services when furnished by a mobile unit, as well as additional settings other than a facility or physician office, beginning on January 1, 2024. The Sec. also requires the Centers for Medicare and Medicaid Services (CMS) to conduct outreach and education to providers on Medicare coverage and payment for crisis psychotherapy services, the ability of peer support specialists and other auxiliary personnel to participate in the furnishing of crisis psychotherapy services, and the ability of peer support specialists and other auxiliary personnel to participate in the furnishing of behavioral health integration services.

Sec. 4124. revises Medicare's partial hospitalization benefit beginning on January 1, 2024 to provide coverage of intensive outpatient services.

Sec. 4125. directs HHS to begin collecting (no later than October 1, 2023) data and other information necessary to revise the existing Medicare prospective payment system (PPS) for inpatient psychiatric hospitals and psychiatric units (IPFs). The HHS Secretary is required to update the methodology for determining payment rates under the IPF PPS beginning in rate year 2025.

Sec. 4126. adds a new exception to the Stark Law to allow for hospitals and other entities to provide evidence-based programs for physicians to improve their mental health, increase resiliency, and prevent suicide among physicians.

Sec. 4127. requires the HHS Inspector General to conduct a review and issue a report to Congress on whether to establish a safe harbor for evidence-based contingency management incentives, which can be used to treat substance use disorders.

Sec. 4128. requires HHS to conduct outreach to physicians and other health care providers on the availability of behavioral health integration services as a covered benefit under the Medicare program. This education will inform practitioners on the requirements to determine eligibility and bill for behavioral health integration codes. This Sec. also requires reports to Congress on the methods used for provider outreach and on the number of Medicare beneficiaries who were furnished behavioral health integration services.

Sec. 4129. requires HHS to conduct outreach to physicians and other health care providers on the inclusion of opioid use disorder treatment services furnished by an opioid treatment program as a covered benefit under the Medicare program. This education will inform practitioners of the requirements to determine eligibility and bill for opioid treatment services. This Sec. also requires HHS to conduct outreach to Medicare beneficiaries on the availability of opioid use disorder treatment services furnished by an opioid treatment program. This Sec. requires reports to Congress on the methods used for provider outreach and on the number of Medicare beneficiaries who were furnished opioid use disorder treatment services.

Sec. 4130. directs the Comptroller of the United States to conduct a study to compare the mental health and substance use disorder benefits offered by Medicare Advantage plans to traditional Medicare and to other benefits offered by Medicare Advantage plans.

Subtitle D — Other Medicare Provisions

Sec. 4131. permits coverage of oral antiviral drugs with an emergency use authorization (EUA) from the Food and Drug Administration (FDA) under Medicare Part D through December 31, 2024.

Sec. 4132. authorizes the Congressional Budget Office (CBO) to access prescription drug payment data, including rebate and direct and indirect remuneration (DIR) data, under Medicare Part D.

Sec. 4133. provides Medicare Part B coverage for compression garments for the treatment of lymphedema, beginning on January 1, 2024.

Sec. 4134. provides permanent Medicare coverage for items and services related to the administration of intravenous immune globulin (IVIG), beginning on January 1, 2024.

Sec. 4135. provides a separate Medicare payment, from 2025 through 2027, for non-opioid treatments that are currently packaged into the payment for surgeries under Medicare's Outpatient Prospective Payment System (OPPS). The Sec. also caps the separate payment at 18 percent of the estimated average OPPS payment amount for the surgeries and other services for which the non-opioid is used in conjunction with.

Sec. 4136. adjusts payment for disposable negative pressure wound therapy devices by using the supply price to determine the relative value for the service.

Sec. 4137. extends, for one year through December 31, 2023, the 1 percent add-on payment provided to certain home health agencies that furnish services in counties with a low population density.

Sec. 4138. revises Medicare coverage rules under the Religious Nonmedical Health Care Institution (RNHCI) benefit to ensure that beneficiaries who receive Medicare-covered vaccinations for COVID-19 do not have their RNHCI benefits temporarily revoked.

Sec. 4139. extends, through December 31, 2023, the temporary blended payment rates provided under the CARES Act for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) in certain non-competitive bid areas.

Sec. 4140. extends the Acute Hospital Care at Home initiative, as currently authorized under CMS waivers and flexibilities, through December 31, 2024.

Sec. 4141. extends the pass-through payment for certain medical devices for which pass-through status would have otherwise expired on January 1, 2022, for one additional year through December 31, 2023.

Sec. 4142. requires HHS to provide publicly available information on the simulation of 60-day episodes under the Medicare home health prospective payment system in effect prior to the Patient Driven Groupings Model. This Sec. also requires HHS to use a public forum to engage with home health stakeholders on the Medicare home health payment rate development within 90 days of enactment.

Sec. 4143. eliminates the annual cap on total payments and excludes any resulting increase from factoring into calculations for nursing and allied health education payments for such hospitals for 2010 through 2019.

Subtitle E — Health Care Tax Provisions

Sec. 4151. extends through Calendar Year 2024 the flexibility to exempt telehealth services from the deductible in high-deductible health plans (HDHPs) that can be paired with a Health Savings Account (HSA).

Subtitle F — Offsets

Sec. 4161. reduces the amount in the Medicare Improvement Fund from $7,278,000,000 to $180,000,000.

Sec. 4162. extends, by one year, the change to the annual updates to the hospice aggregate cap made in the Improving Medicare Post-Acute Care Transformation Act (IMPACT Act) of 2014 and applies the hospice payment update percentage rather than the Consumer Price Index for Urban Consumers (CPI–U) to the hospice aggregate cap through 2032.

Sec. 4163. extends the mandatory Medicare payment reductions under sequestration for the first 6 months of fiscal year 2032, while revising Medicare sequestration percentages to 2 percent for fiscal year 2030 and fiscal year 2031.

TITLE V — MEDICAID AND CHIP PROVISIONS

Subtitle A — Territories

Sec. 5101. extends Puerto Rico's higher federal Medicaid match of 76 percent through fiscal year 2027 and permanently extends a higher federal Medicaid match of 83 percent for American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and the U.S. Virgin Islands. In addition, this Sec. establishes a new framework for Puerto Rico's Medicaid enhanced allotments for the next five fiscal years. The Sec. also makes programmatic improvements to the territories' Medicaid programs, including requiring increased provider payment rates and improving contracting practices for Puerto Rico and providing funding for data system improvements for American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and the U.S. Virgin Islands.

Subtitle B — Medicaid and CHIP Coverage

Sec. 5111. extends funding for the Children's Health Insurance Program (CHIP) for two years through fiscal year 2029.

Sec. 5112. requires children to be provided with 12 months of continuous coverage in Medicaid and CHIP effective January 1, 2024.

Sec. 5113. makes permanent a state option to allow states to continue to provide 12 months of continuous coverage during the postpartum period in Medicaid or CHIP.

Sec. 5114. extends funding for the Medicaid Money Follows the Person Rebalancing Demonstration program at $450 million per year through fiscal year 2027.

Sec. 5115. extends protections against spousal impoverishment for Medicaid recipients of home and community-based services through fiscal year 2027.

Subtitle C — Medicaid and CHIP Mental Health Care

Sec. 5121. requires states to provide justice-involved youth who are eligible for Medicaid or CHIP with screening, diagnostic, and case management services in the 30-day period prior to their release from incarceration in a post-adjudication setting. In addition, this Sec. requires, for at least 30 days following release, such youth to be provided with targeted case management services, including referrals to appropriate care and services. This provision takes effect January 1, 2025.

Sec. 5122. allows states to receive federal matching funds through Medicaid and CHIP for health care services provided to justice-involved youth who are incarcerated in public institutions pending disposition of their charges. This provision takes effect January 1, 2025.

Sec. 5123. codifies requirements that apply to Medicaid managed care organizations, prepaid inpatient health plans, and primary care case management entities regarding the publication of searchable and regularly updated directories of health care providers in their networks, including providers of mental health and substance use disorder services. These requirements would also apply to state Medicaid fee-for-service programs. This provision takes effect July 1, 2025.

Sec. 5124. directs the Secretary of Health and Human Services to issue guidance providing recommendations and best practices to states regarding the development of an effective continuum of crisis care through Medicaid and CHIP. In addition, this Sec. requires the Secretary to establish a technical assistance center to provide support for states in designing and implementing crisis response services.

Subtitle D — Transitioning From Medicaid FMAP Increase Requirements

Sec. 5131. provides funding and requirements for state Medicaid programs to support the transition from the enhanced Medicaid funding and continuous coverage requirements of the Families First Coronavirus Response Act (FFCRA). This Sec. would sunset FFCRA's continuous coverage requirement as of April 1, 2023 and allow for states to begin the process of initiating redeterminations of eligibility over a period of at least twelve months. States would be able to receive enhanced Medicaid funding from April 1 through December 31, 2023, subject to meeting certain conditions such as updating beneficiaries' contact information and using more than one modality to contact beneficiaries in the event of returned mail. The Sec. also establishes public reporting requirements for all states during this temporary redetermination period and provides additional enforcement mechanisms for the Centers for Medicare & Medicaid Services during this period.

Subtitle E — Medicaid Improvement Fund

Sec. 5141. provides $7,000,000,000 in the Medicaid Improvement Fund.

TITLE VI — HUMAN SERVICES PROVISIONS

Sec. 6101. reauthorizes the Jackie Walorski Maternal, Infant and Early Childhood Home Visiting (MIECHV) Program through September 30, 2027. It requires the Secretary of Health and Human Services to create an annually updated, publicly available website containing information on individual and family outcomes for states, territories and tribes. It authorizes five years of funding for the MIECHV Program, and describes how funding for both Federal base grants and Federal matching grants is allocated. It also reserves funds for purposes other than the state/territory grants, including a 6 percent set aside to provide and administer grants to Indian tribes.

The funding allocations for FY23-FY27 are as follows:

- FY 2023: $500,000,000 for base grants
- FY 2024: $500,000,000 for base grants, and $50,000,000 for matching grants
- FY 2025: $500,000,000 for base grants, and $100,000,000 for matching grants
- FY 2026: $500,000,000 for base grants, and $150,000,000 for matching grants
- FY 2027: $500,000,000 for base grants, and $300,000,000 for matching grants

This Sec. also provides an option to provide virtual home visits if a state/ territory provides certain information to the Secretary demonstrating they have met specific conditions, including the requirement of one in-person visit per year.

Sec. 6102. continues funding for the Temporary Assistance for Needy Families program (TANF) and associated programs through the end of fiscal year 2023 without policy changes.

Sec. 6103. continues mandatory and discretionary child welfare programs authorized under Title IV-B of the Social Security Act through the end of fiscal year 2023 without policy changes.

Division GG – Merger Filing Fee Modernization

Merger Filing Fee Modernization: Changes the thresholds for the filing fees to be paid by companies contemplating mergers to reduce them for small and medium-sized businesses. These fees are then divided between the FTC and DOJ for antitrust enforcement. It goes into effect on October 1, 2024.

Disclosure of Subsidies by Foreign Adversaries: Requires companies to disclose subsidies they receive from foreign adversaries like China if they attempt a merger.

Venue for State Antitrust Enforcement: States the same posture as the Federal Government in choosing the appropriate venue for antitrust enforcement actions.

Division HH – Agriculture

Greenhouse Gas Technical Assistance Provider and Third-Party Verifier Program: Directs USDA to establish a program to register entities that provide technical assistance to and verify the practices of farmers, ranchers, and foresters who participate in voluntary carbon markets with the goal of providing information and confidence to producers. This Sec. is an updated version of the Growing Climate Solutions Act, S. 1251, which passed the Senate by a vote of 92-8 on June 24, 2021.

Acceptance and Use of Private Funds for Public-Private Partnerships: Modifies existing authority for the Secretary of USDA to accept private donations to NRCS conservation programs by allowing the private donor the ability to direct how and where those funds would be used as well as give the Secretary of USDA the discretion on whether to match those funds with existing program funds. This Sec. is an updated version of HR. 2606, the SUSTAINS Act, which was reported by the House Committee on Agriculture by voice vote on May 17, 2022

CFTC Whistleblower Program: Extends the authority of the Whistleblower Office and the Office of Customer Education and Outreach at the Commodity Futures Trading Commission (CFTC) through October 1, 2024. This extension authorizes the CFTC to transfer an additional $10 million from the Consumer Protection account which will allow for the continued payment of salaries, customer education initiatives and non-awards expenses, ensuring that the CFTC's whistleblower program can continue to function even when awards obligated to whistleblowers exceed the program fund's balance at the time of distribution.

Modification or Termination of Easements Under the Healthy Forests Reserve Program: Allows for a modification of an easement held under the Healthy Forest Reserve Program (HFRP). The Agricultural Conservation Easement Program (ACEP) and the Emergency Watershed Program (EWP) currently allow for the modification of easements signed under each program and this Sec. would extend the authority for modifications to HFRP easements as well.

SNAP EBT Skimming Regulations and Reimbursement: States have reported SNAP benefits are being stolen through card skimming, cloning, and other similar fraudulent methods. This provision requires the Secretary to coordinate with relevant agencies and stakeholders to investigate the extent of the problem, develop methods to prevent fraud and improve security measures through guidance and regulatory action, and provide replacement of benefits stolen through these fraudulent methods through FY2024. This program is newly established in the FY2023 Consolidated Appropriations Act. No Congressional action aside from this provision has been conducted to address this emerging problem. This provision will enable the Agriculture Committees to better understand and, where appropriate, further investigate and respond to the problem in the upcoming 2023 Farm Bill.

Summer Meals Program EBT & Alternative Options: Updates the summer food service program to permanently allow states to provide non-congregate meals and summer EBT benefits nationwide to eligible children as other options in addition to meals provided at congregate feeding sites. Non-congregate meals, such as grab-and-go or home delivery, would be provided in rural areas to eligible children, and summer EBT benefits would be capped at $40 per child per month. This provision is fully offset.

Pandemic Assistance Payments to Cotton Merchandisers: Provides $100 million for USDA to make payments to merchandisers of cotton who purchased cotton from U.S. producers or marketed cotton on their behalf for economic losses experienced during the COVID-19 pandemic and as a result of other supply chain disruptions.

Assistance to Rice Producers: Provides $250 million for USDA to make a one-time payment to U.S. rice producers. Payments to producers will be calculated based on a payment rate determined by the Secretary, yield history, and the number of certified planted acres and certified acres prevented from planting for the 2022 crop year.

Chronic Wasting Disease (CWD) Research and Management Act: Enacts H.R. 5608, the Chronic Wasting Disease Research and Management Act (companion bill to S.4111). Authorizes $70 million in annual appropriations for Chronic Wasting Disease (CWD) research and management activities administered by USDA's Animal and Plant Health Inspection Service (APHIS). APHIS

is authorized to enter into cooperative agreements with state and Tribal wildlife agencies and agriculture departments to implement research and management activities in order to develop new testing methods, better understand the spread of CWD, develop methods to control and manage CWD in cervid populations, and other uses. Funding is required to be split between research and management activities. USDA is also directed to conduct a review of the Herd Certification program standards.

Pesticide Registration Improvement Act of 2022: Reauthorizes user-fee programs that fund EPA's pesticide registration and review processes. PRIA V includes an increase in registration and maintenance fees to support a more predictable regulatory process and provide important resources for farmworker safety and health care provider training, in addition to other services that advance the safe and effective use of pesticides. PRIA V requires EPA to comply with numerous registration process improvements in order to access additional funding levels and requires manufacturers to phase-in bilingual labels on pesticides products over the next 8 years. PRIA V is supported by a diverse coalition of environmental nonprofit organizations, pesticide manufacturers and users, federal and state regulators, and farmworker advocates. Congress most recently reauthorized PRIA (PRIA 4; P.L. 116-8) in 2018, which expires on September 30, 2023.

Registration Review Deadline Extension: Congress amended the Pesticide Registration Improvement Act of 2007 ("PRIA 2") and established a deadline (October 1, 2022) for EPA to complete Registration Review decisions for all pesticide products registered as of October 1, 2007. As of September 2022, EPA reported approximately 726 "cases," which include over 1,000 unique active ingredients (AI), currently pending Registration Review, which raises potential implications for continued access to those crop protection tools. This language provides EPA with two legal authorities it does not have now: (1) a four-year extension of the deadline to complete the review of certain pesticides registrations, and (2) flexibility for EPA to move forward with interim decisions ("IDs") on registration review between now and October 1, 2026. The language also requires that, where applicable, EPA include mitigations to reduce the effects of pesticides receiving an interim decision on endangered species or any critical habitats taking into account input from the Secretary of Agriculture and other members of the 2018 Farm Bill ESA Interagency Working Group.

Division JJ — North Atlantic Right Whales

Deems the Maine lobster fishery compliant with the Marine Mammal Protection Act and Endangered Species Act for a defined six year period while innovative gear technology is developed. Authorizes $50M annually for a competitive grant program to help fund this innovative gear technology.