THORN RUN PARTNERS
GOVERNMENT RELATIONS

Memorandum *December 20, 2022*

HEALTH-RELATED FY 2023 OMNIBUS TEXT PROVIDES FOR BEHAVIORAL HEALTH, PRESCRIPTION DRUG POLICIES, AMONG OTHERS

Early this morning, congressional appropriators unveiled legislative text for the $1.7 trillion omnibus spending bill for fiscal year (FY) 2023. The Consolidated Appropriations Act, 2023 includes a wide array of health care policy priorities, outlined within the Labor, Health and Human Services, Education, and Related Agencies (explanatory statement; bill summary) and Agriculture, Rural Development, Food and Drug Administration, and Related Agencies (explanatory statement; bill summary) sections of the 12-bill package. Particularly, health-related policies within the omnibus spending package pertain to **behavioral health**, **medical devices**, **accelerated approval**, **cosmetics**, the health care **workforce**, and **telehealth**, among others.

The last major piece of legislation to be passed by the 117th Congress, the legislation would address **Medicare provider payments** — Statutory Pay-As-You-Go (**PAYGO**) Act provisions would be waived and providers would face a two percent cut under the **physician fee schedule** (PFS) after Congress included a 2.5 percent payment bump for 2023 — and mandate oversight of the federal government's **pandemic response** efforts. The spending package additionally stands up several pilot programs, including for **rare disease** drug development, and seeks to bolster **clinical trial** diversity and operability. Under the **Medicaid** program, policies surrounding redeterminations, continuous eligibility for children, and postpartum coverage are also included in today's package. Additionally, the Maternal, Infant, and Early Childhood Home Visiting **(MIECHV) Program** would be reauthorized through 2027. Notably, today's deal **does not include** provisions from the Verifying Accurate Leading-edge IVCT Development (VALID) Act and the Pioneering Antimicrobial Subscriptions to End Surging Resistance (PASTEUR) Act as was discussed during initial negotiations.

- **What's Next?** Senators are scheduled to take the first procedural vote on the omnibus today with the goal of reaching a "time agreement" to expedite consideration. As of now, it is likely that a vote on final passage in the Senate will occur at some point on Thursday, with a final up-or-down vote in the House taking place ahead of Friday's government funding deadline.

Key health care provisions within the legislation include:

NOTABLE BEHAVIORAL HEALTH PROVISIONS

Crisis Care & 9-8-8 Hotline — The first sections of Division FF of this bill would establish a Behavioral Health Crisis Coordinating Office across relevant divisions of the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Medicare and Medicaid Services (CMS), and the Health Resources and Services Administration (HRSA) to better coordinate work relating to behavioral health crisis care and would authorize $5 million for each fiscal year (FY) from 2023 through FY 2027 to carry out this work. It also requires HHS — within one year of this bill's enactment — to publish "best practices" for a mental health crisis continuum of care response. The guidance would be geared towards health care providers, service administrators, and service providers. Additionally, the legislation would reauthorize the National Suicide Prevention Lifeline Program at $501.6 million to fully transition to the 9-8-8 Hotline. HHS would be required to complete a study on the goals and objectives of a plan to provide quality supports and services under the program, to be transmitted to Congress upon completion.

Maternal Health & SUD — The bill would reauthorize Screening and Treatment for Maternal Mental Health and Substance Use Disorders grants that allow states to improve screening, assessment, and treatment for mental health and SUD in pregnant and post-partum women. To carry out this initiative, the bill would provide $24 million per year from FY 2023 through FY 2028. Additionally, the legislation would authorize $10 million from FY 2023 through FY 2028 to establish an information and intervention hotline for pregnant and postpartum women at risk of, or currently experiencing, maternal mental health or SUD.

REACHING Improved Mental Health Outcomes for Patients Act of 2022 — This bill introduced early this morning includes the previously proposed Reauthorizing Evidence-based and Crisis Help Initiatives Needed to Generate (REACHING) Improved Mental Health Outcomes for Patients Act of 2022 (H.R. 7237), which would replace Community Crisis Response Systems Grants with a Mental Health Crisis Response Partnership Pilot Program and authorize $10 million each year from FY 2023 through FY 2027. It would also authorize seven SAMHSA grants related to maternal health from FY 2023 through FY 2027:

- National Mental Health and Substance Abuse Policy Laboratory, authorized at $10 million each FY;
- Interdepartmental Serious Mental Illness Coordinating Committee;
- Mental Health Needs Priority Regions of National Significance (PRNS), authorized at $599.036 million each FY;
- Mental Health Awareness Training (MHAT) Grants, authorized at $24.963 million each FY;
- Adult Suicide Prevention, authorized at $30 million each FY;
- Assertive Community Treatment Grants, authorized at $15 million each FY; and
- Assisted Outpatient Treatment Grant Program for Individuals with Serious Mental Illness, authorized at $22 million each FY.

Anna Westin Legacy Act of 2022 — The Anna Westin Legacy Act of 2021 (H.R. 7249), included in this larger legislative package, would authorize a National Center of Excellence for Eating Disorders

within SAMHSA. The bill would authorize $1 million each year from FY 2023 through FY 2027 to the Center for the purposes of awarding subgrants for developing and providing training and assistance to health care providers surrounding the identification and treatment of individuals with eating disorders.

Community Mental Health Services Block Grant Reauthorization Act — The Community Mental Health Services Block Grant Reauthorization Act (H.R. 7241) is also included in the appropriations bill released earlier today. The bill would reauthorize Community Mental Health Services Block Grants at approximately $857.6 million each year from FY 2023 through FY 2027 to support community efforts focused on adults with "serious mental illness" and children with "serious emotional disturbances." The legislation would also facilitate performance and outcome data collection, and the bill stipulates that five percent of funds must be used for crisis care services and another five percent can be used for early intervention efforts.

Peer Supported Mental Health Services — This chapter of this appropriations bill would authorize grants for consumer-run nonprofit organization, tribes and tribal organizations, Urban Indian organizations, or tribal consortia to provide peer-supported mental health services, which would include virtual peer support.

Native Behavioral Health Access Improvement Act of 2021 — This section includes the Native Behavioral Health Access Improvement Act of 2021 (H.R. 4251), which would reauthorize the Alcohol and Drug Prevention or Treatment Services for Indians and Native Alaskans Grant Program at $40 million each year from FY 2023 through FY 2027. The Program aims to provide culturally appropriate and competent care for mental health and SUD concerns facing Native American and Alaskan Native populations.

Summer Barrow Prevention, Treatment, and Recovery Act — The bill includes provisions from the Summer Borrow Prevention, Treatment, and Recovery Act (H.R. 7234), which would amend the Public Health Service Act to reauthorize 11 SAMHSA programs with respect to mental health conditions and SUD. For each fiscal year from FY 2023 through FY 2027, it would authorize a total of $932.7 million for these programs and an additional $500,000 for a review and report from the National Academy of Sciences to study behavioral health issues. Specifically, these programs include:

- Formula Grants for the Benefit of Homeless Individuals, authorized at $41.304 million each FY;
- Substance Use Disorder Treatment Programs of Regional and National Significance (PRNS), authorized at $521.517 million each FY;
- Prescription Opioid and Heroin Treatment and Interventions Demonstration Grants, authorized at $25 million each FY;
- Substance Use Disorder Prevention PRNS, authorized at $218.219 million each FY;
- Programs to Reduce Underage Drinking, including an annual report, a national media campaign, Community-based Coalition Enhancement Grants to Prevent Underage Drinking, Pediatric Provider Screening and Brief Intervention Grants, and data collection and research, authorized for a collective $23 million FY;

- National Academy of Sciences review and report to Congress authorized at $500,000 for FY 2023;
- Jail Diversion Program and Grants, authorized at $14 million FY;
- Projects for Assistance in Transition from Homelessness Program, authorized at $64.635 million FY;
- Grants for Reducing Overdose Deaths authorized at $5 million FY;
- State Pharmacy Opioid Overdose Medication Access and Education Grants, authorized at $5 million FY;
- State and Local Integrated Comprehensive Opioid Use Disorder Response, authorized at $5 million FY; and
- Emergency Department Alternatives to Opioids Demonstration Grants, authorized at $10 million FY.

Excellence in Recovery Housing Act — This package also includes the Excellence in Recovery Housing Act (H.R. 2376), which would require SAMHSA to promote the availability of high-quality recovery housing for individuals with SUD through various activities. Specifically, this bill would require SAMHSA to (1) develop and publish on its website best practices and guidelines for recovery housing; (2) award grants to states, tribal nations, territories, and localities to implement such standards and guidelines; (3) convene an interagency working group to coordinate federal activities related to recovery housing; and (4) arrange for research on the supply, quality, and effectiveness of recovery housing. Additionally, the bill would reauthorize $5 million for the period of FY 2023 through 2027 for the program and Sec. 1237 would make small technical conforming corrections to the Public Health Services (PHS) Act.

Substance Use Prevention, Treatment, and Recovery Services Block Grant — This proposal includes a provisions of a bill entitled, the Substance Use Prevention, Treatment, and Recovery Services Block Grant Act of 2022 (H.R. 7235), which would make certain improvements with respect to block grants for substance use prevention, treatment, and recovery services, and for other purposes, authorized at $1.908 billion annually for FY 2023 through FY 2027. It would eliminate stigmatizing language relating to substance use, include state plan requirements to describe the recovery support service activities supported by the grants, and would update certain language relating to Tribes.

Timely Treatment for Opioid Use Disorder — Additionally, this package, as proposed, includes the Timely Treatment for Opioid Use Disorder Act of 2022 (H.R. 7238), which would direct HHS to revise opioid treatment program (OTP) admission criteria to eliminate the requirement that patients must be addicted for at least one year prior to being admitted for treatment. This proposal would also require the Assistant Secretary for Mental Health and Substance to conduct a study and report within 180 days on the impact of treatment flexibilities allowed during the COVID-19 pandemic on the effectiveness and safety of the OTP. It would also instruct HHS to establish new criteria to allow certain patients to receive take home medications in either a 14 day or one-month supply.

Additional Addiction Treatment Provisions

- *Prohibition of Funds* — This section would prohibit the use of funds authorized by the title that this section is under from being used to purchase, procure, or distribute pipes or cylindrical objects intended to be used to smoke or inhale illegal scheduled substances.

- *Elimination of the X Waiver* — This section would eliminate 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.

- *Training for Controlled Substance Providers* — This section 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.

- *Time to Administer Controlled Substances* — This section would amend the Controlled Substances Act to increase the time limit for health care providers to hold long-acting injectable (LAI) buprenorphine before administration to a patient, if receiving through a pharmacy, from 14 to 45 days.

Opioid Crisis Response — This bill includes provisions related to efforts to improve the opioid crisis response. It would update sections of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act to require the development and dissemination of training materials for pharmacists who decline to fill a prescription, under certain circumstances. It would also allow the CDC to prioritize jurisdictions with a high burden of drug overdoses when awarding grants to prevent overdoses of controlled substances. Additionally, this bill would require HHS to conduct public education campaigns on synthetic opioids — fentanyl and its analogues — and other drug misuse issues, while disseminating other information about opioids to health care providers and providing training for first responders and individuals with high risk of exposure. This bill also authorizes a new grant program entitled the State Opioid Response (SOR) Grants and Tribal Opioid Response (TOR) Grants — for the purposes of addressing opioid misuse and use disorders with states and tribal organizations — at $1.75 billion for each of FYs 2023 through 2027.

Improving Uptake and Patient Access to Integrated Care Services — The bill would also reauthorize a SAMHSA program to increase uptake and integrated care services, so that states receiving funds through the program that partner with primary care services may use funds to implement evidence-based or evidence-informed integrated models of care, including the psychiatric collaborative care model (CoCM). To carry out this provision, this bill appropriates $60 million for each of FYs 2023 through 2027, with 10 percent of such funds going toward supporting primary care practices implementing CoCM.

Health Care Workforce — Under the bill, several provisions of the Helping Enable Access to Lifesaving Services Act (H.R. 5583) would be included to bolster the health care workforce.

Additionally, the Minority Fellowship Program — which seeks to boost the knowledge of mental and SUD practitioners on issues of prevention, treatment, and recovery, as well as for other purposes — would be reauthorized at $25 million for each of FYs 2023 through 2027. The legislation would also modify the Mental and Behavioral Health Education and Training Grants to include grants for those in masters and doctoral level occupational therapy programs and to include training to meet the needs of children who have gone through trauma, while reauthorizing the program at $50 million for each of FYs 2023 through 2027. The bill would additionally modify the Training Demonstration Program — which seeks to provide further training for health professionals in underserved, community-based settings that integrate primary care with mental and SUD prevention and treatment services — to include pediatric and additional counseling and psychiatric services. It would reauthorize this program at $31.7 million annually for FYs 2023 through 2027.

Eliminating the Opt-Out for Non-Federal Governmental Health Plans — The legislation stipulates that self-funded, non-federal governmental plans would be mandated to adhere to mental health parity requirements beginning 180 days after the bill's enactment. Under the bill, certain exceptions would be provided to allow for an extended compliance period contingent upon the terms of the plan agreement — specifically with regard to certain collectively bargained plans.

Children's Mental Health Care Access — The proposal, which is derived from the Supporting Children's Mental Health Care Access Act of 2022 (H.R. 7076), would reauthorize two programs aimed at improving mental health care access for children, including:

- HRSA's Pediatric Mental Health Care Access Grant Program, which would be authorized at $14 million for each of FYs 2023 through 2025 and $30 million for each of FYs 2026 through 2027. This grant program seeks to integrate behavioral health services into pediatric primary care via the bolstering of related telehealth access programs at the state level; and
- SAMHSA's Infant and Early Childhood Mental Health Grant Program, which would be authorized for a total of $50 million for the entirety of FYs 2023 through 2027. This grant program aims to enhance mental health services for children from birth to the age of 12 to improve overall health outcomes.

Continuing Systems of Care for Children Act — The omnibus includes the Continuing Systems of Care for Children Act (H.R. 7248), which would reauthorize certain mental health programs for children, including the:

- Comprehensive Community Mental Health Services for Children with Serious Emotional Disturbances Grants at $125 million for each of FYs 2023 through 2027. The bill would additionally alter the definition of the term "eligible" within the program to cover parents and/or kinship caregivers; and
- Enhancement and Expansion of Treatment and Recovery Services for Adolescents, Transitional Aged Youth, and their Families (Youth and Family TREE) Grants at $29.605 million for each of FYs 2023 through 2027.

Garrett Lee Smith Memorial Reauthorization — Additionally, the bill incorporates the Garrett Lee Smith Memorial Reauthorization Act (H.R. 7255), which aims to reauthorize several grant programs related to suicide prevention. Specifically, the package includes updates to the:

- Suicide Prevention Resource Center, reauthorized at $9 million for each of FYs 2023 through 2027;
- State and Tribal Youth Suicide Prevention and Early Intervention Grants Program, reauthorized at $40 million for each of FYs 2023 through 2027, and additionally stipulates that such funds can be used by parents, legal guardians, and family members of youths to purchase supplies to properly store and secure commonly used means within the household that youth could use to complete suicide;
- Mental Health Youth Suicide Prevention Campus Grants, reauthorized at $7 million for each year from 2023 through 2027; and
- Mental and Behavioral Health Public Outreach and Education on College Campuses program, to be renamed the "Mental and Behavioral Health Public Outreach and Education at Institutions of Higher Education program." The program would be reauthorized at $1 million for FY 2023 through 2027 and would additionally be mandated to include, in the program's working group, representatives from minority serving institutions and community colleges.

PREVENT PANDEMICS ACT NOTABLE POLICIES

Increasing Federal Oversight of the CDC, Other Items — The legislation includes several provisions that seek to increase oversight of the federal government's pandemic response efforts. It would also require Senate confirmation of a CDC Director and the development of strategic plans aimed at the CDC's priorities and objectives. In addition, the proposed bill provides HHS and Administration for Strategic Preparedness and Response (ASPR) with authority to lead government-wide medical preparedness and response coordination, while strengthening practices for the communication of public health information.

Mobilizing State and Local Preparedness — This language would improve state and local public health security by updating the CDC Public Health Emergency Preparedness (PHEP) cooperative agreements to ensure coordination between health departments and agencies. Additionally, SAMHSA would be required to continue efforts supporting access to mental health and substance use disorder services during PHEs. It also increases funding and directs ASPR to improve rural area trauma care. Additionally, the comptroller general of the U.S. Government Accountability Office would be required to assess states' containment and mitigation of infectious diseases.

Addressing Social Determinants of Health — This language would authorize a grant program to support the reduction of health disparities and address social determinants of health within communities.

Improving Public Health Data Collection — This legislation would modernize the federal government's data collection capabilities of infectious diseases by clarifying the authority of HHS, CDC, NIH, and other departments. Specifically, HHS would be tasked with developing guidance to

support collaboration related to genomic sequencing to better forecast potential epidemic outbreaks.

NOTABLE FDA POLICIES

Alternatives to Animal Testing — The legislation would clarify that drug application sponsors can use alternative testing methods to animal testing for the effectiveness of human drugs. It would also permit sponsors of biosimilar applications to use alternative testing methods to animal studies to demonstrate biosimilarity to a reference product.

Exclusivity for First Interchangeable Biosimilars — If finalized, this provision would clarify that, while a first interchangeable biosimilar biological product's period of exclusivity is pending, the FDA retains the ability to tentatively approve a subsequent interchangeable product.

Advanced Manufacturing Technologies Designation Pilot Program — The bill stipulates that the FDA would be required to: (1) implement a pilot program to designate an advanced manufacturing technology, which would sunset in 2032; and (2) hold a public meeting, issue guidance, and transmit a report to Congress on the pilot program. Under the proposal, a method for manufacturing that receives such a designation would qualify for expedited application development and review.

Medical Devices

- *Ensuring Cybersecurity of Medical Devices* — This bill would require cyber device manufacturers to develop processes to ensure their devices are secure, have plans to identify and address cybersecurity vulnerabilities, provide a software bill of materials in their labeling, and submit this information to the FDA in premarket submissions. Notably, the bill defines cyber devices as those that have software, connect to the internet, or otherwise could be vulnerable to threats. HHS would also be required to produce guidance for industry and FDA staff on device cybersecurity.

- *Small Business Fee Waiver* — Businesses that report a gross income of $1 million or less per year would qualify for a waiver of the Medical Device user fee agreements (UFA) annual establishment registration fees. The HHS Secretary would be given the authority to determine whether such entities should be granted a waiver given the financial hardship that paying such fees would represent.

Accelerated Approval Drug Studies — This proposal would require the FDA to specify conditions for required post-approval studies, by the time the drug is approved, for such approved drugs under accelerated approval. It would also authorize the FDA to require post-approval studies to be underway for such drugs and would also clarify existing authority to withdraw approvals where sponsors fail to conduct studies with due diligence applies to the approved conditions. The FDA would be required to submit a report to Congress on the use of real-world evidence (RWE) surrounding post-approval studies and issue guidance on novel surrogate endpoints as well as clinical trial designs. In addition, the Secretary of HHS would be required to establish an intra-agency

coordinating council to "ensure the consistent and appropriate use" of the accelerated approval pathway.

Modernization of Cosmetics Regulation Act— This proposal includes the Modernization of Cosmetics Regulation Act, which would amend Chapter VI of the FD&C Act to include new provisions for cosmetic products. These amendments would require persons to submit reports and records of adverse events within 15 business days after receiving a report, direct the FDA to establish good manufacturing practice regulations, and require a cosmetics manufacturer to register its facilities and submit to HHS a product listing for each product. Additionally, the provision would amend the FD&C Act to ensure adequate safety substantiation for cosmetic products, increase requirements for labeling of cosmetic products, authorize the FDA to keep and protect detailed and extensive product records, and provide the FDA authority to order a mandatory recall of a product if determined to be unsafe. These amendments would also provide exemptions for small businesses, with average annual sales of less than $1 million for the previous three-year period. This provision would also amend the FD&C Act to allow certain products and facilities that are subject to the drug and device chapters of the FD&C Act to be exempt from the requirements under this section's established Act. Finally, these amendments would preempt state laws with respect only to the amendments mentioned previously.

- *Enforcement* — This proposal would establish new enforcement provisions that would become effective one year after the enactment of the Modernization of Cosmetics Regulation Act of 2022.
- *Records Inspection* — The bill would also make conforming edits to Section 704 of the FD&C Act to require FDA inspections on records and information, such as safety substantiation information, as previously discussed.
- *Talc-containing Cosmetics* — Additionally, the legislation would require the FDA to establish testing methods for detecting asbestos in talc-containing cosmetics.
- *PFAS* — The FDA would be required to consider the use and safety of perfluoroalkyl and polyfluoroalkyl substances (PFAS) within cosmetics and publish a report on its website summarizing its finding within two years of enactment.
- *Animal Testing* — The legislation includes a sense of the Congress that safety testing of cosmetic products should not include animal testing and that such testing should be phased out with certain exceptions.
- *Funding* — This bill would appropriate $14.2 million for FY 2023, nearly $25 million for FY 2024, and nearly $42 million for each of FYs 2025 through 2027 toward the provisions under this section.

Rare Diseases — Under the proposal, the FDA would be required to submit a report prior to September 30, 2026, detailing efforts related to the designation, approval, and licensure of drugs used to treat rare diseases. Subsequently, the GAO would be required to study the FDA's processes for the review of drugs. The legislation additionally directs the FDA to finalize its draft guidance entitled, "Rare Diseases: Common Issues in Drug Development," convene a public meeting to discuss improving rare disease patient and stakeholder engagement, and contract with the National Academies of Sciences, Engineering, and Medicine (NASEM) to study U.S. and European Union methods for determining safety and efficacy of rare disease therapeutics. Notably, under the bill,

small population studies would be considered a "topic for consultation" related to the review of rare disease drugs.

- *Rare Disease Endpoint Advancement Pilot Program* — The legislation would establish a rare disease endpoint advancement pilot program — to sunset on October 1, 2027 — to bolster collaboration with rare disease drug development program sponsors surrounding development of efficacy endpoints. This provision provides that the FDA must hold public workshops and report to Congress.

Emerging Technology Program — The legislation would stand up the Emerging Technology Program, an opportunity for stakeholders to consult with FDA officials to support the development of innovative approaches when designing and manufacturing drugs. The FDA, in accordance with this program, would be required to issue guidance as well as report funding and staff utilization to Congress.

Clinical Trials

- *Diversity* — The legislation would require that sponsors of Phase 3 trials, as well as device studies, develop and implement a diversity action plan and specifies exceptions and requirements for such a plan. The FDA would also be required to issue guidance and submit a report to Congress surrounding such diversity action plans. In conjunction with these provisions, the bill provides that the FDA hold a public workshop with stakeholders to consider ways in which to increase enrollment of underrepresented populations in clinical trials. Trade secrets would remain protected under these provisions. Additionally, with an eye on diversity, the FDA would be required to issue draft guidance to address decentralized clinical trials and finalize this guidance within one year after public comments on the draft guidance close.
- *Flexibilities Provided During the PHE* — Within 180 days of expiration of the COVID-19 public health emergency (PHE), the FDA would be required to convene a public meeting and discuss flexibilities provided during the PHE related to the mitigation of clinical study disruption to inform the incorporation of such flexibilities into permanent guidance.
- *Additional guidance* — Notably, this legislation would require the FDA to issue guidance aimed at "modernizing" clinical trials including by using:
    - Digital health technologies in clinical trials;
    - Decentralized clinical trials to improve trial participant engagement; and
    - Innovative clinical trial designs to support the expedited development and review of drugs and biological products.

Inspections — The legislation would extend the FDA's inspectional authorities to medical devices and clarify the agency's ability to inspect clinical study sites. If finalized, the bill would allow the FDA to enter into agreements with foreign governments related to the inspection of foreign establishments to enable preapproval inspections and would require the GAO to report on such interactions. The legislation would additionally stand up the unannounced foreign facility inspections pilot program and enhance the transparency of drug facility inspection timelines.

Other Policies

- *Marketing Status Reports by Biological Product Manufacturers* — The legislation would require that holders of approved biologics license applications communicate the withdrawal of a product from market to the FDA. Such entities would additionally be required to confirm to the FDA that their respective products included in the Purple Book remain available. Following this, the FDA would be required to make any necessary changes to the Purple Book related to biologics status.
- *Disposal of Opioids* — The proposal would allow the FDA to require that opioids and other drugs with "serious risks" be dispensed to patients in conjunction with in-home disposal systems.
- *Therapeutic Equivalence Evaluations* — With regard to follow-on drugs approved through the 505(b)(2) pathway with similar formulations to other approved products, the FDA would be required to make timely therapeutic equivalence evaluations. Additionally, the legislation enables the automatic substitution of lower-cost drugs at the pharmacy.
- *Grants for Institutions of Higher Education* — Under the legislation, the FDA would be authorized to award grants to institutions of higher education designated as a National Center of Excellence in Advanced and Continuous Pharmaceutical Manufacturing to support innovation and development surrounding continuous and advanced pharmaceutical manufacturing technologies and practices.
- *Generic Drug Labeling and Approvals* — During generic drug applications, this proposal would allow generic drugs to remain eligible for approval regardless of discrepancies between its proposed labeling and that of the listed drug when the listed drug's labeling was revised post-application. Within 60 days of approval, the generic drug sponsor would be required to submit revised labeling. Notably, revisions to the "warnings" section of the labeling would be exempt from this proposal.
- *Infant Formula* — Under the legislation, the FDA would be given the authority to waive the 90-day premarket submission requirement when a supply chain disruption occurs surrounding infant formula. In its place, the FDA would be required to implement a 30-day premarket submission requirement, to remain in effect for 90 days.

Other Reauthorizations

- *Orphan Drug Grants* — The legislation would reauthorize the FDA's jurisdiction over orphan drug development grants at $30 million for each year through 2027.
- *Critical Path Public-Private Partnership* — This bill proposes to reauthorize the Critical Path Public-Private Partnership (P3) — designed to advance innovation and regulatory science through data sharing and partnerships with public and private entities of expertise — at $6 million for each year through 2027.
- *Best Pharmaceuticals for Children Program* — The bill proposes to reauthorize the Best Pharmaceuticals for Children Act (BPCA), which supports pediatric clinical trials, at $25 million through 2027.

- *Humanitarian Device Exemption Incentive* — The package proposes to reauthorize the Humanitarian Device Exemption (HDE) for rare conditions at its current funding level through 2027.
- *Pediatric Device Consortia Program* — This legislation would reauthorize the pediatric device consortia (PDC) program, which provides expert advising to children's device applicants, at $7 million for each year through 2027.
- *Provision Pertaining to Drugs Containing Single Enantiomers* — This section would reauthorize exclusivity provisions for drugs containing single enantiomers at its current funding level until 2027.

NOTABLE MEDICARE POLICIES

Medicare Provider Payments

- *PAYGO* — In 2010, the Statutory PAYGO Act, established a new budget enforcement tool that intends to limit the federal deficit. At the end of each congressional session, OMB determines whether a violation of the PAYGO requirement has occurred If a violation occurs, the President must issue a sequestration order that implements across-the-board cuts in nonexempt direct spending programs sufficient to remedy the violation by eliminating the debit. The American Rescue Plan (ARP) Act, followed by the Protecting Medicare and American Farmers from Sequester Cuts Act, deferred the four percent PAYGO cut to Medicare until January 1, 2023. The PAYGO cut would last through FY 2031. To address these cuts, Congress waived statutory PAYGO for 2023 and 2024. As a result, the four percent cuts are expected to go into effect in 2025.

- *Physician Fee Schedule Payment Bump*— As a response to the COVID-19 pandemic, Congress had provided a one-time 3.75 percent increase to physician payments under the Medicare Physician Fee Schedule (PFS) for CY 2021. While this payment bump expired, the Protecting Medicare and American Farmers from Sequester Cuts Act retained another one-time three percent conversion factor to the Medicare PFS for CY 2022, set to expire on December 31, 2022. As a result of the expected expiration of this bump as well as other technical changes to the PFS, CMS — in its CY 2023 PFS final rule (TRP analysis) — finalized a reduction in the physician pay conversion factor by 4.8 percent for CY 2023. To mitigate the impact of these physician cuts, this legislation would increase physician payments subject to the PFS by 2.5 percent for CY 2023. It would also provide a 1.25 percent bump for CY 2024. As a result of this payment increase, physicians would still face a 2.3 percent payment cut for CY 2023.

- *Extension of Sequestration*— To assist in paying for the large price-tag of this end-of-year package, the legislation would extend Medicare sequestration, which is currently in effect, for the first six months of FY 2032. Notably, however, the sequestration payment cuts would continue at two percent for FY 2030 and FY 2031.

- *Extension of Alternative Payment Model (APM) Bonus Payments* — The Medicare Access and CHIP Reauthorization Act provided qualifying clinicians, participating in an APM, a bonus

payment equal five percent of their Medicare Part B payments. These bonus payments are set to expire in 2024 based on the calendar year 2022 performance period. This legislation would extend these bonus payments, providing a 3.5 percent bonus to qualifying providers for services covered in CY 2025.

- *Extension of Payment Rates for Durable Medical Equipment* — Under the CARES Act, the fee schedule amounts for certain durable medical equipment, prosthetics, orthotics, and supplies furnished in non-rural contiguous, non-competitive bidding areas is based on a blend of 75 percent of the adjusted fee schedule amount and 25 percent of the unadjusted feed schedule amount for the duration of the COVID-19 PHE. A provision in this legislation would further extend those temporary blended payment rates through December 31, 2023.

- *Other Payment Extensions* — In addition to the payment extension mentioned above, this end-of-year package includes an extension of the one percent add-on payment provided to certain home health agencies that furnish services in counties with low population density through December 31, 2023, as well as extensions of the Medicare low-volume hospital payment adjustment and the Medicare-Dependent Hospital program through September 30, 2024. Furthermore, certain add-on payments for ground ambulance services under the Medicare fee schedule are also extended through December 31, 2024.

Extension of Telehealth Flexibilities — During the COVID-19 PHE, the Secretary of HHS provided numerous flexibilities to permit the adoption of telehealth, which are set to expire 151 days after the termination of the PHE. This provision would uncouple these telehealth flexibilities from the PHE and would extend them through December 31, 2024.

Extension of Hospitals at Home Program — In response to the COVID-19 PHE and to increase hospital capacity, the Secretary of HHS provided flexibilities to allow for certain health care services to be provided outside of a traditional hospital setting and within a patient's home. To date, 250 hospitals in 37 states participate in the Hospitals at Home program, which is set to expire once the COVID-19 PHE ends. However, this legislation would continue the program through December 31, 2024.

Phase-in of Medicare Clinical Laboratory Test Payment Changes — Under the Protecting Access to Medicare Act of 2014, CMS was required to base Medicare pay for lab tests on commercial-payer rates. Under current law, the statutory phase-in of the payment reductions resulting from the private payor rate implementation is extended through CY 2024 and payments for CYs 2023 through 2025 cannot be reduced by more than 15 percent. If enacted, this end-of-year package would further delay the implementation of the payment rate cuts by one additional year, resulting in no reduction in payments for CY 2023.

Separate Payments for Non-Opioid Treatments for Pain Relief — This provision would incentivize the adoption of non-opioid treatments to manage pain in the hospital outpatient department and the ambulatory surgical center by requiring CMS to provide separate Medicare

payments for such treatments in these settings. Notably, the separate payments would be available for items furnished on or after January 1, 2025, through December 31, 2027, and shall be equal to the amount that exceeds the payment for the drug or biological paid separately under Part B and what would be paid for the drug or biological under Medicare for outpatient department services. The separate payment amount would be capped at 18 percent of the estimated average outpatient department services amount for surgeries and other services for which the non-opioid treatment is used in conjunction.

Transparency in Home Health — This provision would require the Secretary of HHS to conduct an open-door forum or other appropriate mechanism to receive input from home health stakeholders on home health payment rate development within 90 days of enactment. In addition, the Secretary would also be required to publish on the CMS website electronic data files showing the CMS simulation of 60-day episodes under the home health prospective payment system in effect prior to the Patient Driven Groupings Model.

Part B Coverage of Lymphedema Compression Items — This provision would provide for coverage under Medicare Part B for lymphedema compression treatment items that are furnished on or after January 1, 2024, to individuals with a diagnosis of lymphedema, are prescribed by a physician, and primarily and customarily used to serve a medical purpose for the treatment of lymphedema, as determined by the Secretary.

Part D Coverage of Certain Drugs Approved under Emergency Use Authorization — Upon enactment of this legislation through December 31, 2024, Medicare Part D coverage would be permitted for oral antiviral drugs that are dispensed only upon a prescription and authorized under an emergency use authorization under the COVID-19 PHE.

Behavioral Health

- *Medicare Coverage of Marriage and Family Therapists and Mental Health Counselor Services* — Currently, Medicare Part B covers marriage and counseling therapy only if it is provided by certain providers such as a psychiatrist, physician, clinical psychologist, clinical social worker, or a nurse specialist. However, Medicare does not provide coverage for such services provided by a licensed marriage or family therapists unless they are employees or staff of certain clinical facilities or offices, and the services are provided "incident to" and under direct supervision of the billing physician. While CMS has recently finalized (TRP analysis) its proposal to expand the definition of "incident to" to permit licensed marriage or family therapists to bill under the general supervision of a physician (rather than under direct supervision), current law still places limitations on when Medicare will cover services provided by a marriage or family therapist. This legislation would address this issue by establishing Medicare coverage for mental health services provided by marriage and family therapists and licensed professional counselors, beginning on January 1, 2024.

- *Payment for Mobile Crisis Response Intervention Services* — This provision would require Medicare, beginning January 1, 2024, to cover psychotherapy for crisis services that are

furnished by a mobile unit at a site of service other than an office setting**.** In lieu of the fee schedule amount that would normally be paid for such services, providers would receive a 50 percent payment increase than the Medicare Physician Fee Schedule payment rate for crisis psychotherapy services. The legislation would also require CMS, by January 1, 2024, to conduct outreach and education to providers on (1) the coverage and payment for crisis psychotherapy services and (2) the ability of auxiliary personnel (including peer support specialists) to participate in the furnishing of psychotherapy for crisis services.

- *Data Collection to Revise IPF PPS Methodology* — No later than October 1, 2023, the Secretary of HHS would be required to collect data and information he or she deems appropriate to revise payments under the Medicare Inpatient Psychiatric Hospital Prospective Payment System. For rate year 2025 and any subsequent rate year, the Secretary of HHS would be required, if determined appropriate, to implement revisions to such payment methodology.

- *Coverage for Intensive Outpatient Mental Health Services* — Effective January 1, 2024, Medicare's partial hospitalization benefit would provide coverage for intensive outpatient mental health services for an individual determined to have a need for such services for a minimum of nine hours per week.

- *Distribution of Additional Residency Positions for Psychiatry* — This legislation would expand the Medicare Graduate Medical Education program, beginning in fiscal year 2026, to provide 200 additional slots per year to qualifying hospitals. Notably, at least 100 of these additional slots must be used for psychiatry or psychiatry subspecialty residency programs.

- *Increased Access to Mental Health Programs for Physicians* — Under current law, physicians are prohibited from referring individuals to receive certain "designated health services" payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. This legislation would add another exception to this general rule to permit hospitals and other entities to provide evidence-based or evidence-informed programs for physicians to prevent death by suicide, improve mental health and resiliency, and for training such physicians in appropriate strategies to promote their mental health.

- *Provider Outreach and Reporting on Behavioral Health Integration* — This provision would require the Secretary of HHS to conduct outreach to health care providers on the availability of behavioral health integration services as a covered benefit under Medicare, including describing the requirements to bill for such HCPCS codes 99492 through 99494 or 99484. Within a year after completion of the education initiative, the Secretary of HHS would be required to submit a report to Congress on such outreach.

- *Provider Outreach and Reporting on OUD Treatment Services Furnished by OTPs* — Similar to the provision above, the Secretary of HHS would be required to conduct a one-time education initiative to health care providers to inform them of the inclusion of opioid use disorder

treatment services furnished by opioid treatment programs as a covered benefit under Medicare. The Secretary would also be required to conduct a similar one-time education initiative to Medicare beneficiaries about the eligibility requirements to receive such services. Within a year after completion of the education initiative, the Secretary would be required to submit a report to Congress on such outreach. The Secretary would also be required to report on the number of beneficiaries who were furnished OUD services within 18 months of enactment of this legislation.

IVIG Coverage — Beginning January 1, 2024, the legislation would provide for a permanent in-home benefit for the administration of intravenous immune globulin (IVIG) services.

NOTABLE MEDICAID POLICIES

Medicaid Redeterminations

- *Phase-out of the FFCRA FMAP Bump* — Under current law, beginning January 1, 2020, and ending on the last day of the calendar quarter in which the COVID-19 public health emergency ends, eligible states may receive a 6.2 percentage point increase to their regular FMAP for Medicaid expenditures to which the regular FMAP applies. Section 5131 of this legislation will phase out the FFCRA FMAP bump with an end date of December 31, 2023. The available FMAP bump would be as follows:
    - 6.2 percentage points for each calendar quarter beginning January 1, 2020, and ending March 31, 2023;
    - 5.0 percentage points for each calendar quarter beginning on April 1, 2023, and ending on June 30, 2023;
    - 2.5 percentage points for each calendar quarter beginning July 1, 2023, and ending on September 30, 2023; and
    - 1.5 percentage points for each calendar quarter beginning October 1, 2023, and ending on December 31, 2023.

- *Change in Certain FFCRA MOE Requirements* — Under current law, states are required to meet four maintenance of effort (MOE) requirements to be eligible to receive the current 6.2 percentage point FMAP increase during a calendar quarter. Currently, these MOE provisions prohibit states from (1) implementing any eligibility standards, methodologies, or procedures that are more restrictive than those in effect on January 1, 2020; (2) imposing new or increased premiums on any beneficiary that exceed the amount of the premium on effect as of January 1, 2020; (3) disenrolling any individual who is enrolled as of March 18, 2020 or who newly enrolls during the public health emergency from Medicaid through the last day of the month in which the public health emergency ends; and (4) fails to cover, without cost-sharing, testing services and treatment for COVID-19 in Medicaid, including vaccines, specialized equipment, and therapies. Notably, the third MOE requirement requires states to maintain Medicaid eligibility for an individual through the end of the month in which the public health emergency period ends.

As drafted, this legislation would sunset the current third MOE requirement pertaining to Medicaid eligibility. Specifically, should this provision become law, states would only need to treat individuals enrolled in Medicaid as of March 18, 2020, or individuals who are enrolled between March 18, 2020, through March 31, 2023, as eligible for Medicaid benefits through March 31, 2023. This would permit states to disenroll certain Medicaid beneficiaries, subject to the special rule described below.

- *Eligibility Redeterminations between April 1, 2023 and December 31, 2023* — This provision creates a special rule which stipulates that, between calendar quarters beginning on April 1, 2023 and ending on December 31, 2023, states, subject to certain conditions, are not to be deemed ineligible for the FMAP bump and deemed out of compliance with the MOE requirements if a state initiates Medicaid eligibility renewals, post-enrollment verifications, and redeterminations over a 12-month period for all individuals who are enrolled in the program as of April 1, 2023. In order to not be deemed out of compliance with the Medicaid eligibility MOE requirements, a state, in conducting eligibility redeterminations for a Medicaid enrollee between April 1, 2023, through December 31, 2023, must:
    - Conduct eligibility redeterminations in accordance with federal requirements including complying with renewal strategies or other alternative processes and procedures approved by the Secretary of HHS;
    - Attempt to ensure that it has up-to-date contact information for each individual for whom the state conducts an eligibility redetermination; and
    - Not disenroll any individual who is determined ineligible for Medicaid pursuant to such a redetermination on the basis of returned mail unless the state undertakes a good faith effort to ensure that the state has contact information for such individuals prior to terminating coverage.

- *State Reporting Requirements for Eligibility Redeterminations during Transition from FFCRA FMAP Bump*
    - Monthly reports — Under this legislation, states will be required to submit a monthly report to the Secretary (beginning April 1, 2023, through June 30, 2024) on the activities the state undertook relating to eligibility redeterminations conducted during the month, which shall be made publicly available by the Secretary. The monthly report must include information on the number of eligibility renewals initiated, beneficiaries renewed on a total and *ex parte* basis, and individuals whose coverage was terminated including the number of those whose coverage was terminated for procedural reasons. The monthly reports must also include information on the number of individuals who were screened for eligibility in a basic health program or other ACA qualified health plan.

    - Reduction in FMAP for failure to submit reports — If a state fails to submit monthly reports to the Secretary of HHS as described above, the state's FMAP will be reduced by the product of 0.25 percentage points and the number of fiscal quarters (between July 1, 2023, and June 30, 2024) for which the state has not satisfied the reporting

requirements. The total FMAP reduction under this provision cannot exceed 1.0 percent.

- Corrective action plan— In addition, this bill would authorize the Secretary to assess a state's compliance with federal eligibility redeterminations requirements and submit and implement a corrective action plan if the Secretary determines the state did not comply with such requirements between April 1, 2023, through June 30, 2024. If the state fails to implement the corrective action plan, the Secretary would be authorized to impose a civil monetary penalty of $100,000 for each day the state has not complied.

Permanent Medicaid Funding for U.S. Territories — While states receive open-ended federal funds subject to a specified percentage of their Medicaid expenditures, the U.S. territories (American Samoa, Commonwealth of Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands) receive a capped amount of funding from the federal government. As a result of this financing structure, the U.S. territories have routinely faced a fiscal cliff in their Medicaid program, prompting Congress to act each time to temporarily increase the federal allotments for the territories so that they could continue to receive federal funds for allowable Medicaid expenditures. This bill contains several policies that would make changes to the financing of the Medicaid programs in the territories, including the following:

- *Puerto Rico* — The bill would extend the current FMAP of Puerto Rico's of 76 percent through FY 2027 and would revise the annual Medicaid allotment caps for the territory. In addition, Puerto Rico would be subject to additional program integrity requirements, including requirements to implement asset verification by January 1, 2026, as well as contracting and procurement oversight.
- *American Samoa, Commonwealth of Northern Mariana Islands, Guam, and the U.S. Virgin Islands* — The legislation would permanently extend the higher FMAP of 83 percent for American Samoa, Commonwealth of Northern Mariana Islands, Guam, and the U.S. Virgin Islands in additional to providing 100 percent of the qualifying data system improvement expenditures incurred by these territories on or after October 1, 2023.

Extension of the Children's Health Insurance Program — Under current law, the Children's Health Insurance Program (CHIP), which provides health coverage to low-income children with family incomes too high to qualify for Medicaid, is funded through fiscal year (FY) 2027. This legislation includes a proposal that would further extend CHIP and other related policies through FY 2029.

Continuous Eligibility for Children under Medicaid and CHIP — Under current law, states have the option to provide children under age 19 with 12 months of continuous coverage through Medicaid and the CHIP, even if the family experiences a change in income during the year. While approximately half of states have implemented this state option, this legislation would require states to provide 12 months of continuous eligibility for children enrolled in Medicaid and CHIP. If this

language is enacted, states will have one year upon enactment to implement the 12-month continuous coverage requirement.

Postpartum Coverage — The American Rescue Plan Act provided states the option to extend Medicaid and CHIP coverage for pregnant individuals from 60 days to one year postpartum, beginning April 1, 2022, and ending March 31, 2027. This provision would permanently extend the option for states to offer Medicaid and CHIP coverage for pregnant individuals for one year postpartum.

Medicaid Coverage for Justice-Involved Youth — Under current law, Medicaid cannot cover services for individuals residing in a jail or prison. In the past, states terminated coverage for incarcerated individuals, leaving them to reapply upon release. This legislation would, beginning two years after enactment of this bill, create an exception to the provision that juvenile inmates in nonmedical institutions are not eligible for Medicaid, and would stipulate that juvenile inmates are eligible for Medicaid coverage 30 days prior to their release. In addition, this legislation would also require 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 release, and targeted case management services for at least 30-days following release.

Extension of Other Policies — This bill would also provide $450 million per year for the Medicaid Money Follows the Person Demonstration program through FY 2027. In addition, the protections against spousal impoverishment for Medicaid beneficiaries of home and community-based services would be extended through FY 2027.

Requirements for Searchable Provider Directories — If enacted, this legislation would require, beginning July 1, 2025, Medicaid managed care organizations, prepaid inpatient health plans, and primary care case management entities to publish and regularly update searchable directories of health care providers in their networks, including mental health and substance use disorder providers.

OTHER NOTABLE POLICIES

Reauthorization of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program — The end-of-year package includes the *Jackie Walorski Maternal and Child Home Visiting Reauthorization Act of 2022*. The provisions increase funding and reauthorize the MIECHV program for an additional five-years through September 30, 2027. In addition, the legislation would implement a series of changes to the MIECHV program, including: (1) establishing a public dashboard to report program outcomes; (2) requiring activities to reduce unnecessary data collection, reporting, and other administrative requirements; and (3) allowing for virtual home visits under certain circumstances, among other provisions.

Extension of Temporary Assistance for Needy Families (TANF) Program — This legislation would provide funding for TANF through the end of FY 2023.

Efforts to Improve the Public Health Workforce — Several notable policies intended to address shortages in the public health workforce are contained in the end-of-year package, including:

- Creating a Bio-Preparedness Workforce Pilot Program to provide loan repayment for certain health professionals with expertise in infectious diseases and emergency preparedness response efforts;
- Providing funds to be used to recruit, hire, train, and retain community workers and to support community health workers in providing education and outreach to their communities to promote health behaviors in underserved communities;
- Providing the HHS Secretary the authority to directly appoint up to 500 individuals to preparedness and response positions as an initial response to a public health emergency; and
- Reauthorization of grants to community health centers and rural health clinics to support continuing medical education for primary care providers, among other policies.

HRSA Briefing on 340B Drugs — The agreement would direct HRSA to provide a briefing on actions taken to "safeguard" covered entities' lawful access to discounted drugs. Such a briefing would be required to be issued within 120 days of the legislation's enactment.