Policy Update

Consolidated Appropriations Act, 2023: Health Provisions

Background

The Consolidated Appropriations Act (CAA), 2023, funds US government operations for fiscal year (FY) 2023, providing roughly $1.7 trillion in spending: $772.5 billion in nondefense discretionary spending and $858 billion in defense spending. It also includes policies that extend beyond appropriations in many different areas.

Many healthcare policy provisions were included in Division FF of the bill's text. Highlights include the following:

- Waiving the 4% Medicare Statutory Pay-As-You-Go Act of 2010 (PAYGO) cuts for 2023 and 2024
- Partially mitigating provider payment cuts under the Medicare Physician Fee Schedule (PFS) for two years
- Extending some current telehealth waivers and flexibilities related to the COVID-19 public health emergency (PHE) for two years
- Extending the Advanced Alternative Payment Model (APM) bonus for one year, but at a lower bonus payment rate of 3.5%
- Providing a two-year extension of the Hospital at Home waiver
- Addressing mental health and substance use treatment
- Decoupling the Medicaid continuous coverage requirement from the COVID-19 PHE
- Making additional changes in Medicaid coverage policies.

The Senate passed the CAA on December 22, 2022 and the House of Representatives will vote Friday morning, December 23. President Biden is expected to sign before the midnight Friday, December 23, 2022 deadline.

Read on for a summary of key health-related provisions in the CAA 2023.

Helpful Resources:

- Text of the Consolidated Appropriations Act, 2023
- Press release
- Section-by-section summary of certain Division FF health provisions with Senate Finance Committee jurisdiction
- Section-by-section summary of certain Division FF health provisions with Senate Health, Education, Labor and Pensions (HELP) Committee jurisdiction
- Section-by-section summary of certain Division FF health provisions with House Energy and Commerce Committee jurisdiction

Medicare

Medicare PAYGO 4% Cuts

Background: The Statutory Pay-As-You-Go Act of 2010 (PAYGO) requires that automatic payment cuts of 4% be put into place if a statutory action is projected to create a net increase

in the deficit over either five or 10 years. The enactment of the American Rescue Plan Act in 2021 triggered PAYGO cuts in 2022. The PAYGO sequester has never actually been implemented despite being triggered on multiple occasions. Congress most recently delayed the 4% cut until January 1, 2023, in the Protecting Medicare & American Farmers from Sequester Cuts Act, which was enacted in December 2021. This broad PAYGO policy extends to programs beyond Medicare, but for purposes of healthcare, the pending impact is that providers would face a 4% Medicare cut beginning January 1, 2023.

Provision: The CAA 2023 would "wipe the PAYGO scorecard clean" for FY 2023 and FY 2024, and would put any balance for either of those years onto the FY 2025 scorecard. The CAA 2023 also stipulates that none of the spending included in the bill would be added to the PAYGO scorecard. Because of the way Congress proposes to delay PAYGO cuts required in 2023 and 2024 until 2025, Congress likely will have to contend with PAYGO obligations again in two years.

Medicare Physician Fee Schedule Cuts

Background: The Centers for Medicare and Medicaid Services (CMS) is required by statute to adhere to certain budget neutrality requirements when annually updating the Medicare PFS. Because of these obligations, Congress has had to act repeatedly to prevent scheduled cuts from going into effect. Congress intervened in 2020 with a provision in the CAA 2021 that provided a one-year 3.75% positive adjustment for 2021 to partially offset cuts that were largely driven by payment increases to evaluation and management services. Congress intervened again in 2021 with a provision in the Protecting Medicare & American Farmers from Sequester Cuts Act that provided a one-year 3% positive adjustment for 2022, in addition to staving off other Medicare cuts. For 2023, CMS finalized a 4.47% cut to the physician conversion factor (CF) and a 4.42% cut to the anesthesia CF for 2023.

Provision: The bill would offset the planned cuts by more than 2%, providing a 2.5% positive adjustment to the CF for calendar year (CY) 2023, and a 1.25% positive adjustment to the CF for CY 2024. The 2.5% positive adjustment for 2023 would result in an estimated CF of approximately $33.8872. Accordingly, this adjustment represents a **2.08%** cut from the 2022 CF of $34.6062, but is less than the 4.47% cut based on the initial 2023 CF of $33.0607 announced in the 2023 PFS final rule.

Likewise, the estimated updated anesthesia CF for 2023 would be approximately $21.1249, a **2.03%** cut from the 2022 anesthesia CF of $21.5623, but less than the 4.42% cut based on the initial 2023 anesthesia CF of $20.6097 announced in the 2023 PFS final rule. CMS will likely publish updated information on the final CF to implement these legislative changes in the coming days or weeks.

Advanced Alternative Payment Model Bonus Payment

Background: The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) set up a two-track Quality Payment Program that incentivizes the transition to value-based payment models. Under MACRA, eligible physicians choose between a Merit-based Incentive Payment System track or the APM track. Physicians who opt for the APM track receive a 5% incentive payment to encourage the transition away from fee-for-service payment systems to two-sided risk models. These incentive payments are scheduled to expire at the end of 2022.

Provision: The bill would extend the APM bonus for one year, but provides a 3.5% bonus payment instead of the previous 5% bonus payment. The bill would retain lower revenue and patient count thresholds that APMs must meet to qualify for the bonus. The single year extension would provide a pathway to longer term reforms expected to be discussed as part of a MACRA 2.0 effort in 2023. Earlier in 2022, a bipartisan group of House Members issued a request for information looking for feedback on

a future iteration of MACRA. Stakeholders expect robust debate on the future of MACRA's two track model, which may include revisiting a longer term approach to the APM bonus.

Hospital at Home

Background: CMS implemented the Acute Hospital Care at Home waiver program to allow Medicare beneficiaries the option to receive acute-level healthcare services in their home environment during the COVID-19 PHE. As of December 16, 2022, 114 health systems and 259 hospitals across 37 states are approved to participate in the waiver program. The waiver program has demonstrated positive outcomes, experiences and potential cost savings. However, the federal regulatory flexibilities that enable the model were tied to the duration of the PHE.

Provision: The bill would extend the current Acute Hospital Care at Home waiver initiative until December 31, 2024. The extension in law provides greater stability and predictability for hospitals and health systems looking to invest in this care delivery model.

Medical Device Pass-Through Payments

Background: Under the Medicare Hospital Outpatient Prospective Payment System (OPPS), medical devices may be eligible for incremental payments referred to as transitional pass-through payments. This payment is a statutorily established pathway for new and innovative technologies, should they qualify, to receive payment in addition to the Ambulatory Payment Classification payment for the primary procedure for a period of up to three years. In the CY 2022 OPPS rulemaking cycle, CMS exercised its equitable adjustment authority to extend the transitional pass-through for one device whose eligibility was to end December 31, 2021, because of the impact of the COVID-19 pandemic. However, for CY 2023, CMS finalized its policy to return to the "regular update process" and did not exercise this authority for the upcoming calendar year.

Provision: The bill would extend the transitional pass-through status for one year for the medical devices whose status would have ended on December 31, 2022.

Clinical Laboratory Fee Schedule Cuts

Background: In 2014, Congress included provisions in the Protecting Access to Medicare Act (PAMA) that substantially overhauled how Medicare determines payments for laboratory services paid under the Clinical Laboratory Fee Schedule. PAMA used laboratory-reported, non-Medicare per-test payment information to determine Medicare payments to better align such payments with prevailing market rates. Some laboratory stakeholders have said that the data collection methodology was flawed and that data collected (and the resulting payment amounts) are not representative of market rates.

Congress has acted multiple times in recent years to delay reporting obligations and payment reductions under the PAMA methodology.

Provision: The bill would provide another one-year delay of the PAMA reporting periods (until the first quarter of 2024) and an extension of the 0% freeze for future cuts through December 31, 2023. This provision is expected to save money.

Nursing and Allied Health Professional Education Payments

Background: The Technical Reset to Advance the Instruction of Nurses (TRAIN) Act (H.R. 4407/S. 1568) was introduced earlier in 2022 to waive the cap on annual payments for nursing and allied health education. In 2021, CMS miscalculated payments to nursing and allied health education programs and direct graduate medical education programs based on Medicare Advantage use, and directed Medicare administrative contractors to recoup payments from these programs. About 120 hospital-based nursing schools would have been affected, but H.R. 4407 directed CMS not to seek repayment from nursing and allied health programs.

Provision: The bill includes the provisions of the TRAIN Act, which waives the cap on annual payments for nursing and allied health education payments for certain nursing programs, and would direct CMS not to seek repayment from nursing and allied health programs.

Medicare Coverage of Certain Lymphedema Compression Treatment Items

Background: Medicare Part B covers medically necessary durable medical equipment (DME) when a Medicare-enrolled doctor or other healthcare provider orders such DME for use in a beneficiary's home. CMS establishes payment and benefit category determinations for DME items under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies fee schedule. Currently, Medicare does not cover compression garments that treat lymphedema under the Part B DME category. Legislation (H.R. 3630) to provide Medicare coverage of lymphedema compression treatment item was introduced in the House by Rep. Janice Schakowsky and passed out of the Energy and Commerce Committee in July 2022 with bipartisan support.

Provision: The bill would provide Medicare Part B coverage of and payment for compression garments for the treatment of lymphedema furnished on or after January 1, 2024.

Medicare Coverage of In-Home Intravenous Immune Globulin Services

Background: The Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 authorized a three-year demonstration through the CMS Innovation Center to evaluate the benefits of providing Part B payment for the in-home administration of intravenous immune globulin (IVIG) for the treatment of primary immune deficiency disease. Under the IVIG demonstration, Medicare provides a bundled payment for items and services that are necessary to administer IVIG in the home to enrolled beneficiaries who are not otherwise homebound and receiving home healthcare benefits. Services covered under the demonstration are provided and billed by the specialty pharmacies that provide the immune globulin drug, which is already covered under Medicare Part B. The demonstration covered services are paid as a single bundle and are subject to coinsurance and deductible in the same manner as other Part B services. The traditional Medicare fee-for-service benefit does not currently cover any services to administer the drug to a beneficiary at home.

The demonstration began October 1, 2014, and was initially scheduled to end on September 30, 2017. The Disaster Tax Relief and Airport and Airway Extension Act of 2017 extended the demonstration through December 31, 2020, and the CAA 2021 extended the demonstration through December 31, 2023.

Provision: This bill would provide permanent Medicare Part B coverage of and payment for in-home IVIG services beginning on January 1, 2024.

Medicaid and CHIP

Puerto Rico and Territory Medicaid Funding

Background: The CAA 2022, which passed in March 2022, increased the federal government's share of Medicaid payment in Puerto Rico and the US territories from the 55% set in historic statute to 76% through December 13, 2022. The most recent CR extended the Medicaid funding through December 23, 2022, to line up with the other healthcare extenders. During the COVID-19 PHE, the territories received the 6.2 percentage point increase provided to all states and territories, bringing Puerto Rico's Federal Medical Assistance Percentage (FMAP) to 82.2% and the other territories' FMAPs to 89.2%.

Provision: The bill would permanently extend a federal Medicaid match of 83% for American Samoa, the Commonwealth of the Northern Mariana Islands, Guam and the US Virgin Islands. The bill would extend Puerto Rico's higher federal Medicaid match of 76% through FY 2027, and would establish a new framework for enhanced allotments for the next five fiscal years. The bill would also require Puerto Rico to implement an asset verification program by 2026 or be subject to payment reductions (similar to state Medicaid programs), and to designate a Contracting and Procurement Oversight Lead.

The bill would also make programmatic improvements to the territories' Medicaid programs, including requiring increased provider payment rates and improved contracting practices for Puerto Rico, and providing funding for data system improvements for the other territories.

12-Month Continuous Eligibility for Children Enrolled in Medicaid and CHIP

Background: Medicaid and the Children's Health Insurance Program (CHIP) provide critical health coverage to more than 80 million Americans, including pregnant women, people with disabilities and more than 45 million children. However, many Medicaid beneficiaries each year lose their coverage because of the cycle of enrollment and disenrollment, temporary changes in income levels or administrative issues. Many of these individuals are still eligible for Medicaid. This issue is commonly referred to as Medicaid eligibility churn.

Currently, states have the option to provide children with 12 months of continuous coverage through Medicaid and CHIP.

Provision: The bill would require states to permanently provide 12 months of continuous coverage in Medicaid and CHIP for children.

12-Month Continuous Eligibility for Post-Partum Women Enrolled in Medicaid

Background: The Medicaid program covers 40% of all births in the United States. Federal law requires state Medicaid programs to cover post-partum care for 60 days after birth. The American Rescue Plan Act of 2021 gave states a new option to extend Medicaid postpartum coverage to 12 months through a state plan amendment. This new option took effect April 1, 2022, and is available to states for five years. Twenty-seven states have already implemented related state plan amendments and seven other states are in planning phases. During the COVID-19 PHE, states also must provide continuous coverage to Medicaid enrollees to be eligible for enhanced federal matching funds under the Families First Coronavirus Response Act (discussed in more detail below, under "Offsets"). As a result, post-partum coverage has remained continuous and eligible to Medicaid enrollees during the PHE.

Provision: The bill would permanently extend the state option to provide 12 months of continuous coverage in Medicaid for post-partum women originally provided in the American Rescue Plan.

CHIP Extension

Background: CHIP is a joint federal-state program that provides health coverage to low-income, uninsured children with family incomes that are too high to qualify for Medicaid. More than seven million children receive coverage through CHIP. CHIP funding is a block grant and needs regular reauthorization. Congress created CHIP in 1997 and most recently extended it through FY 2027 in the Bipartisan Budget Act of 2018 (P.L. 115-123).

Provision: The bill would extend reauthorization of the CHIP program for an additional two years, through FY 2029.

Extension of Money Follows the Person

Background: The Money Follows the Person Program was created in 2005 to provide states with enhanced federal matching funds for services and supports to help seniors and people with disabilities move from institutions to home-based care. Forty-four states participate in the program, which has helped more than 90,000 institutionalized residents transition back to their communities. The Affordable Care Act expanded the program, but long-term funding expired in 2016. Since then, lawmakers have passed a series of short-term limited funding bills to continue the program. The program was most recently funded through FY 2023 by the CAA 2021.

Provision: This bill would provide a four-year extension of the Money Follows the Person program through FY 2027.

Medicaid Managed Care Provider Directories

Background: Medicaid managed care plans are required to provide certain information about their network providers. Most recently, the 2020 Medicaid and CHIP Managed Care Final Rule adopted additional changes that ultimately relaxed the requirements for Medicaid managed care plans that were originally proposed in the 2016 Medicaid managed care rule published under the Obama Administration. The 2020 final rule relaxed the provider directory requirements for accessibility of written materials for people with disabilities and those with limited English proficiency, removed requirements to identify whether a provider has completed cultural competence training, decreased the frequency of updating paper provider directories, and extended the timeline for plans to update directories if a provider leaves the network.

Provision: This bill would codify requirements that Medicaid managed care plans have accurate, updated and searchable provider directories by July 1, 2025. Medicaid plans would be required to publish (and update on at least a quarterly basis, or more frequently as required by CMS) an internet-based searchable directory of network providers, which includes physicians, hospitals, pharmacies, providers of mental health services, providers of substance use disorder services, providers of long-term services and supports as appropriate, and other providers as required by CMS. Plans would have to provide the provider's name, address, contact information, website, and cultural and language capabilities, as well as information on whether the provider is accepting new Medicaid patients, whether the office has accommodations for individuals with disabilities, and whether the provider offers telehealth services.

Medicaid Improvement Fund

Background: Congress typically uses the Medicaid Improvement Fund to fund Medicaid policy priorities, and also to store funding from Medicaid policy changes so that it can be used in future policymaking.

Provision: The bill would provide an additional $7 billion to the Medicaid Improvement Fund. The funding could be used at a later date to address future Medicaid policy needs (for example, the pending Medicaid disproportionate share hospital cuts at the end of 2023).

Telehealth

Background: Early in the pandemic, Congress and CMS expanded authority to use telehealth as a tool to provide care while people were less able to seek that care in person. Many of these flexibilities were authorized for the duration of the COVID-19 PHE. Congress acted in early 2022 to separate current telehealth flexibilities from the eventual expiration of the PHE, providing for the extension of many (but not all) telehealth flexibilities for 151 days beyond the PHE's expiration as part of the CAA 2022. In July 2022, the House overwhelmingly passed the Advancing Telehealth Beyond COVID-19 Act (H.R. 4040) by a vote of 416–12. That bill would extend many of the telehealth PHE waivers and flexibilities for two years. The Senate did not act on similar legislation before the lame duck session.

Throughout fall 2022, stakeholders urged Congress to include language in the year-end package to extend telehealth waivers and flexibilities for two years, and to include other priorities such as ensuring continued access to clinically appropriate controlled substances without in-person requirements, increasing access to telehealth services in the commercial market, and extending protections for people with health savings accounts to continue to be eligible to receive telehealth services pre-deductible.

Provision: The bill would extend some of the pandemic-related Medicare telehealth flexibilities for two years through December 31, 2024. Provisions that would be extended include the following:

- Waivers to the geographic and originating site restrictions
- Expansions to the list of eligible practitioners
- Eligibilities for federally qualified health centers and rural health clinics
- Allowing telehealth to be provided through audio-only telecommunications
- Allowing telehealth to be used for a required face-to-face encounter prior to the recertification of a patient's eligibility for hospice care
- Delaying the in-person visit requirement before a patient receives tele-mental health services.

The bill would also require the US Department of Health and Human Services (HHS) to conduct a study on telehealth and Medicare program integrity, with an interim report to be submitted to Congress no later than October 1, 2024, and the final report due by April 1, 2026.

In addition, the bill would extend the safe harbor allowing individuals with health-savings-account-eligible high-deductible health plans to receive pre-deductible coverage for certain telehealth services (a provision that was not tied to the PHE and was set to expire on December 31, 2022, without congressional action) for two years, through December 31, 2024. The provision would allow for coverage for the entirety of the plan years that begin before January 1, 2025.

Not all telehealth provisions of interest to stakeholders are included in this bill. For example, language to classify telehealth services as excepted benefits, in order to increase access to telehealth for part-time (and other traditionally noneligible) employees and their dependents, is not included in the bill. Language to extend a pandemic-related waiver regarding prescription of controlled substances via

telehealth without an in-person visit is also absent, although the bill does include language directing the US Drug Enforcement Administration (DEA) to issue final regulations regarding a special registration for telemedicine providers. However, previous legislation (*e.g.*, The Special Registration for Telemedicine Act of 2018, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act)) also required the DEA to promulgate a regulation on this issue, but the agency has failed to do so for 13 years. Congress and the Administration may need to revisit some of these waiver flexibilities in 2023, depending on the timing of the end of the PHE.

Addressing Mental Health and Substance Use Disorders

Background: Throughout the 117th Congress, each of the four major congressional healthcare committees (House Energy and Commerce; House Ways and Means; Senate Finance; and Senate HELP) worked to develop comprehensive policies to address the nation's growing mental health and substance use disorder (SUD) crises. Each committee approached the effort differently (and within their own legislative jurisdictions), moving at different speeds and producing different proposals.

For example, the Senate Finance Committee produced a series of five discussion drafts, each focusing on a different aspect of mental health policy, but did not introduce actual legislation. Across the Capitol, the House Energy and Commerce Committee assembled H.R. 7666, the Restoring Hope for Mental Health and Well-Being Act, legislation that would reauthorize and provide funding recommendations for existing behavioral health programs, give state Medicaid agencies the option to provide services to justice-involved youth under the Medicaid program, and eliminate the requirement that practitioners apply for a separate DEA waiver to prescribe buprenorphine for SUD treatment. The House of Representatives approved H.R. 7666 in June 2022.

Provisions: The bill includes three main sections addressing mental health and SUD reforms, including many of the provisions of H.R. 7666, a section addressing Medicare provisions, and a section addressing Medicaid and CHIP provisions.

Provisions from H.R. 7666, The Restoring Hope for Mental Health and Well-Being Act

The CAA 2023 would establish or expand upon more than 30 programs that collectively support mental health care and SUD prevention, care, treatment, peer support and recovery support services. The bill would reauthorize the National Suicide Prevention Lifeline Program; the Community Mental Health Service Block Grants; and the renamed Substance Use and Prevention, Treatment, and Recovery Block Grants. It also would include funding to support maternal mental health programs and would establish a maternal mental health hotline and a related task force. The bill would extend mental health parity to state and local government workers, and includes workforce provisions to increase capacity and training.

The bill also includes a provision to eliminate the requirement that practitioners apply for a separate waiver through the DEA to prescribe buprenorphine for SUD treatment, as set forth in the Mainstreaming Addiction Treatment Act (H.R. 1384/S. 445).

The bill would also require the Substance Abuse and Mental Health Services Administration to identify and publish best practices for a crisis response continuum of care related to mental health and SUD, to be published one year after enactment and updated after three years. The bill would also provide grant funding for a mental health crisis response partnership pilot program to divert mental health and SUD crisis response from law enforcement to mobile crisis teams.

Medicare Provisions

The bill would establish Medicare coverage of marriage and family therapists and mental health counselors beginning in 2024, and would provide for the distribution of 200 additional Medicare-funded graduate medical education (GME) residency positions, specifically dedicating half of the total number of positions to psychiatry or psychiatry subspecialty residencies.

The bill also would seek to improve mobile crisis care in Medicare by establishing increased payment rates for crisis psychotherapy services when furnished by a mobile unit and additional settings other than a facility or physician office, beginning in 2024. It would seek to improve integration by requiring HHS to conduct outreach to providers on the availability of behavioral health integration services as a covered benefit under the Medicare program.

The bill includes provisions from the NOPAIN Act (H.R. 3259/S. 586), providing for a separate Medicare payment for non-opioid treatments that are currently packaged into the payment for surgeries under OPPS, from 2025 through 2027.

With respect to physician wellness, the bill would add new exceptions to the Stark Law to allow for hospitals to provide evidence-based programs for physicians to improve their mental health and increase resiliency, and to prevent suicide among physicians.

Medicaid and CHIP Provisions

The bill would require states to provide health screenings, referrals and case management for eligible juveniles in public institutions, and would allow states to receive federal matching funds for healthcare services provided to justice-involved youth incarcerated in public institutions pending disposition of their charges, beginning in 2025.

The bill also would require HHS to issue guidance providing recommendations and best practices to states regarding the development of an effective crisis response continuum of care through Medicaid and CHIP, and to establish a technical assistance center to provide support for states in designing and implementing crisis response services.

Extenders for Expiring Provisions

Medicare Low-Volume Hospital Payment Adjustment

Background: The Medicare low-volume hospital program applies a payment adjustment for certain hospitals with low inpatient volumes. The program supports hospitals in small and isolated communities whose operating costs often outpace their revenue. Congress has historically reauthorized this program for limited periods, the last of which was a five-year extension that expired on October 1, 2022. The most recent continuing resolution provided a short-term patch, extending the low-volume adjustment through December 23, 2022, to give Congress time to enact a longer extension. Efforts to extend the program have bipartisan support in both the House and Senate.

Provision: The bill would provide for a two-year extension of the Medicare low-volume adjustment, through September 30, 2024.

Medicare-Dependent Hospital Program

Background: The Medicare-dependent hospital (MDH) program provides enhanced payment to support certain small rural hospitals for which Medicare patients comprise a significant percentage (at least 60%) of inpatient days or discharges. Because they primarily serve

Medicare beneficiaries, MDHs rely heavily on Medicare payment to sustain hospital operations, making them more vulnerable to inadequate Medicare payments than other rural hospitals. Congress acknowledged the importance of Medicare reimbursement to MDHs and established special payment provisions to buttress these hospitals. Like the low-volume payment adjustment, Congress has historically reauthorized this program for limited periods, the last of which was a five-year extension that expired on October 1, 2022. The most recent continuing resolution provided a short-term extension through December 23, 2022, giving Congress more time to enact a longer-term extension. Extending the MDH program has bipartisan support in Congress.

Provision: The bill would provide for a two-year extension of the MDH program, through September 30, 2024.

Ground Ambulance Add-On Payments

Background: Prior legislation established payment add-ons for certain ground ambulance services. The most recent extension was set to expire at the end of CY 2022.

Provision: The bill would extend several ambulance service payment add-ons for two years through CY 2024, including the 3% increase for ground ambulance trips originating in rural areas, the 2% increase for ground ambulance trips originating in urban areas, and a "super rural" add-on of 22.6% for ambulance services in the "lowest population density" areas.

Home Health Rural Add-On Payments

Background: Congress has recognized the unique needs of home health services delivery in rural areas. These services tend to carry higher costs because of distance between patients and transportation expenses, for example. Home health agencies also are usually smaller in rural areas, with fixed costs that must be spread over fewer patients and fewer visits. As a result, a 3% payment modifier to reimbursements for services provided in rural and underserved areas was provided through Medicare. Congress has repeatedly stepped in to extend rural add-on payments for home health.

Provision: The bill would extend the 1% add-on payment provided to certain home health agencies that furnish services in counties with a low population density for one year through December 31, 2023.

Maternal, Infant, and Early Childhood Home Visiting Program

Background: The Affordable Care Act established the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program as an evidence-based initiative that supports home visits for expectant and new parents who live in communities that are at risk for poor maternal and child health outcomes. Funding for the program was reauthorized in the Bipartisan Budget Act of 2018 through September 30, 2022, then granted a short-term extension through December 23, 2022. The program enjoys broad bipartisan, bicameral support. In fact, the House Ways and Means Committee bill that passed the House earlier in December 2022 was named the Jackie Walorski Maternal and Child Home Visiting Reauthorization Act of 2022 to honor former Representative Jackie Walorski (R-IN), who died in a car accident earlier this year and was a champion for the program.

Provision: The CAA 2023 would authorize five years of funding for the MIECHV Program (increasing the annual funding level to $800 million by 2027), and describes how funding for both federal base grants and federal matching grants would be allocated. It would also reserve funds for purposes other than the state/territory grants, including doubling the amount set aside to 6% to provide and administer grants to Native American tribes.

The bill would also provide an option to provide virtual home visits if a state or territory provides certain information to HHS demonstrating they have met specific conditions, including the requirement to provide one in-person visit per year. The bill would require HHS to establish and operate an outcomes dashboard that is available publicly online and updated annually.

US Food and Drug Administration

Background: The most recent continuing resolution included a five-year reauthorization of the US Food and Drug Administration (FDA) user fee acts (UFAs). The UFAs were initially established in the Prescription Drug User Fee Act (PDUFA), which was enacted in 1992. PDUFA authorized FDA to collect various user fees from companies that submit applications for certain human drug products. In the years that followed, PDUFA resources enabled a more modern and efficient approach to FDA's review of new drug applications. The user fees must be reauthorized every five years and often serve as vehicles for other FDA-related policies. The continuing resolution establishing the most recent five-year reauthorization did not include larger FDA policy riders, which left many key FDA policies unaddressed.

Provision: This bill includes many FDA policy priorities, including the following:

- Expanding the FDA's inspection authorities domestically and abroad
- Providing funding for the National Centers of Excellence in drug manufacturing
- Requiring diversity action plans for clinical trials
- Requiring the FDA to publish justifications of accelerated approvals
- Requiring baby formula makers to notify the FDA of supply disruptions within one week
- Providing the FDA with additional oversight and regulatory requirements for cosmetics
- Allowing FDA to engage external (third-party) reviewers to facilitate the review of future emergency use authorization requests for diagnostics, with ultimate decision-making authority remaining with the FDA.

While there were efforts to also address the Verifying Accurate Leading-edge IVCT Development (VALID) Act in the CAA 2023, it ultimately was not included in the final bill. The VALID Act is discussed in more detail below.

Advanced Research Projects Agency for Health

Background: Congress and the Administration have been working on a bipartisan basis to develop a new agency to conduct innovative, high-risk/high-reward research in the healthcare space called the Advanced Research Projects Agency for Health (ARPA-H). The proposed mission of ARPA-H is to make pivotal investments in breakthrough technologies, capabilities, resources and solutions that have the potential to transform important areas of medicine and health, and that cannot readily be accomplished through traditional research or commercial activity. This new agency is modeled after the Defense Advanced Projects Agency, which is famed for its nimbleness and for backing innovations that led to the creation of the internet.

Despite the lack of authorizing legislation, the CAA 2022 contained $6.5 billion in funding for ARPA-H, which will be allocated over three years. Following that allocation, the White House announced in the *Federal Register* that ARPA-H will be housed within the National Institutes of Health (NIH). ARPA-H will not be physically on the NIH campus, however, and the agency head will report directly to the Secretary of HHS. The Administration has stated that placing ARPA-H in an existing infrastructure such as NIH will assist with administrative processes, including human resources, payroll and general counsel work.

Provision: The bill would authorize the creation of ARPA-H and house it within NIH. The bill also specifies ARPA-H's management structure and identifies its goals, which would include fostering the development of new technologies, supporting breakthrough research to cure and treat diseases and disorders, and investing in high-risk/high-reward research. The bill states that ARPA-H would be an independent entity with its own director. It would not be located on the NIH campus and would have offices in at least three geographic areas.

PREVENT Pandemics Act

Background: The Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics (PREVENT Pandemics) Act was introduced in March 2022 by Senate HELP Committee Chair Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC) after an extensive series of exploratory hearings. The PREVENT Pandemics Act focuses on lessons from the COVID-19 pandemic and strengthening US public health, medical preparedness and response systems.

Provision: The CAA 2023 includes many provisions from the PREVENT Pandemics Act. Highlights include the following:

- Requiring that the director of the Centers for Disease Prevention and Control be Senate approved
- Establishing a White House Office of Pandemic Preparedness and Response Policy to advise the president on these issues
- Emergency use authorization transparency enhancements
- Provisions directing the Biomedical Advanced Research and Development Authority to maintain a "warm base" of critical pandemic equipment and supplies manufacturing
- Requiring the Strategic National Stockpile to periodically review and revise its contents to ensure contents are in working condition and ready to be deployed
- Encouraging the Strategic National Stockpile to enter into contracts or cooperative agreements with vendors (including manufacturers) to maintain and store products for the government.

Other Policies

Conrad 30

Background: The Conrad 30 waiver program allows J-1 foreign medical graduates to apply for a waiver of the two-year foreign residence requirement upon completion of the J-1 exchange visitor program. The program addresses the shortage of qualified doctors in medically underserved areas.

Provisions: This bill would extend the Conrad 30/J-1 visa waiver through September 30, 2023.

Community Project Funding

Background: Community Project Funding (CPF) is a source of grants for projects whose recipients and purposes are specifically identified by Members of Congress in an appropriations act. CPFs are also commonly referred to as earmarks. Many Members of Congress submit requests to fund CPFs in an appropriations act, but not all Members of Congress participate.

Provisions: CPFs were announced in this bill. A full list of approved CPFs can be found here.

Fiscal Offsets

The bill contains several sections intended to offset the cost of other provisions.

Medicare Sequester

The Budget Control Act of 2011 requires mandatory across-the-board reductions in certain types of federal spending, also known as sequestration. The Medicare sequester was set to be implemented through 2030. The CAA 2023 would extend the 2% Medicare sequester for the first six months of FY 2032 and would revise the sequester percentage up to 2% for FY 2030 and 2031, producing cost savings to fund other policies in the bill.

Medicaid Continuous Eligibility Unwinding

The Families First Coronavirus Response Act provided Medicaid programs a 6.2 percentage point increase in the federal share if states meet certain maintenance of eligibility (MOE) requirements that ensure continuous coverage for current enrollees. As a result, all Medicaid beneficiaries are continuously enrolled in Medicaid until the end of the COVID-19 PHE. This increase in Medicaid funds is available to states through the quarter in which the PHE ends. The MOE, including the continuous enrollment requirement, expires at the end of the month in which the PHE ends. CMS requires each state to develop a plan to resume operations post-PHE. It is estimated that as many as 18 million people could lose Medicaid coverage in the 14 months following the end of the PHE because they no longer meet Medicaid eligibility requirements or fail to make it through their state's redetermination process.

In the CAA 2023, Congress would allow states to begin Medicaid eligibility redeterminations and renewals as of April 1, 2023, regardless of whether the COVID-19 PHE has ended. The bill would phase down the increased FMAP from the 6.2 percentage point increase as follows:

- To a 5 percentage point increase from April 1, 2023, through June 30, 2023
- To a 2.5 percentage point increase from July 1, 2023, through September 30, 2023
- To a 1.5 percentage point increase from October 1, 2023, through December 31, 2023.

After December 31, 2023, there would be no additional increase in FMAP.

Under the CAA 2023, states would be allowed to begin the redetermination process earlier, but the bill would establish some guardrails. States would be required to use the most reliable sources of Medicaid beneficiary contact information, make good faith efforts to contact the beneficiary prior to disenrollment, comply with HHS requirements and procedures related to redeterminations and disenrollments, and meet CMS reporting requirements. States would be put on a corrective action plan if they fail to meet the guardrail requirements, and the increased FMAP percentage would be further reduced as an enforcement mechanism.

This provision is expected to save approximately $20.8 billion. These estimated savings were used to fund many other Medicaid policies in the bill, such as continuous eligibility for children and allowing states to permanently provide 12 months of post-partum coverage. The bill would also direct $7 billion to the Medicaid Improvement Fund.

The decreasing FMAP payments incentivize states to proceed with an accelerated timeline for Medicaid redeterminations and renewals regardless of whether the COVID-19 PHE ends in April 2023. However, most anticipate that the PHE will end around that timeframe. That said, Medicaid enrollees could lose Medicaid coverage earlier than under current law. These individuals will need to transition to another form of coverage or become uninsured. Expect ongoing congressional

oversight on this issue in the new Congress, as well as potential congressional intervention depending on how the redetermination process proceeds.

Medicare Improvement Fund

The legislation would spend $7 billion from the Medicare Improvement Fund, leaving only $180 million available in the fund. This would not leave much in the way of funding for additional priorities.

Missing Provisions

As in any negotiation, compromises were made. Stakeholders and their congressional champions sought several priorities that ultimately were omitted from the package. Following is a selection of the more significant and frequently discussed items that did not make the final cut, but which are expected to feature in health policy discussions heading into 2023.

Prior Authorization Protections

The Improving Seniors' Access to Timely Care Act passed the House in September 2022 with broad bipartisan support. The Congressional Budget Office, however, found that the bill's projected cost would increase federal spending by $16.2 billion over the next 10 years, a higher cost than many anticipated. This cost estimate was a major reason the bill was not included in the CAA 2023.

Since September 2022, CMS has proposed new regulations that implement some of the provisions in the Improving Seniors' Access to Timely Care Act. If Congress chooses to pursue this legislation in 2023, the change in the regulatory environment may lower the package's cost and increase the chances of passage.

VALID Act

The VALID Act of 2021 (H.R. 4128) would create a new regulatory framework for the review and approval of diagnostic laboratory tests in an effort to accelerate the development of new technologies, while protecting public health and ensuring that Americans can rely on the test results they receive. The bill's sponsors, FDA and stakeholders have sought to achieve consensus on VALID for more than four years. Advocates for VALID were pleased when it was attached to the FDA UFA legislation during consideration by the Senate HELP Committee earlier in 2022. Although the legislative package passed out of the HELP Committee, Ranking Member Burr (R-NC) (the top Republican on the committee) voted against the bill, causing the committee to attempt to further negotiate an agreement. While there was agreement on many provisions of the VALID Act, ultimately its challenges proved impossible to overcome before the end of the year, and it did not make it into the CAA 2023.

Home Health Payment Cut Delay

The Preserving Access to Home Health Act of 2022 (S. 4605/H.R. 8581) was introduced earlier in 2022 to prevent CMS from implementing any permanent or temporary adjustment to home health prospective payment rates prior to 2026. The CY 2023 Medicare Home Health rule imposed cuts to Medicare home health payments by an aggregate 4.2%. However, instead of imposing a significant rate cut of approximately 4.2%, as was included in the home health proposed rule, CMS finalized an increase in calendar year 2023 Medicare payments to home health agencies by 0.7% in comparison to calendar year 2022. Accordingly, lawmakers did not address Medicare home health payments in the CAA 2023. CMS signaled that it will phase in other cuts and permanent adjustments to home health in future years, however, so this topic may become an issue for future legislation.

COVID-19 and Provider Relief Funding

The bill does not include additional COVID-19 or provider relief funding to support providers continuing to combat the impacts of the COVID-19 pandemic, including revenue losses, workforce shortages and increased costs to the healthcare system. Providers will likely continue to advocate for additional funding to support their operations.

COVID-19 Waiver Authority

On March 13, 2020, at the beginning of the COVID-19 pandemic, the Secretary of HHS invoked authority to waive or modify certain requirements of the Medicare, Medicaid and CHIP programs to ensure that sufficient healthcare items and services were available to meet the country's needs. Many programs, flexibilities and reimbursement policies are tied to this authority through Section 1135 waivers. This authority took effect as of 6 PM EST on March 15, 2020, with a retroactive effective date of March 1, 2020. When the COVID-19 PHE ends, these Section 1135 waivers will no longer be available. It is expected that the COVID-19 PHE will end in 2023. Congress did not address the potential end date of many of these Section 1135 waivers in the CAA 2023, and will likely have to examine the continuation of these programs, flexibilities and policies in 2023.

Conclusion

The CAA 2023 is the final major piece of legislation of the 117th Congress. The omnibus funding and health legislation reflects two realities: First, Democrats are still in control of Congress. The healthcare provisions in the omnibus certainly reflect several Democratic priorities. Second, the legislation is more expansive than may have been predicted a week ago. That spotlights an interest among Senate Republicans to accomplish as much as possible now in order to minimize the need for an extensive healthcare package a year from now.

For healthcare stakeholders, this bill is a reminder that legislation where everyone gets everything they want is exceedingly rare. Stakeholders will find provisions that are positive and some that are negative. It is reasonable to conclude that Congress collectively is more comfortable making formulaic cuts to the healthcare sector then they might have been five years ago. That trend could certainly extend into the next Congress.

Looking ahead to 2023, we can expect a year-end healthcare bill to come before Congress with disproportionate share hospital cuts needing to be addressed, along with several other extenders. External factors—some anticipated, some not—may also cause Congress to consider additional health legislation in 2023. However, after a congressional session in which hundreds of billions of dollars devoted to the healthcare space were discussed regularly, stakeholders should prepare for the severe whiplash that is likely coming. Finding consensus on healthcare packages in a divided Congress, not to mention offsets to finance any such agreements, will likely be very difficult.