

MEMORANDUM

To: Powers Clients and Friends
From: Legislative Practice Group
Date: January 14, 2021
Re: **Summary of Health Provisions in the Consolidated Appropriations Act, 2021 (2021 Omnibus), including COVID-19 Relief/Stimulus**

On December 21, 2020, Congress voted to pass a nearly \$1.4 trillion “omnibus” spending package to fund the federal government through the remainder of Fiscal Year (FY) 2021, which includes legislation to provide an additional \$900 billion in stimulus funds and relief policies to respond to the COVID-19 pandemic as well as a swath of additional provisions addressing year-end priorities for both chambers. After releasing the 5,500-page text of the legislation the morning on December 21, the House passed the legislation that night in two separate votes, passing the appropriations bills for Commerce, Justice, Science, Defense, Financial Services, Energy, Interior, and Related Agencies by a vote of 327-85 and the rest of the package by a vote of 359-53. The Senate passed the full package late that evening by a vote of 92-6. After initially expressing his opposition to the package, in particular the amount of COVID-related direct payments to individuals, President Trump signed the legislation into law on December 27, averting a federal government shutdown.

The full text of the legislation can be found [here](#). The following is a summary of key legislative provisions in this omnibus bill, focusing on the impact for the health care sector. This memorandum does not include a review of the non-COVID-19 related FY 2021 appropriations. A separate document summarizing the changes to the Paycheck Protection Program (PPP) can be found [here](#). Use the hyperlinks below to jump directly to specific sections.

- I. [Coronavirus Response and Relief Supplemental Appropriations](#)
 - a. [COVID-19 Vaccine Development, Purchase, and Distribution](#)
 - b. [Distributing and Tracking the Uptake of the COVID-19 Vaccine](#)
 - c. [Testing and Contact Tracing](#)
 - d. [Substance Abuse and Mental Health Response to COVID-19](#)
- II. [Additional Coronavirus Response and Relief](#)
 - a. [Paycheck Protection Program and Other COVID-19 Stimulus Provisions](#)
 - b. [Telehealth Policies](#)
 - c. [Additional Health Care Policies for COVID-19 Relief](#)
- III. [Private Health Insurance and Public Health Provisions](#)
 - a. [Surprise Medical Billing Reform](#)
 - b. [Health Care Transparency Requirements](#)
 - c. [Additional Public Health Provisions](#)
 - d. [FDA Amendments](#)

- IV. Health Extenders
 - a. Public Health Extenders
 - b. Medicare Extenders
 - c. Medicaid Extenders
 - d. Human Services Programs
 - e. Other Medicare Provisions
 - f. Other Medicaid Provisions
 - g. Health Care Offsets
 - h. Implementation Funding

This bill represents the latest action by Congress and the Trump Administration to respond to the COVID-19 public health crisis and related economic impact. For the latest news and insights from the Powers Law Firm, please visit our COVID-19 resource page:

<https://www.powerslaw.com/covid-19/>.

The Consolidated Appropriations Act, 2021

I. Division M – Coronavirus Response and Relief Supplemental Appropriations Act, 2021

The omnibus package includes both a government funding package for Fiscal Year 2021, and a separate, supplemental appropriations package specifically addressing COVID-19 response and relief. The funding provisions in Title III of this division, funding for the Department of Health and Human Services (HHS), will significantly impact almost all sectors in the health care industry.

COVID-19 Vaccine Development, Purchase, and Distribution

- **Nearly \$23 billion** for the Assistant Secretary for Preparedness and Response (ASPR), of which:
 - **Approximately \$20 billion** can be used to manufacture, produce, and purchase vaccines, therapeutics, and ancillary supplies. This funding can also be used for the construction and renovation of U.S.-based manufacturing facilities.
 - **\$3.25 billion** shall be used to purchase vaccines, therapeutics, and supplies for the Strategic National Stockpile, which can be used as an emergency stopgap to fill holes in the national supply chain.
- **\$1.25 billion** for the National Institutes of Health (NIH) to research the long-term impact of COVID-19 and to enhance the rapid development and acceleration of COVID-19 diagnostics. This could have significant implications for the rehabilitation research community to address long-term functional loss incurred by some COVID-19 patients.
- **\$55 million** for the Food and Drug Administration (FDA) to develop and review COVID-19 vaccines and therapies. This funding includes:
 - **\$9 million** for the development of vaccines and other medical countermeasures
 - **\$30.5 million** to support manufacturing of medical products that can improve drug quality, address shortages of medicines, and speed time to market for vital COVID-19 medicines and vaccines.

Distributing and Tracking the Uptake of the COVID-19 Vaccine

- **\$8.75 billion** to the Centers for Disease Control and Prevention (CDC) to support states in planning for, promoting, distributing, administering, and monitoring COVID-19 vaccines to ensure coverage. Of the funding allocated for distributing and tracking the vaccine, at least **\$4.5 billion** should be distributed to states, localities, territories, tribes, and tribal organizations. Of the amount provided to states, at least:
 - **\$300 million** is allocated for high-risk and underserved populations, including racial and ethnic minority populations and rural communities.
 - **\$210 million** is allocated for transfer to the Indian Health Service (IHS) to support tribes and tribal organizations.
- The bill also requires that the CDC Director provide an updated and comprehensive COVID-19 vaccine distribution strategy and a spending plan that should include the use of and enhancements to existing infrastructure, how to move and store the vaccine, and guidance for states, localities, territories, and tribes on how to prepare, store, and administer the vaccine.

Testing and Contact Tracing

- **\$22.4 billion** in additional funding to states, localities, territories, tribes, and tribal organizations for testing, contact tracing, surveillance, containment, and mitigation to prevent COVID-19. Of the additional funding:
 - **\$2.5 billion** is allocated to improve testing and contact tracing in high-risk communities and underserved populations, including racial and ethnic minority populations and rural communities.
 - **\$790 million** is provided specifically for the IHS to support tribes and tribal organizations in their COVID-19 response.
- The bill also requires that states receiving COVID-19 funding must update their testing and contact tracing plans and continue to update those plans on a quarterly basis.

Substance Abuse and Mental Health Response to COVID-19

- **\$4.25 billion** to the Substance Abuse and Mental Health Services Administration (SAMHSA) to improve mental health and substance abuse services in the COVID-19 response. The funding includes:
 - **\$3.3 billion** in additional resources for substance abuse and mental health block grants
 - **\$600 million** in funding for community behavioral health clinics
 - **\$50 million** in additional support for school-based mental health services
 - **\$10 million** for addressing child traumatic stress.
- This section also requires that no less than **\$125 million** be allocated to tribes and tribal organizations to provide behavioral health services to tribes.

II. Division N – Additional Coronavirus Response and Relief

Paycheck Protection Program and Other COVID-19 Stimulus Provisions

The omnibus provides an additional **\$285 billion** for eligible loans provided via the Paycheck Protection Program (PPP), originally created in the CARES Act. The PPP provisions also extend

the eligibility criteria, creating new qualified borrowers, and allow certain smaller businesses whose loans were previously forgiven to apply for “second draw” PPP loans. These second loans are now capped at \$2 million per recipient, but first-time applicants are still able to seek forgivable loans up to \$10 million. The bill also clarifies that the amount of a forgiven PPP loan will be considered exempt from gross income for tax purposes *and* that business expenses paid using funds from a forgiven PPP loan will be tax deductible. For more details about the new provisions governing the PPP, read our summary [here](#).

The omnibus includes several other general financial relief provisions, including:

- **\$20 billion** in new appropriations for targeted Economic Injury Disaster Loans (EIDL) grants for small business operating in low-income communities
- Another round of direct payments totaling **\$600 per individual** earning less than \$75,000 annually, with gradual phase-outs for those earning higher incomes
- Extension of the federal enhancement for Unemployment Insurance (UI), providing an additional **\$300 per week** for individuals receiving state or local UI through March 14, 2021.

Telehealth Policies

- **FCC Activities** – Sec. 901 appropriates **\$65 million** to the Federal Communications Commission (FCC) to create broadband data maps required under the Broadband DATA Act, and **\$1.9 billion** for the FCC’s Secure and Trusted Communications Network Reimbursement program.
- **Minority Communities** – Sec. 902 establishes an Office of Minority Broadband Initiatives at the National Telecommunications and Information Administration (NTIA) to focus on increasing broadband access and adoption at Historically Black Colleges or Universities (HBCUs), Tribal colleges and universities, and other minority-serving institutions. It also appropriates **\$285 million** for a Pilot Program to award grants to these institutions and certain businesses and nonprofits in the community to support connectivity.
- **FCC COVID-19 Telehealth Program** – Sec. 903 appropriates an additional **\$250 million** for the FCC’s COVID-19 Telehealth Program, originally authorized under the CARES Act. It also establishes significant new transparency and reporting requirements regarding the FCC’s review of applications and directs the Commission to ensure that all states benefit from the program to the extent feasible.
- **Benefit for Broadband Service During COVID-19 PHE** – Sec. 904 establishes a temporary FCC Emergency Broadband Benefit Program for Low-Income Americans, under which eligible households may receive a discount of up to \$50 (or up to \$75 on Tribal lands) off the cost of internet service and a subsidy for low-cost devices such as computers and tablets. Internet service providers who provide the discounted service or devices can receive a reimbursement from the FCC for such costs. This section appropriates **\$3.2 billion** for the program.
- **Grants for Broadband Connectivity** – Sec. 905 establishes two programs at NTIA: a **\$1 billion** grant program to support broadband connectivity on tribal lands; and a **\$300**

million broadband deployment program to support infrastructure in areas that lack broadband, especially rural areas.

Additional Health Care Policies for COVID-19 Relief

- **Provider Reimbursement Cuts in the 2021 Physician Fee Schedule** – Prior to the enactment of the omnibus, the 2021 Physician Fee Schedule (PFS) rule finalized by the Centers for Medicare and Medicaid Services (CMS) included increases to reimbursement for evaluation and management (E/M) services, which in turn would decrease overall reimbursement for PFS services due to the statutory “budget neutrality” requirement. These cuts were estimated to have significant impacts in 2021 for certain specialties, including therapists (7-9% decreases in reimbursement on average), psychiatrists (3% decreases on average), and other specialties facing up to 11% cuts.
 - Sec. 101 provides for a temporary 3.75% increase to *all* PFS services to mitigate the impact of the budget neutrality cuts by transferring **\$3 billion** into the Fee Schedule for 2021.
 - Division CC, Title I, Subtitle B, Sec. 113 also delays the implementation of a “complex patient add-on code” until 2024, which will further reduce the impact of the budget neutrality cuts by approximately 3%.
 - While some specialties will still see a decrease in their 2021 reimbursement, this provision is viewed as a temporary win for provider groups opposing the cuts, and there will likely be additional pressure by providers on Congress to further address the issue in the new year.
- **Delay of Medicare Sequestration Cuts** – Sec. 102 temporarily delays scheduled sequestration cuts of 2% on all Medicare provider reimbursement until March 31, 2021. The cuts were previously set to come into effect on December 31, 2020.

III. Division BB – Private Health Insurance and Public Health Provisions

Surprise Medical Billing Reform (Title I)

After more than a year of congressional negotiations resulted in gridlock, the omnibus included the “No Surprises Act,” a bipartisan compromise to address so-called “surprise” or “balance” medical bills; both refer to costly bills patients may receive after unknowingly receiving out-of-network care. Historically, patients have been responsible for the “balance” between the provider’s charge and their health plan’s in-network reimbursement rate for out-of-network services. The No Surprises Act requires that health plans hold patients “harmless” from surprise bills, requiring individuals to pay only the in-network cost-sharing amount for out-of-network emergency care, ancillary services provided at in-network facilities by out-of-network providers, and out-of-network care provided at in-network facilities without a patient’s informed consent. These protections also apply to air ambulance services, but not ground ambulance services.

The bill provides for a 30-day negotiation period for providers and payers to settle out-of-network claims. If no agreement is reached after this period, either party may opt for a binding independent dispute resolution (IDR) process. The third-party IDR reviewer must consider the

market-based median in-network rate for the service(s) at issue, as well as other factors such as the provider's training and experience, patient acuity, and prior contracted rates. In addition, the No Surprises Act includes new transparency requirements for health plans to communicate in-network and out-of-network deductibles, as well as out-of-pocket caps. The bill also includes language requiring health plans to have publicly available, online, and up-to-date directories for their in-network providers and to offer a price comparison tool for consumers.

Health Care Price Transparency Requirements (Title II)

- **Increasing Transparency by Removing Gag Clauses on Price and Quality Information** – Sec. 201 bans restrictions in contracts between health care providers and group health plans that would prevent the provider or enrollees from receiving cost or quality of care information and data.
- **Disclosure of Direct and Indirect Compensation for Brokers and Consultants to Health Plans and Enrollees** – Sec. 202 requires a covered service provider to disclose to a responsible health plan sponsor any direct or indirect compensation provided to a broker or agent associated with enrolling individuals in the plan. This section also requires a health insurance issuer to disclose to an enrollee, prior to finalization of a plan selection, the amount of direct or indirect compensation provided to an agent or broker associated with a plan received for the enrollment of the individual.
- **Strengthening Parity in Mental Health and Substance Use Disorder Benefits** – Sec. 203 requires group health plans or health insurance issuers that cover mental health or substance use disorder (SUD) benefits and impose non-quantitative treatment limitations (NQTLs) on such services to conduct a comparative analysis of the design and application of NQTLs to determine compliance with the mental health parity law. This legislation requires that NQTLs for mental health and SUDs not be applied more stringently than the application of NQTLs for medical or surgical benefits. The Secretaries of HHS, Labor, and the Treasury must request at least 20 health plans or insurers per year to submit these analyses. If the Secretaries find that the health plan or insurer is not in compliance with the mental health parity law, the plan or issuer must then notify all enrollees of their noncompliance.
- **Reporting on Pharmacy Benefits and Drug Costs** – Section 204 requires that group health plans or health insurance issuers offering group or individual health insurance coverage submit to the Secretaries of HHS, Labor, and the Treasury information on prescription drug spending, including:
 - The 50 prescription drugs that are most frequently dispensed by pharmacies;
 - The 50 prescription drugs that are most costly; and
 - The 50 prescription drugs with the greatest increase in plan expenditures over two plan years.

Health plans and issuers must also report total health care spending by type of costs, including costs and spending on prescription drugs, and share any impacts on premiums due to rebates, fees, and other remuneration paid by drug manufacturers to the plan. This section also states that the Assistant Secretary of Planning and Evaluation (ASPE), in coordination with the HHS Office of Inspector General (OIG), shall publish a report on

the HHS website that covers prescription drug pricing trends and the role of prescription drug costs in contributing to premium increases or decreases.

Additional Public Health Provisions (Title III, Subtitle B)

- **Improving Awareness of Disease Prevention** – Sec. 311 directs HHS and CDC to award grants for a national, evidence-based campaign to increase awareness and knowledge of vaccine safety and effectiveness. This section authorizes **\$15 million per year** through FY 2025 to conduct the campaign(s).
- **Guide on Evidence-Based Strategies for Obesity Prevention Programs** – Sec. 312 directs the CDC to develop a guide on evidence-based strategies for state, territorial, and local health departments to maintain effective obesity prevention and reduction programs, including specific resources for tribes and tribal organizations.
- **Expanding Capacity for Health Outcomes** – Sec. 313 authorizes an HHS grant program to expand the use of technology-enabled collaborative learning and capacity building models to improve the retention of health care providers and increase access to specialty health care services in rural areas, health professional shortage areas, and medically underserved areas. This section also requires a report four years after enactment of the grants awarded under the program, the activities conducted by recipients, and any significant findings. The program will receive **\$10 million per year** for FY 2022-2026.
- **Public Health Data System Modernization** – Sec. 314 requires the CDC to modernize and improve interoperability for its public health data systems, and to award grants for the improvement of state, local, tribal, and territorial public health data systems. This section also requires the CDC to work with the Office of the National Coordinator for Health Information Technology (ONC) to develop public health data standards. **\$100 million per year** for FY 2021-2025 is authorized to carry out these provisions.
- **Native American Suicide Prevention** – Sec. 315 modifies an existing suicide prevention and mental health services grant program to require applicants to consult with Native American health systems when developing a statewide early intervention strategy.

FDA Amendments (Title III, Subtitle C)

- **Rare Pediatric Disease Priority Review Voucher Extension** – Sec. 321 allows the FDA to continue to provide vouchers to expedite the review of drugs that treat rare pediatric diseases.
- **Conditions of Use for Biosimilar Biological Products** – Sec. 322 allows biosimilar applications to include information showing that the proposed conditions the biological product will treat have been previously approved for the “reference product,” or the product the FDA has already approved to which the biosimilar product will be compared.
- **Orphan Drug Clarification** – Sec. 323 clarifies that all drugs with an orphan drug designation that were approved after the enactment of the FDA Reauthorization Act of 2017 must meet the clinical superiority standard, which states that the drug provides a significant therapeutic advantage over the approved drug by being either more effective or safer for the target population.

- **Modernizing the Labeling of Certain Generic Drugs** – Sec. 324 allows the FDA to require a manufacturer to update a drug’s labeling to reflect new scientific evidence that is deemed to have a public health benefit. This section also requires that the labeling of a generic drug reflect labeling changes on its reference drug. The FDA must report on the drugs that were selected for labeling updates and provide a rationale for recommending the updates.
- **Biological Product Patent Transparency** – Sec. 325 requires the FDA to publish, via a public, searchable, electronic database, biological patent information including date of licensure, patent expiration date, marketing and licensure status, and exclusivity periods.

IV. Division CC – Health Extenders

The omnibus extends funding for several so-called “health extenders,” programs whose authorizations and/or funding were previously scheduled to lapse on December 21, 2020. The legislation extends many of these programs at current funding levels through the end of FY 2023. The health extenders and their funding levels are noted together here, though some are funded through provisions in Division BB as well.

- *Public Health Extenders (Division BB, Title III, Subtitle A)*
 - **Community Health Centers** (Sec. 301a) – extended at \$4 billion/year through FY 2023
 - **National Health Service Corps** (Sec. 301b) – extended \$310 million/year through FY 2023
 - **Teaching Health Center Graduate Medical Education Programs** (Sec. 301c) – extended at \$126.5 million through FY 2023
 - **Special Diabetes Program for Type I Diabetes** (Sec. 302a) - extended at \$150 million/year through FY 2023
 - **Special Diabetes Program for Indians** (Sec. 302b) - extended at \$150 million/year through FY 2023
 - **Young Women’s Breast Health Education and Awareness Program** (Sec. 316) - extended at \$9 million/year through FY 2026
 - **School-Based Health Centers** (sec. 317) – extended at “such sums as necessary” for FY 2022-2026.
 - **Rural Community Hospital Demonstration Program** (Subtitle B, Sec. 128) – extended for an additional five years. This provision also expands the eligibility of certain rural community hospitals for the demonstration.
 - **Frontier Community Health Integration Project Demonstration Program** (Subtitle B, Sec. 129) – extended for an additional five years. **\$10 million** in transfers from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund to CMS are authorized for the extension of this program.
- *Medicare Extenders (Title I, Subtitle A)*
 - **Work Geographic Index Floor** (Sec. 101) – extended through January 1, 2024

- **Funding for Quality Measure Endorsement, Input, and Selection** (Sec. 102) – extended at \$26 million for FY 2021 and \$20 million for FY 2022 and 2023 each. This provision also includes additional requirements for mandated reports to detail how CMS has addressed recommendations regarding quality metrics from the Government Accountability Office (GAO).
- **Funding Outreach and Assistance for Low-Income Programs** (Sec. 103) – These provisions include extended funding for state health insurance programs (\$15 million/year), area agencies on aging (\$15 million/year), aging and disability resource centers (\$5 million/year), and funding for Medicare’s contract with the National Center for Benefits and Outreach Enrollment (\$15 million/year) through FY 2023.
- **Medicare Patient Intravenous Immune Globulin (IVIG) Access Demonstration Project** (Sec. 104) – This demonstration project evaluating payment and items for services needed for the in-home administration of IVIG for patients with Primary Immune Deficiency Disease is extended through December 31, 2023.
- **Independence at Home Medical Practice Demonstration Project** (Sec. 105) – This demonstration project evaluating the effectiveness of delivering comprehensive primary care services at home for Medicare beneficiaries with multiple chronic conditions is extended for an additional three years.
- *Medicaid Extenders (Title II)*
 - **Delay of DSH Reductions** (Sec. 201) – Scheduled reductions in payments to Disproportionate Share Hospital (DSH) facilities are delayed until FY 2024.
 - **Money Follows the Person Rebalancing Demonstration Project** (Sec. 204) – This demonstration project providing funding for states to help seniors and people with disabilities move from institutions to the community is extended for an additional three years and funded at \$450 million/year through FY 2023. This provision also mandates a report from HHS by the end of FY 2022 containing best practices from the demonstration for transitioning beneficiaries from institutional to community settings and the most effective uses for grant funds, among other items, and a report from the Medicaid and CHIP Payment and Access Commission (MACPAC) on the types of home and community-based settings and associated services available to MFP participants and other beneficiaries.
 - **Spousal Impoverishment Protections** (Sec. 205) – These income protections for seniors living in the community with a spouse in an institutional setting are extended through FY 2023.
 - **Community Mental Health Services Demonstration Program** (Sec. 206) – This demonstration program evaluating the effectiveness of community behavioral health clinics is extended through FY 2023.
- *Human Services Programs (Title III)*
 - **Temporary Assistance to Needy Families (TANF) and Related Programs** (Sec. 301) – TANF, childcare entitlements to states, and other related programs

- authorized by Part A of Title IV and Section 1108(b) of the Social Security Act are extended through the end of FY 2021.
- **Personal Responsibility Education Program** (Sec. 302) – This program is extended through FY 2023.
 - **Sexual Risk Avoidance Education Program** (Sec. 303) – This program is extended through FY 2023.
 - **Health Professions Opportunity Grants Program** (Sec. 304) – This grant program receives an additional \$3.6 million to cover costs relating to previously awarded grants and required research, evaluation, and reporting activities.
 - **Marylee Allen Promoting Safe and Stable Families Program** (sec. 305) – This program is extended through 2022.

Other Medicare Provisions (Title I, Subtitle B)

- **Post-Acute Care Value-Based Payment Report** – Sec 111 includes a requirement that the Medicare Payment Advisory Commission (MedPAC) submit a report by March 15, 2022 on a value-based payment program for a unified post-acute care (PAC) prospective payment system. The report must include relevant metrics, methodologies for scoring provider performance, and the impacts of implementing a prototype program. A legislative effort in the House Ways and Means Committee two years ago to create a value-based payment system for post-acute care services never materialized but appears to have been resurrected in this legislation.
- **Improving Measurements Under the SNF Value-Based Purchasing Program** – Sec. 111 also modifies the requirements for facilities to participate in the skilled nursing facility (SNF) value-based purchasing program and authorizes HHS to develop additional measures as deemed necessary.
- **Providing MedPAC and MACPAC with Access to Certain Drug Payment Information** – Sec. 112 provides the MedPAC and MACPAC executive directors with access to additional prescription rebate data for the purposes of making recommendations on prescription drug policies.
- **Temporary Freeze of APM Payment Incentive Thresholds** – Sec. 114 temporarily freezes the thresholds for participation in alternative payment models (APMs) through 2024. The percentage of payments for services furnished via an eligible APM entity to qualify for APM participation were scheduled to increase beginning in 2023 and are now set to increase beginning in 2025.
- **Assessments by Occupational Therapists** – Sec. 115 directs HHS to promulgate regulations to permit occupational therapists (OTs) to perform both the initial assessment visit and the comprehensive assessment required for home health services if a beneficiary's home health care plan does not initially include skilled nursing care but does include both occupational therapy and physical therapy or speech language pathology. These regulations are required to go into effect by January 1, 2022.
- **Provider Outreach and Reporting on Cognitive Assessment and Care Plan Services** – Sec. 116 directs HHS to conduct outreach to physicians and certain non-physician practitioners participating in Medicare regarding payment policies for cognitive

assessment and care plan services reported by Healthcare Common Procedure Coding System (HCPCS) code 99483. This section also requires a report from HHS on the outreach conducted, and a report from GAO on the number of beneficiaries who received these services and any recommendations for legislative and administrative action.

- **Continued Coverage of Certain Temporary Transition Home Infusion Therapy Services** – Sec. 117 ensures continued coverage of home infusion therapy services for drugs administered intravenously or subcutaneously through an external infusion pump until the implementation of the permanent home infusion therapy benefit in 2021, as established by the 21st Century Cures Act.
- **Transitional and Retroactive Part D Coverage for Low-Income Beneficiaries** – Sec. 118 permanently authorizes CMS’ Limited-Income Newly Eligible Transition (LI NET) demonstration project, which provides temporary drug coverage for individuals who qualify for Medicare’s low-income subsidy and are eligible for either both Medicare and Medicaid (dual-eligible beneficiaries) or both Medicare and Supplemental Security Income (SSI). Coverage is both retroactive and temporary until the individual enrolls in a Medicare Part D plan.
- **Increasing the Use of Real-Time Benefit Tools to Lower Beneficiary Costs** – Sec. 119 requires that Medicare Part D prescription drug plans implement real-time benefit tools to help individual enrollees compare the cost of their drug to a clinically-appropriate alternative, compare the cost of their prescription at various pharmacy locations, and understand if there are prior authorization requirements for their drug.
- **Beneficiary Enrollment Simplification** – Beginning in January 2023, Sec. 120 requires that Medicare Part B insurance coverage begin the first month following an individual’s enrollment to limit any coverage gaps. This section also allows Medicare to implement special enrollment periods for Medicare Parts A and B insurance to ensure continuity of health care coverage.
- **Waiving Budget Neutrality for Oxygen Under Medicare** – Sec. 121 waives the statutory budget neutrality requirement for HHS to establish separate classes and payment rates for oxygen and oxygen equipment.
- **Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests** – Sec. 122 gradually eliminates the cost-sharing requirement for colorectal cancer screening tests for Medicare beneficiaries when a polyp is detected or removed. Cost-sharing will start to be eliminated beginning 2022 and slowly phased out by 2030.
- **Expanding Access to Mental Health Services Furnished via Telehealth** – Sec. 123 provides an exemption from Medicare’s requirement that, after the PHE declaration is lifted, individuals eligible for telehealth for purposes of diagnosis, evaluation, or treatment of a mental health disorder must be located in a designated rural area. Instead, they will also be allowed to receive reimbursable telehealth services in their homes. This same exception already exists for eligible individuals with an SUD diagnosis or co-occurring mental health disorder. However, under this provision, the physician or practitioner would still need to have furnished an in-person item or service to the individual within six months prior to the first time they provide telehealth services to that individual, as well as during subsequent periods.

- **Public-Private Partnership for Health Care Waste, Fraud, and Abuse Detection** – Sec. 124 codifies in legislation and expands HHS’ Fraud and Abuse Program. This program’s purpose is to detect fraud and waste in health care plans. This provision establishes a public-private partnership made up of health plans, federal and state agencies, and law enforcement agencies. The partnership will support data sharing and analyses to identify waste, fraud, and abuse. This section also tasks the Fraud and Abuse Program with analyzing potential fraudulent billing for substance use providers.
- **Medicare Payment for Rural Emergency Hospital Services** – Sec. 125 creates a new voluntary Medicare payment designation, Rural Emergency Hospital (REH), in an effort to preserve beneficiary access to emergency services in rural locations that can no longer support a fully functional inpatient hospital. The new payment designation allows a Critical Access Hospital (CAH) or a rural hospital with less than 50 beds to apply to convert to an REH and be reimbursed based on the Medicare Outpatient Prospective Payment System (OPPS) plus 5 percent to reflect higher costs of such hospitals. To be considered an REH, the facility must not provide any acute inpatient care, must have a transfer agreement with Level I or II trauma centers, and must meet certain emergency staffing requirements. An REH may provide observation care, SNF services, ambulance services, and telehealth services. REHs will also be deemed a telehealth originating site.
- **Distribution of Additional Residency Positions** – Sec. 126 authorizes the distribution of additional residency positions for certain hospitals, for which Medicare will pay the costs relating to direct graduate medical education (GME). Beginning in FY 2023, HHS may allocate additional positions to applicant facilities, with specific distributions required for rural hospitals, hospitals in health professional shortage areas, and certain other facilities.
- **Promoting Rural Hospital GME Funding Opportunity** – Sec. 127 provides additional flexibility for nonrural hospitals operating training programs in rural areas to receive Medicare funding for GME costs.
- **Improving Rural Health Clinic Payments** – Sec. 130 reforms the Rural Health Clinic (RHC) payment reform plan by phasing in an increase to the RHC statutory cap over an eight-year period to put RHCs more in line with Federally Qualified Health Centers (FQHCs). Under current law, RHCs receive payment based on a maximum payment rate per visit, which is updated annually based on the Medicare Economic Index (MEI) percentage. This reform raises the statutory RHC cap to \$100 starting on April 1, 2021, and gradually increases the upper limit each year through 2028 until the cap reaches \$190.
- **GME Treatment of Hospitals with New Residency Programs** – Sec. 131 establishes authority for hospitals to host a limited number of residents for short-term rotations without being negatively impacted by resident caps or per resident amounts.
- **Medicare Payment for Certain FQHC and RHC Services Furnished to Hospice Patients** – Sec. 132 allows for FQHCs and RHCs to bill for physician-provided hospice services if the provider is employed by or working under contract with the FQHC or RHC.
- **Delay of the Medicare Radiation Oncology Model** – Sec. 133 delays the implementation of CMS’ radiation oncology model by six months, to January 1, 2022. The model tests whether bundled, prospective, site-neutral, modality-agnostic, and

episode-based payments for radiotherapy reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries.

- **Improving Access to SNF Services for Hemophilia Patients** – Sec. 134 adds blood clotting factors and services and items furnished for treating patients with hemophilia and other bleeding disorders to the list of services excluded from the SNF per-diem prospective payment system and clarifies that these items and services are separately payable.

Other Medicaid Provisions (Title II)

- **Supplemental Payment Reporting Requirements** – Sec. 202 directs HHS to develop a system for states to submit reports on supplemental payments under Medicaid as a requirement for state plans or plan amendments that provide for supplemental payments. The system will be publicly available on the CMS website and will collect information regarding how supplemental payments are made, the criteria for providers to receive supplemental payments, methodologies to calculate the payments, and more.
- **Medicaid Shortfall and Third-Party Payments** – Sec. 203 revises the methodology for calculating Medicaid shortfall payments to account for uncompensated costs.
- **Clarifying Authority of State Medicaid Fraud and Abuse Control Units** – Sec. 207 allows Medicaid Fraud Control Units (MFCUs), which operate in all 50 states and investigate and prosecute Medicaid fraud and patient abuse and neglect, to investigate complaints in non-institutional settings.
- **Medicaid Coverage for Citizens of Freely Associated States** – Sec. 208 restores Medicaid eligibility for citizens in the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.
- **Medicaid Coverage of Certain Medical Transportation** – Sec. 209 allows state Medicaid programs to cover medically necessary but non-emergency transportation for patients. The rule also requires a GAO study to assess and identify safeguards to prevent fraud and abuse in regard to coverage of non-emergency transportation services, and for CMS to set up a stakeholders’ meeting to facilitate a discussion about best practices for implementing this provision.
- **Promoting Access to Lifesaving Therapies for Medicaid Enrollees Participating in Clinical Trials** – Sec. 210 requires state Medicaid programs to cover routine patient costs for individuals enrolled in a qualifying clinical trial to determine prevention or treatment for serious, life-threatening diseases or conditions, including costs relating to efforts to prevent, diagnose, or monitor complications from conditions arising from participation in the trial. The covered patient costs must be tied to the clinical trial.

Health Care Offsets (Title IV)

- **Reporting of Drug Pricing Information** – Sec. 401 requires all drug manufacturers to report average sales price (ASP) for drugs and biologics covered under Medicare Part B. It also adds a new requirement that drug manufacturers without a rebate agreement must report ASP. Failure to report information or reporting false information will trigger a fine.

- **Coverage of Immunosuppressive Drugs for Kidney Transplant Patients** – Sec. 402 extends Medicare eligibility for coverage of immunosuppressive drugs for post-kidney transplant patients who do not otherwise have health care insurance. These patients were previously covered under Medicare by having end-stage renal disease (ESRD) prior to their transplant, but only received 36 months of coverage for these drugs post-transplant. Individuals seeking Part B coverage for immunosuppressive drugs will receive coverage beginning January 1, 2023 or the month following when an individual enrolls for coverage and the premium will be equal to 15 percent of the actuarial rate for enrollees age 65 and older.
- **Permitting Direct Payment to Physician Assistants Under Medicare** – Sec. 403 authorizes direct payments to physician assistants for services furnished to Medicare beneficiaries beginning January 1, 2022.
- **Adjusting Hospice Cap Amount Under Medicare** – Sec. 404 extends the existing adjustment methodology for calculating the Medicare hospice aggregate cap amount through 2030.
- **Determination of ASP for Self-Administered Drugs** – Sec. 405 authorizes CMS to exclude self-administered or otherwise non-covered drugs under Medicare Part B when setting payment for Part B drugs. To determine which drugs can be excluded, this policy authorizes the OIG to conduct periodic reviews to identify National Drug Codes for self-administered drugs which are not covered under Part B.
- **Medicaid Improvement Fund** – Sec. 406 rescinds **\$3.46 million** from the Medicaid Improvement Fund.
- **Establishing Hospice Program Survey and Enforcement Procedures** – Sec. 407 creates a new set of requirements for survey and certification of hospice programs at least every three years. This section also increases payment reductions for hospice programs that fail to meet quality data reporting requirements.
- **Medicare Improvement Fund** – Sec. 408 authorizes **\$165 million** for the Medicare Improvement Fund in order to make improvements to the fee-for-service Medicare program.

Implementation Funding (Title V)

Sec. 501 provides \$37 million to CMS to support implementation of the Medicare and Medicaid provisions in the bill.

For further questions regarding the omnibus package or any other COVID-19 related issues, please contact any Powers professional with whom you normally work. Contact information for all professionals and practice groups can be found at <https://www.powerslaw.com/professionals/>.

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