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News

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Summary of Health Care Provisions in the Consolidated Appropriations Act of 2021

Last night, Congress passed a $900 billion COVID-19 relief bill along with $1.4 trillion in appropriations legislation to fund the government. The relief bill includes billions for COVID-19 testing, vaccine administration and relief for health care providers, in addition to surprise medical billing legislation and extending funding for public health care programs. The following is a summary of the health care provisions in the legislation, including:

- Division BB: Private Health Insurance and Public Health Provisions
    - Title I: No Surprises Act (Sections 101-118)
    - Title II: Transparency (Sections 201-204)
    - Title III: Public Health Provisions
        - Subtitle A: Extenders (Sections 301,302)
        - Subtitle B: Strengthening Public Health (Sections 311-317)
        - Subtitle C: FDA Amendments (Sections 321-325)
        - Subtitle D: Technical Corrections (Sections 331)
- Division CC: Health Extenders
    - Title I: Medicare Provisions
        - Subtitle A: Medicare Extenders (Sections 101-105)
        - Subtitle B: Other Medicare Provisions (Sections 111-134)
    - Title II: Medicaid Extenders and Other Policies (Sections 201-210)
    - Title III: Human Services (Sections 301-305)
    - Title IV: Health Offsets (Sections 401-408)
        - Title V: Miscellaneous (Section 501)

Division H – Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2021

Title II – Department of Health and Human Services

Overview of Title II: *This title appropriates funds to health care agencies, injecting an additional $73 billion to HHS to fight the COVID-19 pandemic. Congress also includes descriptive language in some cases to further explain how funds are to be expended. This title includes:*

- $3 billion in additional funds to the Provider Relief Fund. The language also clarifies the definition of lost revenue for previous allocations from the fund, and allows hospital systems to transfer allocations from the fund among hospitals in their system.
- $22.4 billion into the Public Health and Social Services Emergency Fund for testing, contact tracing and surveillance.
- $19.697 to BARDA for vaccine, therapeutic and diagnostic development.
- $3.25 billion to the Strategic National Stockpile.
- $8.75 billion to the CDC for vaccine administration, $4.5 billion of which goes directly to states, localities and territories.
- $1.15 billion to the NIH for research on the long-term effects of COVID-19, and $100 million for Rapid Acceleration of Diagnostics (RADx).
- $4.25 billion to SAMHSA, including grant dollars for substance abuse prevention and emergency grants to states.
- $10.25 billion to the Administration for Children and Families for direct support to child care providers.

Division BB – Private Health Insurance and Public Health Provisions

TITLE I – NO SURPRISES ACT

Overview of Title I: *This title establishes a plan to protect patients from surprise medical bills, including air ambulance bills, while also ensuring a pathway for resolution of payment disputes for health care services. The title includes no benchmarking or rate-setting, rather it allows health care providers to initiate an open negotiation period, and if no resolution is reached within 30 days, to pursue an independent dispute resolution process. The independent resolution process decides an appropriate payment for services based on the facts and relevant data of each case. There is no dollar amount threshold to enter the open negotiation and independent dispute resolution process.*

Section 101: Short Title

- States that this title may be cited as the "No Surprises Act."
- Impact: None.

Section 102: Health Insurance Requirements Regarding Surprise Medical Billing

- Amends Title XXVII of the Public Health Service Act to require that health plans hold patients harmless from surprise medical bills, ensuring that patients are only required to pay the in-network cost sharing (i.e., co-payments, coinsurance and deductibles) amount for out-of-network emergency care, certain ancillary

services provided by out-of-network providers at in-network facilities, and out-of-network care provided at in-network facilities without the patient's informed consent.

- Requires that patients' in-network cost-sharing payments for out-of-network surprise bills are attributed to their in-network deductible.
- Requires the Secretary of Health and Human Services (HHS), in consultation with the of Labor and Treasury, to establish an audit process by Oct. 1, 2021, for group health plans and health insurance issuers offering group or individual health insurance coverage. Requires the HHS Secretary to submit annual reports to Congress on the audits beginning in 2022.
- Requires the HHS Secretary, in consultation with the Secretaries of Labor and Treasury, to establish payment methodologies for health plans and health insurance issuers by July 1, 2021.
- Impact: Protects patients from surprise medical bills, effective with respect to plan years beginning on or after Jan. 1, 2022, by requiring that patients pay no more than the in-network sharing amount for out-of-network care.

Section 103: Determination of Out-of-Network Rates to be Paid by Health Plans; Independent Dispute Resolution Process

- Provides for a 30-day open negotiation period for providers and payers to settle out-of-network claims. If the parties are unable to reach a negotiated agreement, they may access a binding arbitration process – referred to as Independent Dispute Resolution (IDR) – in which one offer prevails.
- Providers may batch similar services in one proceeding when claims are from the same payer.
- The IDR process will be administered by independent, unbiased entities with no affiliation to providers or payers. Payments must be made within 30 days of the date on which the IDR's determination is made.
- The IDR entity is required to consider the market-based median in-network rate, alongside relevant information brought by either party, information requested by the reviewer, as well as factors such as the provider's training and experience, patient acuity and the complexity of furnishing the item or service, in the case of a provider that is a facility, the teaching status, case mix and scope of services of such facility, demonstrations of good faith efforts (or lack thereof) to enter into a network agreement, prior contracted rates during the previous four plan years, and other items. Billed charges and public payer rates are excluded from consideration.
- Following IDR, the party that initiated the process may not take the same party to IDR for the same item or service for 90 days following a determination by the IDR entity, in order to encourage settlement of similar claims. All claims that occur during that 90-day period, however, may still be eligible for IDR upon completion of the 90-day period.
- Requires the Secretaries of HHS, Labor and Treasury to establish the IDR process within one year of the bill's enactment.
- Requires publication of information related to the IDR process and parties involved on the Treasury Department's website for each calendar quarter in 2022 and each calendar quarter in a subsequent year.
- Impact: Puts in place a binding arbitration process for providers and payers to settle out-of-network claims if a negotiated agreement is not able to be reached within 30 days of a notice of denial of payment or coverage being received by the provider or facility.

Section 104: Health Care Provider Requirements Regarding Surprise Medical Billing

- Prohibits out-of-network facilities and providers from sending patients surprise bills for more than the in-network cost-sharing amount, in the surprise billing circumstances defined in Sec. 102.
- Prohibits certain out-of-network providers from surprise billing patients unless the provider gives the patient notice of their network status and an estimate of charges 72 hours prior to receiving out-of-network services, and the patient provides consent to receive out-of-network care. Disclosure notices must be sent via postal or electronic mail, beginning no later than Jan. 1, 2022.
- In the case of appointments made within 72 hours of receiving services, the patient must receive the notice the day the appointment is made and consent to receive out-of-network care.
- Requires the Secretary of HHS to set up a complaint process for participants and beneficiaries of group health plans for alleged violations by Jan. 1, 2022.
- Impact: Prohibits out-of-network providers from surprise billing patients without providing them with a written notice, including an estimate of charges, in advance of receiving services, and sets up a complaint process for alleged violations.

Section 105: Ending Surprise Air Ambulance Bills

- States that patients are to be held harmless from surprise air ambulance medical bills.
- Patients are only required to pay the in-network cost-sharing amount for out-of-network air ambulances, and that cost-sharing amount is applied to their in-network deductible. Air ambulances are barred from sending patients bills for more than the in-network cost-sharing amount.
- Provides for a 30-day open negotiation period for air ambulance providers and payers to settle out-of-network claims. If the parties are unable to reach a negotiated agreement, they may access the binding arbitration, which is the same as outlined in Section 103, with additional factors to account for the cost of providing air ambulance service in rural and frontier areas.
- Impact: Ensures patients are held harmless from surprise air ambulance medical bills and sets up an IDR process, similar to that for hospital bills, if the dispute is not settled within a 30-day open negotiation period. This provision is effective with respect to plan years beginning on or after Jan. 1, 2022.

Section 106: Reporting Requirements Regarding Air Ambulance Services

- Requires air ambulance providers to submit two years of cost data to the Secretaries of HHS and Transportation and insurers to submit two years of claims data related to air ambulance services to the Secretary of HHS, beginning no later than 90 days after the last day of the first calendar year on or after the date on which the final rule is promulgated.
- Requires the Secretaries to publish a comprehensive report on the cost and claims data submitted within one year of the enactment of this bill.
- Establishes an advisory committee on air ambulance quality and patient safety within 60 days of the enactment of this bill, composed of the two Secretaries, appointees representing a state health insurance regulator, health care provider, group health plan and health insurance issuer, patient advocacy group, accrediting body with expertise in quality measures, three representatives from the air ambulance industry,

and three additional representatives not covered in the aforementioned categories.

- Impact: Requires data reporting on air ambulance services by providers and insurers and establishes an advisory committee to review options to establish quality, patient safety and clinical capability standards for air ambulances.

Section 107: Transparency Regarding In-Network and Out-of-Network Deductibles and Out-of-Pocket Limitations

- States that a group or individual health plan shall include on their plan or insurance identification card issued to the enrollee the amount of the in-network and out-of-network deductibles and the in-network and out-of-network out-of-pocket maximum limitations.
- Identification cards must also include a telephone number and website address through which an individual may seek consumer assistance information.
- Impact: Provides clear information to patients on their in- and out-of-network deductibles and out-of-pocket maximum limitations, effective with respect to plan years beginning on or after Jan. 1, 2022.

Section 108: Implementing Protections against Provider Discrimination

- Requires the Secretaries of HHS, Labor, and Treasury to promulgate a rule no later than January 1, 2022 implementing protections against provider discrimination.
- The Secretaries must accept and consider public comments for a period of 60 days after the date of issuance, and the Secretaries must issue a final rule implementing the protections within six months of the conclusion of the comment period.
- Impact: Requires the issuance of a rule implementing protections against provider discrimination.

Section 109: Reports

- Requires the Secretary of HHS, in consultation with the Federal Trade Commission (FTC) and Attorney General, to conduct a study by January 1, 2023 and annually thereafter for the next four years on the effects of the provisions in the Act.
- Requires the Government Accountability Office (GAO) to submit to Congress a report on the impact of surprise billing provisions no later than Jan 1, 2025; a report on adequacy of provider networks no later than Jan. 1, 2023; and a report on Informal Dispute Resolution (IDR) process and financial relationships no later than Dec. 31, 2023.
- Impact: Establishes reporting requirements to examine the effects and impact of surprise billing provisions and the adequacy of provider networks and IDR process and financial relationships.

Section 110: Consumer Protections Through Application of Health Plan External Review in Cases of Certain Surprise Medical Bills

- Allows for an external review to determine whether surprise billing protections are applicable when there is an adverse determination by a health plan no later than Jan. 1, 2022.
- Impact: Provides consumer protections via external review for adverse health plan determinations.

Section 111: Consumer Protections Through Health Plan Requirement for Fair and Honest Advance Cost Estimate

- For health plan years beginning on or after Jan. 1, 2022, requires the provision of Advance Explanation of Benefits for scheduled services at least three days in advance to give patients transparency into which

providers are expected to provide treatment, the expected cost and the network status of the providers.

- Provides HHS Secretary with the authority to modify timing requirements in the case of specified items and services.
- Impact: Provides consumer protection timelines and provider status for advance cost estimates.

Section 112: Patient Protections Through Transparency and Patient-Provider Dispute Resolution

- States that health care providers and facilities must verify, three days prior to service and no later than one day after scheduling of service, type of coverage the patient is enrolled in and provide notification of a good faith estimate to the payer or patient whether or not patient has coverage.
- Requires the HHS Secretary to establish a patient-provider dispute resolution process for uninsured individuals no later than January 1, 2022.
- Impact: Amends previous provisions and timelines for patient appointments and dispute resolutions.

Section 113: Ensuring Continuity of Care

- States that if a provider changes network status, patients with complex care needs have up to a 90-day period of continued coverage at in-network cost-sharing to allow for a transition of care to an in-network provider.
- Impact: Provides transitional continuous coverage and notification requirements for patients with complex care needs.

Section 114: Maintenance of Price Comparison Tool

- Requires health plans to offer and maintain a price comparison tool and guidance for consumers by telephone or internet for plan years beginning on or after Jan. 1, 2022.
- Impact: Increases price transparency and guidance for consumers.

Section 115: State All Payer Claims Databases

- Establishes a grant program to create and improve state All Payer Claims Databases.
- Grants shall be for a period of years and in the amount of $2.5 million, of which $1 million shall be made available to the State for the first 2 years of the grant period and $500,000 for the third year.
- Requires grant recipients to make data available to authorized users, including researchers, employers, health insurance issuers, third-party administrators, and health care providers for quality improvement and cost-containment purposes. The HHS Secretary may waive these requirements if a state All Payer Claims Database is substantially in compliance.
- Authorizes appropriations for grant program of $50 million for FY 2022 and 2023 and $25 million for FY 2024 to remain available until expended.
- Requires the Secretary of Labor to convene an advisory committee no later than 90 days of enactment and develop a standardized format for voluntary reporting by group health plans to state All Payer Claims Databases.
- Requires an advisory committee report to Congress no later than 180 days from date of enactment.
- Authorizes appropriations to implement this section of $5 million for FY 2021 to remain available until expended.

- Impact: Improves health plan data reporting and compliance of state All Payer Claims Databases.

Section 116: Protecting Patients and Improving the Accuracy of Provider Directory Information

- Requires health plans, for plan years beginning on or after Jan. 1, 2022, to maintain an accurate and up-to-date directory and database of their in-network providers, to be available to patients online or within one business day of an inquiry. If a patient provides documentation that they received incorrect information from a plan about a provider's network status prior to a visit, the patient will only be responsible for the in-network cost-sharing amount.
- Impact: Requires health plans to provide accurate and up-to-date in-network provider information and timely response verification protocols.

Section 117: Advisory Committee on Ground Ambulance and Patient Billing

- Requires the HHS, Labor, and Treasury Secretaries to establish an advisory committee, no later than 90 days of enactment, for reviewing options to improve disclosure of charges and fees for ground ambulance services, inform consumers of insurance options for such services, and protect consumers from surprise billing.
- Requires a committee report on recommendations no later than 180 days after first meeting.
- Impact: Establishes multiagency accountability to improve consumer price transparency for ground ambulance services.

Section 118: Implementation Funding

- Provides funding to HHS, Labor, and Treasury Secretaries to carry out the amendments made by the No Surprises Act, including preparing, drafting and issuing proposed and final regulations or interim regulations; preparing, drafting and issuing guidance and public information; preparing and holding public meetings; preparing, drafting and publishing reports; enforcement of such provisions; reporting, collection and analysis of data; establishment and implementation of processes for independent dispute resolution and implementation of patient-provider dispute resolution; conducting audits; and other administrative duties necessary for implementation.
- Appropriates $500 million for FY 2021 to remain available through 2024.
- Each of the Secretaries shall report annually to Congress on the funds expended under this section.
- Impact: Provides $500 million to agencies in implementation funding for fiscal year 2021 through 2024 or until expended.

TITLE II—TRANSPARENCY

Overview of Title II: *This title imposes several mandates on health insurance issuers to increase overall transparency throughout insurance plan transactions.*

Section 201: Increasing transparency by removing gag clauses on price and quality information.

- Amends sections of the Public Health Service Act (PHSA), the Employee Retirement Income Security Act of 1974 (ERISA) and the Internal Revenue Code (IRC) to restrict the use of contractual language between health plans and providers that prevents health plan sponsors, group and individual market consumers from accessing provider-specific cost and quality of care information.

- This applies to financial information included within the provider contract, provider information including names and clinical designation, and service codes.
- Impact: Bans gag clauses in contracts between providers and health plans so that enrollees, plan sponsors and referring providers can now see cost and quality data on providers. It also removes barriers to promote the use of de-identified claims data that could be shared under Health Insurance Portability and Accountability Act (HIPAA) business associate agreements, with third parties for plan administration and quality improvement purposes.

Section 202: Disclosure of direct and indirect compensation for brokers and consultants to employer-sponsored health plans and enrollees in plans on the individual market.

- Amends sections of ERISA and the PHSA to require brokers and consultants to disclose any direct or indirect compensation they may receive for referral services. Brokers and consultants must disclose this information to plan sponsors, enrollees in the individual market or enrollees purchasing short-term limited duration insurance.
- This also applies to compensation that may not be confirmed upon entering the contract that the provider may reasonably expect to receive in connection with such services.
- Impact: Brokers and consultants must fully disclose whether they are receiving payments for referrals to increase transparency for consumers purchasing health plans.

Section 203: Strengthening parity in mental health and substance use disorder benefits.

- Amends sections of the PHSA, ERISA and IRC to require group health plans, and health insurance issuers offering group or individual coverage, to conduct comparative analyses of the nonquantitative treatment limitations used for medical and surgical benefits as compared to mental health and substance use disorder benefits.
- Directs the Secretaries of Human Health Services, Labor and the Treasury to annually collect analyses from at least 20 plans involving potential violations of mental health parity or complaints regarding noncompliance with mental health parity. If an analysis is found to be noncompliant, issuers will have 45 days to implement administrative suggestions before enrollees must be notified.
- Impact: Requires plans to conduct analyses to gain deeper insight into nonquantitative treatment limitations for mental health and substance use disorder benefits, and sets up a system for HHS to identify potential violations of mental health parity.

Section 204: Reporting on pharmacy benefits and drug costs.

- Amends sections of the PHSA, ERISA and IRC to require group health plans and health insurance issuers to submit plan-specific information to the Secretaries of Human Health Services (HHS), Labor and Treasury regarding medical costs and prescription drug spending.
- Directs the HHS Assistant Secretary of Planning and Evaluation to collaborate with the Office of the Inspector General to publish a report to the HHS website summarizing drug pricing trends based on issuer supplied information. The first report will be posted within 18 months post enactment and updated biannually.
- Impact: Requires issuers to record and submit coverage data, specifically regarding prescription drug rates, from the previous plan year in efforts to monitor prescription drug pricing trends.

TITLE III—PUBLIC HEALTH PROVISIONS

SUBTITLE A—EXTENDERS

Overview of Title III, Subtitle A: *The subtitle aims to increase access to care by reducing barriers such as cost, lack of insurance, distance, and language. The subtitle also ensures continued research and better care outcomes for individuals with type 1 diabetes.*

Section 301: Extension for Community Health Centers, the National Health Service Corps, and Teaching Health Centers that Operate GME Programs

- Amends section 10503(b)(1)(F) of the Patient Protection and Affordable Care Act to extend funding for community health centers, the National Health Service Corps and the Teaching Health Center Graduate Medical Education Program at current levels for fiscal years 2021 through 2023.
- Impact: Aims to increase access to care by extending funding for community health centers, the National Health Service Corps and the Teaching Health Center Graduate Medical Education Program through 2023.

Section 302: Diabetes Programs

- Amends section 330B(b)(2)(D) of the Public Health Service Act to extend funding for the Special Diabetes Program for Type I Diabetes and the Special Diabetes Program for Indians at current levels for each of fiscal years 2021 through 2023.
- Impact: Seeks to advance cure therapies, prevention studies and treatments for type 1 diabetes.

SUBTITLE B—STRENGTHENING PUBLIC HEALTH

Overview of Title III, Subtitle B: *This subtitle launches several evidence-based national campaigns to increase knowledge and awareness of public health issues, such as the COVID-19 vaccine and breast cancer. The subtitle brings relevant stakeholders in conjunction with the Department of Health and Human Services (HHS) to develop strategies for obesity prevention and suicide prevention among Native American youth. The subtitle promotes health equity by removing barriers to medical care for children. It also explores the use of telehealth to increase access to care for underserved and rural populations, among others, and improves public health data reporting through modernization efforts of the current data infrastructure.*

- Authorizes an evidence-based national campaign through the Centers for Disease Control and Prevention (CDC) to increase awareness and knowledge of the safety and effectiveness of vaccines and combat misinformation to increase vaccination rates.
- Directs the Secretary of HHS to expand and enhance, and, as appropriate, establish and improve, programs and activities to collect, monitor and analyze vaccination coverage data.
- Requires the National Vaccine Advisory Committee to update, as appropriate, the report entitled, "Assessing the State of Vaccine Confidence in the United States: Recommendations from the National Vaccine Advisory Committee," with respect to factors affecting childhood vaccination.
- Impact: Aims to combat misinformation and increase public confidence in the COVID-19 vaccines to improve vaccination rates.

Section 312: Guide on Evidence-Based Strategies for Public Health Department Obesity Prevention Programs

- Authorizes the Secretary of HHS to develop and disseminate guides on evidence-based obesity prevention and reduction strategies for state, territorial and local health departments and Indian tribes and tribal

organizations.

- Impact: Provides state, territorial and local health departments and Indian tribes and tribal organizations with guidance to reduce obesity rates.

Section 313: Expanding Capacity for Health Outcomes

- Appropriates $10 million for each fiscal year from 2022–2026 for the Secretary of HHS to award grants to evaluate, develop and expand the use of technology-enabled collaborative learning and capacity-building models to improve retention of health care providers and increase access to specialty health care services in rural areas, frontier areas, health professional shortage areas and medically underserved areas.
- Requires the Secretary of HHS to provide Congress a report about grants awarded.
- Impact: Encourages development and implementation of telehealth technologies to increase access to specialty care and improve retention.

Section 314: Public Health Data System Modernization

- Requires the Secretary of HHS to conduct activities to expand, modernize, improve and sustain applicable public health data systems used by the CDC.
- Authorizes $100 million for each fiscal year from 2021–2025 for the Secretary of HHS to award grants or cooperative agreements to state, local, tribal or territorial public health departments for the expansion and modernization of public health data systems based on data and technology standards established by the CDC and the Office of the National Coordinator for Health Information Technology.
- Requires the Secretary of HHS, in consultation with all relevant stakeholders, to submit to Congress a coordinated strategy and accompanying implementation plan that identifies and demonstrates measures utilized to improve public health data systems.
- Impact: Aims to reduce lag in and increase accuracy of public health data reporting.

Section 315: Native American Suicide Prevention

- Amends section 520E(b) of the Public Health Service Act to require states to consult with Indian tribes, tribal organizations, urban Indian organizations and Native Hawaiian Health Care Systems in developing and implementing youth suicide early intervention strategies.
- Impact: Ensures youth suicide prevention strategies are appropriately crafted to address needs of Native American communities.

Section 316: Reauthorization of the Young Women's Breast Health Education and Awareness Requires Learning Young Act of 2009

- Reauthorizes the young women's breast health awareness and education program $9 million for each fiscal year from 2022–2026.
- Impact: Reestablishes the national education campaign to increase awareness of the threat posed by breast cancer to young women.

Section 317: Reauthorization of School-Based Health Centers

- Reauthorizes the School-Based Health Center program for each fiscal year from 2022–2026.
- Impact: Improves health equity among school-aged children and adolescents by providing access to medical, behavior, dental and vision care.

SUBTITLE C: FDA Amendments

Section 321: Rare Pediatric Disease Priority Review Voucher Extension

- Allows the Food and Drug Administration (FDA) to continue to award priority review vouchers for drugs that treat rare pediatric diseases and are designated no later than Sept. 30, 2024, and approved no later than Sept. 30, 2026.
- Impact: Extends priority review vouchers for approved and designated pediatric rare disease drugs for four additional years.

Section 322: Conditions of Use for Biosimilar Biological Products

- Clarifies that biosimilar applicants can include information in biosimilar submissions to show that the proposed conditions of use for the biosimilar product have been previously approved for the reference product.
- Impact: Outlines the inclusion of conditions of use information for biosimilar biological product submissions.

Section 323: Orphan Drug Clarification

- Clarifies that the clinical superiority standard applies to all drugs with an orphan drug designation for which an application is approved after the enactment of the FDA Reauthorization Act of 2017, regardless of the date of the orphan drug designation.
- Impact: Clarifies conditions under which the clinical superiority standard for drugs with an orphan drug designation applies.

Section 324: Modernizing the Labeling of Certain Generic Drugs

- Allows FDA to identify and select certain covered generic drugs for which labeling updates would provide a public health benefit and require sponsors of such drug applications to update labeling.
- Requires FDA to report on the number of covered drugs and a description of the types of drugs selected for labeling changes, the rationale for such recommended changes, and provide recommendations for program modifications.
- Impact: Modernizes the labeling of certain FDA covered generic drugs by requiring labeling updates by sponsors of such drug applications and requires FDA reporting on related changes.

Section 325: Biological Product Patent Transparency

- Requires patent information to be submitted to FDA and published in the “Purple Book” and codifies the book’s publication as a single, searchable list of information of each licensed biological product, including marketing and licensure status, patent information and relevant exclusivity periods.
- Impact: Increases transparency of patent information for biological products.

Section 325: Biological Product Patent Transparency

- Requires patent information to be submitted to FDA and published in the “Purple Book” and codifies the

book's publication as a single, searchable list of information of each licensed biological product, including marketing and licensure status, patent information and relevant exclusivity periods.

- Impact: Increases transparency of patent information for biological products.

SUBTITLE D: Technical Corrections

Section 331: Technical Corrections

- Makes technical amendments to the Coronavirus Aid, Relief, and Economic Security (CARES) Act.
- Impact: Makes technical corrections to CARES Act provisions for conformity.
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DIVISION CC: HEALTH EXTENDERS

Title I – Medicare Provisions

Overview of Title I: *This title extends a number of Medicare programs, including the work geographic index floor, funding for quality measure endorsement, input and selection, funding and outreach for low-income Medicare beneficiaries, IVIG demonstration, and the Independence at Home demonstration. It also makes a number of statutory changes to Medicare policy, including allowing HHS to add quality measures to the Skilled Nursing Facility Value-Based Purchasing Program, providing the Medicare Payment Advisory Commission and Medicaid and CHIP Payment Access Commission with additional drug pricing information, temporarily freezes the current APM payment incentive thresholds, provides continued coverage of certain temporary transitional home infusion services, requires plan sponsors to implement real-time benefit tools for Part D beneficiaries, gradually lowers coinsurance for Medicare beneficiaries who get colorectal cancer screening tests, expands access for mental health services to be furnished by telehealth under Medicare, creates a public-private partnership to detect waste, fraud and abuse, creates a new designation for Rural Emergency Hospitals, makes several alterations to graduate medical education (GME) slots, and delays implementation of the radiation oncology model to Jan. 1, 2022.*

SUBTITLE A – MEDICARE EXTENDERS

Section 101: Extension of the Work Geographic Index Floor Under the Medicare Program

- Extends funding for the Medicare work geographic index floor through Jan. 1, 2024, which increases payments for the work component of physician fees in geographic areas where labor cost is lower than the national average.
- Impact: Extends Medicare work geographic index floor through Jan. 1, 2024.

Section 102: Extension of Funding for Quality Measure Endorsement, Input, and Selection

- Extends funding through Sept. 30, 2023, and provides $66 million in funding to CMS for quality measure selection and to contract with a consensus-based entity to carry out duties related to quality measurement and performance improvement. Institutes new reporting requirements.
- Impact: Extends funding for quality measure endorsement, input and selection through Sept. 30, 2023.

Section 103: Extension of Funding Outreach and Assistance for Low-Income Programs

- Extends funding through Sept. 30, 2023, for low-income Medicare beneficiary outreach, enrollment and education activities through the State Health Insurance Assistance Programs, Area Agencies on Aging, Aging and Disability Resource Centers, and the National Center for Benefits and Outreach and Enrollment. Provides

for $50 million in funding for these programs for fiscal years 2021, 2022 and 2023.

- Impact: Extends funding for outreach and assistance for low-income Medicare programs.

Section 104: Extension of Medicare Patient IVIG Access Demonstration Project

- Extends the Intravenous Immunoglobulin (IVIG) treatment demonstration that is administered in the home through Dec. 31, 2023, allowing to up to 2,500 additional Medicare patients with primary immunodeficiency diseases to enroll in the demonstration, and requiring an updated evaluation of the demonstration.
- Impact: Extends the IVIG demonstration program through Dec. 31, 2023.

Section 105: Extending the Independence at Home Medical Practice Demonstration Program Under the Medicare Program

- Extends the Independence at Home demonstration program through Dec. 31, 2023. Expands the size of the demonstration from 15,000 to 20,000 Medicare beneficiaries.
- Impact: Extends the Independence at Home demonstration program through Dec. 31, 2023.

SUBTITLE B – OTHER MEDICARE PROVISIONS

Section 111: Improving Measurements Under the Skilled Nursing Facility Value-Based Purchasing Program Under the Medicare Program

- Allows the HHS Secretary to add no more than 10 quality measures to the Skilled Nursing Facility Value-Based Purchasing Program, which may include measures of functional status, patient safety, care coordination or patient experience.
- Not later than March 15, 2022, MedPAC shall submit a report to Congress on establishing a prototype value-based payment program under a unified prospective payment system for post-acute care services.
- Impact: Allows HHS to add quality measures to the Skilled Nursing Facility Value-Based Purchasing Program.

Section 112: Providing the Medicare Payment Advisory Commission and Medicaid and CHIP Payment Access Commission with Access to Certain Drug Payment Information Certain Rebate Information

- Provides for the respective executive directors of the Medicare Payment Advisory Commission and Medicaid and CHIP Payment Access Commission to have access to drug pricing and rebate data.
- There are restrictions on disclosures, including the specific amounts or the identity of the source of any rebates, discounts, price concessions or other forms of direct or indirect remuneration.
- Impact: Provides Medicare Payment Advisory Commission and Medicaid and CHIP Payment Access Commission with additional drug pricing information.

Section 113: Moratorium on Payment Under the Medicare Physician Fee Schedule of the Add On Code for Inherently Complex Evaluation and Management Visits

- Prior to Jan. 1, 2024, the Secretary of HHS may not make payment under the Physician Fee Schedule for services described by Healthcare Common Procedure Coding System (HCPCS) code G2211, or any successor or substantially similar code.
- Impact: Prohibits HHS from moving forward on payments for the G2211 as described in the Medicare Physician Fee Schedule until Jan. 1, 2024.

Section 114: Temporary Freeze of APM Payment Incentive Thresholds

- For physicians participating in Advanced Alternative Payment Models (APMs), freezes the current payment and patient count thresholds for payment years 2023 and 2024 (covering performance years 2021 and 2022).
- It also temporarily freezes the Partial Qualifying APM payment threshold and patient count threshold at current levels for payment years 2023 and 2024 (covering performance years 2021 and 2022).
- Impact: Temporarily freezes the current APM payment incentive thresholds.

Section 115: Permitting Occupational Therapists to Conduct the Initial Assessment Visit and Complete the Comprehensive Assessment with Respect to Certain Rehabilitation Services for Home Health Agencies Under the Medicare Program

- Not later than Jan. 1, 2022, the Secretary of HHS shall revise subsections (a)(2) and (b)(3) of Section 484.55 of Title 42 to permit occupational therapists to conduct initial assessment visits and complete comprehensive assessments for certain home health services if the referral order by the physician does not include skilled nursing care but includes occupational therapy and physical therapy or speech language pathology.
- Impact: Requires HHS by Jan. 1, 2022, to allow occupational therapists to conduct initial assessment visits.

Section 116: Centers for Medicare & Medicaid Services Provider Outreach and Reporting on Cognitive Assessment and Care Plan Services

- Requires HHS to conduct outreach to physicians and appropriate nonphysician practitioners regarding Medicare payment for cognitive assessment and care plan services furnished to individuals with cognitive impairment, such as Alzheimer's and related dementias.
- HHS is required to submit a report to Congress on provider outreach not later than one year after this Act.
- Impact: Requires HHS and CMS to conduct outreach to physicians regarding reimbursement for cognitive assessment services.

Section 117: Continued Coverage of Certain Temporary Transitional Home Infusion Therapy Services

- Provides for continued coverage of home infusion therapy services for Medicare beneficiaries taking self-administered and biological drugs that are currently included under the temporary transitional home infusion therapy benefit when the permanent home infusion therapy benefit takes effect Jan. 1, 2021.
- Impact: Provides continued coverage of certain temporary transitional home infusion services.

Section 118: Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries

- Beginning not later than Jan. 1, 2024, HHS shall carry out a program to provide transitional coverage for covered Part D drugs for Limited Income Newly Eligible Individuals (LI NET).
- Impact: Provides transitional coverage and retroactive Part D coverage for eligible low-income Medicare beneficiaries.

Section 119: Increasing the Use of Real-Time Benefit Tools to Lower Beneficiary Costs

- Requires Part D and Medicare Advantage plan sponsors to implement real-time benefit tools under Part D. These real-time benefit tools should be capable of integrating with provider electronic prescribing (e-prescribing) and electronic health record (EHR) systems.

- With respect to a covered Part D drug, the real-time benefit tool should transmit information including:
    - A list of clinically appropriate alternatives to such drug included in the formulary.
    - Cost-sharing information and the negotiated price for such drug and alternatives at multiple pharmacy options.
    - The formulary status of such drug and alternatives, any prior authorization or other utilization management requirements.
- Impact: Requires plan sponsors to implement real-time benefit tools for Part D beneficiaries.

Section 120: Beneficiary Enrollment Simplification

- Requires that Part B insurance coverage begins the first of the month following an individual's enrollment and provides a Special Enrollment Period for Part A and Part B for "exceptional circumstances," such as hurricanes and other natural disasters.
- Impact: Requires Part B coverage to begin the first month after an individual's enrollment.

Section 121: Waiving Budget Neutrality for Oxygen Under the Medicare Program

- This section would specify that the budget neutrality requirement for establishing new payment classes of oxygen and oxygen equipment no longer applies.
- Impact: Waives budget neutrality for oxygen and oxygen equipment.

Section 122: Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests

- Gradually lowers the coinsurance percentage for Medicare beneficiaries with respect to colorectal cancer screening tests. The percentages are:
    - For 2022, 80%.
    - For 2023 through 2026, 85%.
    - For 2027 through 2029, 90%.
- Impact: Gradually lowers coinsurance for Medicare beneficiaries who get colorectal cancer screening tests.

Section 123: Expanding Access to Mental Health Services Furnished Through Telehealth

- This section expands access to telehealth services to allow Medicare beneficiaries to receive mental health services through telehealth, including from the beneficiary's home.
- To be eligible, the beneficiary must have been seen in person at least once by the physician or nonphysician practitioner during the six-months period prior to the first telehealth service, with additional face-to-face requirements determined by HHS.
- Impact: Expands access for mental health services to be furnished by telehealth under Medicare.

Section 124: Public-Private Partnership for Health Care Waste, Fraud, and Abuse Detection

- Codifies a public-private partnership to detect waste, fraud and abuse.
- HHS shall enter into a contract with a trusted third party for purposes of carrying out these duties. The third party shall:

  - Provide technical and operational support to facilitate data sharing.
  - Analyze data to identify fraudulent billing patterns.
  - Conduct aggregate analyses of health care data.
  - Identify outlier trends and potential vulnerabilities.
- Impact: Creates a public-private partnership to detect waste, fraud and abuse.

Section 125: Medicare Payment for Rural Emergency Hospital Services

- This section creates a new, voluntary Medicare payment designation that allows either a Critical Access Hospital (CAH) or a small, rural hospital with less than 50 beds to convert to a Rural Emergency Hospital (REH).
- REHs can also furnish additional medical services needed in their community such as observation care, outpatient hospital services, telehealth services, ambulance services and skilled nursing facility services.
- REHs will be reimbursed under all applicable Medicare prospective payment systems plus an additional monthly facility payment and an add-on payment for hospital outpatient services.
- HHS shall establish quality measurement reporting requirements for REHs, which may include the use of a small number of claims-based outcomes measures or surveys of patients.
- Impact: Creates a new designation for Rural Emergency Hospitals.

Section 126: Distribution of Additional Residency Positions

- Beginning fiscal year 2023, provides for the distribution of additional Medicare-funded graduate medical education (GME) residency positions.
- Rural hospitals, hospitals already above their Medicare cap for residency positions, hospitals in states with new medical schools, and hospitals that serve Health Professional Shortage Areas (HPSAs) will be eligible for these new positions.
- Impact: Increases the number of Medicare-funded GME positions.

Section 127: Promoting Rural Hospital GME Funding Opportunity

- Modifies the Medicare graduate medical education (GME) Rural Training Tracks (RTT) program in order to provide greater flexibility for rural and urban hospitals to partner and address the physician workforce needs of rural areas.
- Impact: Provides greater flexibility for GME programs in rural areas.

Section 129: Extension of Frontier Community Health Integration Project Demonstration

- Extends the Frontier Community Health Integration Project (FCHIP) demonstration by five years, beginning July 1, 2021.
- Impact: Extends the FCHIP demonstration by five years.

Section 130: Improving Rural Health Clinic Payments

- Implements a payment reform plan for Rural Health Clinics (RHCs). Phases in a steady increase in the RHC statutory cap over an eight-year period, subjects all new RHCs to a uniform per-visit cap, and controls the

annual rate of growth for uncapped RHCs whose payments are above the upper limit.

- RHCs with an all-inclusive rate (AIR) above the upper limit would continue to experience annual growth, but the payment amount would be constrained to the facility's prior year reimbursement rate plus MEI.
- 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 per visit. In each subsequent calendar year, starting in 2029, the new statutorily set RHC cap would revert back to an annual MEI inflationary adjustment.
- Impact: Increases statutory cap for RHCs.

Section 131: Medicare GME Treatment of Hospitals Establishing New Medical Residency Training Programs After Hosting Medical Resident Rotators for Short Durations

- Allows hospitals to host a limited number of residents for short-term rotations without being negatively impacted by a set permanent full-time equivalent (FTE) resident cap or a Per Resident Amount (PRA).
- Impact: Allows hospitals to host short-term rotations.

Section 132: Medicare Payment for Certain Federally Qualified Health Center and Rural Health Clinic Services Furnished to Hospice Patients

- Beginning Jan. 1, 2022, allows Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) to furnish and bill for hospice attending physician services when RHC and FQHC patients become terminally ill and elect the hospice benefit.
- Impact: Allows RHCs and FQHCs to bill for hospice benefits.

Section 133: Delay to the Implementation of the Radiation Oncology Model Under the Medicare Program

- Provides for a statutory six-month additional delay, in addition to the delay announced by CMS of the Medicare radiation oncology model to Jan. 1, 2022.
- Impact: Delays implementation of the radiation oncology model to Jan. 1, 2022.

Section 134: Improving Access to Skilled Nursing Facility Services for Hemophilia Patients

- Adds blood clotting factors and items and services related to their furnishing to the categories of high-cost, low-probability services that are excluded from the skilled nursing facility (SNF) per diem prospective payment system (PPS) and are separately payable.
- This change is applicable to items and services furnished on or after Oct. 1, 2021.
- Impact: Improves access to blood clotting factors indicated for patients with hemophilia.

TITLE II—MEDICAID EXTENDERS AND OTHER POLICIES

Overview of Title II: *The title aims to increase transparency and program integrity through increased reporting requirements. The title extends several protections and demonstration programs under Medicaid, including the Community Mental Health Services Demonstration Program, the Money Follows the Person Rebalancing Demonstration, and spousal impoverishment protections. It also restores Medicaid eligibility to citizens of the Freely Associated States living lawfully in the United States.*

Section 201: Eliminating DSH Reductions for Fiscal Years 2021 through 2023

- Eliminates disproportionate share hospital (DSH) payment reductions from fiscal years 2021–2023. DSH payment reductions are reinstated at $8 billion for each fiscal year from 2024–2027.
- Impact: Supports safety net hospitals amid the coronavirus pandemic by eliminating Medicaid DSH cuts until fiscal year 2024.

Section 202: Supplemental Payment Reporting Requirements

- Requires the Secretary of HHS to establish a supplemental payment reporting system for each state to submit supplemental payment data, as appropriate. Data from states must include eligibility criteria and methodology used to calculate the payment amount, among other things.
- Requires the data to be posted publicly on the Center for Medicare and Medicaid Services' website.
- Excludes DSH payments.
- Impact: Increases transparency for non-DSH supplemental payments.

Section 203: Medicaid Shortfalls and Third Party Payments

- Codifies the methodology for calculating Medicaid shortfalls.
- Defines Medicaid shortfall to include costs and payments for individuals who are eligible for Medicaid, individuals for whom Medicaid is the primary payor of such services and individuals with no health insurance.
- Impact: Defines Medicaid shortfall for purposes of third-party payments, which did not exist before in Medicaid statute.

Section 204: Extension of Money Follows the Person Rebalancing Demonstration

- Extends funding for the Medicaid Money Follows the Person Rebalancing demonstration program at $450 million per fiscal year through fiscal year 2023.
- Reduces the institutional residency period from 90 days to 60 days.
- Requires states to include a work plan in their applications for each fiscal year that addresses use of funds, objectives, expected results and sustainability and provide quarterly updates.
- Authorizes the Secretary of HHS to implement a corrective action plan should states fail to carry out reporting requirements.
- Requires the Secretary to submit a report to Congress that contains findings and conclusions on best practices from the demonstration plan.
- Impact: Aims to improve performance outcomes of the Money Follows the Person Rebalancing demonstration program.

Section 205: Extension of Spousal Impoverishment Protections

- Extends the protections against spousal impoverishment for partners of Medicaid beneficiaries who receive home and community-based services through fiscal year 2023.
- Impact: Ensures financial stability of the spouse of a Medicaid beneficiary receiving home or community-based services.

Section 206: Extension of Community Mental Health Services Demonstration Program

- Extends the community mental health services demonstration program through Sept. 30, 2023.
- Impact: Provides mental health and substance use disorder treatment and recovery services amid COVID-19, which has significantly exacerbated these issues.

Section 207: Clarifying Authority of State Medicaid Fraud and Abuse Control Units

- Allows state Medicaid fraud control units to investigate complaints of abuse or neglect of patients in board and care facilities and of Medicaid beneficiaries in noninstitutional or other settings.
- Impact: Enhances protections for elderly or disabled patients living in group homes or other health care facilities from abuse and neglect.

Section 208: Medicaid Coverage for Citizens of Freely Associated States

- Extends Medicaid eligibility to citizens of the Freely Associated States (the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau) lawfully residing in the United States under the Compacts of Free Association.
- Impact: Corrects a drafting error in a 1996 welfare reform bill that excluded the citizens of the Freely Associated States from Medicaid. Research shows Medicaid ineligibility exacerbated rates of disease and death in these populations living in the United States.

Section 209: Medicaid Coverage of Certain Medical Transportation

- Ensures that state Medicaid programs cover nonemergency medical transportation to necessary services.
- Requires the Comptroller General of the United States to conduct a study and submit a report to Congress on ways to prevent fraud with respect to coverage under the Medicaid program of nonemergency transportation to covered services.
- Requires CMS to meet with relevant stakeholders to discuss leading practices for improving Medicaid integrity with respect to coverage of nonemergency transportation to medically necessary services.
- Impact: Aims to prevent fraud within Medicaid and improve program integrity with respect to coverage of nonemergency transportation to medically necessary services.

Section 210: Promoting Access to Life-Saving Therapies for Medicaid Enrollees by Ensuring Coverage of Routine Patient Costs for Items and Services Furnished in Connection with Participation in Qualifying Clinical Trials.

- Requires state Medicaid programs to cover routine patient costs for items and services that are provided in connection with a qualifying clinical trial regarding serious or other life-threatening conditions starting Jan. 1, 2022.
- Requires coverage determinations to be completed within 72 hours based on attestation regarding the appropriateness of the qualifying clinical trial by the health care provider and principal investigator.
- Impact: Ensures patients with life-threatening conditions access to the best treatment option for their conditions.

TITLE III—HUMAN SERVICES

Overview of Title III: *The title extends funding for human services and public assistance, including Temporary Assistance for Needy Families (TANF) and programs that promote healthy families and public health education.*

Section 301: Extension of TANF, Child Care Entitlement to States, and Related Programs.

- This section would extend current funding and policy for the Temporary Assistance for Needy Families, the Child Care Entitlement to states and other related programs, including the Healthy Marriage and Responsible Fatherhood grants, through the end of fiscal year 2021.
- Impact: Extends TANF funding through FY 2021.

Section 302. Personal Responsibility Education Program.

- This provision extends the Personal Responsibility Education Program (PREP) through fiscal year 2023.
- Impact: Extends PREP funding through FY 2023.

Section 303. Sexual Risk Avoidance Education.

- This provision extends the Sexual Risk Avoidance Education (SRAE) program through fiscal year 2023.
- Impact: Extends SRAE funding through FY 2023.

Section 304. Extension of support for current health professions opportunity grants.

- This section provides $3.6 million to cover the cost of ongoing technical assistance and other Department of Health and Human Services administrative costs related to Health Profession Opportunity Grants (HPOGs) through the end of fiscal year 2021. Funding also covers costs related to evaluation and reporting through the end of fiscal year 2022.
- Impact: Funds administration costs for HPOGs through FY 2021 and reporting costs through FY 2022.

Section 305. Extension of MaryLee Allen Promoting Safe and Stable Families Program and State court support.

- This section extends current funding and authorization for the MaryLee Allen Promoting Safe and Stable Families program, including the Court Improvement Program (CIP), through the end of fiscal year 2022, and makes changes and clarifications to CIP that take effect Oct. 1, 2021.
- Impact: Funds the program through FY 2022.

TITLE IV—HEALTH OFFSETS

Overview of Title IV: *The title enacts legislation to offset the cost of public health programs elsewhere in the bill. It requires manufacturers that do not have rebate agreements through the Medicaid Drug Rebate Program to report average sales price (ASP) information and authorizes CMS to review and exclude payments made for the self-administered versions of Part B drugs that are not covered. It also extends coverage for immunosuppressive drugs to Medicare beneficiaries that have had kidney transplants.*

Section 401. Requiring certain manufacturers to report drug pricing information with respect to drugs under the Medicare program.

- This section requires all manufacturers of drugs covered under Medicare Part B to report average sales price (ASP) information to the Secretary of HHS beginning on Jan. 1, 2022.

- Impact: Requires manufacturers that do not have a rebate agreement through the MDRP to report ASP information.

Section 402. Extended months of coverage of immunosuppressive drugs for kidney transplant patients and other renal dialysis provisions.

- This section establishes eligibility for immunosuppressive drug coverage through Medicare to post-kidney transplant individuals whose entitlement to benefits under Part A ends (whether before, on or after Jan. 1, 2023) and who do not receive coverage of immunosuppressive drugs through other insurance.
- Impact: Extends Medicare coverage for immunosuppressive drugs to post-kidney transplant individuals for beneficiaries.

Section 403. Permitting direct payment to physician assistants under Medicare.

- This section allows direct payment under the Medicare program to physician assistants for services furnished to beneficiaries on or after Jan. 1, 2022.
- Impact: Medicare can directly reimburse physicians assistants for services rendered.

Section 404. Adjusting calculation of hospice cap amount under Medicare.

- This section extends the change to the annual updates to the hospice aggregate cap made in the Improving Medicare Post-Acute Care Transformation Act (IMPACT Act) of 2014 and applies the hospice payment update percentage rather than the Consumer Price Index for Urban Consumers (CPI–U) to the hospice aggregate cap for fiscal years 2026 through 2030.
- Impact: Changes the calculation of the hospice cap under Medicare.

Section 405. Special rule for determination of ASP in cases of certain self-administered versions of drugs.

- This section requires the Inspector General of the Department of Health and Human Services to conduct periodic studies to determine drugs that are self-administered and for which payment may not be made, in line with its previous findings in a 2017 report.
- This section authorizes CMS, when determining payment for products covered under Medicare Part B, to review and exclude payments made for the self-administered versions of products that are not covered.
- Impact: Excludes the consideration of payments for self-administered drugs not covered under Part B.

Section 406. Medicaid Improvement Fund.

- This section rescinds $3,464,000,000 from the Medicaid Improvement Fund.
- Impact: None.

Section 407. Establishing hospice program survey and enforcement procedures under the Medicare program.

- This section makes changes to the Medicare hospice survey and certification process to increase oversight. It gives the Secretary authority to use intermediate remedies to enforce compliance with hospice requirements. This section also extends the requirement that hospices be surveyed at least once every 36 months.
- This section creates a new Special Focus Facility Program for poor-performing hospice providers, who will be surveyed at least once every six months. It increases the penalty for hospices that do not report quality data to the Secretary from two to four percentage points, beginning in fiscal year 2024.

- Impact: Heightens oversight of hospice programs and increases the penalty for hospices that do not report quality data.

Section 408. Deposit into the Medicare Improvement Fund.

- This section deposits $165 million into the Medicare Improvement Fund.
- Impact: None.

TITLE V—MISCELLANEOUS

Section 501. Implementation Funding.

- Appropriates $37 million from the Department of the Treasury to CMS for FY 2021, until expended.
- Impact: None.

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