

HEALTH CARE PROVISIONS IN THE END-OF-YEAR 2020 DEAL

EXECUTIVE SUMMARY

House and Senate leadership released the [text](#) of their end-of-year deal, including a COVID-19 relief and stimulus package, a \$1.4 trillion fiscal year (FY) 2021 appropriations package, and a slew of miscellaneous provisions. This is likely the final major legislation that will go through the 116th Congress. The House is set to vote on the legislation this evening, and the Senate will follow thereafter, setting up a possible Presidential signature prior to the deadline of midnight to avert a government shutdown.

The nearly 5,600-page bill includes \$900 billion in COVID-19 relief. This includes additional relief for providers impacted by the COVID-19 pandemic by allocating additional funding and providing for an increase to Medicare Physician Fee Schedule to offset reductions to evaluation and management (E/M) services that were necessitated by budget neutrality requirements. In addition, the bill provides around \$9 billion to states for vaccine distribution and an additional \$20 billion for the procurement of vaccines and therapeutics.

The deal includes a three-year extension at level funding for a group of “health extenders,” or expiring programs that require periodic reauthorization. For the past two years, these programs have received a succession of short-term extensions as Congress sought a longer deal. This bill represents that deal, placing the deadline to reauthorize these programs three years down the road. The extenders are paid for by a series of offsets, including new drug price transparency measures and a program to provide continued immunosuppressant coverage to individuals who have received a kidney transplant.

In addition to the COVID-19 relief and appropriations divisions, the cornerstones of the bill, several bipartisan priorities are catching a ride on this legislation. The most notable among them is a ban on “surprise medical billing,” which would limit patient liability for unavoidable out-of-network care to in-network rates. Under the provision, payment disputes between insurers and providers will be settled through an independent dispute resolution (IDR) process, which will be binding. Additional priorities that received attention in this bill include telehealth coverage of mental health services in Medicare, Medicaid coverage of non-emergency medical transportation, patent transparency for biologics, mental health parity, and more.

The following memo examines these issues, FY 2021 appropriations funding, and more in a summary of the bill’s health care provisions.

COVID-19 RELIEF

The \$900 billion COVID-19 relief package includes \$69 billion for health care-related spending, \$250 million for FCC telehealth funding, and a \$13 billion increase to the Supplemental Nutrition Assistance Program in order to provide higher benefits. The amounts described below are supplemental appropriations and are in addition to any funding provided under regular appropriations, described in the next section.

- **Provider Relief** — The bill includes \$9 billion in support for health care providers, which comprises an extension of relief from Medicare sequester cuts through March 31, 2021, an additional \$3 billion and new distribution requirements for the Provider Relief Fund, and \$3 billion in budget neutrality adjustments to the Medicare Physician Fee Schedule. The \$3 billion in additional grants for hospital and health care providers aims to reimburse for health care related expenses or lost revenue directly attributable to the public health emergency resulting from coronavirus, along with direction to allocate not less than 85 percent of unobligated funds in the Provider Relief Fund through an application-based portal to reimburse health care providers for financial losses incurred in 2020.
- **Food Insecurity and SNAP** — \$13 billion will be allocated to combat food insecurity on the rise due to the economic impacts of the pandemic. This bill will help address rampant food insecurity by increasing SNAP benefits by 15%. For Puerto Rico and territories that do not have access to the SNAP program, the bill has dedicated \$614 million in funding for nutrition assistance block grants. An additional \$400 is allocated for The Emergency Food Assistance Program (TEFAP) to fund the continued work of food banks.
- **Hospitals** — In addition to \$3 billion in new provider relief grants, the bill expands Paycheck Protection Program (PPP) eligibility for more critical access hospitals. This section also permits the U.S. Department of Housing and Urban Development (HUD) to finance up to one year of operating losses for certain hospital and residential care facilities insured by the Federal Housing Administration (FHA) under Sections 232 and 242 of the National Housing Act.
- **Nursing Homes** — The legislation permits the U.S. Department of Housing and Urban Development (HUD) to finance up to one year of operating losses for certain hospital and residential care facilities insured by the Federal Housing Administration (FHA) under Sections 232 and 242 of the National Housing Act. Additionally, the bill includes – \$100 million to address abuse, neglect, and exploitation of the elderly, including adult protective service and long-term care ombudsman activities.
- **Mental Health Funding** — The Substance Abuse and Mental Health Services Administration will be allocated \$4.25 billion, including:
 - *Mental Health Services Block Grant* — \$1.650 billion, of which, no less than 50 percent of funds shall be directed to behavioral health providers.
 - *Substance Abuse and Prevention Treatment Block Grant* — \$1.650 billion.
 - *Certified Community Behavioral Health Clinics* — \$600 million.
 - *Suicide Prevent Programs* — \$50 million.

- *Project AWARE* — \$50 million to support mental health once children return to school.
- *Emergency Grants to States* — \$240 million for flexible emergency grants to states.
- *Tribes* — \$125 million.
- **Other COVID-19 Funding** — This bill extends the availability of funds provided to states and localities by the Coronavirus Relief Fund in the CARES Act until December 31, 2021. The bill provides more than \$22 billion, all sent directly to states, for testing, tracing and COVID mitigation programs. Of this total, \$2.5 billion will be sent out as grants specifically targeted at needs in underserved areas, including both communities of color and rural communities. The bill includes more than \$1 billion for NIH to research COVID-19. The bill also includes \$55 million for continued work on FDA efforts to facilitate the development and review, both pre-market and post-market, of medical countermeasures, devices, therapies, and vaccines to combat the coronavirus. In addition, funds will support medical product supply chain monitoring and other public health research and response investments. This bill also has \$1 billion in direct funds to the Indian Health Service to carry out these services.
- **FCC COVID-19 Telehealth Program** — This legislation includes an additional \$250 million in funding for the FCC’s COVID-19 telehealth program.
- **Vaccine Procurement and Distribution** — The bill includes roughly \$20 billion to BARDA for procurement of vaccines and therapeutics, nearly \$9 billion to the CDC and states for vaccine distribution, and more than \$3 billion for the strategic national stockpile. This includes \$300 million specifically directed to high risk and underserved areas for distribution, including communities of color. This legislation includes \$4 billion in funding for GAVI, a private-public partnership aimed at getting vaccines to low-income countries around the globe.

FISCAL YEAR 2021 APPROPRIATIONS

The \$1.4 trillion omnibus appropriations package includes funding for health-related agencies and priorities for fiscal year 2021. Appropriations for health care items are described below.

- **Department of Health and Human Services (HHS)** — The bill includes a total of \$97 billion for HHS, an increase of \$2.1 billion above the 2020 enacted level and \$9.9 billion above the president’s budget request.
 - **National Institutes of Health (NIH)** — The bill provides a total of \$42.9 billion for NIH, an increase of \$1.25 billion above the 2020 enacted level, including funding for new initiatives, such as \$10 million for research on premature births and \$50 million for research on artificial intelligence to address chronic diseases.
 - **Centers for Disease Control and Prevention (CDC)** — The bill includes a total of \$7.9 billion for CDC, an increase of \$125 million above the 2020 enacted level. This includes \$856 million in transfers from the Prevention and Public Health Fund, \$201 million in influenza planning and response, and \$695 million in public health emergency preparedness cooperative agreements with State and local health departments. Additionally, it includes \$361 million, an increase of \$7.5 million, to

strengthen epidemiologic and laboratory capacity, and includes \$50 million to support modernization of public health data surveillance and analytics at CDC, State and local health departments.

- *Substance Abuse and Mental Health Services Administration (SAMHSA)* — The bill funds SAMHSA at \$6 billion, an increase of \$133 million above the 2020 enacted level. SAMHSA funding contains increased support for mental health services, including a new \$35 million crisis care initiative within the Mental Health Block Grant, expanded services and support for mental for children and youth including \$107 million for Project AWARE, an increase of \$5 million, and \$72 million for the National Child Traumatic Stress Initiative, an increase of \$3 million. The bill includes \$3.8 billion for substance abuse treatment and \$208 million for substance abuse prevention. Finally, the bill includes \$250 million for Certified Community Behavioral Health Clinics.
 - *Health Resources and Services Administration (HRSA)* — The bill includes \$7.5 billion for HRSA, which is \$151 million above the 2020 enacted level. This includes \$1.7 billion for the Health Centers program and \$975 million for programs to improve maternal and child health.
 - *Agency for Healthcare Research and Quality (AHRQ)* – The bill provides \$338 million for AHRQ, the same as the 2020 enacted level.
 - *Centers for Medicare and Medicaid Services (CMS)* — The bill provides \$4 billion for CMS administrative expenses, the same as the 2020 enacted level.
 - *Administration for Children and Families (ACF)* – The bill provides \$24.7 billion in discretionary funding for ACF, an increase of \$251 million above the 2020 enacted level.
 - *Administration for Community Living (ACL)* – The bill funds ACL at \$2.3 billion, which is \$35 million above the 2020 enacted level.
 - *Office of the Secretary—General Departmental Management* – The bill provides \$551 million, an increase of \$6 million above the 2020 enacted level. The amount includes \$62 million for the Office of Minority Health and \$35 million for the Office on Women’s Health.
 - *Public Health and Social Services Emergency Fund (PHSSEF)* – The bill provides \$2.8 billion for PHSSEF, an increase of \$110 million above the 2020 enacted level. The total funding level includes: (1) \$597 million for the Biomedical Advanced Research and Development Authority (BARDA); (2) \$770 million for Project BioShield; (3) \$705 million for the Strategic National Stockpile; and (4) \$287 million for Pandemic Influenza Preparedness.
- **Food and Drug Administration (FDA)** — The FDA receives a total of \$3.2 billion in discretionary funding in the bill, \$43 million above the 2020 enacted level. Total funding for the FDA, including user fees, is \$5.97 billion. Within this total, the bill provides targeted increases for medical product and food safety activities, including new initiatives to advance new influenza vaccine manufacturing technologies and leverage emerging technologies to monitor food and medical product safety. Funding is also included to support the development of a framework for regulating CBD products, continue FDA’s efforts to enable

faster responses to foodborne illness outbreaks, and increase the safety and cybersecurity of medical devices. In addition, the bill includes a strong focus on continuing FDA’s efforts to inspect foreign food and drug products. The bill also appropriates \$70 million to accelerate medical product development as authorized in the 21st Century Cures Act. Additionally, the bill includes language directing the FDA to develop a plan to identify, detain, and refuse the import of FDA-regulated products from a foreign establishment that did not allow physical access to FDA investigators.

HEALTH EXTENDERS AND OFFSETS

Over the past two years, a bevy of Medicare, Medicaid, and public health-related programs have received numerous short-term reauthorizations of less than one year. Most recently, these programs have received very short-term authorizations after the CARES Act extended the programs to the end of November 2020. While there is general agreement over the need for authorizations for these programs, difficulties in passing these “extenders” have arisen in (1) reauthorization timeframes and (2) offsets to pay for the extenders. In the year-end deal, lawmakers reached an agreement to extend most programs for three years at level funding. Offsets to pay for the extenders include extended coverage for immunosuppressants for kidney transplant recipients, an adjustment in Medicare’s hospice cap amount, a special rule for determining average sales price (ASP) for certain drug products, and funding modifications to the Medicare and Medicaid Improvement Funds.

Health extenders, along with their new expirations, are described below.

Extender	Description	New Expiration
Geographic Practice Cost Index Floor	Maintains a floor on the work geographic practice cost index, keeping rural providers from facing low reimbursements.	December 31, 2023
National Quality Forum	An authorization for funding for a contract with the National Quality Forum to produce quality measure endorsement, input, and selection.	September 30, 2023
Low-Income Outreach and Assistance	Authorizes funding for State Health Insurance Programs, Area Agencies on Aging, Aging and Disability Resources Centers, and the National Center for Benefits and Outreach Enrollment.	September 30, 2023
Certified Community Behavioral Health Centers (CCBHC)	Continuation of the CCBHC demonstration. CCBHCs provide a comprehensive range of mental health and substance use disorder services to vulnerable individuals. In return, CCBHCs receive an enhanced Medicaid reimbursement rate based on their anticipated costs of expanding services to meet the needs of these complex populations.	September 30, 2023
Disproportionate Share Hospital	Delays scheduled reductions to Medicaid DSH allocations in the Affordable Care Act (ACA).	September 30, 2023

(DSH) Reduction Delay		
Spousal Impoverishment	Rules on the treatment of certain assets of spouses of individuals receiving long-term services and supports through Medicaid., preventing them from becoming impoverished to allow their spouse to qualify for Medicaid.	September 30, 2023
Money-Follows-the-Person (MFP) Rebalancing	Permits demonstrations that allow home- and community-based long-term care in Medicaid.	September 30, 2023
Temporary Assistance to Needy Families (TANF)	TANF provides grant funds to states and territories to provide families with financial assistance and related support services. State-administered programs may include childcare assistance, job preparation, and work assistance.	September 30, 2021
Sexual Risk Avoidance Education (SRAE) Program	SRAE funds projects to implement sexual risk avoidance education that teaches participants how to voluntarily refrain from non-marital sexual activity.	September 30, 2023
Personal Responsibility Education Program (PREP)	PREP seeks to reduce teen pregnancy through the use of evidence-based programs. The goals of the PREP Evaluation are to document how programs funded through the State PREP program are implemented in the field and to assess selected PREP-funded programs' effectiveness.	September 30, 2023
Community Health Centers/National Health Service Corps/Graduate Medical Education	Funding for Health Resources and Services Administration (HRSA) programs including community health centers, which focus on low-income communities; the National Health Service Corps, which incentivizes providers to locate in communities in need; and funding for residencies nationwide.	September 30, 2023
Special Diabetes Programs (SDP)	The SDP funds Type 1 diabetes research at NIH and the Special Diabetes Program for Indians (SDP-I) funds diabetes treatment, education, and prevention programs for American Indian and Alaska Native populations.	September 30, 2023

Additional Extenders

This legislation includes extensions of programs that have not been part of the short-term extenders packages of the past two years. These programs are described below.

Extender	Description	New Expiration
Medicare Patient IVIG Access Demonstration Project	This demonstration extends a demonstration program for the in-home administration of intravenous immune globulin (IVIG) for the treatment of primary immune deficiency disease (PID).	December 31, 2023
Independence at Home Medical Practice Demonstration Program	Under the Independence at Home Demonstration, the CMS Innovation Center works with medical practices to test the effectiveness of delivering comprehensive primary care services at home and if doing so improves care for Medicare beneficiaries with multiple chronic conditions. Additionally, the Demonstration rewards health care providers that provide high quality care while reducing costs.	September 30, 2021
Rural Community Hospital Demonstration Program	The demonstration tests the feasibility and advisability of establishing “rural community hospitals” to furnish covered inpatient hospital services to Medicare beneficiaries in states with low population densities. Participating hospitals are mostly paid using reasonable cost-based methodology instead of the inpatient prospective payment system.	December 31, 2026
Priority Review Vouchers	Priority review vouchers are awarded to sponsors of rare pediatric disease drugs upon FDA approval. Such vouchers entitle the holder to designate another product for expedited FDA review.	September 30, 2024
EARLY Act	The EARLY Act authorizes a public education and a health care professional education campaign focusing on breast cancer awareness and prevention.	September 30, 2026
School-Based Health Centers	School-based health centers often are operated as a partnership between the school and a community health organization, such as a community health center, hospital, or local health department. Students can be treated for acute illnesses, such as flu, and chronic conditions, including asthma and diabetes. They can also be screened for dental, vision and hearing problems.	September 30, 2026

Offsets

Extensions of the programs described above must be paid for. The policies below are offered as offsets to the costs of the programs that will be reauthorized through this bill.

- **Drug Price Transparency** — Requires all drug manufacturers, including those that do not have a rebate agreement through the Medicaid Drug Rebate Program (MDRP), to report average sales price (ASP) information to HHS.

- **Coverage of Immunosuppressants** — Creates eligibility for immunosuppressant drug coverage through Medicare for individuals who have received a kidney transplant and whose Part A coverage through the end-stage renal disease (ESRD) benefit ends.
- **Payment for Physician Assistants** — Permits direct payments to physician assistants — as opposed to “incident-to” billing — for services rendered to Medicare beneficiaries beginning in calendar year 2022.
- **Hospice Cap** — Modifies the calculation of the hospice cap, including by applying the hospice payment update percentage rather than CPI-U to the hospice cap for FY 2026-2030.
- **ASP for Certain Drugs** — Allows CMS to review and exclude payments for self-administered versions of drug products that are not covered under Part B.
- **Medicaid Improvement Fund** — Rescinds \$3.5 billion from the Medicaid Improvement Fund.
- **Medicare Improvement Fund** — Provides \$165 million to the Medicare Improvement Fund.
- **Hospice Program Survey** — Permits HHS to use intermediate remedies to enforce compliance with hospice requirements, creates a new program to focus on poor-performing hospice providers, and increases penalties for not reporting quality data to HHS.

SURPRISE BILLING

A surprise billing fix, long an elusive bipartisan priority, is included in the bill. It creates an arbitration system for out-of-network surprise medical bills centered around the median in-network payment for services. The included deal would protect patients from surprise medical bills by ensuring they are only responsible for the in-network payment rates. The bill would require arbiters to settle disputes between providers and insurers, and the arbiters would consider median in-network rates, information related to the providers’ experience, and the complexity of services. The independent dispute resolution would be binding, payments would be made within 30 days, and there is no monetary threshold for triggering arbitration. Parties would be allowed to initiate dispute resolutions once every 90 days. The deal also included a ban on air ambulance surprise bills and would prohibit out-of-network providers from billing patients unless patients are notified 72 hours before receiving out-of-network services. Notably, “timely billing” provisions included in an earlier iteration of the bipartisan surprise billing agreement is not included in the final package.

MISCELLANEOUS PROVISIONS

A multitude of additional provisions hitched a ride on this bill, which is likely one of the last pieces of legislation that Congress will take up this year. Major policies that are included in the bill are described below.

Medicaid

- **NEMT** — The deal includes the Protecting Patients Transportation to Care Act ([H.R. 3935](#)), which statutorily requires coverage of non-emergency medical transportation (NEMT) by state Medicaid programs. It also establishes quality and safety standards for NEMT.

- **Clinical Trials** — Requires state Medicaid programs to cover patient costs related to clinical trials for investigational items or services that are connected to a serious or life-threatening disease or condition.
- **Medicaid Coverage for the Freely Associated States** — Restores Medicaid eligibility for citizens of the Freely Associated States.

Medicare

- **Physician Fee Schedule** — The bill provides for a one-year increase in the Medicare physician fee schedule (PFS) of 3.75 percent. This is designed to compensate providers for reductions in the PFS to evaluation and management (E/M) services that were instituted as a result of budget neutrality requirements. This across-the-board increase will not fully fill the gap created by the cuts, and it will expire at the end of this year. In addition, the bill prohibits payments under the PFS for inherently complex E/M visits until January 1, 2024.
- **Sequestration** — The deal provides for a three-month extension of a CARES Act suspension of the Medicare sequester, ending March 31, 2021. This will result in a temporary increase in Medicare payments across the board.
- **Home Infusion** — The permanent home infusion therapy benefit in Medicare takes effect January 1, 2021. This bill ensures that beneficiaries who are currently taking self-administered drugs and biologics under the transitional home infusion benefit will enjoy continued coverage when the permanent benefit takes effect.
- **Part D Transitional Coverage** — This bill permanently authorizes the Limited Income Newly Eligible Transition (LI NET) demonstration, which provides immediate temporary Part D coverage for individuals as their eligibility for Part D low-income subsidies is processed.
- **Oxygen Budget Neutrality** — This bill waives budget neutrality regarding new payment classes of medical oxygen and oxygen equipment. This will increase payments for some oxygen equipment.
- **Occupational Therapists** — Occupational therapists would be allowed to conduct the initial assessment visit for the home health benefit, provided that the referral for home health services does not include skilled nursing but does include occupational therapy, physical therapy, or speech-language pathology.
- **Real-Time Benefits Tools** — Part D plans will be required to implement real-time benefit tools (RTBT) that can integrate with e-prescribing and electronic health record (EHR) systems. This is intended to lower drug costs by allowing for better understanding of costs at the time of prescribing.

Drugs

- **Orphan Drug Clarification** — The bill clarifies that the clinical superiority standard applies to all drugs with an orphan drug designation for any orphan drug approved after the enactment of the FDA Reauthorization Act of 2017. The date of the orphan designation does not matter for this purpose.
- **Generic Labeling** — The bill would allow FDA to identify generic drugs for which labeling updates would be a public health benefit and require sponsors to update labeling.

- **Biosimilars Conditions of Use** — The bill would clarify that biosimilar applicants can demonstrate that proposed conditions for use have already been approved for the reference product.
- **Purple Book** — The bill codifies the Purple Book as a single, searchable list about each licensed biologic, including licensure status, patent information, and exclusivity periods. It also requires patent information to be submitted to FDA to be published in the purple book.
- **MedPAC and MACPAC Data Access** — The bill would give MedPAC and MACPAC access to drug pricing data, including rebate information, for monitoring, analysis, and recommendation development.

Insurance

- **Mental Health Parity** — The bill requires steps to move towards mental health parity. It requires responsible agencies to request comparative analyses of at least 20 plans per year that may involve violations of mental health parity. If the agencies find that coverage is out of compliance with mental health parity laws, then they may specify corrective actions. Failure to implement corrective action plans would result in enrolled individuals being notified of the plan's noncompliance.
- **All-Payer Claims Databases** — The bill imposes some standardization on all-payer claims databases (APCD) run by states and provides grants of up to \$2.5 million for states to stand up or modify their APCDs.
- **Gag Clauses** — The bill bans so-called “gag clauses” that prohibit enrollees, plan sponsors, and referring providers from seeing certain cost and quality data on providers.
- **Drug Cost Transparency** — Requires health plans to report medical cost and prescription drug spending information to the Secretaries of HHS, Labor, and the Treasury.

Telehealth

- **Mental Health Services** — Includes the Mental Health Telemedicine Expansion Act ([HR 1301](#)), which permanently expands access to telehealth services in Medicare to allow beneficiaries to receive mental health services via telehealth, including from the beneficiary's home. To be eligible to receive these services via telehealth, the beneficiary must have been seen in person at least once by the physician or non-physician practitioner during the six months period prior to the first telehealth service, with additional face-to-face requirements determined by the Secretary.