Summary of Key Health Provisions in the Consolidated Appropriations Act, 2021

December 31, 2020

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INTRODUCTION

The novel coronavirus (COVID-19) continues to affect millions of lives and every aspect of the US economy. After months of debate and discussion, Congress passed a $900 billion COVID-19 relief package that was attached to the $1.4 trillion Consolidated Appropriations Act, 2021 (H.R 133). H.R. 133 funds the government through the end of the current fiscal year (September 30, 2021); the COVID-19 provisions deliver additional aid to businesses, provide a $300 per week increase in unemployment insurance benefits, and direct $600 stimulus payments to certain Americans. The bill also provides targeted relief for healthcare providers and further funds vaccine and testing distribution. Additionally, the massive bill served as a vehicle for dozens of non-COVID-19-related healthcare provisions.

Highlights from the healthcare provisions include:

- Provider relief, including additional funds for the Provider Relief Fund, a three-month extension of sequester relief, and mitigation of anticipated cuts to physician payments
- Funds for testing, tracing and vaccine distribution
- Changes to Medicare policies
- Improvements to rural facility reimbursement
- Extension of Medicare, Medicaid and public health programs
- Provisions barring surprise billing and establishing new transparency requirements
- Delays to scheduled disproportionate share hospital cuts.

This legislation passed the House and Senate on December 21, 2020, by votes of 327-85 and 92-6, respectively. President Trump signed the bill six days later, on December 27th after expressing dissatisfaction with the amount of relief to individuals and families, among other things, asking that Congress increase the $600 stimulus checks to $2,000 for individuals and $4,000 for families. House Democrats approved a separate bill providing the additional stimulus money consistent with the President's request, but a companion was not approved by the Senate before this Congress concluded.

Timeline of COVID-19 Relief Legislation

March 6, 2020: Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020
- P.L. 116-123

March 18, 2020: Families First Coronavirus Response Act
- P.L. 116-127
- McDermottPlus +Insight

March 27, 2020: Coronavirus Aid, Relief, and Economic Security (CARES) Act
- P.L. 116-136
- McDermottPlus +Insight

April 24, 2020: Paycheck Protection Program and Health Care Enhancement Act
- P.L. 116-139
- McDermottPlus +Insight

June 5, 2020: Paycheck Protection Program Flexibility Act of 2020
- P.L. 116-142

July 4, 2020: A bill to extend the authority for commitments for the Paycheck Protection Program and separate amounts authorized for other loans under section 7(a) of the Small Business Act, and for other purposes
- P.L. 116-147

Passed Congress December 21, 2020: Consolidated Appropriations Act, 2021
- H.R. 133

This article offers an overview of the major federal healthcare program provisions in the package. It is not an exhaustive summary of all the health care provisions in the legislation.

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Helpful Resources

- Text of the Consolidated Appropriations Act, 2021
- House Ways and Means Committee Summary of Provisions
- House Appropriations Committee Division-by-Division Summary of COVID-19 Relief Provisions
- House Appropriations Committee Division-by-Division Summary of Authorizing Matters
- House Appropriations Committee Division-by-Division Summary of Appropriations Provisions
- M+ COVID-19 Resource Center

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COVID-RELIEF PROVISIONS

PROVIDER RELIEF FUND (PRF)

Background: The Provider Relief Fund (PRF), first established by the CARES Act, appropriated $175 billion to help providers contend with COVID-19-related costs and lost revenues. Of the $175 billion, $147 billion has been allocated thus far, but the US Department of Health and Human Services (HHS) reports that only $98 billion has been attested to by providers as of December 21, 2020.

Retention and use of the PRF payments is directed by an evolving set of Frequently Asked Questions (FAQs) and other subregulatory guidance that has at times offered conflicting guidance. In June 2020, HHS issued an FAQ stating that providers could use any reasonable method to account for lost revenues, including comparing actual 2020 revenue to a budget. On September 19, 2020, HHS revised reporting guidance that defined lost revenue as a change in year-over-year net operating income. On October 22, 2020, the agency retreated somewhat and instructed recipients to compare 2019 to 2020 patient care revenue. While the October interpretation represented an improvement from the September guidance for some recipients, it still presented challenges for many stakeholders that had relied on the June FAQ. Many providers questioned whether they could retain and use their funds under the revised interpretation.

Provision: The legislation includes an additional $3 billion for the Provider Relief Fund for eligible healthcare providers for healthcare-related expenses and/or lost revenues associated with COVID-19. This amount is substantially less than amounts included in earlier proposals that would have added $35 billion to the PRF.

The bill also includes statutory text around retention and future use of the funds. Specifically, the bill includes language requiring a return to the approach to calculating lost revenues provided in the June guidance, including and expressly allowing providers to account for lost revenues using the difference between the provider's budgeted and actual revenue if the budget was established and approved before March 27, 2020, the date of enactment of the CARES Act. This should be a welcome change for many providers, particularly those concerned about the September and October subregulatory guidance curtailing their ability to retain funds. In addition, the statutory nature of this change provides greater stability than the previous subregulatory guidance updates, which clearly changed with some frequency, little notice and little predictability.

The new law also requires that at least 85% of future distributions after enactment of the bill will be paid to providers based on applications that consider financial losses and changes in expenses in the third and fourth quarter of 2020 and first quarter of 2021. This marks a departure from early days of the PRF, when funds were sent to recipients pursuant to a formula, without an application. It also, for the first time, provides more explicit direction to HHS as to whom remaining funds should be distributed.

VACCINE DISTRIBUTION

Background: Congress has directed almost $10 billion to Operation Warp Speed through supplemental funding, including the CARES Act, and has appropriated other flexible funding to develop and deploy a COVID-19 vaccine. The nearly $10 billion specifically includes more than $6.5 billion designated for countermeasure development through the Biomedical Advanced Research and Development Authority (BARDA) and $3 billion for National Institutes of Health (NIH) research.

On December 11, 2020, the Food and Drug Administration (FDA) issued the first emergency use authorization (EUA) for a COVID-19 vaccine, clearing Pfizer-BioNTech's product for distribution in the United States. On December 18, the FDA authorized Moderna's COVID-19 vaccine, which also is now being shipped across the country. Several other products are in late-stage trials and could become available early next year.

Provision: The bill provides heavy investment to facilitate vaccine distribution, including the following:

- $20 billion for the purchase of authorized products
- $3.42 billion for direct grants for states, localities, territories and tribes for the purposes of vaccine distribution (the legislation also allows states, localities, territories and tribes to use these funds for tracking systems and data modernization)
- $2.5 billion for Centers for Disease Control and Prevention (CDC) vaccine distribution and infrastructure.

The bill allows for a contingency/discretionary fund to be utilized by HHS to send additional aid to states to assist with vaccine distribution.

Distribution of the COVID-19 vaccines will be a major challenge over the next several months. During the public health emergency, the federal government covers the cost of the authorized vaccines and ancillary kits; however, states and localities are responsible for managing local distribution, providing community outreach and education, and establishing procedures to effectively prioritize populations and report public health data. States have voiced concerns that these efforts will cost billions and slow the rapid deployment of the COVID-19 vaccines. While this new funding offers additional support, challenges will persist. Expect additional oversight and advocacy as people across the country begin to line up for vaccines.

TESTING AND TRACING

Background: Congress has provided more than $13 billion through the various COVID-19 relief packages to states and localities, CDC and BARDA for activities related to testing, contract tracing and surveillance, including developing, purchasing, administering, processing and analyzing COVID-19 tests.

Provision: This bill provides $22.4 billion in direct grants for states, localities, territories and tribes for testing, contract tracing and surveillance initiatives. Of the $22.4 billion, $2.5 billion is specifically available to improve testing capabilities and contact tracing for high-risk and underserved populations, including racial and ethnic minority populations and rural communities; $790 million of the $22.4 billion is specifically for the Indian Health Service. The bill describes a broad set of parameters for the use of these funds, including a variety of tests (antigen, molecular and serological, for example), procurement of personal protective equipment for administering the tests, and the development and validation of rapid, molecular point-of-care tests.

States, localities, territories and tribes can use these funds to support testing, contract tracing and surveillance for employers, schools, childcare facilities and long-term health care facilities, and to assist public health, academic, commercial and hospital laboratories in scaling up testing capacity. States that receive funds must submit plans on COVID-19 testing and contact tracing to HHS within 60 days and then provide HHS quarterly updates on the use of such funds. These plans will be made public.

$22.4 billion represents a significant increase in dollars flowing directly to the states, localities, territories and tribes, a recognition of the importance of and need for testing, tracing and surveillance at the local level. However, expect continuing oversight from Congress and the media in terms of how—and how quickly and effectively—these resources are being deployed.

CORONAVIRUS RELIEF FUND

Background: The CARES Act provided $150 billion for states (defined to include the District of Columbia, Puerto Rico, the United States Virgin Islands, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa), tribal governments, and certain eligible local governments with more than 500,000 residents to cover unbudgeted costs incurred due to the COVID-19 public health emergency. Under the CARES Act, states, tribal governments and localities were required to use this funding by December 31, 2020. Many eligible recipients complained that they could not deploy available relief before year-end.

Provision: The legislation extends the time states, tribal governments and localities can use the coronavirus relief funding by one year, until December 31, 2021.

With the COVID-19 pandemic still ongoing, states, tribes and localities had sought additional time to use funds from the Coronavirus Relief Fund. Since Congress could not come to an agreement on additional aid for state, local and tribal governments in this end-of-year package, this extension provides important access to funds for ongoing efforts to combat the pandemic.

PAYCHECK PROTECTION PROGRAM

Background: To support small businesses, the CARES Act made significant changes to Small Business Administration (SBA) loan programs, including creating a loan program called the Paycheck Protection Program (PPP) that is designed to help small businesses avoid closure or layoffs. Recipients could use the loans to cover payroll, utilities, insurance premiums, and rent and mortgage interest payments. PPP loans are 100% guaranteed by the SBA. Importantly, the loans are fully forgivable under certain circumstances. The program received so many applications that the $350 billion included in the CARES Act was obligated within 13 days of the loans becoming available. Subsequent legislation, the Paycheck Protection Program and Health Care Enhancement Act, added another $320 billion to the program. The Paycheck Protection Program Flexibility Act of 2020 amended the PPP to expand the loan forgiveness period from eight weeks of eligible costs to 24 weeks, or December 31, 2020, whichever is earlier.

Provision: In order to further buttress small businesses, the package infuses another $284 billion in additional funding into the PPP and extends the program through March 31, 2021, with modifications. Importantly, as in the initial iteration of the program, PPP loans can be converted to grants provided certain criteria are met. Twenty billion in additional monies is also provided for targeted Economic Injury Disaster Loans.

The agreement reopens the PPP, expands PPP eligibility to additional types of entities, allows certain smaller businesses to apply for a second forgivable PPP loan, and expands the types of expenses that may be eligible for forgiveness to include, for example, expenses for personal protective equipment. Expect this new round of PPP loans to be enormously popular.

MEDICARE PROVISIONS

PAYMENT FOR PHYSICIAN SERVICES

Background: The FY 2021 Physician Fee Schedule Final Rule, issued on December 1, 2020, and effective January 1, 2021, includes a significant payment increase for office/outpatient evaluation and management (E/M) services, typically delivered by primary care providers and certain specialty physicians. The rule created a payment add-on code (G2211) to report E/M services for complex patients. These changes resulted in a significant increase in spending for the PFS in CY 2021, with almost 1/3 resulting from the addition of the new add-on code. To offset anticipated increased spending, the rule made an unusually large and controversial budget neutrality adjustment, which resulted in a 10.2% reduction to the conversion factor.

The impact of these policies vary significantly across specialties, with those that do not generally bill office/outpatient E/M visits potentially facing cuts of as much as 10%, while other specialties, benefitting from payment increases to individual E/M services, are expected to experience increases of up to 16%. Some physician specialty societies were vigorously pressing for relief and turned to Congress to resolve the cuts, especially considering the pandemic's impact on the financial health of many practices.

Provision: The legislation includes two provisions that significantly reduce, but do not eliminate, scheduled payment cuts for physician services. First, the legislation directs Medicare to makes a 3.75% positive adjustment to the calendar-year (CY) 2021 physician payments, offsetting some of the 10.2% reduction. Second, the legislation places a three-year moratorium (through CY 2023) on payment for the

add-on code (G2211), further offsetting the cut. Combined, these two provisions should reduce the scheduled 10.2% payment cuts by about two-thirds. While the reduction in the payment cut will be a boost to all physicians and healthcare professionals, some primary care physicians and certain specialists that care for complex patients will be disappointed that it was achieved by placing a moratorium on G2211. Moreover, the 3.75% payment boost is authorized for only one year, meaning physicians will face similar reductions again in 2022.

MEDICARE PAYMENT TO PHYSICIAN ASSISTANTS

Background: Under current law, physician assistants (PAs) bill Medicare through their employers rather than billing Medicare directly.

Provision: The legislation includes, as an offset, a provision that allows Medicare to make direct payments to PAs for services furnished to Medicare beneficiaries on or after January 1, 2022. This has been a high priority for the PA community. The PA community has argued that a growing number of patients receive most of their medical care from PAs, and lacking the ability to directly bill Medicare creates inefficiencies and inhibits access to care, especially in rural and underserved areas.

MEDICARE SEQUESTRATION

Background: The Budget Control Act of 2011, as amended, established that Medicare payments are subject to across-the-board reductions of up to 2% from 2013 through 2029. The CARES Act suspended Medicare sequestration payment reductions from May 1, 2020, through December 31, 2020. To make up for the budget savings lost during this temporary suspension, sequestration was extended through 2030.

Provision: The new law extends the suspension another three months. The sequester holiday provides some additional economic relief for providers who have been financially challenged due to increased COVID-related costs and declines in revenues. The short duration of this provision could tee up the need for additional legislation in the first quarter of 2021.

MEDICARE ALTERNATIVE PAYMENT MODELS AND DEMONSTRATIONS

Background: On a bipartisan basis, Congress has worked to encourage providers to move into payment models that reduce expenditures while maintaining or improving the quality of care for beneficiaries. The Medicare Access and CHIP Reauthorization Act (MACRA) included a 5% incentive payment for qualifying participants to participate in certain two-sided risk alternative payment models (APMs). In order to qualify for the bonus payment, the APM entity had to receive a specified threshold of revenue from patients in the APM. Those thresholds jumped significantly in 2021, such that many providers would have lost their APM bonus eligibility had the increases gone into effect.

Separately, the Centers for Medicare & Medicaid Services (CMS) established the Independence at Home Demonstration, which allows health care providers to offer certain services in the patient's home environment. Participating primary care practices provide home-based care to chronically ill beneficiaries. Practices may share in savings if they generate sufficient savings and meet quality standards. This demonstration was slated to expire at the end of 2020.

Additionally, earlier in 2020, CMS announced a mandatory radiation oncology model intended to test whether bundled, prospective, site neutral episodic-based payments for radiotherapy episodes of care reduces Medicare expenditures while preserving or enhancing quality. The new model was initially scheduled to be implemented January 1, 2021, but CMS delayed implementation to July 1, 2021.

Provisions: The legislation freezes APM thresholds at 2020 levels for two additional years. This is welcome news for participants in advanced APMs who will now be able to qualify for the 5% incentive payment.

The legislation also extends the Independence at Home Demonstration through December 31, 2023, and expands the size of the demonstration from 15,000 to 20,000 beneficiaries. Stakeholders have

enthusiastically embraced this demonstration and its extension and expansion will be welcome news for participants.

The new law delays implementation of the radiation oncology model an additional six months, to January 1, 2022. This additional delay affords stakeholders more time to work with the incoming Biden administration to shape this demonstration before it is launched.

MEDICARE GRADUATE MEDICAL EDUCATION

Background: Graduate Medical Education (GME) payments directly fund teaching hospitals training medical residents. These payments are the largest federal investment in healthcare workforce training. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the Affordable Care Act (ACA) included provisions for redistributing Medicare GME residency slots, but the number of residency slots has not been increased in a meaningful way since 1996.

Provisions: The legislation included several provisions relating to Medicare GME. First, beginning on January 1, 2023, the legislation lifts the cap on Medicare-funded residency slots, adding a total of 1,000 positions. However, only 200 new residency slots will be made available per year. Of these 200 slots, at least 10% must be allocated to rural hospitals, hospitals with residency positions that already exceed their facility's Medicare cap, hospitals in states with new medical schools, and hospitals that serve Health Professional Shortage Areas. To receive additional residency slots, hospitals must apply; hospitals will be limited to a maximum of 25 new residency slots.

Additionally, the legislation creates flexibility in the Medicare GME Rural Training Tracks (RTT) program to allow for urban and rural hospitals to partner to establish residency programs and allows hospitals to host a limited number of residents for short-term rotations without being negatively impacted by a set residency cap.

Further, the new legislation permits hospitals that inadvertently triggered permanent low GME resident and cost limits by hosting rotating medical residents from teaching programs at other hospitals or medical schools.

Advocates have worked to increase the number of Medicare GME residency slots for years; however, lawmakers have largely pushed back on these efforts and sought a different funding model. The public health emergency highlighted the need to invest in the healthcare workforce, particularly focusing on rural and underserved communities

SURPRISE BILLING AND TRANSPARENCY

SURPRISE BILLING

Background: In 2019, Congress came close to enacting legislation addressing surprise billing of patients, the situation where a patient unwittingly receives services from an out-of-network provider and is billed and responsible for the cost of those services. As a result of competing, intense lobbying efforts by stakeholders, there were two primary surprise billing legislative proposals circulating late that year. The first, supported by Energy and Commerce Committee Leadership, Frank Pallone (D-NJ) and Greg Walden (R-OR), and Senate Health, Education, Labor and Pensions (HELP) Committee Chairman Lamar Alexander (R-TN), proposed to resolve payer-provider payment disputes using a combination of benchmark rates and arbitration. The second proposal, with support from Ways and Means Committee leadership, Richard Neal (D-MA) and Kevin Brady (R-TX), also included the arbitration approach but, importantly, did not include a minimum negotiated rate or a threshold amount to enter arbitration. (View our summary of the previous surprise billing proposals here.)

Provisions: Under the new legislation, beginning January 1, 2022, plans and providers (including hospitals, facilities, individual practitioners and air ambulance providers) are prohibited from billing patients more than in-network cost-sharing amounts. The prohibition applies to emergency care and to certain non-emergency situations where patients do not have the ability to choose an in-network provider. To reconcile payment disputes between plans and providers, the legislation directs negotiation between the parties, and then a prescribed arbitration process if negotiations fail. The arbitration methodology is applicable to providers and payors and, notably, to air ambulances (inclusion of air ambulance-related disputes in the prohibition has been one of the more contentious issues). The new law does not include a minimum negotiated payment rate to trigger arbitration.

Several changes were made to a draft compromise released the previous week (the No Surprises Act). These changes include removing the requirements on the timely billing provisions, which would have set up a 90-day timeframe in which a patient must receive a bill after a discharge or the end of a visit. If the patient did not receive the bill within the 90 days, the patient would not be obligated to pay. This provision caused concern from some stakeholders, as it put in place a short window for plans and providers to work out payment discrepancies. The other change excludes public payor rates (*e.g.*, Medicare and Medicaid) from consideration in the arbitration process. This is a change that providers had sought since these rates are typically lower than commercial reimbursement amounts.

The arbitration process is baseball-style: each party submits an offer and the mediator selects one of the offers. The decision is then final and payment must be made within 30 days. Providers and payors cannot initiate a new arbitration process for 90 days for the same items or services.

The inclusion of the surprise billing provisions is a culmination of more than two years of congressional focus and intense advocacy efforts. These policies represent a significant step in addressing surprise billing. By using arbitration, rather than pegging payment rates to specific cost thresholds, the legislation follows an approach providers preferred. The latest version moves even further in favor of doctors and hospitals by banning the arbiter from considering the lower payment rates paid by federal government programs. However, there are many provisions that require agency rulemaking, including details of the informal dispute resolution (IDR) process, leaving room for input from a new administration as well as stakeholders before the bill goes into effect in January 2022. Expect continued lobbying of Congress and the administration, and possibly more changes in the lead-up to implementation.

TRANSPARENCY

Background: Transparency-related provisions were coupled with the surprise billing proposals introduced in Congress late last year (referenced above). Transparency policies have focused on improving patient access to information on out-of-pocket costs, provider directories and prescription drug costs.

Provisions: In this legislation, transparency-related provisions include disclosures to patients on costs, provider directories, a prohibition of contracts that bar disclosing cost, price or quality information, and reporting on prescription drug costs. Specifically, the new legislation makes the following changes:

- Group or individual health plans will be required to identify on insurance cards the amount of the in-network and out-of-network deductibles and the in-network and out-of-network out-of-pocket maximum limitations.
- Health plans will be required to have up-to-date directories of their in-network providers.
- Health plans must provide direct access to certain providers, including obstetrics and gynecology (OB-GYN) services, without requiring prior authorization or referral.
- Health plans must provide an Advance Explanation of Benefits for scheduled services at least three days in advance of the provision of such services.

- Payers are prohibited from entering contracts with providers if such contracts would bar the payer from disclosing provider-specific cost, price or quality information, or from accessing de-identified claims information for the purposes of analysis and improvement.
- Employer-sponsored plans and individual market plans, including short-term limited duration plans, are required to disclose direct or indirect compensation with an agent or broker enrolling individuals into the plan.
- Plans must report prescription drug and spending information. This information includes the 50 brand-name prescription drugs most frequently dispensed by pharmacies for claims paid by the plan or coverage, and the total number of paid claims for each such drug; the 50 most-costly prescription drugs with respect to the plan or coverage by total annual spending, and the annual amount spent by the plan or coverage for each such drug; and the 50 prescription drugs with the greatest increase in plan expenditures. Additionally, plans must also report total healthcare spending by hospital costs, provider costs, prescription drug costs and other medical costs, and any impacts on premiums due to rebates, fees or any other renumeration (this provision was included in the Lower Health Care Costs Act).

Additionally, the bill codifies the requirement for Part D plans to implement electronic real-time benefit tools, which allow beneficiaries to identify the applicable cost sharing and formulary status of covered Part D drugs and their alternatives. Similarly, the legislation establishes requirements for e-prescribing software to incorporate real-time cost and coverage information for Part D drugs. These were included as part of the CMS rule "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses" published in May 2019.

Finally, the bill includes a provision requiring the Secretary of HHS to make one-time grants to eligible states to establish or improve existing state All Payer Claims Databases.

In general, the transparency provisions are likely to impose additional administrative burden and costs on plans and providers. Patients could benefit from these provisions in making decisions regarding their healthcare services, but additional studies would be needed to determine overall effectiveness. The reporting requirements on prescription drug costs could also provide researchers and policymakers new information to support prescription drug payment reforms.

These requirements also come on the heels of two major CMS rules governing hospital and health plan transparency. The hospital requirements for pricing disclosure are set to go into effect January 1, 2021 (although there are lawsuits pending), and require hospitals to, among other things, provide clear, accessible pricing information online about the items and services they provide. The health plan transparency requirements do not go in effect until January 1, 2022, and require plans and insurers to disclose cost-sharing estimates and publicly post negotiated rates for in-network providers, historical out-of-network allowed amounts and billed charges, and drug pricing information. These changes have been opposed by providers and plans, with advocacy focused on the administration, as well as Congress. However, these rules, along with the increased requirements in this bill, signal that Congress and the incoming administration are unlikely to be sympathetic to providers and plans in making significant adjustments.

MEDPAC AND MACPAC ACCESS TO PRESCRIPTION DRUG AND REBATE DATA

Background: The Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access Commission (MACPAC) are nonpartisan, government agencies that advise Congress and HHS on Medicare and Medicaid policies, respectively.

Provision: The legislation provides the executive directors of MedPAC and MACPAC access to certain Medicare Part D payment and pharmaceutical manufacturer rebate data for purposes of monitoring, analysis and making program recommendations.

Both commissions will have access to additional prescription and rebate data, which will allow the commissions to conduct deeper analyses and research and develop reports and, potentially, recommendations that relate to prescription drug policy. These analyses will be important, as Congress and the administration often rely on commission reports to help inform policy decisions. Further, prescription drug costs, especially drug rebates, have been a priority issue for several years.

MEDICAID

DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENTS

Background: The ACA reduced Medicaid DSH payments based on the expectation that expanded access to coverage achieved by the new law would reduce the need to reimburse hospitals for uncompensated care. As a result of shifting market dynamics and policies, however, Congress has revised and delayed those reductions in subsequent legislation. Most recently, the CARES Act and the Continuing Appropriations Act, 2021 and Other Extensions Act further delayed the cuts until December 18, 2020. Each time Congress has intervened, the delayed cut is deferred, but not eliminated, resulting in cuts looming in the future.

Additionally, over the last few years, Congress has increasingly scrutinized supplemental payments, *i.e.*, payments made to hospitals in addition to base Medicaid payments. Base payments are tied to specific services provided to a Medicaid beneficiary, while supplemental payments are payments made to hospitals that are not tied to specific care, but that can help offset losses arising from uncompensated care. Supplemental payments fall into two categories: DSH payments and non-DSH supplemental payments. There are limited reporting requirements for supplemental payments, which leads to confusion on how these payments are distributed and the amount of funding going to providers.

Finally, the last issue related to DSH focuses on third-party payments. In 2017, CMS released a final rule revising how the Medicaid DSH payment program determines uncompensated care costs for Medicaid-eligible patients who also have another third-party source of coverage. The rule clarified that for purposes of Medicaid DSH, the total cost of uncompensated care equals the cost of inpatient and outpatient hospital services remaining after accounting for all third-party revenues, including but not limited to payments by Medicare and private insurance, associated with Medicaid-eligible or uninsured individuals. This change had the effect of reducing DSH payments, in some instances substantially, to some providers. There were several legal challenges to the rule, but they were resolved in favor of CMS. Since this time, some hospitals have sought a legislative fix to this rule to change the definition of Medicaid shortfall in calculating uncompensated cost.

Provisions: First, the bill includes a three-year DSH payment reduction delay, pushing back scheduled DSH reductions through fiscal year (FY) 2023. However, as it has done in the past, it extends DSH reductions for two additional years on the back end. DSH reductions are now scheduled to be $8 billion per year from FY 2024 through FY 2027. Delaying DSH payment reductions will support hospitals serving low-income and uninsured beneficiaries. However, extending DSH payment reductions in FY 2026 and FY 2027 increases the amount of the DSH payment reduction moving forward. Stakeholders will undoubtedly continue to seek further delays as 2023 approaches.

The law also includes transparency and reporting provisions related to supplemental payments. The new bill adopted the supplemental reporting language that originally appeared in the December 2019 Grassley-Wyden Prescription Drug package, the Prescription Drug Pricing Reduction Act of 2019. The transparency provisions require HHS to establish a system for each state to submit reports on supplemental payments data. Specifically, states will be required to report how they calculate and distribute supplemental payments, criteria for supplemental payment distribution, and total supplemental payments distributed to each provider (if known), or total amount distributed. These state reports and data will be published on the CMS website (the transparency reporting requirements do not apply to DSH supplemental payments). For the new transparency reporting requirements, this will result in additional administrative burdens for states and providers in collecting and reporting these elements. There could also be additional scrutiny of supplemental payments. However, these transparency reporting

requirements are less rigorous and less detailed than the supplemental reporting requirements laid out in the now-withdrawn Medicaid Fiscal Accountability Regulation.

Finally, the bill also included a change in how third-party payers are used in calculating Medicaid shortfalls. This provision is retroactive to January 1, 2020. This provision will have varying impacts on hospitals depending on patient mix and the number of Medicaid patients who also have third-party coverage.

MEDICAID COVERAGE FOR QUALIFIED NON-CITIZENS

Background: The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (commonly known as "welfare reform") established that only certain "qualified non-citizens" are eligible for full Medicaid coverage. Due to a drafting error, this change excluded individuals living in Governments of the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau from receiving Medicaid coverage.

Provision: The legislation will allow individuals living in Governments of the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau to be eligible for Medicaid. This will allow thousands of Pacific Islanders access to Medicaid coverage, improve access to care and reverse a draft error included in the 1996 welfare reform bill.

MEDICAID STATE FRAUD AND ABUSE CONTROL UNITS

Background: Medicaid Fraud Control Units (MFCUs) investigate and prosecute alleged Medicaid provider fraud as well as patient abuse or neglect in healthcare facilities and board-and-care facilities. MFCUs operate in all 50 states as well as the District of Columbia, Puerto Rico and the US Virgin Islands. The MFCUs, usually a part of the state attorney general's office, employ teams of investigators, attorneys and auditors; are constituted as single, identifiable entities; and must be separate and distinct from the state Medicaid agency.

Provision: The legislation extends MFCU investigation and authority beyond institutional settings. This provision will expand MFCU oversight and could result in more Medicaid fraud, abuse and neglect prosecutions.

RURAL HEALTH

Background: Prior to the COVID-19 public health emergency, the rural healthcare infrastructure in the United States was under pressure. From 2005 through 2019, more than 150 rural hospitals closed. Of those closures, 70 occurred in the five-year period from 2015 through 2019. The pandemic has exacerbated and accelerated that strain—in the first 10 months of 2020, nearly 20 rural hospitals closed.

Provisions: In a large change in policy, the bill establishes a new, voluntary Medicare payment designation that allows either a critical access hospital (CAH) or a rural hospital with 50 beds or less to convert to a rural emergency hospital (REH). REHs would be prohibited from providing acute inpatient services, must meet certain emergency department staffing requirements and must have a transfer agreement in place with a Level I or II trauma center. Although REHs cannot provide acute inpatient services, they are permitted to provide additional medical services needed in their community, including observation care, outpatient hospital services, telehealth services, ambulance services and skilled nursing facility services. REHs will be reimbursed under the Medicare Outpatient Prospective Payment System plus a 5% add-on. Certain REHs will also receive an additional monthly facility payment based on critical access hospital payments. Notably, REHs are also deemed as a telehealth originating site.

The bill also establishes a comprehensive rural health clinic (RHC) payment reform plan, based on language from H.R. 2788, Improving Rural Health Clinic Payments. Under current law, RHCs, except for

certain provider-based facilities, are subject to a maximum payment rate per visit, which was established by Congress and is updated annually based on the Medicare Economic Index (MEI) percentage. This change raises the statutory RHC payment limit to $100 starting on April 1, 2021, and gradually increases the upper limit each year through 2028 until the cap reaches $190, bringing the RHC upper payment limit roughly in line with the federally qualified health centers (FQHC) Medicare base rate. Starting in 2029, increases to the payment limit will be adjusted annually based on the MEI. This section also subjects all new RHCs to a uniform per-visit payment limit and controls the annual rate of growth for RHCs whose payments are above the upper limit by limiting increases for these facilities to the MEI.

Finally, RHCs and FQHCs can furnish and bill for attending physician services when RHC and FQHC patients become terminally ill and elect the hospice benefit, beginning January 1, 2022. As a result, Medicare beneficiaries will continue to receive hospice-related care from their known provider.

As the traditional inpatient model continues to challenge small rural hospitals, many states have explored the idea of an emergency-only hospital model. One of the key issues they have faced is how Medicare would treat reimbursement, since there was not a specific methodology for an emergency-only stand-alone hospital. The new REH designation will streamline this process and provide smaller hospitals with options besides closure.

Congress' acknowledgment of the challenges rural healthcare providers face is likely to continue in 2021, with potential added flexibilities for requirements such as distance, bed count and payor mix.

MEDICARE, MEDICAID AND PUBLIC HEALTH EXTENDERS

Background: Many Medicare, Medicaid and public health programs are funded and authorized on a temporary, short-term basis. The programs listed below were last extended through December 21, 2020, and needed to be extended, or face expiration.

Provisions:

Community health centers (CHCs): CHCs serve more than 25 million people and rely on federal discretionary funds of about $3.6 billion annually (almost one-fifth of their total revenue) to provide services to uninsured patients, expand capacity and offer an expanded set of healthcare services, such as oral health and substance abuse disorder services. The ACA provided a significant increase in funding for CHCs through 2015, and Congress subsequently extended that funding several times. This bill funds CHCs at current levels and for an additional three years through FY 2023.

Teaching health centers: The Health Resources and Services Administration operates Teaching Health Center Graduate Medical Education programs focused on increasing the primary care workforce in medically underserved communities. The program was established and funded for five years under the ACA and has been reauthorized and funded several times since then. Most of the training programs currently operating in the states are conducted in CHCs. This bill funds teaching health centers at current levels for an additional three years through FY 2023.

National Health Service Corps: The National Health Service Corps (NHSC) was established in 1972 to focus on connecting primary care clinicians to underserved communities across the country. Over 17 million people receive care from more than 16,000 clinicians serving at NHSC-approved sites in urban, rural and tribal communities. This bill funds the NHSC at current levels through FY 2023.

Money Follows the Person Program: The Money Follows the Person Program was created in 2005. The program provides states with enhanced federal matching funds for services and supports to help seniors and people with disabilities move from institutions to home-based care. Forty-four states participate in the program, which has helped more than 90,000 institutional residents transition back to their communities.

The ACA expanded the program, but long-term funding expired in 2016. Since then, lawmakers have passed a series of short-term limited funding bills to continue the program. This bill funds Money Follows the Person for three more years through FY 2023.

Special Diabetes Program: The Bipartisan Budget Act of 1997 created two programs: the Special Diabetes Program for Indians at the Indian Health Service and the Special Statutory Funding Program for Type 1 Diabetes Research at the NIH. These programs fund evidence-based diabetes treatment and prevention programs in local communities as well as NIH research. This bill funds these programs through FY 2023.

Geographic Practice Cost Indices work floor: Medicare payments to physicians are geographically adjusted to reflect the varying cost of delivering physician services across areas. The adjustments are made by indices, known as the Geographic Practice Cost Indices that reflect how each geographic area compares to the national average. In 2003, Congress established that for three years there would be a "floor" of 1.0 on the "work" component of the formula used to determine physician payments. Congress has repeatedly extended the 1.0 floor. There are concerns that without these adjustments, physician services in rural areas would be disproportionately affected by lower Medicare payments. This bill extends the floor three additional years, through December 31, 2023.

Medicare quality measure endorsement, input and selection: CMS is tasked with developing reliable and meaningful quality measurement that focuses on outcomes. Congress has supported these efforts with funding for CMS to provide for quality measure selection and to contract with a consensus-based entity to carry out some of the tasks associated with this effort. This bill provides $66 million in funding to CMS through September 30, 2023, for this purpose. It also includes additional reporting requirements, facilitates measure removal, and prioritizes maternal morbidity and mortality measure endorsement.

Funding outreach and assistance for low-income programs: There are a several programs that provide Medicare beneficiary outreach, enrollment and education activities for low-income populations. These are generally provided and funded through state health insurance assistance programs; area agencies on aging; aging and disability resource centers; and the National Center for Benefits and Outreach and Enrollment. Congress has regularly supported these programs and continued that trend by providing funding through September 30, 2023.

FISCAL OFFSETS

Background: The bill contains several sections intended to offset the cost of other provisions, including addressing drug pricing, coverage of certain kidney care drugs, and extension of a payment policy for hospice caps and extending hospice reporting requirements.

Provisions:

Drug pricing: The legislation adds a new requirement for manufacturers that do not have a rebate agreement through the Medicaid Drug Rebate Program to report Average Sales Price (ASP) information. The bill also provides for a special rule for determination of ASP in cases of certain non-covered self-administered drug products.

Hospice: The calculation of the hospice cap amount under Medicare is changed by extending the IMPACT Act policy into the year 2030. The bill also establishes hospice program survey and enforcement procedures under the Medicare program and increases the penalty for hospices not reporting quality data from two to four percentage points, beginning in fiscal year 2024.

Coverage of immunosuppressive drugs: Many Medicare beneficiaries qualify for Medicare by virtue of having end-stage renal disease. However, when these patients receive a kidney transplant and resolve their disease, they often lose their Medicare eligibility, leaving them liable for the cost of expensive

immunosuppressive drugs. In a change of policy for dialysis patients, the bill allows transplant recipients to continue to qualify for Medicare for coverage of immunosuppressive drugs.

Payment to physician assistants: This section restates the provision allowing for physician assistants to bill Medicare directly for their services beginning January 1, 2022.

Medicaid Improvement Fund: The legislation strips $3.4 billion from the Medicaid Improvement Fund.

MISSING PROVISIONS

As with any negotiation, compromises are made. Democrats and republicans each pursued various priorities that ultimately were left out of the final package. Stakeholders also lobbied different priorities, some of which were included in previous iterations of the bill, but ultimately were excluded. Following are some of the more significant and frequently discussed items that did not make the final cut, but which are expected to be front and center when congress considers the next relief and stimulus package in 2021.

FUNDING FOR STATE, LOCAL AND TRIBAL GOVERNMENTS

Background: The CARES Act established the $150 billion Coronavirus Relief Fund for state, local and tribal governments. The federal relief funds are restricted and can be used only for expenses that directly relate to COVID-19. Although this legislation did not provide new CARES Act funding, it did extend the time states, tribal governments and localities could use the CARES Act funding.

Current State of Play: This issue has been one of the strongest points of disagreement during negotiations over the past several months. Republicans—led by Senate Majority Leader Mitch McConnell (R-KY)—have labeled these “blue state bailouts,” meaning the funds are subsidizing Democrat-led states that were struggling financially before the pandemic due to issues such as state pension-fund shortfalls. Meanwhile, Democrats have urged robust funding to support state and local governments. For example, House Democrats passed the HEROES Act in May 2020, which included $500 billion for states and $375 billion for local governments. Since a consensus between the parties on the amount of funding could not be met, the bipartisan group chose to separate this provision.

States, tribal governments and localities may experience budget deficits in 2021 and future years relating to the COVID-19 pandemic without additional funding. These entities may look to cut services throughout a variety of sectors to balance budgets.

MEDICARE ACCELERATED AND ADVANCED PAYMENTS TO PROVIDERS

On March 28, 2020, CMS expanded the existing Accelerated and Advance Payments Program, which allows pre-payment of Medicare claims in emergencies, to a broader group of Medicare providers. On April 26, 2020, CMS announced the suspension of these payments.

Despite efforts by many providers pushing for more favorable terms for loan repayment, the Accelerated and Advanced Payments were not addressed in this bill. This is likely because the loans are not due for repayment until next year. The Continuing Appropriations Act, 2021 and Other Extensions Act changed the repayment schedule, allowing providers up to one year from receiving the accelerated or advance payments before reimbursing CMS. After that point, for 11 months, Medicare payments owed to providers and suppliers will be recouped at a rate of 25%. After that time period, Medicare payments owed to providers and suppliers will be recouped at a rate of 50% for another six months. After those final six months, the remaining balance will be due. Expect stakeholders to continue to press for relief into 2021.

LIABILITY PROTECTION

The Public Readiness and Emergency Preparedness Act provides limited immunity from liability for entities and individuals involved in the development, manufacture, testing, distribution, administration and use of countermeasures to diseases such as COVID-19. General business and healthcare stakeholders have been pushing for broader protection from claims of liability they view as inevitable after the pandemic. There has been a nearly eight-month impasse over these protections. Republicans generally have argued that these protections are needed for those who are acting in good faith, while Democrats are concerned about providing overly broad immunity. In recent months, Senate Majority Leader Mitch McConnell (R-KY) has called for a five-year period of liability protection for healthcare providers, business and schools. On December 11, 2020, Republicans reportedly made an offer of an 18-month protection, which Democrats rejected. Expect this conversation to continue into 2021 as employers, schools and healthcare providers continue to reopen.

FEDERAL MEDICAL ASSISTANCE PERCENTAGES (FMAP)

The Families First Coronavirus Response Act provided an additional 6.2% of the federal portion of the FMAP for states beginning January 1, 2020 and is available through the quarter in which the public health emergency period ends. Additionally, the Families First Coronavirus Response Act incorporates a maintenance-of-effort (MOE) requirement that prohibits states from implementing new eligibility restrictions or terminating coverage while receiving the extra federal funds.

There have been calls from state government organizations such as the National Governors Association, the National Association of Counties and the National Conference on State Legislatures to provide a 12% increase to Medicaid FMAP due to the COVID-19 pandemic. However, efforts to increase FMAP have decreased over the last few months, as has interest in this goal. As it relates to the MOE, in November 2020, CMS released an interim final rule with comment period (IFC), “Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency.” In this IFC, CMS made changes to the MOE by adding flexibilities for states to modify eligibility and coverage requirements while keeping the increased FMAP.

Without an increase in FMAP, state Medicaid agencies may seek to cut optional Medicaid services or provider rates.

TELEHEALTH

Congress and the Administration have authorized a number of waivers and flexibilities during the public health emergency allowing greater use of telehealth services. These have resulted in a significant expansion of telehealth, increasing access for patients and giving providers additional means to ensure continuity of care while in-person visits are limited during the pandemic. They have also resulted in new, innovative ways providers are treating those with mental and behavioral health conditions, as well as chronic conditions such as diabetes and hypertension.

Most of these waivers are tied to the authority provided through the public health emergency. Therefore, once the emergency ends, the waivers will too. The current emergency declaration is set to end January 21, 2021. The new administration is expected to extend it; however, concern remains that the frequency of renewals are dependent on the administration and there currently is no regulatory ability to provide a transition period. As such, stakeholders had advocated for a legislative extension of the waiver authority for a time certain, effectively untying it from the need for an administrative declaration. In a previous proposal, lawmakers had included this authority through December 31, 2021. It was not included in this legislation. The legislation did include a narrow provision on tele-mental health services. However, we expect that in 2021 stakeholders will once again return to Congress to seek additional telehealth policy.

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CONCLUSION

The Consolidated Appropriations Act, 2021 is the final major piece of legislation of the 116th Congress. It is a sweeping year-end legislative package that not only funds the government for FY 2021, but also includes a COVID-19 fiscal relief package, surprise billing prohibitions and tax extenders. This package represents the culmination, but not necessarily the conclusion, of months of contentious negotiations.

In the healthcare space, there are a number of policies that represent forward progress for some stakeholders. These range from healthcare extender funding to Medicare GME expansions. But not all of the policy changes will be met with support, nor does this bill represent all the issues that healthcare stakeholders wanted addressed before the end of 2020. For his part, President-elect Biden has consistently referred to this bill as a "down payment," signaling his intent to push for more and likely bigger relief and stimulus legislation. This sets up Congress and the healthcare community to return to many of these issues in the first quarter of 2021. We expect stakeholders to continue to advocate for issues that did not make it across the finish line, and for Congress to return to these and other discussions at the start of 2021.

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