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Policy Update

2019 Year-End Appropriations: Health Highlights

Summary

On December 19, 2019, the United States Senate gave final congressional approval to a Fiscal Year (FY) 2020 appropriations package; the President is expected to sign the measure. This bill funds all government agencies through the end of FY 2020. The package also includes policy changes, including a number of significant health program provisions.

What is in:

1. Repeal of three Affordable Care Act (ACA) taxes
2. Short-term extensions of expiring healthcare programs
3. Increase in the age to purchase tobacco products to 21

This package is also notable in terms of what it does not include.

What is out:

1. Long-term extensions of expiring healthcare programs
2. Sweeping drug pricing policies
3. Surprise billing provisions

Congress could not come to agreement on two priority policy areas: drug pricing and surprise billing. These issues will remain at the legislative forefront going into 2020. The reason? Lawmakers likely will need policies that save money to offset the cost of a long-term extension of health programs that now will expire in May 2020. As we have noted before, drug pricing and surprise billing could provide those pay-fors.

Highlights of What Is In

Key Provision: Repeal of three healthcare taxes

The bill permanently repeals three taxes originally enacted in and used to reduce the cost of the Affordable Care Act: the medical device tax, health insurance tax and a tax on high-cost health plans, commonly referred to as the “Cadillac tax.” The bill does not provide an offset to pay for these provisions.

- *Medical Device Tax:* The ACA imposed a tax on the sale of certain medical devices at the manufacturer or importer level. The tax was initially delayed through December 31, 2017. Earlier this year, Congress delayed it again through December 31, 2019. The tax is now permanently repealed beginning in 2020.
- *Health Insurance Tax:* The ACA imposed a tax on insurers that offer fully insured health coverage in the individual market, the group market or public programs. In 2017, Congress approved a one-year moratorium on the tax. The tax took effect again in 2018 before Congress suspended it for a second time through December 31, 2019. This package permanently repeals the tax for 2021 and beyond, but leaves it in effect for 2020.
- *Cadillac Tax:* The ACA imposed a 40% tax on high-cost health plans (more than $11,200 per year for an individual policy or $30,150 for family coverage). Congress had previously suspended this tax through December 31, 2022. The tax is now permanently repealed.

Key Provision: Short-term extension of expiring healthcare programs

In general, most healthcare programs that expired at the end of the fiscal year, or that were set to expire at the end of the calendar year have been extended until May 22, 2020. These extenders include:

- *Delaying the Medicaid DSH Allotment Reduction:* The ACA reduced the amount of Medicaid disproportionate share hospital (DSH) payments based on the expectation that expanded access to coverage included in the other portions of the 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. The previous suspension was adopted in a February 2018 budget bill that delayed DSH reductions through 2019, but maintained a $4 billion reduction for FY 2020 and increased the annual DSH reduction to $8 billion per year for FY 2021–2025. This bill further suspends implementation until May 2020, but without changes to the formula in subsequent years.
- *Community Health Centers:* Community Health Centers (CHCs) serve more than 25 million people and rely on federal discretionary funds of about $3.6 billion annually (nearly 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 has subsequently extended that funding several times.
- *Teaching Health Centers:* The Health Resources and Services Administration operates Teaching Health Centers 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 57 training programs currently operating in the states are conducted in CHCs. In 2018–2019, this program supported the training of 728 residents in 56 residency programs across 23 states.

- *Money Follows the Person:* 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.
- *Special Diabetes Program:* The Bipartisan Budget Act of 1997 created two Special Diabetes 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 National Institutes of Health (NIH). The program funds evidence-based diabetes treatment and prevention programs in local communities as well as NIH research.
- *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 (GPCI), 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 in particular would be disproportionately affected by lower Medicare payments.

Key Provision: Medicaid funding for Puerto Rico

Medicaid funding in the US territories is provided through base funding established in the Social Security Act and additional funding appropriated by Congress. Unlike the 50 states and Washington, DC, where the federal government will match all Medicaid expenditures at the determined Federal Medical Assistance Programs (FMAP), in Puerto Rico the FMAP is applied until spending reaches the cap of the appropriated funds. The ACA authorized Medicaid funding for Puerto Rico from July 1, 2011, to September 30, 2019. The most recent Continuing Resolution extended Medicaid funding for the territories until December 20, 2019. This bill provides Puerto Rico and the territories with Medicaid funding through FY 2021. However, the package also includes program integrity and data requirements, as well as Medicaid reviews, for Puerto Rico's and the other territories' Medicaid programs.

Key Provision: Raising the age to purchase tobacco to age 21

This bill amends the Federal Food, Drug, and Cosmetic Act to increase the minimum age of purchase of tobacco products from 18 to 21 years of age.

Key Provision: CREATES Act

The appropriations bill includes the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, legislation that allows a biosimilar or generic-drug manufacturer to sue in federal court for an injunction to obtain samples it needs from the product's manufacturer to create generic alternatives, and provides the US Food and Drug Administration more discretion to approve alternative safety protocols to ensure that a product developer cannot use safety protocols to delay access to samples.

Key Provision: Prohibiting the Administration from ending "silver loading" and auto-enrollment

The bill includes a provision that prevents the Secretary of the US Department of Health and Human Services from ending the practice of "silver loading" for plan year 2021. In 2017, the Trump Administration ended the cost-sharing reductions (CSR) as previously provided under the ACA. These payments were supposed to lower copayments and deductibles for exchange enrollees with annual incomes below 250% of the federal poverty level (FPL). As a result of this change in policy, many insurers offering plans through the exchange marketplace increased silver-level plan premiums to off-set the loss of the CSRs, and because the ACA allows for those premiums to be used to determine the amount of federal subsidies available to individuals with annual incomes below 400% of the FPL, a phenomenon called "silver loading." When premiums for silver plans rose sharply as a result, federal subsidies rose along with them. CMS has previously said it wants to end the practice of silver loading, which could make plans more expensive and inaccessible to many people. The new law prohibits CMS from ending this practice. It also requires the Secretary to establish a plan for auto-enrollment for certain individuals receiving coverage through a qualified health plan on the marketplace for plan year 2021. In the past, CMS has also signaled interest in eliminating the option for auto-enrollment.

Key Provision: The Laboratory Access for Beneficiaries (LAB) Act

The spending package incorporated the Laboratory Access for Beneficiaries (LAB) Act. This will delay reporting of lab payment data required by the Protecting Access to Medicare Act (PAMA) by one year. However, it will not change the period for data collection, which remains the first half of 2019. Additionally, it will not impact the potential for further cuts in 2021 based upon data reported in 2017 if those data show median rates below the 2020 rates. Finally, it calls for a Medicare Payment Advisory Commission (MedPAC) study looking to identify the least burdensome approach to data collection that would provide data representative of the entire laboratory market, including hospital laboratory and physician office laboratory market segments that are underrepresented under the current rules.

Highlights of What Is Out

Key Takeaway: Many health policy priorities, such as surprise billing and prescription drug pricing reforms, were not included in the package.

Congressional Landscape

Congress spent much of 2019 working on two transformative health policy objectives: surprise billing and prescription drug reforms. While neither was included in this bill, there was a flurry of activity in the lead up as five committees of jurisdiction and both parties' leadership worked on five different bills:

- The Senate Finance Committee leadership announced a bipartisan agreement on prescription drug costs (S. 2543 the Prescription Drug Pricing Reduction and Health and Human Services Improvements Act). Notably, Senate Majority Leader Mitch McConnell (R-KY) had concerns about Republican support for the Senate Finance Committee package.

- The Senate Health, Education, Labor, and Pensions (HELP) Committee Chairman Lamar Alexander (R-TN) and Democratic and Republican leaders of the House Energy and Commerce Committee (Frank Pallone (D-NJ) and Greg Walden (R-OR)) released an agreement mainly focusing on surprise billing and a small set of drug pricing transparency proposals.
- Considerable committee and floor time was expended advancing the House Democrats' drug pricing bill (H.R. 3, Elijah E. Cummings Lower Drug Costs Now Act), as well as assembling the Republican's alternative (H.R. 19, Lower Costs, More Cures Act of 2019).
- Finally, the House Ways and Means Committee announced a late-breaking bipartisan surprise billing proposal that purportedly would avoid the more controversial provisions of the HELP and Energy and Commerce package (more on this below).

The inability of the four committees with jurisdiction over these two health policy topics to achieve consensus on the varying legislative proposals led leadership to defer action on these proposals this year.

Prescription Drugs

Throughout 2019 the rising costs of prescription drugs was a focus for both Congress and the Administration. More than 100 bills were introduced in 2019 to address prescription drug costs. The Administration released its Blueprint to Lower Drug Prices and continues to pursue several regulations to lower prescription drug costs.

Although prescription drug reform appeared to be an area of bipartisan agreement, very little was actually accomplished in this space this year. In this spending package, only one prescription drug pricing measure advanced: the CREATES Act. However, because the healthcare extenders now must be addressed in May 2020, there is still opportunity for bipartisan agreement on prescription drug pricing measures in the new year.

In terms of where that agreement could occur, three of the major prescription drug packages (H.R. 3, H.R. 19 and S. 2543) include areas of overlap. All three include provisions relating to capping Part D out-of-pocket costs for Medicare beneficiaries; restructuring the catastrophic coverage phase in Medicare so that the federal government pays less, but manufacturers and plans pay more; increasing consumer access to prescription drug prices; and pharmacy benefit manager reforms.

There also are areas of bipartisan support in prescription drug pricing beyond these three proposals. For example, H.R. 983 (the BLOCKING Act[1]), H.R. 1520 (the Purple Book Continuity Act of 2019[2]), H.R. 1503 (the Orange Book Transparency Act of 2019[3]), H.R. 1781 (the

[1] H.R. 983, the BLOCKING Act, amends the Federal Food, Drug, and Cosmetic Act with respect to eligibility for approval of a subsequent generic drug to remove the barrier to that approval posed by the 180-day exclusivity period afforded to a first generic applicant that has not yet received final approval.
[2]H.R. 1520, the Purple Book Continuity Act of 2019 amends the Public Health Service Act to provide for the publication of a list of licensed biological products.
[3] H.R. 1503, the Orange Book Transparency Act of 2019, would require that drug manufacturers update their information with the FDA in a timely fashion.

Payment Commission Data Act of 2019[4]) and H.R. 1499 (the Protecting Consumer Access to Generic Drugs Act of 2019[5]) have received bipartisan support and have been incorporated into H.R. 19. Other areas of agreement include addressing the high costs of insulin, allowing for a "smoothing" mechanism in Medicare that would allow Medicare beneficiaries to distribute their out-of-pocket expenses throughout the calendar year, and requiring direct-to-consumer advertising regarding prescription drug prices.

The Administration also has voiced support for prescription drug proposals, in particular the Grassley-Wyden package. The Administration likely will continue to push for a prescription drug package in 2020. We are also likely to see regulations from the Administration addressing prescription drug pricing, such as the International Pricing Index (IPI) model. The IPI model is expected to test phasing down the current Medicare payment amount for selected Part B drugs to more closely align with international prices. A similar proposal was also included in H.R. 3.

With all these areas of overlap, there is definitely room in 2020 for a bipartisan prescription drug package. However, whether there is political willingness to reach a compromise like this in an election year remains to be seen.

Surprise Billing

Similar to prescription drug pricing reforms, surprise billing was a hot topic throughout 2019. In the end, provisions relating to surprise billing failed to make it into the spending package.

As we look ahead to 2020, there are two primary surprise billing proposals on the table. First, the HELP and Energy and Commerce reconciled consensus proposal reflects a compromise between the legislation that passed out of each committee over the summer. The consensus contains two of the more controversial provisions: arbitration and a benchmark rate. The proposal requires that in instances of qualifying payment disputes, insurers pay at minimum the market-based median in-network negotiated rate for the service in the geographic area where the service was furnished. If the median in-network rate payment is above $750, the provider or insurer may elect to go to "baseball-style" binding arbitration—referred to as independent dispute resolution. If a bill goes to arbitration, the arbitrator is required to consider information brought by the parties related to the training, education and experience of the provider; the market share of the parties; and other extenuating factors, such as patient acuity and the complexity of furnishing the item or service. Following arbitration, the party that initiated the arbitration may not take the same party to arbitration for the same item or service for 90 days following a determination by the arbitrator.

[4] H.R. 1781, the Payment Commission Data Act of 2019, allows certain payment information relating to covered drugs under the Medicare prescription drug benefit and Medicaid to be disclosed to additional entities. Specifically, certain subsidy and rebate information, as reported by prescription drug plan sponsors and drug manufacturers, may be disclosed to the Medicare Payment Advisory Commission and the Medicaid and Children's Health Insurance Program Payment and Access Commission, in accordance with specified confidentiality restrictions.

[5] H.R. 1499, the Protecting Consumer Access to Generic Drugs Act of 2019, prohibits brand name drug manufacturers from compensating generic drug manufacturers to delay the entry of a generic drug into the market, and prohibits biological product manufacturers from compensating biosimilar and interchangeable product manufacturers to delay entry of biosimilar and interchangeable products.

The hybrid benchmark and arbitration approach is a concession for the HELP Committee, which approved just a benchmark as the resolution mechanism. The $750 threshold is a concession to the provider community, as it is a decrease from the $1,250 threshold approved by the Energy and Commerce Committee in its legislation. While an official Congressional Budget Office score of the consensus bill is not yet available, the bill is expected to save the federal government approximately $22 billion over 10 years, according to committee leaders, making it an attractive pay-for for other spending priorities.

A few important things to note about this proposal:

- There is no legislative text for the compromise, just the section-by-section. The devil is in the details, and this gives more time for stakeholders to influence the final text.
- Senate HELP Ranking Member Patty Murray (D-WA) has not endorsed the compromise.
- Senate Minority Leader Chuck Schumer (D-NY) heard significant opposition from stakeholders and was a key player in delaying this to 2020.

A second new proposal emerged four days after the HELP and Energy and Commerce agreement was announced. The House Ways and Means Committee released a very high level summary of a bipartisan proposal; legislative text is not expected until early 2020. The summary states that there will be a "robust reconciliation process," but fails to describe whether that process includes a benchmark rate, arbitration or rulemaking by a relevant federal agency. Without a benchmark or arbitration provisions, there will be minimal savings realized.

Supporters of the HELP and Energy and Commerce compromise advocated for its inclusion in an end-of-year legislative package, touting bipartisan support and cost savings. An opportunity emerged to use the surprise billing policies along with the Senate Finance Committee drug pricing package to pay for a long-term extension of the expiring healthcare programs. However, outstanding concerns from party leadership and pushback from stakeholders, along with the new proposal from the House Ways and Means Committee, led leaders to decide to defer action on these issues in the remaining days of 2019.

What Happens Next

As a consequence of the decision to punt on drug pricing and surprise billing, the pay-for for a long-term extension of expiring healthcare programs was off the table. Congress settled on a short-term extension of the expiring programs through May 22, 2020. Given the overall cost of a long-term extension, surprise billing and prescription drug pricing proposals likely will continue to be in the mix as we enter 2020.

Looking forward to next year, supporters of a surprise billing package will continue to push for their proposals. In fact, Energy and Commerce Committee Chairman Pallone voted against the FY 2020 spending measure because it did not address surprise billing. The contentious and varying positions on surprise billing among both lawmakers and relevant stakeholders complicates the prospects of getting a package across the finish line.

Regarding prescription drug reforms, there continues to be room for compromise going forward. However, any movement on this front will hinge on political willingness to reach an agreement. The first few months of 2020 are shaping up to resemble the last few months of 2019.

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