



## Health Reform Update – Week of November 13, 2017

### CONGRESS

#### ***Senate to vote on tax reform plan that increases individual health care costs***

The Senate Finance Committee approved legislation last week that would repeal the individual mandate under the Affordable Care Act (ACA) to help offset the cost of the Republican's \$1.5 trillion plan to reform the nation's tax code.

The House passed their version of the tax reform plan earlier in the week (H.R. 1) with only 13 Republican defections, which did not include a repeal of the individual mandate. The Senate's *Tax Cuts and Jobs Act* includes that repeal, which would reduce the federal budget deficit by roughly \$338 billion over ten years (per the Congressional Budget Office) but cause up to 13 million Americans to become uninsured and increase individual market premiums by roughly ten percent (or \$1,000 per year for a middle-class family). However, House Speaker Paul Ryan (R-WI) has said that he would support the repeal if it were passed as part of the Senate plan.

The full Senate is expected to vote on the plan after Congress returns from Thanksgiving recess. However, it remains unclear whether they have the 50 votes needed to pass the measure through budget reconciliation (with Vice President Pence breaking the tie). Senator Susan Collins (R-ME) opposed making the individual mandate repeal a part of the legislation and both her and Senator Lisa Murkowski (R-AK) urged the Senate to concurrently pass the bipartisan market stabilization plan released last month by Senators Lamar Alexander (R-TN) and Patty Murray (D-WA), which would restore the ACA cost-sharing reductions eliminated by the Trump Administration (see Update for Week of November 6<sup>th</sup>).

Conservative Senators have thus far opposed the Alexander-Murray bill, insisting that the ACA should be repealed and not "fixed". However, Republicans can only afford two defections and key moderates like Senator John McCain (R-AZ) have yet to indicate how they intend to vote on the measure. Collins, Murkowski, and McCain were responsible for blocking Senate efforts to repeal and replace the ACA last summer (see Update for Week of August 14<sup>th</sup>).

These Senators have also expressed concerns about Congressional PAYGO rules that could automatically trigger \$136 billion in sequester cuts to mandatory spending, including \$25 billion to Medicare next year if the bill is not amended. This sequester could only be avoided if Republicans enacted other measures to offset this \$136 billion or secured the unlikely support of at least eight Senate Democrats to circumvent the PAYGO rules.

The Senate bill does maintain the medical expense deduction for those with unreimbursed costs exceeding ten percent of their adjusted gross income. H.R. 1 would eliminate this deduction entirely, saving the federal government roughly \$10 billion per year (see Update for Week of November 6<sup>th</sup>).

The Senate bill also notably caps the orphan drug tax credit at 27.5 percent (instead of 50 percent under current law), in contrast to the House's plan to eliminate it entirely, a move strongly opposed by biotech and consumer groups (see Update for Week of November 6<sup>th</sup>).

However, the final version of the Senate bill may need to undergo substantial changes next week in order to secure support from key Senators.



## ***PhRMA opposes new Democratic bill to give Medicare D price negotiation authority***

Senator Bernie Sanders (I-VT) and Rep. Elijah Cummings (D-MD) introduced legislation in their respective chambers late last month (S. 2011/H.R. 4138) that would allow the Department of Health and Human Services (HHS) to negotiate drug prices under the Medicare Part D program.

The bills, which both members introduced late in the previous Congress, would specifically eliminate the non-interference provision under the *Medicare Modernization Act of 2003* (creating Part D) that prohibits HHS from negotiating drug prices. It would for the first time give HHS the authority to prioritize the negotiation of high-cost drugs, drugs with “significant price increases”, drugs that “drive up Medicare Part D spending”, and single-source drugs and biologics.

According to the sponsors, Medicare Part D pays 73-80 percent more than Medicaid and the Department of Veteran’s Affairs for brand-name drugs, because of this prohibition (which does not apply to the other two programs). They estimate that the federal government could save between \$15.2 billion and \$16 billion a year if Medicare Part D paid the same prices as Medicaid or VA.

Under the legislation, fallback prices would automatically be adopted if negotiations between the Secretary and a drug manufacturer are not successful after one year. These prices would be the lowest of the federal ceiling price, the lowest price charged by 10 OECD countries with similar gross domestic products (GDPs) during the most recent 12-month period, or the Medicaid “best price” for the most recent drug rebate period.

The legislation would restore rebates on drugs covered under Part D for low-income beneficiaries, which were eliminated when Part D was created. According to the Congressional Budget Office, this move would save taxpayers \$145 billion over the next decade.

In their press release, the bill sponsors note that President Trump supported giving HHS this authority as a candidate. However, he has not commented on the issue since assuming office. Most conservative lawmakers are likely to continue opposing price negotiations absent the President’s support for the change and such a policy has long been opposed by the Pharmaceutical Research and Manufacturers of America, which insists it would lead to government rationing and price controls.

The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule last week that seeks public comment until January 16<sup>th</sup> on ways that the agency can share in the hidden rebates and discounts that are already being negotiated by drugmakers and pharmacists with Medicare Part D insurers. A bipartisan group of 54 House members has already asked CMS to force Part D insurers to give enrollees a larger share of these rebates, discounts and pharmacy price concessions.

## **FEDERAL AGENCIES**

### ***Shorter Marketplace enrollment period spurs early sign-ups***

According to the Department of Health and Human Services (HHS), nearly 1.5 million consumers have signed-up for coverage in the 39 Marketplaces using the federal web portal for 2018.

That figure is 47 percent higher than over the first two weeks of open enrollment last year, despite the Trump Administration’s 90 percent cut in marketing and outreach as well as their elimination of cost-sharing reductions (see Update for Week of October 2<sup>nd</sup>). Analysts largely attributed the unexpected spike in enrollment to the Administration’s decision to cut the open enrollment period in half for 2018 (ending on December 15<sup>th</sup> instead of January 31<sup>st</sup>).



Avalere Health consultants pointed out that the shorter period means one-third of open enrollment has already been completed, and comparing sign-ups to the one-third milepost last year actually shows sign-ups are lagging 25 percent behind 2017. In addition, the number of new consumers enrolling in coverage during the first two weeks is slightly lower than the comparable period one year ago (23 percent compared to 24 percent).

State-based Marketplaces are reporting similar bumps in enrollment despite extending their enrollment periods beyond December 15<sup>th</sup> (see Update for Week of November 6<sup>th</sup>). The number of new consumers signing-up for Covered California, whose open enrollment period does not end until January 31<sup>st</sup> (the same deadline as last year), are up by 23 percent over the same period in 2017.

### ***IRS to start enforcing employer mandate penalties under ACA***

The Internal Revenue Service (IRS) has started the process of enforcing the controversial employer mandate under the Affordable Care Act (ACA), sending out the first round of notices to businesses with at least 100 full-time employees that failed to offer their workers minimum essential health coverage in 2015 and owe financial penalties to the agency.

Under the employer shared responsibility provision, large companies (with 50 or more employees) are required to offer MEC or pay a per employee assessment. The Obama Administration delayed the mandate until 2015 for companies with more than 100 workers and 2016 for those with 50-100 employees (see Update for Week of February 10, 2014). However, the IRS has yet to enforce this provision, insisting that it needed more time and resources to build compliance systems.

The agency was not expected to enforce the employer mandate under the Trump Administration, which has vigorously sought to repeal the mandate and much of the ACA altogether. IRS officials issued a written statement last week stating that it had no choice but to begin enforcement because “the A.C.A.’s employer mandate unfortunately remains the law of the land.”

However, IRS’ decision to go forward was likely due to Congressional Budget Office (CBO) projections showing that enforcement would more than \$207 billion in new revenue over the next decade. Penalties for employers can quickly mount, as a large employer with 100 workers would pay more than \$158,000 per year, based on the assessment of \$2,000 per employee (excluding the first 30).

The penalty is activated if the employer fails to offer MEC that meets the ACA affordability threshold at least one employee purchases subsidized coverage in the ACA Marketplace. According to the Kaiser Family Foundation, roughly eight percent of companies with 50-199 workers currently do not offer coverage that meets the ACA standard and would be subject to the assessment.

### ***Medicare cuts in Section 340B drug payments faces pushback from hospitals, Congress***

Hospital groups filed suit last week against the Department of Health and Human Services (HHS) seeking to block implementation of a final rule that made substantial cuts for drugs furnished to safety-net providers participating in the Section 340B drug discount program.

The lawsuit was brought by the American Hospital Association, Association of American Medical Colleges, America’s Essential Hospitals, and three health systems in response to a 27 percent reduction rate in the hospital reimbursement rate for 340B drugs that were part of the agency’s final rule for the 2018 hospital outpatient payment system (OPPS). The plaintiffs insist that such a dramatic cut would “undermine the 340B Program by depriving eligible hospitals of critical resources Congress intended to provide those hospitals through 340B discounts.”

Hospitals participating in 340B currently receive six percent on top of the drug’s average sales price (ASP) under Medicare. However, the final rule would change the formula to ASP minus 22.5



percent, which would result in a \$1.6 billion in cut in 340B payments to hospitals. According to HHS, the change would ensure that Medicare pays hospitals for 340B drugs “at a price more consistent with the actual cost hospitals and other providers pay to acquire those drugs” (see Update for Week of July 10<sup>th</sup>).

The influential Medicare Payment Advisory Commission (MedPAC) had recommended last year that Medicare payments for Part B drugs purchased by 340B providers be cut by ten percent of ASP (see Update for Week of March 7, 2016).

An upcoming executive order on drug pricing from President Trump was rumored to include directives that the HHS Secretary reduce the size of the 340B program, which the pharmaceutical industry contends has far exceeded its initial intent (see Update for Week of August 28<sup>th</sup>). Drug sales under 340B reached \$16.2 billion in 2016, a 34 percent spike from the year before. Spending under 340B has more than tripled since 2005 and now accounts for five percent of all prescription drug sales.

The 340B program has also been under increasing Congressional scrutiny after reports from the HHS Inspector General and Government Accountability Office (GAO) suggested that the dramatic growth may be resulting in “windfall profits” for some safety-net providers (see Update for Weeks of July 1 and 8, 2013). Congressional hearings since June have focused on ways that both Congress and HHS could improve 340B oversight and transparency. However, the dramatic Part B payment cut in the final rule has resulted in bipartisan pushback from at least 285 members of Congress, including 90 Republicans, most of whom have been pushing for greater 340B reporting requirements.

Reps. David McKinley (R-WV) and Mike Thompson (D-CA) introduced legislation last week (H.R. 4932) that would reverse the final rule, fearing its impact upon rural hospitals. However, its prospects to advance appear slim.

### ***CMS reverses Obama Administration policy on common billing codes for biosimilar drugs***

The Centers for Medicare and Medicaid Services (CMS) reversed an Obama Administration last week that drugmakers and consumer groups insisted would harm the emerging biosimilar drug market.

The Affordable Care Act (ACA) created the first regulatory pathway for lower-cost biosimilar products, in an effort to allow for competition with more costly brand-name biologic drugs and the Food and Drug Administration (FDA) has used it to approve at least four biosimilar products since 2015 (see Update for Weeks of May 29<sup>th</sup> and June 5<sup>th</sup>).

CMS had initially decided to place biosimilars that reference the same brand-name biologics into common billing codes (see Update for Weeks of July 27 and August 3, 2015). This policy differed from how CMS treats generic drugs, which share billing codes with each other and the brand drugs they copy.

Under this policy, Medicare Part B paid for biosimilars under the Physician Fee Schedule based on the average sales price (ASP) of all biosimilar products within the same HCPCS code—grouping together all biosimilar products with the same reference product to calculate an ASP. This arrangement meant that physicians were reimbursed the same amount for all biosimilars of the same reference product.

However, under the rule finalized last week CMS will start next January to begin issuing new unique HCPCS codes to each individual biosimilar product, separating the codes for biosimilars from the codes for their brand-name reference products, so that as a biosimilar’s price is reduced, so does its ASP and reimbursement (while not affecting the brand-name’s ASP).

Nearly 200 consumer, physician, and biosimilar stakeholder groups had supported the change when it was first proposed last September, insisting that unique HCPCS codes for each biosimilar would



help ensure a “robust, competitive biosimilar market”. CMS agreed that the change would promote competition and “ensure millions of patients will have access to new lower cost therapies.” However, the influential Medicare Payment Advisory Commission opposed the new policy, claiming it constituted “price protections” for biosimilar drugs because “separate billing codes will artificially keep prices higher than they otherwise would be under a single billing code.”

An Office of Management and Budget official intimated last week that the Trump Administration may “revisit” this change “if ultimately it’s going to show that it’s going to cost taxpayers much money and it’s really an easy industry to get into.”

## STATES

### ***CMS issues emergency CHIP funds to 14 states, but 28 more will need funding by December***

The Centers for Medicare and Medicaid Services (CMS) announced last week it has distributed roughly \$600 million in leftover Children’s Health Insurance Program (CHIP) to 14 states and territories but will need an additional Congressional reauthorization to cover 28 states whose funding will run-out by the end of 2017.

Due to their focus on repealing and replacing the Affordable Care Act (ACA), Congress allowed the current authorization for CHIP funding to expire at the end of the 2017 federal fiscal year on September 30<sup>th</sup> (see Update for Week of October 2<sup>nd</sup>). The House passed a reauthorization bill last month (H.R. 3922) but the companion Senate bill remains bogged down over disagreements over how to offset the costs (see Update for Week of November 6<sup>th</sup>).

Florida has received the largest amount of emergency redistribution funding (roughly \$63 million). Arizona and Minnesota had already exhausted 2017 CHIP funding in October and are projected to run out of their redistribution funding in December. California, Oregon, and Washington are expected to use up all redistribution funds in January.

Only 19 states have enough CHIP funding from 2017 to last until next June, while just two states (Illinois and Wyoming) could last through the summer. Several states, most recently West Virginia, have already announced that they will cease enrollment before they run out of funding (see Update for Week of November 6<sup>th</sup>).

### ***Zero-premium bronze plans will be available to nearly all FFM consumers with ACA subsidies***

A new study released last week by Avalere Health consultants reveals that nearly 98 percent of counties in the 39 federally-facilitated Marketplaces (FFM) will have free bronze-tier plans available to consumers earning at or below 150 percent of the federal poverty level (FPL).

The zero-premium plans will be available to this group (individuals earning around \$18,000 per year or less) because the Trump Administration’s elimination of Affordable Care Act (ACA) cost-sharing reductions increased silver-plan premiums so significantly that the concurrent jump in the amount of premium tax credits offered to low-income consumers made other plan options more affordable (see Update for Week of November 6<sup>th</sup>).

Not only will the nearly all of subsidized FFM consumers in this income group have zero-premium bronze options, but free silver-tier options will be available to consumers in 18 percent of counties, and free gold-tier options will be offered to consumers in ten percent of counties. Furthermore, in 28 percent of counties, FFM consumers will find gold-tier options that cost only \$10 more than silver-tier options. Gold plans typically come with much lower deductibles, coinsurance, and maximum out-of-pocket limits than silver plans, making them a better value for consumers with high-cost medical conditions.





## Arizona

### ***Supreme Court unanimously rejects Republican effort to void Medicaid expansion***

In a unanimous decision, the Arizona Supreme Court upheld the constitutionality of the hospital assessment that funds the state's share of costs for the Medicaid expansion under the Affordable Care Act (ACA).

Former Governor Jan Brewer (R) was the first Republican governor to agree to participate in the expansion but had to strong-arm lawmakers into approving her plan, following through on her threat to veto all legislation until it was passed by a bare majority (see Update for Week of June 10, 2013). A group of 36 current and former Republican lawmakers and the conservative Goldwater Institute promptly filed to sue to invalidate the assessment, insisting that it was a tax that required a two-thirds majority to enact according to a voter referendum passed in 1992.

Their claim was rejected by both a lower court (see Update for Week of March 16, 2015) and the Arizona Court of Appeals last year. The Supreme Court affirmed the appellate court ruling, ensuring that the Medicaid expansion will remain in place for the nearly 400,000 Arizonans that have subsequently benefited. The high court concluded that the assessment was not a tax because it was voluntarily agreed to by the state hospital association and directly benefits hospitals by reducing their uncompensated care costs and increasing their payments.

## Idaho

### ***New waiver requests would let Idaho use the ACA Marketplace to expand Medicaid***

The Department of Health and Public Welfare has proposed as part of its fiscal year 2018 budget request to seek federal waivers that would allow it to cover those ineligible for Medicaid or Affordable Care Act (ACA) premium subsidies through the ACA Marketplace.

Roughly 78,000 Idahoans are caught in this so-called "coverage gap" that was created when the U.S. Supreme Court gave states the flexibility to opt-out of the ACA's Medicaid expansion (see Update for Week of June 25, 2012). Despite support from Governor Butch Otter (R) and the recommendations of his legislative task force that Idaho expand Medicaid (see Update for Week of March 11, 2013), conservative lawmakers have consistently refused to approve any form of expansion (see Update for Weeks of February 22 and 29, 2016), even though the state Medicaid program currently covers only those with dependent children who earn up to 26 percent of the federal poverty level (FPL).

Under the dual waivers, Idaho would effectively become the tenth state to use ACA expansion funds to instead cover those made newly-eligible under private plans. However, state officials insisted that the proposal was not "Medicaid expansion" in an effort to limit political opposition to the plan.

The proposal would essentially be the type of "partial expansion" that the Obama Administration consistently refused to approve (see Update for Week of November 30, 2015), as it would offer coverage only to those earning up to 100 percent of FPL, the minimum threshold for ACA subsidies, instead of the 138 percent threshold that the ACA requires for states to receive expansion funds. The Trump Administration has hinted that it would be more flexible in considering partial expansion requests, though none has been approved to date.

Idaho is making its waiver request contingent on federal approval for the state to create a "complex needs program" through Medicaid for residents earning up to 400 percent of FPL who have certain chronic conditions. These high-cost patients would be shifted out of the Marketplace risk pool and into Medicaid, theoretically lowering Marketplace premiums.



In addition, the waiver would allow Idaho to create a reinsurance program through the state's high-risk pool (though a funding mechanism has not been identified). The Trump Administration has encouraged states to implement reinsurance programs that compensate insurers for exceptional claims and approved such requests from three states (Alaska, Minnesota, and Oregon)(see Update for Week of November 6<sup>th</sup>).

#### New Hampshire

##### ***Medicaid expansion commission to recommend reauthorization following substantial changes***

The chair of the legislative commission created to assess the future of New Hampshire's Medicaid expansion alternative will recommend that the program be extended for five additional years but with significant changes.

New Hampshire is one of eight states that received federal approval to use ACA matching funds for the Medicaid expansion to instead purchase private coverage for those that the law makes newly-eligible for Medicaid (see Update for Week of September 29, 2014). The Premium Assistance Program (PaP) has been very successful, enrolling more than 52,000 consumers since 2015 or roughly 42 percent of the entire individual market (see Update for Week of August 14<sup>th</sup>). However, Republican lawmakers have reauthorized the program only through the end of 2018 and created the Commission to recommend more conservative-favored reforms such as work requirements and eligibility verification measures that were disallowed by the Obama Administration (see Update for Week of December 5<sup>th</sup>).

Despite calling for the repeal of "Obamacare", Governor Chris Sununu (R) has supported modifying instead of eliminating the PaP, including changes to the provider assessment used to fund the program, which the Trump Administration determined was unlawfully being conditioned on the receipt of voluntary donations from hospitals (see Update for Week of August 14<sup>th</sup>).

Among the changes the 15-member Commission to Evaluate the Effectiveness and Future of the Premium Assistance Program considered included moving PaP enrollees into their own high-risk pool and moving-out those the state identified as medically frail whose costs tend to be more than three times higher than other enrollees. However, Anthem Blue Cross and Blue Shield of New Hampshire has cautioned that this could impact more than a third of PaP enrollees (see Update for Week of August 14<sup>th</sup>).

The report due to the legislature on December 1<sup>st</sup> is expected to call for the newly-eligible population to obtain coverage through Medicaid managed care plans instead of the ACA Marketplace. The Commission concluded that this group tends to be more costly than non-Medicaid consumers and thus puts upward pressure on Marketplace premiums by being in the Marketplace risk pool.

In addition, the report will recommended a work requirement for childless adults, which the Trump Administration has indicated is likely to receive federal approval (see Update for Week of November 6<sup>th</sup>).