

Health Reform Update – Week of January 9, 2017

CONGRESS

House and Senate start process to repeal key ACA provisions despite deficit, insurer concerns

House and Senate Republicans voted this week to start the process of repealing key provisions of the Affordable Care Act (ACA) through budget reconciliation.

The resolution (S.Con.Res.3) sets forth the federal budget for fiscal year 2017 and budgetary levels through 2026. It includes specific instructions for Congressional committees to draft bills by January 27th that will roll back parts of the ACA that directly impact the federal budget, including penalties for the individual and employer mandates, premium and cost-sharing subsidies, and taxes on insurers, pharmaceuticals, device manufacturers, and wealthy Americans that were used to fund the health insurance reforms. By using the budget reconciliation process, Republicans need only a simple majority in each chamber to pass the repeal (though they would require 60 votes to overcome a Senate filibuster of any bill to remove most of the ACA's consumer protections or approve a replacement plan.)

Senator Rand Paul (R-KY) was the lone Senate Republican to vote against the measure due to his opposition to rescinding rules that previously required budget resolutions not to increase the federal deficit (eight House Republicans also joined in opposition). However, Congress cannot repeal the taxes in the ACA without dramatically raising the deficit, causing Paul and other libertarian groups such as the House Liberty Caucus to oppose what it terms "the worst budget ever seriously considered by Congress" as it immediately adds \$1 trillion to the national deficit and "grows the national debt by more than \$9 trillion over the next decade." The Committee for a Responsible Federal Budget estimated that a full repeal would increase the federal deficit by \$350 billion over the next decade as more than \$800 billion in tax revenues and \$1.1 trillion in savings to Medicare and other programs are lost.

Republican leaders plan on holding votes on the reconciliation bills after January 27th and delivering a final repeal bill to President Trump by February 20th. They rebuffed attempts from at least five Senate Republicans (led by Health, Education, Labor, and Pensions Committee chairman Lamar Alexander (R-TN)) to delay the repeal votes until March so that a replacement plan could be developed and passed simultaneously, in order to avoid the exodus of insurers from ACA Marketplaces that is expected to result if the ACA is repealed without any consensus on a transition period or replacement.

However, Republicans are under intense pressure from conservative groups like the Heritage Foundation that are supporting an immediate repeal of the ACA, as well as President-elect Trump, who stated this week that he wanted any transition period to be limit to several weeks, instead of the 2-5 year delay favored by Senate Republicans. Trump's statement broke with one of his leading supporters, Rep. Chris Collins (R-NY), who earlier in the week tried to assure insurers that "there's not going to be any changes" to the ACA in either 2017 or 2018 as insurers have already either entered into contracts or are currently negotiating the 2018 plan designs and premiums that they must file by May.

The President-elect stated that he would offer his own replacement plan that would "cover everyone" once his nominee for Health and Human Services (HHS) Secretary is confirmed.

Key Republican pledges to fund ACA cost-sharing subsidies in the short term

The chairman of the powerful House Energy and Commerce Committee pledged this week to fund cost-sharing subsidies provided under the Affordable Care Act (ACA) for 2017, despite his party's plans to repeal the subsidies as part of the reconciliation bill to be voted on later this month (see above).



House Republicans successfully obtained a lower court order blocking the cost-sharing subsidies, which had been stayed pending the appeal by the Obama Administration (see Update for Week of May 16th). The appellate court agreed last month to delay its decision until after the Trump Administration assumes office, allowing the President-elect an opportunity to decide whether to simply drop the appeal and thus immediately terminate the subsidies (see Update for Week of December 5th).

However, chairman Walden insisted this week that Congress would approve continuing the subsidies through 2017 even without the approval of the President-elect, as federal contracts with Marketplace plans allow them to cancel coverage mid-year if the subsidies are invalidated. Rep. Walden insisted that Congress has no intention of "pull[ing] the rug out from under people." Rep. Tom Cole (R-OK), chairman of the House Labor-HHS appropriations subcommittee was not as committed to funding the cost-sharing subsidies, but echoed Walden's pledge not to do what was necessary to ensure that Marketplace coverage remains uninterrupted for 2017.

Only one in five Americans support repealing the ACA without a simultaneous replacement

Polling done since the election has consistently shown waning support for a full repeal of the ACA, with only about half of surveyed Republican voters now in favor (see Update for Week of December 5th). However, the latest Kaiser Family Foundation tracking poll released last week showed that only one in five Americans support the Republicans current plan to repeal certain parts of the ACA without a concurrent replacement plan, with nearly half (47 percent) opposed to any repeal. The Kaiser survey also showed that only 27 percent of those surveyed support a replacement plan that does not include protections against insurer discrimination based on pre-existing conditions.

Quinnipiac University polling this week found a similarly low number supporting total repeal (only 18 percent). An unrelated POLITICO-Harvard School of Public Health poll also showed that support for repealing and replacing the ACA was being driven largely by those who voted for President Trump, 85 percent of whom identified it has their top priority (exceeding even immigration at 78 percent). However, among the general public the survey found that only 44 percent supported repeal and replacement. For both groups, only 15 percent of that survey supported a stand-alone repeal.

Studies shows partial ACA repeal would cause massive job losses, spikes in uncompensated care

The Commonwealth Fund released a new study last week showing that the repeal of key provisions of the Affordable Care Act (ACA) could result in a \$140 billion cut in health spending in 2019 lead to 2.6 million job losses, nearly all of which would occur in the private sector.

The analysis is based on an assumption that major provisions of the law are eliminated via the budget reconciliation process requiring only a simple majority in Congress (see above). This includes the ACA's premium and cost-sharing subsidies and Medicaid expansion. It does not evaluate the offsetting impact of any forthcoming ACA replacement plan.

Although the health care sector makes up one-fifth of the national economy, George Washington University researchers that prepared the analysis stressed that most of the losses will occur in sectors like construction, real estate, and retail industries that have benefited from the cascading effect of billions of dollars in federal funding being injected into state budgets. They note that even states that opted-out of the Medicaid expansion were propped up by the ACA matching funds and would experience job losses "because economic benefits and losses flow across state lines."

Overall, researchers predict that business output would fall by \$2.6 trillion by 2023 as revenue decreases and higher uncompensated care costs cause \$48 billion to be lost from state treasuries. Gross state products would decrease by roughly \$1.5 trillion nationwide



The findings are consistent with a study released last month by University of California-Berkeley's Center for Labor Research and Education, which showed that repealing the ACA would eliminate more than 209,000 jobs in California alone and cost the state economy \$20.3 billion in gross domestic product.

An unrelated report also released this week by the Urban Institute reached similar conclusions. It projected that the number of uninsured would more than double in 2019 if the ACA is partly repealed through reconciliation, as the uninsured rate would climb to at least 21 percent or well above pre-ACA levels. Of the nearly 30 million Americans that would lose health insurance coverage, 22.5 million would become uninsured absent the ACA subsidies, Medicaid expansion, and individual mandate penalties while another 7.3 million would have their coverage dropped due to the "near collapse" of the individual market. As a result, the Urban Institute predicts that reconciliation would add more than \$1.1 trillion in uncompensated care costs for hospitals from 2019-2028.

Conservative ACA replacement plan would end tax deduction for employer-sponsored coverage

The conservative Republican Study Committee (RSC) released their plan this week to fully repeal and eliminate all provisions of the Affordable Care Act (ACA) effective January 1st (including health insurance Marketplaces, premium and cost-sharing subsidies, and the Medicaid expansion) and replace it with tax deductions for health care, a return to state high-risk pools for those with costly conditions, and an expansion of health savings accounts (HSAs).

The plan called the *American Health Reform Act of 2017* was reintroduced by Rep. Phil Roe (R-TN) and mirrors his legislation from the last Congress. It is likely to be the starting point for Republican negotiations over an ACA replacement plan as it is favored by Rep. Tom Price (R-GA), the incoming Secretary for the Department of Health and Human Services (HHS).

The bill (H.R. 277) specifically would create an annually-indexed standard tax deduction for health insurance coverage of \$7,500 for individuals and \$20,500 for family coverage. It could be used to pay for either employer-sponsored insurance (ESI) or individual or small group plans.

According to Rep. Roe, a physician, the plan also "massively" broadens the use of HSAs by increasing the maximum contribution limit to the current annual out-of-pocket maximums under the ACA (\$6,550 for individuals as of 2017) and removing numerous restrictions on their use. It would also allocate \$25 billion to segregate the most costly patients in high-risk pools run by states, as was done prior to the ACA. High-risk pool premiums would be limited to 200 percent of the average statewide premium, which the RSC claims is an improvement from pre-ACA standards.

Funding would come largely from ending the tax exclusion for both employer and employee-paid premiums for ESI, as well as the self-employed health deduction—a move long-favored by economists from across the political spectrum as it distorts how workers are paid, effectively resulting in lower wages. However, lawmakers have largely been reluctant to propose its elimination, as it would dramatically increases the cost of employer coverage for workers.

The ESI exclusion is by far the single largest tax expenditure, costing the federal government roughly \$250 billion in income and payroll taxes in 2015 alone, an amount that would make it the nation's third largest health program behind Medicare and Medicaid and be sufficient to provide health insurance coverage to all of the 42 million Americans that were uninsured prior to the opening of the ACA Marketplaces. According to the Joint Committee on Taxation, the exclusion disparately benefits the wealthy, as it saves those earning more than \$200,000 roughly \$4,580 per year in premium costs compared to only \$1,650 for those earning less than \$30,000.

However, the most controversial part of the plan is the repeal of the ACA's guaranteed issue mandate for all consumers regardless of medical history and return to the HIPAA guaranteed availability provisions. This means that consumers would only have protection from pre-existing condition exclusions



if they have maintained continuous coverage (no gap in coverage of more than 62 days). The only change from pre-ACA standards is that the prior coverage no longer needs to be employer-based nor does the consumer first have to exhaust COBRA benefits.

Other controversial provisions are likely to be the elimination of the federal anti-trust exemption for health insurers and allowing insurers to sell policies across state lines while only complying with the regulations of their home state. Republicans claim both provisions would boost competition although a Georgia law allow for interstate plans failed to attract any insurers (see Update for Week of April 9, 2012).

Senator Bill Cassidy (R-LA), another physician, announced that he will introduce a separate ACA repeal and replacement bill next week that will be modeled after two bills he previously sponsored (the *Patient Freedom Act of 2015* and the *World's Greatest Health Care Plan of 2016*). It would create a two-year transition period while moving towards a system in which the federal government deposits funds into individual HSAs. States would be allowed to opt-out during that two year period if they so choose.

Any ACA replacement plan will require the support of at least eight Democrats to reach the 60-votte margin needed to break a Senate filibuster.

Republicans not supportive of President-elect's call for Medicare Part D price negotiation

Republican lawmakers unanimously rejected President-elect Trump's call this week to give Medicare the authority to negotiate prices for Part D drugs.

A provision in the Medicare Modernization Act of 2003 (the law creating the Part D drug program) expressly bars Medicare from using its clout to negotiate drug prices. Democratic lawmakers have repeatedly sought to reverse this prohibition and used it as leverage in negotiations with the pharmaceutical industry to garner their support for the Affordable Care Act (ACA).

Pew Charitable Trusts estimated earlier this year that potential savings from allowing Part D price negotiation could range up to \$541 billion over ten years but such substantial savings would likely require Part D to adopt a drug formulary of its own or negotiate prices to the levels charged in other countries with fixed price controls.

In his first news conference since the election, the President-elect reiterated his earlier embrace of Medicare drug price negotiation. His spokesperson later suggested that the President-elect could insist that it be included as part of any ACA replacement legislation in an effort to secure the eight votes from Senate Democrats that are needed to reach a filibuster-proof 60-vote margin, although the President-elect later indicated that his preference was to pursue it separately.

Democrats subsequently offered an amendment to the Senate budget resolution authorizing the repeal of key ACA provisions that would allow Part D price negotiation. However, no Republicans voted in support of the measure. Republicans also have not signed onto House and Senate legislation introduced last week that would provide such negotiation authority with most insisting that increasing competition was the preferred means to reducing drug prices.

A dozen Senate Republicans did vote in favor of an amendment that would lower drug prices by allowing drug re-importation from Canada. However, that amendment was defeated after 13 Democrats voted against it.

Federal court allows class action lawsuit over failed ACA risk corridor payments

In a surprise move, Judge Margaret Sweeney of the United States Court of Federal Claims refused last week to dismiss the second of a dozen lawsuits brought by insurers that are owed payments



under the Affordable Care Act (ACA) risk corridor program and certified it as a class action, potentially providing all aggrieved insurers with relief.

The risk corridor fund is one of three temporary risk mitigation programs created by ACA. They were meant to stabilize insurance markets during the initial three years of full ACA implementation by compensating insurers that incur an extraordinary number of high-cost claims.

Unlike the reinsurance fund where collections have largely aligned with expectations (see Update for Weeks of February 8th and 15th), the risk corridors program has a \$2.5 billion shortfall forcing insurers to receive only 12.6 percent of the payments they were due for 2014 (see Update for Week of September 28th). As a result, CMS is using all 2015 collections to pay outstanding amounts owed to insurers for 2014 (see Update for Week of September 12th).

The shortfall and subsequent losses are largely blamed for the insolvency and liquidation of all but four of the initial 23 Consumer Operated and Oriented Plans (CO-OPs) created with ACA loans, as well as by several major insurers to exit ACA Marketplaces for 2017 (see Update for Week of August 15th). As a result, at least four of the surviving CO-OPs (including Health Republic of New Jersey) and eight other insurers are suing CMS to recover their 2014 costs (see Update for Week of August 15th). One of the plaintiffs, Evergreen Health Cooperative of Maryland, announced last month that it will no longer issue or renew individual market plans.

The first of these lawsuits brought by Land of Lincoln Health CO-OP was dismissed last month by a Republican-appointed judge in the very same court, who agreed with the Obama Administration that the ACA does not impose a binding contract on CMS to pay insurers the amounts they are due each year in under the risk corridor program, but only after it expired December 31st (see Update for Week of December 5th). However, Judge Sweeney (also a Republican appointee) ruled in the case brought by the Health Republic CO-OP that amounts due for 2014 and 2015 did have to be paid each year.

Republican lawmakers had objected to efforts by the Obama Administration to settle the risk corridor lawsuits with a settlement fund maintained by the U.S. Department of Justice, as deficit reduction agreements they negotiated with Democrats barred CMS from transferring funds from other accounts whenever there is a shortfall in the risk corridor program (see Update for Week of October 24th). It is not clear whether they will rescind this prohibition and settle the claims once the Trump Administration assumes control.

FEDERAL AGENCIES

ACA Marketplace enrollment up 2.5 percent despite ACA repeal threat, premium increases

The latest enrollment figures released this week by the Department of Health and Human Services (HHS) shows that a record number of Americans are signing-up for coverage in Affordable Care Act (ACA) Marketplaces despite the threat that the law will be repealed (see above) and double-digit rate hikes in some states.

More than 11.5 million individuals enrolled in coverage from the November 1st start of the 2017 open enrollment period until December 24th, an increase of more than 286,000 (or 2.5 percent) above the comparable period last year. More than 2.6 million enrollees (or nearly 23 percent) are new consumers.

HHS officials stressed that the actual enrollment figure is actually closer to 12.2 million because two states (Minnesota and New York) elected to instead receive enhanced federal funding by enrolling roughly 700,000 Marketplace enrollees earning 138-250 percent of the federal poverty level into the Basic Health Plan (BHP) option created by the ACA (see Update for Week of October 10th).



A concurrent report issued by the Council of Economic Advisors also emphasized that the enrollment figures show that the significant premium increases that some Marketplaces faced due to limited ACA reinsurance payments "are not having substantial adverse effects on either individual market enrollment or the risk pool." It concluded that "premium and plan design changes [by insurers], together with recent policy changes, appear roughly sufficient to return premiums to a sustainable level, implying that this year's increases were a one-time correction."

That analysis was supported by an Urban Institute study later in the week concluding that the "premium volatility" in some markets was primarily due to "underpricing during the first two years of exchange operations" and is "likely to be a short-term phenomenon." Researchers stressed that although premiums for the most popular silver-tier plans jumped by more than a 21 percent average for 2017, the averages were distorted by massive rate hikes in certain markets like Arizona (125 percent), while premiums actually fell on average in five states where one in ten Marketplace consumers reside.

The premium increases do appear to have increased the number of returning consumers that are shopping for new coverage (56 percent compared to 51 percent last year). However, roughly the same number (81 percent) remain eligible for the premium tax credits provided by the ACA. The share of young and presumably less costly adults (age 18-34), the critical demographic for insurers, also remains the same as for 2016 at 26 percent.

An unrelated study by the consulting firm Avalere Health revealed that mass exodus of insurers from several Marketplaces may yet to have impacted premiums in those areas as they largely occurred after insurers filed their initial rates for 2017. Almost a third of United States counties now have only one Marketplace insurer, compared to only seven percent for 2016. However, premiums in those counties have remained roughly the same as in multiple insurer counties, despite the lack of competition.

As a result, Avalere predicts that Marketplace consumers in these counties may see major premium increases for 2018, especially if a Congressional vote to repeal the ACA spurs even more insurers to exit the Marketplaces before 2018 rates have to initially be filed in May.

OIG says dramatic cost increases for specialty drugs threatens viability of Medicare Part D

The Office of Inspector General (OIG) for the Department of Health and Human Services (HHS) is directly blaming high-cost specialty drugs for a three-fold rise in Medicare Part D spending for "catastrophic coverage" from 2010 to 2015.

Under the Part D prescription drug program, Medicare is responsible for 80 percent of drug costs after enrollees pass the catastrophic threshold (\$4,950 for 2017). Federal payments beyond this threshold exceeded \$33 billion in 2015, with two-thirds of this spending attributable to drugs costing more than \$1,000 per month.

The OIG report stressed that just ten drugs accounting for one-third of all catastrophic spending, and six of these ten had "sharp price increases" since 2010 (with the average monthly cost rising by \$600). The highest growth followed the 2014 approval of new and costly "cures" for Hepatitis C, with catastrophic spending for just one of these drugs (Harvoni) reaching \$6.3 billion in a single year.

OIG warned that the pace of catastrophic spending growth is threatening the very viability of the Part D program and requires additional tools from Congress to manage. It specifically recommended giving Part D the authority to negotiate drug prices, a policy change long favored by Democrats and endorsed by President-elect Trump (see above).



Final FDA guidance requires random suffixes for biosimilar names

The Food and Drug Administration (FDA) finalized guidance this week on how to name generic biosimilar copies of brand-name biologic drugs.

The guidance follows up on an earlier 2015 draft and requires biosimilar copies to have a distinct non-proprietary suffix attached to the core name for the branded biologics (see Update for Weeks of August 17 and 24, 2015). Biosimilar companies and insurers had lobbied FDA to assign the same non-proprietary names the same way they do for generic prescription drugs, arguing that different name could cause confusion and slow uptake for the lower-cost biosimilars. However, the FDA decided that unique suffixes will make it easier to track the safety and usage of the biosimilar copies.

Under the regulatory pathway created by the Affordable Care Act (ACA), the FDA has approved four biosimilar products, with not more than one competitor for a single product (see Update for Weeks of March 2 and 9, 2015). However, the initial approval assigned a suffix that indicated the biosimilar manufacturer (i.e. Sandoz's filgrastim-sndz). Subsequent approvals have used random suffixes adopted in the latest guidance.

The FDA has yet to decide on a naming policy for those biosimilars that are deemed "interchangeable" with their branded counterpart and can be freely substituted for the reference product by physicians. These products are still likely to include a core name and unique suffix but FDA is still debating whether to make the suffixes random or indicative of the manufacturer.

U.S. Senator Bill Cassidy (R-LA) has insisted that Republican lawmakers would keep the biosimilar approval pathway intact if the rest of the ACA was repealed (see Update for Week of December 5, 2016).

The U.S. Supreme Court also agreed this week to hear the case involving the first FDA biosimilar approval of a copy of Amgen's Neupogen, which treats a common side effect of chemotherapy (see Update for Week of December 5th). Sandoz had appealed a lower court ruling that as a biosimilar applicant it must wait for FDA approval before sending the brand-name drugmaker the 180-day notice of intent to market, arguing that the delay effectively gives the reference product six additional months of market exclusivity.

STATES

Connecticut

Insurance committee to consider latest bill to limit cost-sharing for prescription drugs

Senator Martin Looney (D) introduced legislation this week that would prohibit health insurers from imposing cost-sharing or out-of-pocket charges that exceed \$130 for a 30-day supply of any covered prescription drug. The bill (S.B. 22) increased this threshold from the \$100 limit proposed under similar legislation last session, which died in committee (see Update for Week of February 29th).

S.B. 22 also bars insurers from placing all prescription drugs for a given class of drugs into the highest cost-sharing tier of a tiered prescription drug formulary. Comparable prohibitions have been stripped out of earlier legislation in Connecticut and several other states (see Update for Week of May 11, 2015) even though such a practice was determined to be discriminatory by the insurance commissioners in Florida and Illinois, as well as the federal Centers for Medicare and Medicaid Services (see Update for Week of February 23, 2015).

The measure was referred to the Joint Committee on Insurance and Real Estate.



Hawaii receives first State Innovation waiver under ACA

The federal Centers for Medicare and Medicaid Services (CMS) has approved Hawaii's request to drop the requirement that it operate a Small Business Health Options Program (SHOP) under the Affordable Care Act (ACA).

Starting on January 1st of this year, Section 1332 of the ACA allowed states to receive five-year waivers to pursue their own creative and innovative health reforms so long as they provide comprehensive coverage to a comparable number of residents as the ACA and do not increase the federal deficit. Hawaii was the first state to apply for such a waiver.

Under the terms of the State Innovation waiver, Hawaii will no longer operate the small group version of the ACA Marketplace and can instead use the tax credits paid to small employers through the Marketplace to support a fund that helps them cover employee health care costs.

Michigan

Republican governor lobbies against Medicaid expansion repeal due to dramatic state savings

Governor Rick Snyder (R) urged federal lawmakers last week to allow Michigan to retain its unique alternative to the Medicaid expansion under the Affordable Care Act (ACA).

In April 2014, Michigan become only the fourth state under full Republican control to participate in the Medicaid expansion (see Update for Week of March 31, 2014). The Healthy Michigan demonstration approved by Obama Administration had more than 470,000 sign-ups during its first year (far surpassing initial projections of 320,000) and it now serves more than 642,300 state residents.

The expansion was backed by Republicans because it include unique requirements for those earning from 100-138 percent of the federal poverty level, including copayments that can be reduced through "healthy behaviors" such as smoking cessation, as well as a requirement that enrollees contribute up to two percent of their income to health savings accounts that can be used to pay out-of-pocket medical costs, similar to the Medicaid expansion alternative that Vice President-elect Mike Pence (R) enacted in Indiana (see Update for Weeks of January 26 and February 2, 2015).

The law creating Healthy Michigan has an automatic termination clause if the state share of costs (that will phase-up to ten percent in 2020 and beyond) exceeds the savings from the program. However, the House Fiscal Agency reported that due to federal matching funds received under the ACA that will not happen any time before 2022, as the Medicaid expansion has allowed Michigan to save \$235 million per year on spending for other health-related programs, such as prisoner health care.

Governor Snyder pointed to a University of Michigan study published last week in the *New England Journal of Medicine* affirming these findings. Although Michigan's share of costs will reach nearly \$400 million in 2021, the increase in economic activity as a result of the expansion will bring in approximately \$145-153 million per year in new state tax revenue. This is largely because the expansion added more than 39,000 new jobs in 2016 (and will add roughly 30,000 jobs per year through 2021) as state and private resources are freed up to be spent for non-Medicaid purposes, resulting in a \$2.2-2.5 billion increase in personal income.

According to the study, this additional state tax revenue offsets nearly all of Michigan's projected new spending for Healthy Michigan in 2017 and about 37 percent of these costs in 2021. In addition, researchers found that "uninsured hospital stays dropped significantly during the first eight months of the expanded Medicaid eligibility", which should further boost economic activity by reducing the uncompensated care costs for hospitals.



Senate passes premium relief plan for those ineligible for ACA subsidies

The Senate passed legislation this week that would create a \$285 million premium assistance program for those enrolled in qualified health plan (QHP) coverage that are earning 300-800 percent of the federal poverty level (FPL).

S.F. 1 was sponsored by Deputy Majority Leader Michelle Benson (R), who chairs the Health and Human Services Finance and Policy Committee. It would set-up the program only for calendar year 2017 and apply only to those ineligible for premium tax credits under the Affordable Care Act (ACA), which are provided to those earning 100-400 percent of FPL who are enrolled in ACA Marketplace plans. Eligibility for the temporary program would be broader than the ACA tax credits as premium assistance would be available for QHP coverage in or outside of the MNSure Marketplace.

The centerpiece of the plan is a state rebate directly to consumers that would equal 25 percent of their premium. However, assistance would revert after April to a sliding scale and range from 20-30 percent of the total premium cost.

S.F. 1 would also allow for-profit insurers into the MNSure Marketplace, which is currently restricted to non-profit insurers like Blue Cross and Blue Shield.

The measure attracted the support of only one Democrat in the Republican-controlled Senate, as it competes directly Democratic bills and proposals by Governor Mark Dayton (D) to use the state's \$313 million budget surplus to funnel money through insurers that would give a flat 25 percent rebate to any of the 120,000 Minnesotans facing premium spikes without access to ACA subsidies (see Update for Week of October 24th). His Administration argues that the Republican plan to allocate relief by income would cost \$20 million just to create the apparatus to verify eligibility and delay implementation by 8-12 weeks, instead of getting a bill to him by January 19th that would go into effect immediately.

House Republicans are also expected to pass a slightly different version next week. Both S.F. 1 and other House and Senate bills include a state reinsurance program for insurers with exceptional claims. Governor Dayton had lobbied for reinsurance payments that can make up for the expiration of those that were made under the ACA from 2014-2016 (see Update for Week of October 24th). However, he has thus far objected to including them as part of premium assistance bills, fearing it could jeopardize their passage and slow down urgently needed relief.

The Department of Commerce has specifically blamed the loss of reinsurance payments for the 59 percent average premium increase that MNSure Marketplace are facing this year, noting that the rates would have climbed by only 14 percent on average were it not for the top 1.79 percent of consumers whose claim expenses exceeded \$100.000 (see Update for Week of October 10th).

A family of four now in Minnesota now pays roughly \$1,396 per month for benchmark coverage, or 28 percent more than the \$1,090 average across 44 states, according to federal data (see Update for Week of October 24th).

The Minnesota Council of Health Plans has not objected thus far to either the Republican or Democratic premium assistance proposals.

New Hampshire

New bill would prohibit copay assistance from drug manufacturers

Rep. Neal Kurk (R), chair of the House Finance Committee, introduced legislation this week that would prohibit prescription drug manufacturers from offering to pay or reimburse individuals for their health insurance copayments. It would be effective January 1, 2018.



H.B. 443 was referred to the House Commerce and Consumer Affairs Committee.

North Carolina

Republicans thwart new governor's last-minute effort to expand Medicaid under the ACA

New Governor Roy Cooper (D) released his proposal last week to make North Carolina the 32nd state to expand Medicaid under the Affordable Care Act (ACA).

The Governor planned to formally submit the proposal to the federal Centers for Medicare and Medicaid Services (CMS) following a ten-day public comment period, with the hope that it would be approved just before President Obama leaves office on January 20th. CMS had promised a quick decision, but the Republican-controlled legislature successfully obtained a temporary restraining order barring the plan's submission until a state court holds a hearing within the next two weeks to determine whether the expansion is barred by a 2013 state law enacted while Governor Pat McCrory (R) was in office. That law prohibits any governor from expanding Medicaid without legislative approval.

Even if approved by CMS under the Trump Administration, the expansion would not take effect until 2018 and would require a hospital assessment that would cover the ten percent state share of costs. However, the North Carolina Hospital Association has thus far refused to back any assessment for an expansion plan that is not "bipartisan".

Governor Cooper has been at odds with Republican lawmakers since winning a narrow victory over McCrory last fall. Republican lawmakers promptly enacted legislation stripping the new governor of his control over state and local election boards, as well as the state university system. That law has also been temporarily blocked by a lower court pending appeal. However, it does not impact the governor's authority over state health programs.

Ohio

Governor signs biosimilar substitution bill into law

Governor John Kasich (R) signed legislation last week making Ohio one of at least 23 states to regulate a pharmacist's substitution of biosimilar drugs for their brand-name reference product.

H.B. 505 largely follows model legislation supported by the Biotechnology Innovation Organization (BIO). It would allow substitution of biosimilar products deemed interchangeable by the Food and Drug Administration (FDA), but only if the pharmacy informs the patient of the substitution and retains a record of the biosimilar dispensed. However, prescribers will be able to prevent substitutions when appropriate by indicating that pharmacies should "dispense as written".

The Affordable Care Act (ACA) created the first regulatory pathway for approval of biosimilar drugs (see Update for Weeks of March 2 and 9, 2015). Although the FDA is in charge of determining whether a biosimilar is "interchangeable", it is up to states to judge whether one product may be substituted in place of a physician prescription and whether a pharmacist must inform patients or physicians if they make a substitution.

<u>Utah</u>

Obama Administration will not act on "bare bones" Medicaid expansion proposal

The Obama Administration announced this week that it will not take action on the Department of Health's request to approve a limited Medicaid expansion under the Affordable Care Act (ACA) before it leaves office on January 20th.



The move leaves the approval decision up to the new Administrator for the Centers for Medicare and Medicaid Services (CMS). President-elect Trump has nominated Seema Verma to the post, who has previously drafted Medicaid expansion waiver requests for conservative-leaning states like Utah that included partial expansions.

Under President Obama, CMS had made Medicaid expansion an "all or nothing" proposition, approving "private sector" alternatives only if the state expanding all the way up to the 138 percent of federal poverty level threshold set by the ACA. However, Ms. Verma is expected to grant states additional flexibility that may include approving partial expansions to as low as 100 percent of FPL, the threshold for ACA subsidies.

The Department submitted its "bare bones" expansion plan last summer (see Update for Week of July 25th), which would cover only 11,000 residents earning up to 55 percent of the federal poverty level (FPL), after the Republican-controlled legislature refused to approve the "private sector" alternative that Governor Gary Herbert (R) negotiated with CMS that would cover all 146,000 Utahns earning up to 138 percent of FPL. That plan would have allowed Utah to use more than \$420 million in ACA matching funds to purchase Marketplace coverage for those earning 100-138 percent of FPL and subject them to monthly premiums, similar to models that CMS approved in eight other conservative-learning states (see Update for Weeks of October 5 and 12, 2015). The current plan would draw down only \$70 million.

Governor Herbert sent a letter to Congress this week urging them not only retain the Medicaid expansion under the ACA, but warning of the "disastrous" consequence of repealing either the ACA premium and cost-sharing subsidies or individual mandate without a comparable and immediate replacement (see above). His concerns were echoed by at least five other Republican governors in Arkansas, Massachusetts, Michigan, Nevada, and Ohio.