

Health Reform Update – Week of January 7, 2019

CONGRESS

Democratically-controlled House votes to defend against lawsuit declaring ACA unconstitutional

The House voted 235-192 to this week to intervene in the federal lawsuit brought by 20 Republican attorneys general and governors seeking to invalidate the entire Affordable Care Act (ACA).

Speaker Nancy Pelosi made defense of the lawsuit the first priority of the House once Democrats assumed control for the 116th Congress. Judge Reed O'Connor with the U.S. District Court for the District of Texas had ruled last month that the entire law was now unconstitutional after Congress repealed the individual mandate tax penalty for 2019 (see Update for Week of December 17th). That ruling has been appealed to the Fifth U.S. Circuit Court of Appeals by the 18 Democratic attorneys general defending the suit (see below).

Three Republicans joined with Democrats in approving the resolution (H.Res.6), which directs the Office of General Counsel for the House to file a motion with the court to intervene. The Department of Justice had previously declined to defend the lawsuit, although it asked the court to only overturn the provisions that the U.S. Supreme Court previously deemed to be inter-connected with the individual mandate, such as the prohibitions on insurer discrimination based on health status (see Update for Week of September 10th).

Democrats announce drug pricing agenda for coming year

Senator Bernie Sanders (I-VT) joined this week with House Oversight and Government Reform Committee chair Elijah Cummings (D-MD), Rep. Ro Khanna (D-CA), Chellie Pingree (D-ME), and other House Democrats to reintroduce three perennial Democratic proposals to reduce the cost of prescription drugs. The measures would give Medicare Part D the authority to negotiate price discounts with manufacturers (H.R. 275/H.R. 448/S.99), set local drug prices on those paid by five countries (H.465/S.102), and allow consumers to purchase lower-cost drugs from Canada or other countries (H.R. 447/H.R. 478/S.97).

While the proposals are likely to move through the House with a new Democratic majority, they still have only scant support from Republican lawmakers in either chamber. Rep. Francis Rooney (R-FL) is the lone Republican to cosponsor the first House bill from Rep. Peter Welch (D-VT) to allow price negotiation (H.R. 275), which would save the federal government \$156 billion over ten years according to prior estimates. Senate counterparts (S. 62/S.99) sponsored by Senators Amy Klobuchar (D-MN) and Sanders have no Republicans among its 40 initial cosponsors.

One key Republican has joined Senator Klobuchar to introduce legislation (S.64) that would allow lower-cost drugs to be imported from approved pharmacies in Canada. Senator Charles Grassley (R), the new chair of the Finance Committee, has been a long-time advocate for drug importation and previously urged the Department of Health and Human Services (HHS) to create such a program (see Update for Week of July 23rd). He also expressed some support this week for basing Medicare prices based on those paid in other countries. However, Senator Grassley reiterated his opposition to giving Part D the authority to negotiate drug prices.

A separate bill (S.3) introduced by Senator Ben Cardin (D-MD) would create a public health insurance option with the Affordable Care Act (ACA) Marketplaces, increase the upper eligibility limit for ACA premium tax credits from 400 to 600 percent of the federal poverty level, and likewise give negotiation authority to Medicare Part D.

President Trump had expressed support for both drug importation and Medicare price negotiation authority as recently as March 2017. However, the “blueprint” to reduce drug prices that he released last year did not include either proposal (see Update for Week of May 7th).

Rep. Cummings announced later in the week that his committee has launched an unprecedented investigation into the drug pricing practices of at least a dozen manufacturers whose products have either experienced the highest price increases in the past five years or are among the costliest for Medicare Part D. A series of hearings is scheduled to begin January 29th.

New Democratic Senator joins with Republicans in effort to repeal ACA tax on health insurers

Senators John Barrasso (R-WY) and Cory Gardner (R-CO) reintroduced legislation at the outset of the 116th Congress that would repeal the annual assessment on health insurers used to fund the premium tax credits under the Affordable Care Act (ACA).

Republicans have repeatedly sought to repeal the insurer tax since its inception with a handful of Democratic cosponsors (see Update for Week of May 4, 2015). However, the last version of the *Jobs and Premium Protection Act* (S.80) was also sponsored by new Senator Kyrsten Sinema (D-AZ), giving them a key Democrat to push their argument that the tax adds “hundreds of dollars” to health insurance premiums.

Senators Barasso and Gardner pointed to a study by Oliver Wyman consultants showing that individual market consumers will pay an average of \$165 more in premiums by 2020 due to the tax, while small employers will be forced to pay an additional \$449 for each employee.

The Congressional Budget Office (CBO) calculated the cost of repealing the insurer tax at \$14 billion. The legislation does not propose how to offset this cost.

FEDERAL AGENCIES

Federal court overturns dramatic cut to Medicare payments for Section 340B drugs

A federal judge has issued a permanent injunction against the 27 percent cut in Medicare Part B payments for drugs that safety-net hospitals purchase through the Section 340B drug program.

The American Hospital Association and other hospital groups challenged the Centers for Medicare and Medicaid Services (CMS) regulation when it was promulgated as part of the Medicare outpatient prospective system (OPPS) in late 2017 (see Update for Week of November 13, 2017). Judge Rudolph Contreras with the U.S. District Court for the District of Columbia initially dismissed their lawsuit for lack of standing since it was “premature” but allowed them to refile after the \$1.6 billion reimbursement cut went into effect on January 1, 2018 (see Update for Week of September 10th).

The CMS action drew strong opposition from both sides of the aisle and House legislation (H.R. 4392) to overturn the cut quickly gained 174 cosponsors. However, Congress was not able to include a “fix” as part of spending resolutions for fiscal year 2018 (see Update for Week of March 19th).

The latest ruling by Judge Contreras (appointed by President Obama) decided that CMS lacked the authority to unilaterally impose a payment cut of this magnitude. Because it affects “potentially thousands of pharmaceutical products found in the 340B Program”, he concluded that it was the type of “basic and fundamental change” to the rate structure set by Congress that would be outside of CMS’ discretion to make “adjustments as determined to be necessary to ensure equitable payments” within the OPPS.

However, Judge Contreras did not vacate the entire CMS rule nor specify when and how hospitals will be able to recoup the payments they lost for 2018. He instead ordered a supplemental hearing on that issue. The judge also did not enjoin the payment cut from being applied for 2019, likely forcing the plaintiffs to file a separate challenge this year.

CMS officials indicated that they are likely to appeal the ruling.

HEALTH CARE COSTS

Payers expect drug costs to rise 3-5 percent annually over the next three years

A survey of 27 managed care organizations, pharmaceutical benefit managers, and hospitals released this week by the Cowen consulting firm revealed that per-unit acquisition costs for prescription drugs are likely to rise 3-5 percent over the next three years (down from 7-9 percent last year).

The payers surveyed were responsible for roughly one-third on all U.S. retail drug purchases in 2016. A full forty percent of them attribute at least three-quarters of the increase to higher-priced, newer therapies (compared to only 26 percent last year).

Biosimilars are expected to make further inroads over the next three years. For biologic drugs for which a biosimilar is available, an average of 25 percent of dispensed prescriptions are likely to be biosimilar substitution, rising to an average of 47 percent whenever three or more biosimilars are available. This is presuming that the biosimilar approval pathway created by the Affordable Care Act (ACA) is not invalidated by the recent lower court ruling striking down the entire ACA (see Update for Week of December 17th).

Respondents indicated that price discounts would need to average 33 percent in order to switch from a brand-name biologic to a biosimilar product.

Despite the rhetoric from Congress (see above), only 23 percent of respondents believe any form of price controls for prescription drugs are likely to be enacted in the next three years. However, this is more than double the percentage from last year (only 11 percent).

STATES

Democratic attorneys general appeal lower court ruling striking down entire Affordable Care Act

California Attorney General Xavier Becerra (D) filed a Notice of Appeal this week with the U.S. Fifth Circuit Court of Appeals seeking to overturn last month's lower court ruling declaring the entire Affordable Care Act (ACA) to be unconstitutional following Congress' repeal of the ACA's individual mandate tax penalty (see Update for Week of December 17th).

Becerra's appeal will be joined by 16 other Democratic attorneys general who had signed-on to his defense of lawsuit brought by Texas Attorney General Ken Paxton (R) last summer (see Update for Week of September 10th). Newly-elected Democratic attorneys general in Nevada, Michigan, and Wisconsin have also pledged to join the appeal. However, a court will have to decide whether Wisconsin Attorney General Josh Kaul (D) can be added after outgoing Governor Scott Walker (R) signed legislation enacted last month by the Republican-controlled legislature that barred him from doing so without legislative approval (see Update for Week of December 17th).

Judge Reed O'Connor (appointed by President George W. Bush) confirmed this week that his order invalidating the ACA was stayed pending appeal, which could take up to a year after the Fifth Circuit agreed this week to the Trump Administration request to pause the lawsuit during the current federal government shutdown (see above).

States consider renewed prohibition on prescription drug price gouging despite adverse court ruling

State lawmakers have continued to introduce legislation nationwide that would prohibit “unconscionable” price increases for essential off-patent or generic drugs, despite a federal appellate court declaring Maryland’s “price-gouging” law unconstitutional.

Maryland’s law was the first in the nation (see Update for Weeks of May 29 and June 5, 2017) and at least 16 other states including Colorado, Illinois, Louisiana, and New Hampshire had advanced similar price-gouging prohibitions that were modeled upon it (see Update for Week of February 26th) before the Fourth U.S. Circuit Court of Appeals declared it unconstitutional on the basis that Maryland could not regulate out-of-state drug transactions (see Update for Week of April 16th). The Maryland Attorney General has appealed that decision to the U.S. Supreme Court (see Update for Week of October 15th).

Lawmakers in at least seven states have quickly proposed new “price-gouging” laws at the outset of their state legislative sessions, under the expectation that the U.S. Supreme Court will overrule the Fourth Circuit. These include Indiana (S.B. 415), Minnesota (H.F. 4), Mississippi (H.B. 283), New York (S.B. 256), Oregon (H.B. 2696), Rhode Island (H.5095), and Virginia (S.B. 1308). The Mississippi bill is the only one sponsored by a Republican lawmaker.

California

New Governor signs executive orders to expand health insurance coverage, lower drug prices

Governor Gavin Newsom (D) signed several executive orders upon taking office this week that would create a state alternative to the individual mandate under the Affordable Care Act (ACA), expand Medicaid to undocumented immigrants under age 26, and consolidate the state’s prescription drug purchases into a state-run program.

The moves would make California only the fourth state (including the District of Columbia) to implement their own version of the ACA’s individual mandate, following Congress’ repeal of the mandate’s tax penalty starting in 2019 (see Update for Week of July 23rd). The legislature would have to work out whether California would impose a different tax penalty or apply the same exemptions as the federal model.

The individual mandate, which the governor predicts will raise \$500 million in annual revenue, would work concurrent with a state supplement to the ACA premium tax credits also proposed by the Governor. The budget plan he released this week would provide those earning 250 to 400 percent of the federal poverty level (FPL) with an additional \$10 per month on average, on top of the tax credits for which they are eligible under the ACA.

However, for those earning from 400 to 600 percent of FPL, the state supplement would average about \$70 per month. This would benefit individuals earning \$48,560 to \$72,840 per year (or \$100,400 to \$150,600 for a family of four). This population currently earns too much to qualify for ACA tax credits but struggles to afford the full cost of coverage in the Covered California Marketplace created pursuant to the ACA.

The combination of an individual mandate and expanded subsidies are expected to significantly mitigate premium increases among individual market insurers, which have increased by 8.7 percent and 10.5 percent on average over the current and previous plan years (see Update for Week of July 23rd). However, the Governor’s proposal does not provide any projection related to premium increases.

The Governor’s executive orders would also make California the first in the nation to extend Medicaid coverage to undocumented immigrants up to age 26, in an effort to be consistent with the age that the ACA allows parents to keep dependent adult children on their group health plans. California was the first to extend Medicaid coverage to undocumented children up to age 19 and at least four states have since followed (see Update for Week of October 5 and 12, 2015).

However, further expanding Medi-Cal for this population comes with an estimated cost of \$260 million per year. Since that cost would have to be borne entirely by the state (because the ACA bans federal Medicaid funds for coverage of undocumented immigrants), it is not expected to be approved, even by a legislature as Democratically-dominated as California.

The Governor's executive orders also attempt to curb increases in prices for prescription drugs by making the state consolidate drug purchases into one agency. Currently, Medi-Cal and other state agencies separately negotiate drug prices. However, consolidating purchases would give the state more leverage to negotiate price discounts for bulk purchasing, especially once the order allows small businesses and individuals join the state-run collective.

Governor Newsom's proposals largely have the support of the California Medical Association and Covered California, the ACA Marketplace. Democratic lawmakers were also mostly in favor, although Assemblyman Jim Wood (D), who is sponsoring legislation (A.B. 174) that would create a state-funded supplement for the ACA tax credits, acknowledged that the expected cost could still make the proposals a "heavy lift" for Democrats.

Governor Newsom addressed the cost concerns by pointing out that California has its highest budget surplus in more than two decades (at \$21.5 billion). Roughly 30 percent of the Governor's proposed \$209 million budget will go to health reforms that he insists will save the money in the long-run by reducing drug costs, premium increases, and uncompensated care.

The Governor also sent a letter this week to Congress and the White House asking for changes in federal laws that will give California the regulatory freedom to ultimately move towards a single-payer health care system, a move that will not be as well received by California insurers. The legislature flirted with single-payer bills as recently as 2010 only to scuttle proposals in face of cost estimates that were "politically unrealistic" and a promised veto from Governor Arnold Schwarzenegger (R), who instead supported the ACA (see Update for Week of June 28, 2010).

Colorado

Democrats use new majority to push bills creating public option, allowing prescription drug importation

Democrats have made health reform a focus of the first five bills introduced last week in each chamber since assuming control at the start of the legislative session.

Senate Republicans had successfully blocked legislation last session that would have created a Medicaid buy-in, reinsurance program, and state-funded premium subsidies (see Update for Week of May 7th). However, Democrats gained control of the Senate and all statewide offices in the midterm elections, paving the way for passage of their long-sought reforms (see Update for Week of November 12th).

A new Senate bill (S.B. 4) would create a public option health insurance plan on the Connect for Colorado Marketplace that the state operates pursuant to the ACA. The public option is specifically intended to give consumers on the western slope, who face some of the highest premiums in the nation, a more affordable plan that would pay insurers based on Medicare reimbursement rates (see Update for Week of July 9th). Under S.B. 4, the public option would be available for the 2020 open enrollment period via a pilot program that would not require federal approval. However, a companion bill (H.B. 1004) that will be heard January 23rd in the Health and Insurance Committee would delay implementation until the 2021 open enrollment period, depending on whether the Trump Administration would approve the required federal waiver.

Senator Robert Rodriguez (D) also introduced legislation this week that would let Coloradans import lower-cost prescription drugs from Canada (S.B. 5). It has the backing of new Governor Jared Polis (D), who supported drug importation during his campaign.

Vermont enacted legislation last year that would create a wholesale drug importation program (see Update for Week of May 28th) and Democratic lawmakers have already introduced bills to create a similar importation program in Oregon (H.B. 2689/S.B. 409) and West Virginia (H.B. 2319/S.B. 250) or to study the issue (H.B. 1228 in Indiana and S.B. 127 in Missouri). However, the Trump Administration has yet to approve the required waiver for Vermont and the state's Agency on Human Services issued a December 2018 report to the legislature warning that the cost of administering a drug importation may outweigh the potential savings, at least for the 17 commonly-used drugs that they evaluated.

Governor Polis has also called for the legislature to authorize a federal waiver within his first 100 days that would make Colorado at least the eighth state to create a reinsurance program compensating insurers for exceptional claims (see Update for Week of December 17th).

Florida

New Medicaid director is strong advocate for Medicaid work requirements, limited eligibility

Upon assuming office last week, new Governor Ron DeSantis (R) immediately appointed the controversial former director of Maine's Medicaid program to oversee Florida's Agency for Health Care Administration (AHCA).

Mary Mayhew had lead the effort by former Maine Governor Paul LePage (R) to block the Medicaid expansion approved by the voters last year (see Update for Week of December 18, 2017) and has been fervent advocate for LePage's efforts to eliminate eligibility for entire categories of Medicaid enrollees (see Update for Week of December 1, 2014). She recently applied for and obtained a federal waiver allowing Maine to implement work requirements on adult Medicaid enrollees before serving a Director of the Medicaid division within the federal Centers for Medicare and Medicaid Services (CMS) for only three months.

Mayhew's appointment sends a strong signal that the DeSantis Administration is likely to oppose Medicaid expansion in Florida just as staunchly as his predecessor and the Republican-controlled legislature. DeSantis has also pledged to tighten Medicaid eligibility requirements in Florida, which are already some of the most stringent in the nation.

Idaho

Key Senator rebuffs Governor's plan to restrict voter-mandated Medicaid expansion

The chairman of the Senate Health and Welfare Committee promised this week not to add any restrictions to the Medicaid expansion that was approved by the voters.

Idaho was one of three states (along with Nebraska and Utah) where voters approved ballot referendums last fall mandating that their state participate in the Medicaid expansion under the Affordable Care Act (see Update for Week of November 12th). Maine became the first state with a voter-approved expansion referendum last year (see Update for Week of November 13, 2017).

New Governor Brad Little (R) announced after the election that he would honor the will of the voters and implement the expansion, unlike his counterpart in Maine (see above). However, Governor Little also proposed several restrictions on the expansion, led by a requirement that the newly-eligible population be engaged in full-time work, school, or job training activities. This work requirement would be similar to the one Virginia lawmakers imposed last year on their expansion that started January 1st (see Update for Week of December 17th) and which the Trump Administration has already approved for five states (see Update for Week of October 29th).

However, Chairman Fred Martin (R) insisted that "it's incumbent upon us in the legislature to not make changes" and honor the will of the voters. He noted that nearly 61 percent of voters support the expansion and stated "the people have spoken". (His committee has jurisdiction over the Governor's proposed changes).

The state Supreme Court will have the ultimate say on the Medicaid expansion as it prepares to hear a legal challenge later this month that was brought by the Idaho Freedom Foundation.

Maine

New Governor immediately issues executive order to implement Medicaid expansion

Governor Janet Mills (D) issued her promised executive order this week implementing the voter-approved Medicaid expansion that had been blocked by her predecessor.

Voters made Maine the first state to pass a ballot referendum to participate in the Medicaid expansion under the Affordable Care Act (ACA) (see Update for Week of November 6, 2017). However, Governor Paul LePage (R) refused to submit the required State Plan Amendment paperwork to the Trump Administration by the referendum's April 2017 deadline forcing consumer groups to secure a court order from the Maine Supreme Judicial Court (see Update for Week of September 10th). Governor LePage, who has vetoed six attempts by the Democratically-controlled legislature to expand Medicaid, subsequently refused to let the state's Department of Health and Human Services (HHS) promulgate the required regulations (see Update for Week of December 3rd).

A lower court ordered HHS last month to implement new rules by February 1st and make coverage retroactive to last July 1st, the effective date set by the voter referendum (see Update for Week of December 3rd). However, Governor Mills (who previously served as attorney general) promised she would direct HHS to do so as her first order of business after this week's inauguration.

Governor LePage, who could not remain in office due to term limits, had threatened to run against Mills in four years should she follow through with her promise to expand Medicaid (see Update for Week of December 3rd).

Legislature moves to codify key ACA provisions into state law

Senate President Troy Jackson (D) introduced L.D. 1 last week in an effort to preserve key consumer protections in the Affordable Care Act (ACA) for Maine residents.

The bill, which has the support of new Governor Janet Mills (D), is a direct response to last month's federal court ruling declaring the entire ACA unconstitutional following Congress' repeal of the individual mandate tax penalty for 2019 (see Update for Week of December 17th). It would specifically codify into Maine insurance law the ACA's prohibitions on insurer discrimination based on pre-existing conditions, the ban on lifetime caps on limits on annual caps, and the requirement that insurers cover essential health benefits that are "substantially similar" to those benefits provided under the ACA. Similar bills have been introduced by Democratic lawmakers in at least Indiana (S.B. 204) and New Hampshire (H.B. 233).

Governor Mills stressed this week that Maine was never one of the 20 states backing the Republican lawsuit to overturn the ACA (see Week of December 17th). As attorney general, Mills refused to give Governor Paul LePage (R) that authority to add Maine as a plaintiff and he signed-on only in his individual capacity. Mills will not add Maine to the list of plaintiffs and denounced the federal court ruling invalidating the ACA, insisting that it would be overturned on appeal.

Maryland

Democratic lawmakers resurrect plan to create state alternative to ACA individual mandate

Senator Brian Feldman (D) and Delegate Joseline Peña-Melnyk (D) plan to reintroduce legislation as early as next week that would create a state alternative to the individual mandate under the Affordable Care Act (ACA).

Four states (including the District of Columbia) currently have some form of individual mandate requiring consumers to purchase minimum essential coverage they can afford or pay a penalty that does into a general pool to

offset the costs of their uncompensated care. Massachusetts' mandate predated the ACA, while New Jersey, Vermont, and DC enacted theirs following Congress' repeal of the ACA tax penalty starting in 2019 (see Update for Week of July 23rd).

However, instead of a tax penalty, the Maryland legislation would make it the first state to levy a fine that would go to the Maryland Health Exchange (created by the ACA), which would use it as a down-payment to automatically enroll the consumer in a health plan. If the consumer opts out, the fine would be used to stabilize the individual market.

Two very similar bills failed to clear committee last session (see Update for Week of April 16th). However, Senator Feldman insists that the current bill will have additional momentum following successful legislation last year that made Maryland one of seven states with a reinsurance program to compensate insurers for exceptional claims, resulting in a dramatic and immediate reduction in premium increases from the state's dominant insurer (see Update for Week of September 10th). He also emphasized New Jersey's success in dramatically mitigating premium increases after enacting both an individual mandate and reinsurance program (see Update for Week of September 10th).

Delegate Peña-Melnyk pointed to last year's analysis by the Urban Institute showing that absent an individual mandate, roughly 69,000 Marylanders are expected to lose their health insurance while individual market premiums will rise by a projected average of 16 percent.

New York

New York City to create \$100 million public health insurance option for anyone not enrolled in Medicaid

New York City Mayor Bill de Blasio (D) proposed last week to spend \$100 million to ensure all city residents can purchase health insurance coverage.

His NYC Cares Plan is would build upon the existing Metro Plus plan for city employees and expand coverage to about 600,000 residents who either are beyond Medicaid eligibility levels, cannot afford private coverage, or are undocumented immigrants. If selected, the city-funded health insurance option would assign a primary care doctor to each plan participant and help patients find specialists.

Premiums would be based on a sliding scale depending on the plan participant's income. The plan would be offered later this year for Bronx residents and be available to all boroughs by 2021.

The Medicaid program for New York state already provides coverage for all eligible children, regardless of immigration status, as does California (see above), the District of Columbia, Illinois, Massachusetts, Oregon, and Washington.

Washington

Governor announces plan to create public option, expand premium subsidies

Governor Jay Inslee (D) joined with Democratic lawmakers this week to announce proposed legislation that would create a new public health insurance option within the Marketplace that Washington operates pursuant to the Affordable Care Act (ACA).

Governor Inslee presented the proposal as a "first step" towards universal coverage, although its primary purpose is to mitigate against premium increases that had spiked in recent years. The Cascade Care plan would be offered in every county by at least one insurer participating in the Washington Healthplanfinder. It would offer "consistent" deductibles and cost-sharing.

The Governor's proposed budget would include \$500,000 over the next two years to create the public option. Subsequent funding would have to be authorized by the legislature.



The legislation would also provide state-funded premium subsidies for those ineligible for ACA premium tax credits, in order to ensure consumers are not required to spend more than ten percent of their income on health plan premiums. However, a funding mechanism was not identified.

According to the Governor's office, Marketplace consumers in 14 mostly rural counties currently have only one participating insurer.

LEADING PATIENTS TO POSITIVE OUTCOMES

P.O. Box 5930, Midlothian, VA 23112 • 800-366-7741 • www.patientservicesinc.org