

Health Reform Update – Week of December 17, 2018

CONGRESS

Federal judge declares entire ACA unconstitutional

A lower court ruled late last week that the entire Affordable Care Act (ACA) must be overturned because Congress zeroed out the tax penalty for the law's mandate that everyone purchase health insurance they could afford.

The decision by Judge Reed O'Connor in the U.S. District Court for the District of Texas has no immediate impact as he stayed his ruling pending appeal. However, because it was timed to coincide with the December 15th end of the open enrollment period for most ACA Marketplaces (see below), it is likely to cause broad confusion among consumers, providers, and insurers.

Judge O'Connor (appointed by President George W. Bush) relied upon the prior U.S. Supreme Court decision that upheld the individual mandate and the entire ACA (see Update for Week of June 25, 2012). In that case, Chief Justice John Roberts declared that the individual mandate was unconstitutional under the Commerce Clause but still permissible under Congress' taxing authority because it gave consumers a choice between buying insurance or paying the tax penalty.

Judge O'Connor reasoned that because consumers are no longer required to pay the tax penalty starting in 2019 (see Update for Week of December 18, 2017) that means that the U.S. Supreme Court would now find that the individual mandate is unconstitutional. Because Congress did not include language allowing the individual mandate to be severed from the rest of the ACA, he concluded the entire 900 plus page law must fail in its entirety.

The case was brought last year by Texas Attorney General Ken Paxton (R) in a direct effort to get the issue before Judge O'Connor, a favorite of conservative opponents of the ACA since he had previously blocked specific ACA provisions on gender discrimination and health insurer taxes. It was joined by 19 other Republican-controlled states and two Texas residents (see Update for Week of September 10th).

Three Department of Justice attorneys withdrew from the case last fall to protest the White House's decision not to defend against the lawsuit. However, the White House had asked the court only to strike down the consumer protections that were impossible to separate from the individual mandate, namely the requirement that insurers provide coverage regardless of pre-existing conditions and not vary premiums based on health status.

The White House acknowledged at the time that even the loss of these three key provisions would cause "chaos" in the individual marketplace. Judge O'Connor's ruling does not evaluate the mass disruption and uncertainty that would result from undoing the ACA's system-wide reforms, which would not only eliminate the popular protections from pre-existing condition discrimination, but terminate coverage for more than 20 million Americans who gained coverage under the ACA. The lost provisions would specifically include:

- Giving parents the ability to put dependent children on their group plans until age 26.
- Closing the Medicare Part D "doughnut hole" in which enrollees had to pay all of their drug costs.
- Providing rebates to consumers whenever insurers claimed excess profits.
- Expanding state authority to protect consumers from excessive premium increases.
- Creating an FDA approval pathway for biosimilar drugs that are less costly than biologic products.

In addition, terminating the existing Medicaid expansions for 34 states would result in gaping budget deficits as states relied on ACA matching funds to cover expansion costs over the next several years.

The decision was widely-criticized by legal experts from both sides of the aisle, with the typically-conservative *Wall Street Journal* agreeing with the defendants' position that Judge O'Connor failed to consider the intent of the amending Congress in repealing only the tax penalty for the individual mandate, which the editorial board argued should weigh just as heavily as the intent of the Congress that enacted the ACA. Jonathan Adler, the conservative architect of the unsuccessful challenge against the ACA's premium tax credits, called O'Connor's ruling "bananas" while several Republican lawmakers that voted in favor of repealing the tax penalty, including Senators Susan Collins (R-ME) and Jerry Moran (R-KS), insisted that neither they nor their colleagues intended to disturb the rest of the law.

California Attorney General Xavier Becerra (D), who is leading the 17 Democratically-controlled states that signed on as defendants in the lawsuit, pledged to promptly appeal Judge O'Connor's decision to the Fifth U.S. Circuit Court of Appeals. Many of those states have already taken action to preserve key provisions of the ACA for their residents and Congressional Democrats along with several Republicans indicated they will introduce legislation next year seeking to do so at the federal level. Maryland Attorney General Brian Frosh (D) has already asked a federal court in his state to issue a counter ruling to the Texas lawsuit (see Update for Week of September 10th).

Based on Judge O'Connor's reasoning, several Democrats also suggested that Congress could ensure the ACA remains in place simply by reinstating the individual mandate penalty to an amount as low as one dollar—a change that could be passed through budget reconciliation with only a bare Senate majority. However, the likelihood of the Republican-controlled Senate undoing their repeal of the individual mandate penalty appears to be slim.

Senate Republicans blocked an effort this week by Senator Joe Manchin (D-WV) to direct the Senate counsel to intervene and defend against the lawsuit. However, the House is expected to pass a comparable resolution as soon as Democrats take control next year.

House-passed measure to further delay ACA taxes not expected to receive Senate approval

The House passed legislation this week (H.R. 88) that would further delay several taxes imposed by the Affordable Care Act (ACA).

The bill sponsored by Ways and Means Committee chairman Kevin Brady (R-TX) includes a two-year delay of the annual fee on health insurers (through 2021), a five-year delay of the tax on device manufacturers (through 2024), and an additional one-year postponement (through 2022) of the 40 percent tax on high-benefit "Cadillac" health plans.

The legislation is not expected to pass the Senate before the end of the year, in large part because it does not include offsets for the \$15.5 billion projected cost of delaying the "Cadillac" tax, which has never gone into effect (see Update for Week of January 23rd). It also contains a controversial repeal of the prohibition on non-profit churches or charities making political endorsements, which is not likely to receive Democratic support.

Although past efforts to delay or eliminate certain ACA taxes has received some bipartisan support, the new Democratically-controlled House is not expected to advance such bills next year.

Senator Cassidy to drop bill governing gene therapy reimbursement under Medicare, Medicaid

Senator Bill Cassidy (R-LA), a physician, announced earlier this month that he is drafting legislation that will govern how Medicare, Medicaid, and other federal programs can cover emerging gene therapies.

The Food and Drug Administration (FDA) is already creating a fast-track process that would allow for marketing approval if a gene therapy shows significant benefit before all clinical trials have been completed, so long as the trials are continued after the drug is on the market (see Update for Week of May 28th). The new process will initially be applied to hemophilia products as pricing for new gene therapies for that disorder is expected to top \$1 million.

Cassidy's bill would allow federal health programs to cover the exceptionally high-cost therapies under either a subscription payment model or an outcome-based, pay-over-time model. He noted that the Medicaid program in his state is already exploring the use of the former to pay for the costly Hepatitis C virus "cures" that came to market in 2014-15. However, the "best price" rule under existing federal Medicaid law stands as an obstacle to that model as it requires Medicaid get the lowest price for drugs sold anywhere within the United States.

The Oklahoma Medicaid program is currently seeking a federal waiver that would allow it to base drug reimbursement on health outcomes, as the State Plan Amendment (SPA) for Medicaid will not otherwise let the state use outcome-based contracts that reimburse gene therapy drugs in installments.

The Trump Administration has already granted Oklahoma a waiver to negotiate supplemental drug rebates with drug manufacturers involving value-based purchasing (see Update for Week of June 25th). The move allows the state to receive additional rebates whenever certain clinical outcomes are not achieved.

Senate Democrats introduce bill to give HHS authority to block excessive price hikes for prescription drugs

Senator Richard Blumenthal (D-CT) and three other Senate Democrats introduced legislation this week that would give the Department of Health and Human Services the authority to punish drug manufacturers who engage in "price gouging."

The *CURE High Drug Prices Act* (S.3754) defines price gouging as an increase that drugmakers cannot reasonably justify based on greater production costs or expanded access, or price hikes that consumers are unable to avoid because the market lacks competition. HHS would presume price gouging in instances where the average manufacturer price (AMP) increased at least ten percent over the previous year, at least 20 percent over the previous three years, or at least 30 percent over the previous five years.

If HHS deems a price hike as "excessive", it could force drugmakers to pay an extra amount to payers and other consumers. Manufacturers could also make the drug available at the old price for a specific period under qualified or federal health plans.

Maryland enacted the first "price-gouging" law last year that sought to prevent "unconscionable" prices for essential off-patent or generic drugs (see Update for Weeks of May 29 and June 5, 2017). At least 16 other states including Colorado, Illinois, Louisiana, and New Hampshire had advanced similar price-gouging prohibitions modeled on the Maryland law (see Update for Week of February 26th) until the Fourth Circuit Court of Appeals overturned the Maryland law 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).

Senator Warren proposes getting federal government into generic drug manufacturing

Senator Elizabeth Warren (D-MA) released proposed legislation this week that would effectively create a government-run pharmaceutical manufacturer to mass-produce generic drugs

The *Affordable Drug Manufacturing Act* would establish an Office of Drug Manufacturing that would be required to manufacture at least 15 different generic drugs in its first year whenever it determines there is a market failure. The standards that define market failure include:

- If no company is producing the generic drug;
- If just 1-2 companies are producing the generic drug and there is a shortage or recent price hike that exceeds medical inflation;

- If the drug is on the World Health Organization’s “essential medicine” list and the price is deemed too high while being produced by only 1-2 companies.

Senator Warren cited ongoing government investigations into excessive price increases for insulin as justification for creating the new office.

The Association for Accessible Medicines (representing generic drug manufacturers) quickly opposed the legislation, calling it an “unrealistic distraction from policies that would meaningfully reduce drug prices, such as combating patent abuse and cultivating a robust biosimilars market.” Industry analysts largely dismissed the legislation as impractical given the bureaucratic hurdles that would need to be overcome in order to create a new government entity.

FEDERAL AGENCIES

Late surge puts Marketplace enrollment only slightly behind 2018 total

Data released this week by the Centers for Medicare and Medicaid Services (CMS) shows that 8.45 million consumers signed-up for coverage in one of the 39 federally-facilitated Marketplaces (FFMs) during the 2019 open enrollment period that ended December 15th.

The figure is 4.2 percent below the 8.8 million total for the 2018 enrollment period. However, that is a dramatic improvement from earlier this month when enrollment lagged 11 percent behind last year (see Update for Week of December 3rd). It also is a slight improvement from the five percent decline in enrollment from 2017 to 2018.

As with last year, analysts largely blamed the Trump Administration’s dramatic cuts to marketing and outreach that greatly limited the number of enrollment assisters available to FFM consumers (see Update for Week of December 3rd). They point to the fact that most of the 11 state-based Marketplaces (SBMs), whose marketing and outreach budgets remain untouched by the FFM cuts, are all reporting significant bumps in enrollment.

For example, New York saw record enrollment of more than 4.7 million consumers signed-up through December 15th, even though the state’s open enrollment period runs through January 31st. Enrollment in Minnesota’s ACA Marketplace, where enrollment runs through January 13th, is 11 percent ahead of last year’s pace and only about 3,000 shy of its 2018 total. Colorado (which has a January 15th deadline) is running five percent ahead of last year as is Massachusetts (which has a January 23rd deadline). Maryland’s enrollment increased by two percent before its December 15th deadline.

Other SBMs have extended their deadlines as follows: Vermont (December 21st), Washington (December 28th), Rhode Island (December 31st), California (January 15th), and the District of Columbia (January 31st).

Florida continues to far outpace all other FFM states in total enrollment, with nearly 1.8 million sign-ups for 2019, a slight increase from last year (see Update for Week of August 27th). Texas was the only other FFM to break one million, with just under 1.1 million enrollees (a 3.6 decline from 2018). The third highest state (North Carolina) had less than half the Texas total.

Florida, Hawaii, Mississippi, Oklahoma and Wyoming were the only FFM states that showed an increase in enrollment from last year. By contrast, Louisiana and West Virginia each saw enrollment decline by more than 15 percent.

Enrollment of first-time consumers was also down by 15 percent for 2019, which analysts largely attributed to Congress’ repeal of tax penalty for consumers not purchasing coverage they can afford (see Update for Week of December 18, 2017), along with the Trump Administration’s allowance for cheaper non-ACA compliant plans outside the Marketplaces (see Update for Week of August 13th). However, the CMS Administrator tried to dispel that notion by

emphasizing that enrollment in New Jersey's FFM Marketplace fell by eight percent even though that state enacted their own individual mandate and put limits on short-term health plans (see Update for Week of May 7th).

Kaiser Family Foundation previously found the loss of the individual mandate penalty and plethora of non-compliant plans caused average FFM premiums for benchmark plans to decrease by only 1.5 percent instead of 17.5 percent (see Update for Week of October 29th). However, a new study released last week found that 4.2 million uninsured consumers could still purchase bronze-tier coverage this year in ACA Marketplaces at no cost. Bronze coverage is the cheapest but least generous plan offering.

The availability of free coverage was created by the Trump Administration decision shortly before the start of the 2018 open enrollment period to eliminate the cost-sharing reductions (CSRs) under the ACA (see Update for Week of November 13, 2017). Most states allowed insurers to compensate for the unpaid CSRs they were owed by increasing premiums only for the silver-tier plans to which the CSRs were tied, a practice called "silver-loading" which the Trump Administration will not prohibit until the next open enrollment period (see Update for Week of June 11th). For consumers eligible for the ACA premium tax credits, that increased the amount of their subsidy to the point where they could use it to purchase the bronze-tier coverage for free.

FDA issues new regulations and guidance on biosimilar drug approvals

The Food and Drug Administration (FDA) issued a proposal rule and set of guidance documents last month that are intended to more quickly facilitate the approval of biosimilar drugs.

The Affordable Care Act (ACA) created the first approval pathway for biosimilar competitors to high-cost biologics (see Update for Week of March 4, 2013). However, the FDA has only approved 15 biosimilar products since it was enacted.

FDA commissioner Scott Gottlieb has frequently blamed "anti-competitive behavior" for hindering biosimilar development such as abuse of the agency's risk mitigation plans, "opaque" rebate agreements between insurers and brand-name manufacturers (see Update for Week of March 19th), and "pay-to-delay" patent infringement settlements (see Update for Week of October 1st).

The latest rulemaking and guidance expands on the commissioner's Biosimilars Action Plan issued last summer and specifically would facilitate access to samples of reference products, which the commissioner insists that brand-name drugmakers are frequently withholding from potential competitors. The *Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act* (S.974) currently being considering in Congress would also prevent this practice (see Update for Week of May 28th). However, the agency is weighing whether to immediately allow companies developing biosimilars to obtain reference product samples from abroad.

STATES

Arkansas

Medicaid enrollees can now phone in documentation proving they comply with work requirements

The Department of Human Services (DHS) announced last week that Medicaid expansion enrollees will be able to report their compliance with the new work requirements over the phone as of December 19th, rather than solely through an online web portal.

As of last June 1st, adults who are not disabled, age 30-49, and enrolled in the Arkansas Works Medicaid expansion program have been required to document they are working or enrolled in job training, school, or volunteer activities for at least 80 hours per month (see Update for Week of June 25th). (The work requirement will broaden to those

age 19 to 29 starting January 1st.) Those that fail to comply for three consecutive months lose coverage for the remainder of the calendar year.

The move is intended to blunt mounting criticisms of the work requirements, which has caused nearly 17,000 enrollees to lose coverage since being implemented June 1st. Consumer groups had repeatedly complained that DHS for forcing coverage losses by preventing enrollees from providing this documentation by any means apart from the web portal, since as many as one-third of those subject to the work requirement lack any internet access.

The dramatic coverage losses compelled the Medicaid and CHIP Payment and Access Commission (MACPAC) to urge the Trump Administration not to approve any future work requirements until it can develop adequate methods to evaluate whether those who lose coverage are able to obtain insurance from other sources (see Update for Week of October 29th). Even the conservative American Enterprise Institute (which has favored the work requirements) agreed that Medicaid enrollees should be able to report their compliance through means that “doesn’t require extraordinary efforts.”

The federal Centers for Medicare and Medicaid Services (CMS) has approved Medicaid work requirements for five states (see Update for Week of October 29th). Due to court rulings, Arkansas remains the only one to go into effect although several more are slated to start January 1st. A lawsuit challenging the Arkansas work requirement remains pending in the same federal court that blocked CMS’ approval of Kentucky’s Medicaid work requirement (see Update for Week of August 13th).

CMS is expected to shortly approved Oklahoma’s comparable waiver request (making Oklahoma and Wisconsin the only two non-expansion states with Medicaid work requirements). However, Administrator Seema Verma indicated earlier this month that the agency is closely monitoring coverage terminations in Arkansas and may make modifications to existing and future waivers in order to mitigate those losses.

Legal Aid of Arkansas, which filed the pending lawsuit against the work requirements, compared DHS’ latest change as “fixing a leaky faucet on a sinking ship.” They insisted that the primary cause of the massive coverage losses was the lack of sufficient outreach since most enrollees are not even aware they are required to provide the needed documentation.

California

Covered California extends deadline for January 1st coverage in response to anti-ACA court ruling

Covered California Executive Director Peter Lee announced this week that the Marketplace will extend its deadline for consumers to sign-up for coverage that starts January 1st, in response to the federal court ruling declaring the Affordable Care Act (ACA) to be unconstitutional (see above).

California is one of three states (including the District of Columbia) that maintained the full 12-week open enrollment period for 2019 (see Update for Week of September 10th). However, it was the only Marketplace to move the start date up to October 15th (from November 1st).

Although Covered California’s enrollment period remains open through January 15th, consumers had to sign-up by December 15th if they wanted coverage to be effective on January 1st. The Marketplace has now agreed to push that deadline back to December 22nd, due to confusion caused by the court decision, which was stayed pending appeal.

Missouri

New bill would authorize federal waiver to provide reinsurance payments for insurers

Senator Paul Wieland (R-MO) pre-filed S.B. 99 earlier this month, seeking to make Missouri the latest state to seek federal approval to mitigate premium increases by compensating individual market health insurers for exceptional claims.

The Trump Administration has already grant seven waivers for states to operate such a reinsurance program and at least a dozen other states have enacted or are seeking legislation authorizing agencies to submit such a waiver request (see Update for Week of December 3rd). They are intended to replace the temporary reinsurance payments that insurers received under the Affordable Care Act (ACA) through 2016.

Virginia

New Medicaid expansion enrolls more than 182,000 residents

Governor Ralph Northam (D) announced this week that 182,209 Virginians have enrolled in the Medicaid expansion program that starts January 1st.

Virginia became the 34th state to participate in the Affordable Care Act (ACA) expansion when the legislature passed compromise legislation following years of a bitter standoff between conservative lawmakers and former Governor Terry McAuliffe (D) (see Update for Week of May 28th). Enrollment in the program started November 1st and exceeds initial projections, as the Department of Medical Assistance Services had predicted that only up to 400,000 residents would enroll by 2020 (see Update for Week of October 15th).

Three other states (Idaho, Nebraska, and Utah) have since expanded Medicaid through ballot referendums, bringing the overall total to 37 states (see Update for Week of November 12th).