



Health Reform Update – Week of December 15, 2014

CONGRESS

President signs full-year spending bill that includes some ACA limits

President Obama signed the \$1.1 trillion spending bill passed by both the House and Senate that will fund the federal government through the end of fiscal year 2015 in September and avert a government shutdown.

The measure (H.R. 83) largely funds federal agencies at the same level as fiscal 2014 (consistent with the bipartisan spending agreement last winter) and extends the ongoing budget sequester from 2011 (see Update for Week of December 8th). However, it also includes several provisions targeting the Affordable Care Act (ACA), including a prohibition on the Department of Health and Human Services transferring additional funds for the three-year reinsurance and risk corridors program that offsets losses for health insurers with exceptional claims (see Update for Week of December 1st). Provisions to rescind \$10 million from the ACA's Independent Payment Advisory Board and attach a bill permanently exempting expatriate health plans from the ACA's individual and employer mandates (H.R. 4414) both had some bipartisan support (see Update for Week of December 8th).

President to sign bipartisan bill creating tax-free savings account for the disabled

Landmark legislation that will allow up to 54 million disabled Americans to open tax-free bank accounts to pay for health care and other expenses was included by the Senate this week in legislation that President Obama is expected to shortly sign.

The *Achieving a Better Life Experience Act (ABLE) Act* faced only nominal opposition from the Heritage Foundation and other conservative groups that insisted the measure was "expanding the welfare state" and objected to the Medicare changes that helped offset the \$2 billion cost (see Update for Week of December 1st). They also protested exempting the ABLE savings accounts from the \$2,000 asset limit under the federal Supplemental Security Income (SSI) program for low-income disabled.

Under the *ABLE Act*, SSI enrollees can retain their SSI eligibility so long as their ABLE account savings do not exceed \$100,000. Medicaid coverage will continue no matter how much money is deposited in the accounts.

The accounts are available for those already receiving federal disability benefits and those diagnosed with a disability by age 26 that results in "marked and severe functional limitations". Families can deposit up to \$14,000 annually to pay for long-term needs. Contributions would be in after-tax dollars but earnings would grow tax-free.

The *ABLE Act* (H.R. 647) is the first major Congressional legislation since the Americans with Disabilities Act to expand federal assistance for the disabled. It was attached to legislation retroactively extending more than 50 tax breaks for individuals and businesses (H.R. 5771).

House appropriators direct HRSA to study Section 340B drug discount program

House appropriators included a provision in the fiscal year 2015 spending bill enacted this week (see above) that urges the Health Resources and Services Administration (HRSA) within the Department of Health and Human Services (HHS) to investigate whether the federal 340B drug discount program for safety net providers is operating as intended .



Although Congress has held just one oversight hearing on 340B in the past two decades, the program has come under recent scrutiny after the Government Accountability Office and HHS Inspector General found that providers were reaping “windfall profits” from the discounts due to scant federal oversight (see Update for Weeks of July 1 and 8, 2013).

HRSA has responded by strengthening oversight through rulemaking and guidance and the House Energy and Commerce Committee already sought the input of the Medicare Payment Advisory Commission (even though 340B is technically outside of their jurisdiction).

House appropriators sought to mandate an additional review by HRSA, directing it to “work with covered entities to better understand the way these entities support direct patient benefits from 340B discounted sales.”

Bipartisan Senate bill offers 15 years of data exclusivity for dormant therapies

Senators Orrin Hatch (R-UT) and Michael Bennet (D-UT) introduced legislation late last week that would give brand-name drugmakers an unprecedented 15 years of data exclusivity for treatments that serve an unmet medical need.

The *Dormant Therapies Act* (number not yet assigned) is essentially a companion to a comparable provision in the *MODERN Cures Act* (H.R. 3116), which gained 94 cosponsors since being introduced last year. The goal is to give brand-name drug makers further incentive to develop and designate drugs for so-called dormant therapies.

Currently, brand-name drugmakers receive only five years of data exclusivity for prescription drugs and (pursuant to the Affordable Care Act) 12 years for a biologic.

FEDERAL AGENCIES

Federal Marketplace withstands enrollment surge, but states/insurers forced to extend deadlines

The December 15th deadline for January 1st coverage created a surge of applications late last week on the web portal for the federally-facilitated Marketplace (FFM).

Despite the volume, the rebuilt web portal appeared to operate without the slew of technical glitches and website failures that plagued the FFM during the inaugural open enrollment period (see Update for Week of November 11, 2013) and withstood up to 250,000 simultaneous users. However, HHS officials acknowledged that some returning customers had difficulties unlocking prior accounts and the call centers were experiencing “longer than normal wait times” (an average of 13 minutes instead of six minutes). As a result, HHS will let about 500,000 consumers that started applications before December 15th have an unspecified amount of “extra time” to complete them.

The 14 state-based Marketplaces (SBM) experienced similar demand surges, forcing several including California, Idaho, New York, Maryland, Massachusetts, Minnesota, Rhode Island and Washington to either extend their deadlines to purchase coverage starting January 1st or establish later cut-off dates for changes. The MNSure Marketplace in Minnesota reported a record volume of 1,000 calls per hour while a 30 percent surge in call volume for the new SBM in Idaho resulted in several technical glitches.

America’s Health Insurance Plans (AHIP) also announced that Marketplace carriers may, at their discretion, give both new and returning customers additional time to enroll for January 1st coverage.



Overall, roughly 2.5 million consumers enrolled in 2015 coverage through www.healthcare.gov as of December 12th and four million have submitted applications. More than half (52 percent) of enrollees are renewing coverage from 2014, but HHS acknowledges that 335,000 returning consumers have been forced to switch plans because their 2014 plan was discontinued.

Another 740,000 consumers enrolled in SBMs (with nearly half that amount coming from California and New York), bringing total Marketplace enrollment to nearly 3.2 million or nearly a third of the 9.1 million target for the entire open enrollment period. However, only three states have identified the proportion of sign-ups that are returning customers. Roughly 42 percent of enrollees in Minnesota have been renewals, while the vast majority of sign-ups in Kentucky and Washington have been returning customers (89 and 82 percent respectively).

Avalere Health consultants predicted this week that 4.5-6 million new enrollees will purchase coverage from state or federal Marketplaces by the February 15th end of open enrollment and up to 11.5 million will do so by the end of 2015 (including renewals).

Medicaid and CHIP enrollment continues to rise overall, but with wide state variation

According to updated figures released this week by the Centers for Medicare and Medicaid Services (CMS), enrollment in Medicaid and the Children's Health Insurance Program (CHIP) grew by 9.7 million people in October or 17 percent more than the period just before Affordable Care Act (ACA) Marketplaces opened in October 2013.

Enrollment in states participating in the ACA's Medicaid expansion increased by 24 percent, while opt-out states experienced only a seven percent increase. However, these growth rates varied wildly, with Kentucky, Nevada, and Oregon spiking by 64.2-71.5 percent. By contrast, Utah actually experienced a nearly six percent decline while Nebraska's enrollment fell by 2.7 percent.

Survey data from the National Center on Health Statistics confirmed this disparity. It revealed that the uninsured rate among Medicaid expansion states fell from 18.4 percent to 14.1 percent during the first half of 2014, but only from 22.7 percent to 20.2 percent in opt-out states.

Most 340B drugmakers are refusing to comply with HRSA directive to discount orphan drugs

The Health Resources and Services Administration (HRSA) overseeing the federal 340B drug discount program announced this week that several brand-name drugmakers will retroactively discount certain orphan drugs consistent with the agency's recent directive, though most have refused to comply.

HRSA had given more than 50 manufacturers 30 days to state whether they will follow the agency's "interpretive" rules that require discounts for orphan drugs used to treat common conditions or off-label uses (see Update for Weeks of October 20th and 27th). A federal court ruled last spring that HRSA lacked the authority to issue formal regulations codifying this interpretation of the Affordable Care Act provision that the industry believes should exempt orphan drugs from the mandatory discounts for safety-net providers participating in the 340B program (see Update for Week of June 9th).

HRSA issued "interpretive" rules in an effort to circumvent that injunction, forcing the Pharmaceutical Research and Manufacturers of America (PhRMA) to refile their lawsuit (see Update for Weeks of October 6th and 13th). PhRMA indicated this week that most drugmakers are likely to wait for resolution of that litigation before deciding whether to comply with HRSA's directive.

It is not yet clear if HRSA will actually bring enforcement action against drugmakers that do not comply, since "interpretive" rules are not binding.



FDA's 35 drug approvals exceed last year's total, thanks to surge in orphan drugs

The Food and Drug Administration (FDA) has approved 35 drugs so far in 2014, far outpacing the 27 approvals recorded for all of 2013.

According to a breakdown released this week by the FDA, 15 of these approvals (or 43 percent) were for orphan drugs, the highest number recorded since passage of the *Orphan Drug Act* in 1983. More than half of approvals (57 percent) were expedited by priority review designations, while another 37 percent went through the fast track review route. Three-quarters were approved after only one review cycle.

The FDA has been flooded with requests for breakthrough therapy designations that can jump a drug from mid-stage trials to quick approval since the pathway was created by Congress in 2012. However, it approved only 11 in 2014, most notably the latest Hepatitis C "cure" Harvoni. Neurology and oncology drugs scored the most breakthrough therapy approvals (11 percent each). Rejected applications were primarily the result of a lack of appropriate clinical trial data, according to the report.

Median approval times were significantly reduced in 2014 from 7.9 months to 6.5 months. However, the agency notes that this figure tends to vacillate, dropping to a low of 5.8 months in 2011 from a median of nine months in 2010.

STATES

Medicaid managed care exceeding traditional fee-for-service enrollment

An analysis by the accounting firm PricewaterhouseCoopers found this week that the number of Medicaid beneficiaries enrolled through private managed care plans is growing faster than those in traditional fee-for-service.

The survey completed for the Medicaid Health Plans of America showed that 9.3 million more Medicaid beneficiaries enrolled in managed care plans in 2014, while FFS enrollment fell for the first time, dropping by 300,000.

At least 40 states currently rely on some form of Medicaid managed care (up from 37 in 2013) with several states including Arizona, Florida, Kentucky, Louisiana, New Mexico, and Tennessee moving the vast majority of their Medicaid beneficiaries into private managed care plans. (Utah and Virginia have the lowest proportion of Medicaid beneficiaries enrolled in managed care).

An average of 134,000 Medicaid beneficiaries per state are enrolled in managed care. However, Medicaid managed care participation continues to be dominated by ten of the nation's largest insurers. UnitedHealthCare serves more than 4.4 million Medicaid managed care enrollees in 21 states, while Anthem has 4.3 million in 17 states. Aetna, Centene, HealthNet, and Wellcare head the list of other large insurers with more than one million Medicaid managed care enrollees.

The Centers for Medicare and Medicaid Services (CMS) is expected to issue regulations next year that propose major changes to Medicaid managed care oversight.

California

Insurance commissioner declares Aetna's small group rate hike "unreasonable"

Insurance Commissioner Dave Jones (D) announced this week that premium hikes sought by Aetna for the small group market were "excessive and unreasonable".



The commissioner has frequently used his authority under state law and the Affordable Care Act (ACA) to publicly shame insurers whose actuarial data does not support their rate filings. However, his long-sought ballot initiative to give the commissioner authority to actually modify or reject “excessive and unreasonable” rate hikes went down to defeat last month (see Update for Week of November 3rd).

Jones and consumer advocates have pledged to continue pushing for legislation or ballot referendums that would give the commissioner the same authority it has to modify or reject rate hikes for automobile or property insurance. However, without that authority, Jones continues his effort to “jawbone” insurers into lowering their rates.

Aetna stood by its calculations this week, insisting that the average 10.7 percent increase accurately reflects expected medical costs and utilization over the coming year, based on an analysis completed by the Milliman consulting firm. However, the commissioner insisted that Aetna overstated the costs of complying with the ACA by assuming that its risk pool will be far less healthy than actual experience has shown during the first year of full implementation. He also disputed that plan use will grow by 2.5 percent over the next two years and determined that the 10.7 percent average increase would cost small employers more than \$23.5 million in “excessive” premiums.

Commissioner Jones had already declared Anthem’s small group rate hike “unreasonable” for overstating prescription drug costs (see Update for Weeks of October 20th and 27th). According to Consumer Watchdog, his office has deemed roughly \$250 million in premium increases “unreasonable” over a 15-month period ending in November 2013 (see Update for Weeks of June 30th and July 7th).

Florida

Humana becomes third insurer to settle discrimination complaint over HIV drug coinsurance

Humana agreed this week to settle a discrimination complaint filed by consumer advocates over their coverage of HIV/AIDS medications in Florida’s health insurance Marketplace operated pursuant to the Affordable Care Act (ACA).

Three of the four insurers targeted by the complaint have now settled with the Florida Office of Insurance Regulation instead of risking a finding of discrimination (see Update for Week of December 1st). All four had moved all drugs for HIV/AIDS into specialty tiers that charged subscribers 40-50 percent of the total drug cost.

In order to settle the Florida complaint, both CIGNA and Coventry (an Aetna subsidiary) decided to instead cap out-of-pocket expenses for four widely-prescribed HIV/AIDS drugs at \$200 per month for their 2015 Marketplace plans. They also moved generic HIV/AIDS drugs from specialty tiers into lower tiers with fixed copayments.

However, Humana negotiated very different settlement terms, which limits specialty tier coinsurance at ten percent of the drug’s total cost, but applies to all HIV/AIDS drugs instead of just the four most widely-prescribed. Humana will also require only a \$50 copayment for HIV/AIDS drugs that cost less than \$600.

As with the other two settlements, the cost-sharing reductions will apply only to Marketplace plans for 2015. They also do not resolve the discrimination complaint filed by The AIDS Institute (TAI) and National Health Law (NhELP) Program with the Office of Civil Rights for the U.S. Department of Health and Human Services (see Update for Week of June 2nd). This complaint remains pending even though proposed federal regulations now discourage the practice (see Update for Week of December 1st).

None of the three insurers have yet to apply the cost-sharing reductions under their settlements to Marketplace plans in other states. The fourth insurer, Preferred Medical, is still deciding whether to settle.



Business and provider coalition pushes Medicaid expansion by a different name

Several prominent Republican lawmakers are backing a new alternative to the Medicaid expansion under the Affordable Care Act (ACA) proposed last week by a business and provider coalition.

Republicans control both legislative chambers in Florida. However, the more conservative caucus in the House rejected a Senate-passed plan last session (see Update for week of March 31st) that would have accepted federal ACA matching funds to expand Medicaid, but instead provided coverage in the state's existing Children's Health Insurance Program—similar to a model already federally-approved in five states that typically provide alternative coverage in ACA Marketplaces.

The latest plan largely follows that blueprint but extends coverage only to the roughly 740,000 uninsured Floridians that fall in the “coverage gap” between Florida Medicaid eligibility levels at 35 percent of the federal poverty level (FPL) and the ACA threshold for premium tax credits that starts at 100 percent of FPL.

However, in effort to win over House conservatives, the plan called A Healthy Florida Works makes no reference to the ACA's Medicaid expansion and imposes mandatory premiums on those within this gap, which would act as contributions to individual savings accounts that cover health care costs, similar to the models proposed by Indiana (see Update for Week of November 10th) and Tennessee (see below). The plan also includes a requirement that enrollees work full-time or enroll in job training programs.

The Obama Administration has consistently rejected provisions in Medicaid alternative proposals for Indiana, Pennsylvania, Tennessee, and Utah that charge premiums for those below 100 percent of FPL or impose work or workforce training requirements (see Update for Week of December 1st).

The South Florida Healthcare Association is among the many business or provider groups backing the plan, which has also attracted the support of Senate Rules Chairman David Simmons (R) and Rep. Richard Corcoran (R), who authored a similar bill last year. It predicts that that net savings under the proposal would exceed \$1.76 billion through 2020.

Kentucky

New bill would limit specialty tier coinsurance for highest-cost drugs

Rep. James Kay (D) pre-filed legislation this week that would limit cost-sharing for prescription drugs placed on a specialty tier to no more than \$100 per month for up to a 30-day supply or \$200 per month in the aggregate. Similar to bills in other states, H.B. 99 also would allow subscribers to request an exception to the tiered cost-sharing structure. However, it also explicitly would prohibit insurers from placing all drugs of the same class within a specialty tier, a practice that has been the subject of discrimination complaints in states like Florida and Illinois (see Update for Week of December 1st).

The measure is very similar to H.B. 578 that failed to move last session (see Update for Week of March 3th). PSI Government Relations testified in support of both bills, which will be considered after the new session begins next month.

Minnesota

Lingering Marketplace flaws are not impeding 2015 enrollment, record-low uninsured rate

The MNsure health insurance Marketplace created pursuant to the Affordable Care Act (ACA) reported this week that nearly 24,000 consumers have purchased qualified health plans for 2014 but acknowledged that the web portal continues to suffer from technological glitches despite \$8 million in repairs over the past several months.



The MNSure board hired Deloitte Consulting last summer to fix the error-plagued site that caused enrollment to reach only 45 percent of their projected target in year one (see Update for Week of July 28th). However, insurers quickly complained during the first month of open enrollment for year two that the Marketplace is still not transferring workable data on those signing up for their plans. As with last year, insurers are largely relying on manual processes to complete enrollments in a timely manner.

Deloitte points out that nearly two-thirds of MNSure systems were “absent or non-functioning” when it was brought in (see Update for Week of June 9th) and insists that remaining issues will shortly be resolved.

Despite the lingering problems, MNSure’s enrollment is already 36 percent of their 2015 target of 67,000 enrollees. Dramatic increases in Medicaid enrollment also enabled the state to reduce its uninsured rate for working age adults to a record low of 6.7 percent by September, down from 10.7 percent before the opening of the ACA Marketplace. The Department of Health figures mesh with findings from the University of Minnesota last summer showing a statewide uninsured rate of 4.9 percent when accounting for children and the elderly (see Update for Week of June 9th).

Tennessee

Governor proposes Medicaid expansion alternative relying on health reimbursement accounts

Governor Bill Haslam (R) released his long-awaited proposal this week for a “free market” alternative to the Medicaid expansion under the Affordable Care Act (ACA).

The Governor’s Insure Tennessee plan would be only a two-year pilot that would accept ACA matching funds for the expansion but instead offer adults age 21-64 a choice of the Health Incentives Plan or the Volunteer Plan. The former would be a redesigned component of Medicaid that requires enrollees to use Health Reimbursement Accounts (HRAs), similar to plans advanced by Indiana (see Update for Week of December 1st). The HRAs would be used to cover required premiums and cost-sharing.

By contrast, the Volunteer Plan would provide those made newly Medicaid eligible with a health insurance voucher to pay for the costs of any employer-based coverage for which the applicants are eligible. The voucher would be valued at slightly less than the average TennCare per-enrollee cost.

Governor Haslam said he plans to call a special session in January for lawmakers to debate the proposal. Lt. Governor Ron Ramsey (R) insisted that the model was one that the Republican-controlled legislature could support as it does not create any new taxes or added cost to the state budget.

The Tennessee Hospital Association, one of the expansion’s strongest proponents, had pledged to cover any additional state expenses created by the Governor’s plan. A recent Vanderbilt University poll of registered voters in the state found that nearly 60 percent support some form of Medicaid expansion.

The Governor has been negotiating with the federal Centers for Medicare and Medicaid Services (CMS) for the past year on the terms of the proposal. Although the premium levels he sought have been rejected, Governor Haslam insists that he has a “verbal agreement” from CMS on the remainder of his terms and will be submitting a formal waiver in the next few weeks with the expectation that it will be approved.

CMS has approved comparable expansion alternatives in Arkansas (see Update for Week of March 25, 2013), Iowa (see Update for Week of December 9, 2013), Michigan (see Update for Week of July 14th), New Hampshire (see Update for Week of June 23rd), Pennsylvania (see Update for Weeks of August 25th and September 1st), and Utah (see Update for Week of December 1st).



Vermont

Governor abandons planned move to single-payer health system by 2017

Calling it the “biggest disappointment” of his career, Governor Peter Shumlin (D) announced this week that Vermont will no longer launch the nation's first single-payer health care system in 2017.

The Governor had signed a 2011 law (Act 48) that started the process of transitioning the state to single-payer, including moving the entire individual and small group health insurance markets into the new Marketplace created by the Affordable Care Act (ACA). It also created the Green Mountain Care Board to regulate all health care financing decisions, including provider rates and the move to global budgets similar to the payment methodology used in the national health system for neighboring Canada (see Update for Week of May 23, 2011).

However, financing the plan remained largely a mystery until this week, when the report released by Green Mountain Care concluded that the single-payer system would cost the state \$2.5 billion in 2017, nearly exceeding its \$2.7 billion in annual revenue. Funding the model would thus require a 9.5 percent premium assessment on individuals and a separate 11.5 percent payroll tax on businesses. It also revealed that federal funding for the transition would be \$150 million lower than expected.

Governor Shumlin, whose re-election margin last month was so thin it has yet to be certified, decided that now “is not the right time” to impose such “detrimental” tax increases on Vermonters, and announced that he would no longer support the single-payer plan. He insisted that Vermont has a “tremendous amount of responsibility” to “get single-payer health care right” and create an initial success that other states can follow, instead of setting back the effort by years or decades with a failed model.

Single payer supporters including the Healthcare is a Human Right Campaign held rallies this week to protest the decision, insisting that the Governor must follow Act 48 unless the legislature officially repeals it.

Critics have long-emphasized that Act 48 would not create a true single-payer model, as the state lacks the authority under federal ERISA law to regulate self-insured plans offered by large employers and Medicare enrollees would also have remained exempt (see Update for Week of May 23, 2011).

Washington

Marketplace enrollment remains ahead of projections despite lingering technical glitches

Officials with the Washington Healthplanfinder revealed this week that the health insurance Marketplace created pursuant to the Affordable Care Act (ACA) has already enrolled more than one-quarter of its target for the entire open enrollment period that started on November 15th.

However, only about 10,000 of the roughly 56,000 individual sign-ups are new customers. Healthplanfinder officials hope to bring that number up to 85,000 during the expected surge in enrollment shortly before the December 23rd deadline to purchase coverage that starts on January 1st.

In addition, technological glitches continued to surface last week, as the web portal shut down for several hours at a time after its new lead contractor Deloitte Consulting implemented manual data fixes to customer invoices. The latest outages came after the site failed on the second day of open enrollment and Deloitte inadvertently canceled plans for more than 6,000 subscribers during the first two weeks (see Update for Week of December 1st). Only about 4,000 of these subscribers have been re-enrolled.

The chief executive officer for the Healthplanfinder announced that payments to Deloitte are being withheld due to these “unacceptable errors.” Deloitte was brought in over the summer to correct problems from the last open enrollment period, such as incorrect data on premium payments being



transmitted between the Marketplace and insurers (see Update for Week of July 28th). However, several of these glitches remain unresolved.

The lingering issues have caused Insurance Commissioner Mike Kreidler (D) to question last week whether the Healthplanfinder should be stripped on some of its authority, including the ability to collect premium payments. The board overseeing the Healthplanfinder already voted last month to hire an independent contractor to conduct a review of all information technology infrastructure and contracts.

The commissioner noted that four other state-based Marketplaces that now use Deloitte as its primary contractor (Connecticut, Kentucky, Maryland, and Rhode Island) are not experiencing similar problems and demanded a response as to why they are unresolved in Washington. However, Deloitte has been unable to resolve non-functional data transfers to insurers under the Minnesota Marketplace (see above).

Wyoming

Lawmakers reject Governor's Medicaid expansion alternative

The Joint Labor, Health, and Social Services Committee deadlocked this week on whether to approve the Medicaid expansion alternative advanced by Governor Matt Mead (R) (see Update for Week of December 1st), effectively tabling the plan in favor of more limited expansion bill crafted by several committee members.

Senator Charles Scott (R), the committee chair who has been in the legislature since 1979, led the opposition to the Governor's plan and backed the substitute which would instead provide the newly-eligible population with Medicaid-funded health savings accounts (HSAs) that they could use to purchase private health insurance, similar to Medicaid expansion alternatives advanced in Indiana (see Update for Week of December 1st) and Tennessee (see above). The concept has been floated in the legislature since first proposed by a Medicaid task force in 1994. However, previous proposals were rejected due to the greater cost of covering Medicaid enrollees in private plans.

Fellow Republicans like Rep. Eric Barlow (R) were skeptical that HSAs would incentivize enrollees to be more efficient consumers of health services. Democrats like Rep. Mary Throne encouraged individual lawmakers to instead sponsor the Governor's plan so that it at least receives a full debate and vote.

Earlier this year, lawmakers had given the Governor and Department of Health (DOH) authority to negotiate the terms of a Medicaid expansion alternative with the Centers for Medicare and Medicaid Services (CMS) but did not allow them to actually submit an application (see Update for Week of February 10th).