



Health Reform Update – Weeks of May 18 and 25, 2015

CONGRESS

Full Energy and Commerce Committee unanimously passes 21st Century Cures initiative

The House Energy and Commerce Committee voted unanimously this week to advance legislation creating more regulatory flexibility for drugmakers to develop “cures” for rare disorders.

The measure (H.R. 6) is now expected to move to the House floor by the third week of June with a Senate vote planned for August. It would allow the Food and Drug Administration (FDA) to consider “real-world evidence” and shorten clinical trials, while manufacturers would be able to expand drug indications based on observational data indicating how it performs in the field (see Update for Week of May 11th).

The package also includes a \$550 million Cures Innovation Fund and permanently protects the FDA user fees funding from ongoing sequestration cuts imposed by the *Budget Control Act of 2011* (see Update for Week of August 1, 2011). The user fees were reduced by roughly \$85 million in 2013 due to sequestration but temporarily protected by Congress through 2016.

Committee members were able to agree on \$13.2 billion in offsets to help pay for significant boosts in funding for the FDA and National Institutes of Health (see Update for Week of May 11th). The offsets include changes in the timing of pre-payments for Medicare Part D, limits on the federal Medicaid matching rate for durable medical equipment, and accelerated modernization of x-ray imaging.

Safety net providers were pleased that the Committee elected not to include proposed reforms to the Section 340B drug discount program as part of the *21st Century Cures Act*. These reforms, including clearer definitions of patient eligibility for 340B, are still likely to be part of a separate package (see Update for Week of May 11th). Several lawmakers had sought to also include requirements for 340B hospitals to track how savings from 340B discounts are spent as part of the *Cures Act*. However, hospital groups insisted that these provisions would have been “rushed” and required more legislative debate.

Rep. Schakowsky (D-IL) also withdrew her initial amendment that would require drugmakers disclose research and production costs for drugs and biologics when seeking FDA approval. Similar bills were rejected in the California and Oregon legislatures but continue to surface in several other states (see Update for Week of May 4th).

The Senate Health, Education, Labor, and Pensions (HELP) Committee is continuing to work on a counterpart to H.R. 6, though at a much slower pace. Chairman Lamar Alexander (R-TN) does not anticipate moving legislation until early next year.

Two new bills would extend Medicaid drug rebates to generics

Senator Bernie Sanders (I-VT) and Rep. Elijah Cummings (D-MD) formally re-introduced legislation last week (S.1364/H.R. 2391) that would extend Medicaid drug rebates to generic drug whenever prices increase at a rate that exceeds inflation.

Such a requirement is already in place for brand-name drugs, but not generics. Both lawmakers insisted that their measure would save taxpayers more than \$1 billion.



The *Medicaid Generic Drug Price Fairness Act* was introduced late last year in both the House and Senate but failed to move (see Update for Week of December 1, 2014). It is backed by several consumer and provider groups including Families USA, the American Public Health Association, and the National Association of Community Health Centers.

Senator Sanders and Rep. Cummings have already asked the Inspector General for the Department of Health and Human Services to investigate the spike in generic drug prices over the past several years, after generic drug makers reportedly refused their request to turn over “meaningful records” on pricing (see Update for Week of May 11th).

New bill would create special watchdog for Affordable Care Act

Senators Pat Roberts (R-KS) and Rob Portman (R-OH) introduced S. 1368 last week, which would create an Office of the Special Inspector General for Monitoring the Affordable Care Act (SIGMA).

The office would report to the Secretary for the Department of Health and Human Services (HHS). However, it would have the authority to conduct investigations across multiple agencies, as opposed to the agency-specific oversight assigned to the Inspectors General for HHS, Treasury, Labor, Homeland Security, etc. By coordinating audits, Senator Roberts argued that the Special Inspector General could better assess or more effectively oversee implementation and funding for Affordable Care Act subsidies, Marketplaces, the Independent Payment Advisory Board, and the individual and employer mandates.

Rep. Peter Roskam (R-IL) introduced a companion bill in the House (H.R. 2400).

FEDERAL AGENCIES

Health plans upset with profit caps in new “uber rule” for Medicaid managed care

The Centers for Medicare and Medicaid Services (CMS) released its long-awaited “uber rule” last week that seeks to update Medicaid managed care standards for the first time since 2003.

Managed care plans were quick to denounce the most contentious provision in the proposed rule, which is the agency’s plan to apply a national medical-loss ratio (MLR) to Medicaid managed care plans. The rule would require Medicaid managed care plans to spend at least 85 percent of premium revenue on direct medical care starting in 2017, limiting the amount they could devote to administration and profit to no more than 15 percent.

The 85 percent MLR is the same threshold that the Affordable Care Act (ACA) sets for large group plans. However, unlike the ACA, the proposed rule would not require that plans issue rebates to consumers if they fail to meet the MLR.

CMS is seeking to ensure that Medicare Advantage (MA), Medicare Part D plans, Medicaid managed care plans, and large group plans would all have the same MLR. Most Medicaid managed care plans do not currently apply MLRs, although some states like Florida were required to implement an MLR as part of the federal demonstration waivers allowing them to move nearly all Medicaid enrollees into managed care plans (see Update for Week of June 17, 2013).

Other provisions of the “uber rule” would establish minimum standards for network adequacy, align quality standards to MA and Marketplace plans, create a grading system similar to the star ratings assigned to MA plans, and allow for managed care plans to be used within the Children’s Health Insurance Program (CHIP).



Medicaid programs in 39 states now have contracts with managed care plans. Roughly two-thirds of all Medicaid beneficiaries nationwide are enrolled in some form of managed care.

HEALTH COSTS

New studies show ACA has reduced but not eliminated unaffordability of medical care

A study released last week by the Urban Institute found that the percentage of adults reporting difficulty paying their medical bills fell from 22 percent in September 2013 to 17 percent in March 2015.

The results translate to about 9.4 million Americans that can better afford to pay their bills since the full implementation of the Affordable Care Act (ACA). States participating in the Medicaid expansion under the ACA saw a five percent decline (from 20 to 15 percent). However, opt-out states also experienced a four percent drop (from 24 to 20 percent).

However, a companion study from the Urban Institute found that 70 percent of those that incurred medical debt had health insurance but were unable to afford their cost-sharing and other out-of-pocket expenses. A concurrent study from The Commonwealth Fund reinforced these findings, showing that 31 million people or 23 percent of American adults were underinsured in 2014, the same percentage as in 2012.

Researchers attributed the failure of the ACA to reduce the level of underinsurance to the dramatic increase in the number of high deductible health plans, noting that about 14 million of this figure had deductibles that amounted to at least five percent of their annual income (up from 11 million in 2012). Another 27 percent of respondents had deductibles ranging from \$1,000-2,900 last year. Of those with annual deductibles of at least \$1,000, half of underinsured adults and 41 percent of adults with private coverage reported that they paid at least \$4,000 in accumulated medical bills in 2014.

A recent survey of more than 800 adults completed by the Kaiser Family Foundation similarly found that despite overall satisfaction among Marketplace consumers with plan coverage, cost-sharing, and networks, a “significant minority of enrollees” in or out of the Marketplace still struggle with affordability. For example, nearly half (46 percent) report difficulty paying monthly premiums while more than a third (38 percent) feel vulnerable to high out-of-pocket costs. Roughly 40 percent of all non-group enrollees reported having to pay an annual deductible of at least \$1,500 for an individual or \$3,000 for family coverage.

By contrast, nearly 60 percent of respondents enrolled in Marketplace plans reported that they are “very” or “somewhat” satisfied with the value of their coverage. Seventy percent said they were similarly satisfied with the amount they had to pay out-of-pocket for prescription drugs, a figure that declined to 65 and 60 percent respectively for monthly premium and annual deductible costs.

STATES

California

Covered California caps prescription drug costs

The board overseeing Covered California unanimously voted this week to cap prescription drug costs for most enrollees at \$250 per prescription per month.

Covered California officials had initially proposed a \$500 post-deductible cap but agreed to lower the cap to \$150-250 for all but the lowest bronze-level plans starting January 1st, in response to complaints from Insurance Commissioner David Jones (D) and consumer advocates that the \$500 cap



was too high and “discriminatory” towards those with high-cost conditions (see Update for Weeks of April 6th and 13th). Covered California predicts that the cap will increase 2016 premiums by only one percent.

According to Covered California’s executive director, the move is the first by a health insurance Marketplace created pursuant to the Affordable Care Act to ensure that “all consumers have access to the medication they need.” However, he noted that a “broader solution is needed to curtail the explosion in specialty drug costs so that consumers get the care they need without driving up insurance costs so much that consumers can no longer afford coverage.”

The cap is part of the drug benefit changes for participating plans that were previously approved by the board, which also voted to require at least one drug for a certain condition be included in the lowest drug tier. Plans must define what drugs will be placed in specific pricing tiers (including the highest specialty tier) and post that information online (see Update for Weeks of April 6th and 13th).

Several consumer health bills to receive floor votes next week

Several bills to expand health insurance coverage and limit out-of-pocket (OOP) costs cleared committees this week and are expected to receive floor votes next week in the Assembly and Senate prior to the June 5th deadline for this year’s legislation.

Headlining these measures is S.B. 4, which is the controversial bill to expand Medi-Cal eligibility to 1.5 million undocumented children and adults. It would also permit undocumented immigrants to purchase Covered California coverage with their own funds, subject to a federal waiver. The measure had been on hold after a legislative fiscal analysis estimated the cost at \$175-740 million (see Update for Week of May 4th). However, it ultimately cleared the Senate Appropriations Committee with only two dissenting votes.

Several other measures backed by consumer groups like Health Access CA include S.B. 137, which would standardize Marketplace provider directories and require greater oversight to ensure accuracy. The bill responds to several class-action lawsuits filed against insurers last year after consumers unexpectedly incurred out-of-network costs during 2014 due to provider directories that were frequently unavailable, incomplete, or erroneous (see Update for Week of September 29th). S.B. 137 unanimously cleared the Senate Appropriations Committee.

A.B. 533 unanimously passed the Assembly Appropriations Committee, and would prevent “surprise” bills from out-of-network providers for patients that sought care with an in-network provider. Out-of-network providers would also have to refund any excess cost-sharing charges. A.B. 1305, which also unanimously cleared the committee, would ensure that individual patients be subject only to the annual OOP maximum set by the Affordable Care Act (ACA) for individuals (currently \$6,600), even if they are in a family plan.

The Assembly Appropriations Committee also approved a measure that would limit out-of-pocket costs for prescription drugs to 1/24 of the annual OOP limit applicable to individual coverage for a supply of up to 30 days. As with the Health Committee (see Update for Week of May 4th), A.B. 339 passed with only five dissenting votes. It was amended to clarify that the cost-sharing limits apply only to covered outpatient prescription drugs that constitute essential health benefits under the ACA. However, a provision barring plans from placing most or all of the drugs to treat a specific condition on the highest cost tiers of a formulary was retained.

Florida

Feds offer to phase-out Low Income Pool in effort to break Medicaid expansion impasse

The Centers for Medicare and Medicaid Services (CMS) notified the Agency for Health Care Administration (AHCA) this week that it was willing to temporarily provide some federal funding to cover



uncompensated care costs for Florida hospitals over the coming fiscal year, if the state expands Medicaid pursuant to the Affordable Care Act (ACA).

CMS had made it clear last year that the state's Low Income Pool (LIP) waiver would not be continued past its June 30, 2015 expiration (see Update for Week of April 21, 2014). Governor Rick Scott (R) and state officials have been frantically trying to negotiate an extension with CMS as the legislature's failure to expand Medicaid under the ACA will leave Florida with a gaping budget deficit on July 1st once the \$1.3 billion in federal LIP funds go away.

CMS had insisted that no extension would be granted, as Florida could more than fill the budget gap with the \$2-4 billion in federal funds it would immediately start receiving by participating in the ACA expansion. However, in an effort to facilitate budget negotiations during the special legislative session that starts June 1st, CMS now agrees to pay \$1 billion through June 30, 2016 and \$600 million through June 30, 2017 before terminating the waiver.

Governor Scott had filed a federal lawsuit against CMS alleging that the agency was unduly coercing Florida into expanding Medicaid, contrary to the U.S. Supreme Court's 2012 decision holding that states must have the discretion to opt-out of the expansion without penalty (see Update for Week of May 4th). It is not clear what impact the lawsuit had on CMS' change of heart.

CMS has warned nine other states with similar uncompensated care waivers that funding will not be continued unless they also participate in the Medicaid expansion (see Update for Week of May 4th).

House and Governor promptly reject Senate compromise on Medicaid expansion

Governor Rick Scott (R) and Republican House leaders quickly rebuffed a Medicaid expansion compromise sought this week by Senate President Andy Gardiner (R).

Senator Gardiner had proposed to delay the start of the expansion to January 1st and jettison several requirements in the Senate plan, including the mandate that enrollees first be enrolled in a Medicaid HMO for six months. Instead, the compromise bill would let the federal matching funds provided by the Affordable Care Act (ACA) be used to purchase Medicaid-equivalent coverage for enrollees in either the federally-facilitated Marketplace operated pursuant to the ACA or an ACA-compliant private health insurance exchange created by the state.

Enrollees would also be required to seek full-time work using the state workforce portal (Career Source). Similar work requirements have been a favorite of conservative lawmakers in other states but rejected by the Obama Administration in favor of state-offered assistance to find work (see Update for Weeks of April 6th and 13th). House Speaker Steve Crisafulli (R) noted the likelihood that the work requirement would not be federally approved in announcing his disapproval of the plan.

Governor Scott insisted that the Senate compromise would "cost Florida taxpayers \$5 billion over ten years" and "raise taxes in order to implement Obamacare." The Governor had initially supported the state's participation in the ACA expansion while running for re-election but reversed his position earlier this year (see Update for Week of March 30th).

Senator Gardiner had for the first time sought to de-link Medicaid expansion from the state budget, noting that lawmakers could rely on other spending cuts to fill the budget gap that will result from the Obama Administration's refusal to renew the state's LIP waiver (see above). However, the Administration's agreement this week to provide start phasing down the LIP funding next year will greatly mitigate the gap that needs to be covered over the next two years, increasing the likelihood the lawmakers could reach agreement during the special session on a budget bill that does not include any controversial Medicaid expansion provisions.



Minnesota

Legislature makes only limited changes to MNSure, despite calls to overhaul the ACA Marketplace

Governor Mark Dayton (D) signed a health and human services appropriations bill last week (S.F. 1458) that included changes to the MNSure health insurance Marketplace created pursuant to the Affordable Care Act (ACA).

MNSure has been beset by persistent software flaws and technical glitches that caused enrollment targets to be reduced by less than half of original estimates (see Update for Weeks of March 2nd and 9th). As a result, leading Republicans had pushed for federal control of the Marketplace while many Democrats sought to expand state control over MNSure by moving it into a state agency and disbanding the oversight board.

However, S.F. 1458 included only limited changes. These include a requirement that MNSure release final premium rates at least one month before the start of the annual open enrollment period, removes several of MNSure's current exemptions from state technology rules, and strips MNSure of the ability to engage in "super" expedited rulemaking. In addition, the legislation requires the Commerce commissioner and MNSure to seek a federal waiver that would allow eligible consumers to purchase health plans directly from health insurers instead of through MNSure and still receive ACA premium subsidies.

Proposals to add a surcharge on MNSure plans to offset the lower than expected revenue from depressed enrollment failed to make into the final legislation.

Nevada

New law allows Marketplace board members to be affiliated with health insurers

Governor Brian Sandoval (R) signed A.B. 86 this week, which formally removes the existing prohibition on Silver State Health Insurance Exchange board members being affiliated with a health insurer. The bill requires that no more than two of the seven voting members for the Marketplace created pursuant to the Affordable Care Act would be allowed to represent any particular area or expertise (see Update for Week of May 4th). In addition, the Marketplace is no longer required to be "state-based", since it has indefinitely defaulted to the online web portal for the federally-facilitated Marketplace (see Update for Week of June 2nd).

Senate passes legislation requiring greater transparency of patient costs for formulary drugs

The Assembly Commerce and Labor Committee is hearing legislation passed last week by the Senate that would require health insurers to post details on prescription drug formularies on the websites for the Commissioner of Insurance and Silver State Health Insurance Exchange. Under S.B. 328 sponsored by Senator Patricia Farley (R), the details must include an identification of the out-of-pocket costs that subscribers must incur for each formulary drug, including all applicable copayments and deductibles.

Pennsylvania

New bill would limit cost-sharing for specialty tier drugs

Senator Bob Mensch (R) has introduced legislation that would limit cost-sharing charges for a specialty tier prescription drug to not more than \$100 per month for a 30-day supply. S.B. 841 would also limit the aggregate cost for all specialty tier drugs to no more than \$200 per month. It was referred to the Senate Banking and Insurance Committee.

A separate provision of the bill bars health plans from place all prescription drugs of the same class in a specialty tier. Comparable prohibitions have been proposed in several states including





California (see above) after 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 23rd). However, they have been removed from the final bill versions in states like Connecticut, Louisiana, and Oregon (see Update for Week of May 11th).

Texas

Lawmakers send Obamacare “shaming” legislation to Governor after “scarlet letter” removed

Governor Greg Abbott (R) received legislation this week that would require labels on health insurance cards for plans purchased in the federally-facilitated Marketplace (FFM).

H.B. 1514 cleared the Senate by a 20-11 margin after previously passing the House with only eight dissenting votes (see Update for Week of May 11th). It would add the label “QHP” designating a qualified health plan consumer. However, the final bill omitted earlier provisions requiring the label “QHP-S” if the consumer is receiving premium or cost-sharing subsidies provided by the Affordable Care Act.

Provider and consumer groups had insisted that the labels—in particular the QHP-S designation—were effectively a “scarlet letter” inviting discrimination against low-to-moderate income enrollees. However, bill sponsor Rep. J.D. Sheffield (R), a family practice physician, insisted the measure was needed to help physicians remind patients to continue making monthly premium payments and let physicians know if patients were part of the narrow provider networks that Marketplace plans often employ.