



Health Reform Update – Weeks of July 27 and August 3, 2015

CONGRESS

Senate committee confirms that it will delay action on 21st Century Cures Act

The chairman for the Senate Health, Education, Labor, and Pensions (HELP) Committee announced this week that his committee expects to complete their own version of the 21st Century Cures Act no earlier than November or December of this year.

Bipartisan sponsors of the House version of the medical innovation legislation had urged the HELP committee to act by September, in order to avoid pushing a Senate floor vote into the 2016 election year (see Update for Week of July 20th). However, Chairman Lamar Alexander (R-TN) has always been determined to work at a more deliberate pace on a bill that is more narrow in scope than the comprehensive legislation that overwhelmingly passed the House (see Update for Weeks of June 29th and July 6th).

The House version (H.R. 6) is intended to facilitate the development of breakthrough cures for rare disorders by removing regulatory obstacles and providing enhanced funding, primarily to the National Institutes of Health.

House Democrats and Republicans join to oppose CMS reimbursement proposal for biologics

A bipartisan group of 33 House lawmakers urged the Centers for Medicare and Medicaid Services (CMS) this week to forego its plan to create single billing codes for biosimilars that reference the same brand biologics.

Manufacturers of biosimilars have opposed the CMS provision in the proposed physician fee schedule for 2016. In that rule, CMS sought to calculate the Medicare payment for billing codes based on the average sales price of all biosimilars that reference a common biologics license application (see Update for Weeks of June 29th and July 6th). However, the 33 lawmakers insist that this move would lower reimbursement for biosimilars and effectively treat them “as if they are generic drugs.”

The letter was spearheaded by Reps. Joe Barton (R-TX) and Anna Eshoo (D-CA), a key author of the provision within the Affordable Care Act (ACA) that created the new regulatory pathway for biosimilars, under which the first Food and Drug Administration (FDA) approval was granted earlier this year (see Update for Weeks of April 6th and 13th). Both members serve on the Energy and Commerce committee. However, many members of the Ways and Means Committee also signed on to the letter as that committee has jurisdiction over Medicare reimbursement policies.

The letter points out that the CMS proposal may contradict the intent of Congress as the biosimilar provision in the ACA spells out how each biosimilar should receive its own billing code. However, drug industry representatives have insisted that the ACA provision is “a little ambiguous” and could be interpreted as “implying that multiple products should be placed in the same billing code.”

CMS will continue to receive public comments on the proposal until the first week of September.

HHS report shows that increased competition lowered Marketplace premiums for 2015

A new report released this week by the Department of Health and Human Services (HHS) credits increased competition within the health insurance Marketplaces created by the Affordable Care Act (ACA) for driving down premiums in 2015.

Researchers found that 86 percent of Marketplace consumers were able to choose plans offered by at least three participating insurers during the 2015 open enrollment period that concluded last February, a big jump from only 70 percent during the inaugural period for 2014. Most counties gained at least one insurer in 2015, while 33 percent held steady and only eight percent saw a decline in competition. Average premiums for 2015 were nine percent lower in counties with at least three insurers compared to those with only 1-2 participating insurers.

HHS stressed that average premiums increased by only two percent from 2014 to 2015 for the second lowest-cost silver tier plan, thanks to the increased number of Marketplace participants for most counties.

The report was the latest in a string of studies by HHS and private groups like Kaiser Family Foundation, the Urban Institute, and Avalere Health to find a direct correlation between competition and premium levels (see Update for Week of January 12th).

CMS says Part D premiums to remain steady despite specialty drug costs

The Centers for Medicare and Medicaid Services (CMS) announced this week that the basic Medicare Part D premium will remain an estimated \$32.50 per month for 2016.

The projection from Office of the Actuary at CMS is based on bids submitted by participating insurers for the 2016 benefit year, which starts with the open enrollment period that runs from October 15th through December 7th.

CMS notes that Part D premiums did not rise despite a nearly 11 percent increase in per capita spending for Part D in 2014, which was “driven largely by high cost specialty drugs.” This is due to a six-year slowdown in medical inflation. However, that trend is expected to end for 2016 with national health spending projected to increase by roughly six percent per year through 2024.

CMS report shows continued rise in Medicaid and SCHIP enrollment

The latest figures released by the Centers for Medicare and Medicaid Services (CMS) show that enrollment in Medicaid and the Children’s Health Insurance Program (CHIP) continued to inch upward in May to 71.6 million Americans.

This total is 12.8 million or nearly 22 percent higher than the three-month period just before the Affordable Care Act (ACA) Marketplace opened in late 2013 and 509,082 higher than recorded in April.

State-based Marketplaces can permanently defer to CMS for individual mandate exemptions

Frequently answered questions (FAQ) documents issued last week by the Centers for Medicare and Medicaid Services (CMS) confirms that forthcoming regulations will let CMS take over the processing of individual mandate exemptions from the state-based Marketplaces (SBMs) created pursuant to the Affordable Care Act (ACA)



The document emphasizes that for the upcoming open enrollment period for 2016, no SBMs will be punished for channeling the process of granting exemptions through CMS instead of trying to do so themselves, even if the proposed rule has yet to be finalized. This option applies only to SBMs, as CMS already performs this task for state partnership Marketplaces and those states defaulting to the federally-facilitated Marketplace.

The option was actually created in 2013 final regulations (see Update for Week of June 24, 2013) and only Connecticut has thus far elected to oversee their own exemption process. However, those rules initially ended federal oversight for the 2016 open enrollment period. Federal oversight would simply be extended under the new proposed rule.

States that want CMS to handle their exemption process must meet several requirements to be spelled out in the proposed rule. For example, they must agree to obey the eligibility determination made by CMS, provide the agency with any Marketplace data that applicants would need to complete an exemption application, and publicly disclose exemption information through their web portals and call centers.

According to the Internal Revenue Service, roughly 12 million Americans claimed an exemption from the individual mandate for 2014, while another 300,000 were subject to the tax penalty for failing to buy minimal coverage despite qualifying and failing to apply for an exemption (see Update for Week of July 20th).

Final FDA rule on drug shortage notification will go into effect in September

The Food and Drug Administration (FDA) released final regulations last month that imposed new notification requirements on manufacturers facing shortages of drugs and biologics.

Effective September 8th, manufacturers must notify the FDA at least six months in advance of any anticipated discontinuation of shortage of a drug of biologic product, including plasma-derived products and their recombinant analogs. They must also notify the FDA no later than five business days following any permanent discontinuance of interruption.

The FDA first proposed the new standards in 2013, which codified much of the 2011 executive order from President Obama requiring manufacturers to promptly notify the agency of any permanent or temporary disruption in drug supplies (see Update for Week of October 31, 2011). The order responded to a tripling of drug shortages from 2007-2011 (to 251), particularly for cancer medications.

The FDA credited the executive order for helping to avert 195 drug shortages in 2011 and 282 shortages in 2012 (see Update for Week of October 28, 2013). However, it relied on voluntary notification by manufacturers until Congress passed the *Food and Drug Administration Safety and Innovation Act* (FDASIA) in 2012, giving FDA the power to require companies to give notice of any "discontinuance or interruption of the production of life-saving drugs," at least six months before the interruption, "or as soon as practicable."

Under the proposed rule, the FDA exercised the discretion given by Congress to extend these notification requirements to biologic drugs and refuse to reverse its decision despite industry protests. It also specified how FDA will respond with letters of noncompliance for inadequate notifications and publicly post the letters if a satisfactory explanation or resolution is not received.

The FDA maintains a listing on their website of all drugs and biologics that are currently in short supply.



Arizona

Governor to seek federal approval to increase burdens on “able-bodied” Medicaid adults

Governor Doug Ducey (R) formally released his proposal this week that would seek federal approval to substantially raise premiums and impose work requirements for “able-bodied” adults receiving Medicaid.

The plan will affect only about a quarter of the 1.7 million Arizonans enrolled in Medicaid, and will not apply to children, the disabled, or the elderly. The “able-bodied” population would have to pay up to two percent of their income into health savings accounts, as well as copayments capped at three percent per year. The accounts could be used only for non-covered services like eyeglasses or if the enrollee meets certain wellness incentives, participates work search programs, or regularly attends school. The funds would be returned to enrollees that leave Medicaid so they could cover premium and cost-sharing for private coverage.

According to the Governor, the premiums and copayments would amount to about \$26 per month for a Medicaid enrollee earning just under 138 percent of the federal poverty level, the threshold for the Medicaid expansion under the Affordable Care Act (ACA). Governor Ducey’s Republican predecessor narrowly obtained legislative approval to participate in the ACA expansion, though several Republican lawmakers filed a lawsuit seeking to block the hospital assessment that funds the expansion, as it was not enacted with a two-thirds majority (see Update for Week of May 4th).

Ducey signed a law this year requiring the Arizona Health Care Cost Containment System (AHCCCS) to apply for a waiver requiring able-bodied participants to work and limiting benefits for a lifetime maximum of five years. Former Governor Jan Brewer (R) vetoed a bill with those requirements in 2014 and the federal Centers for Medicare and Medicaid Services has said such limitations were unlikely to be approved.

The Governor plans to submit the proposed waiver to the Obama Administration in late September following a public comment period.

California

Marketplace premiums to increase by four percent average for 2016

Covered California officials announced last week that the average premium for private plans offered through the Marketplace will increase by an average of four percent for 2016.

California is one of only a handful of state-based Marketplaces that elected to follow the “active purchaser” model permitted by the federal Centers for Medicare and Medicaid Services (see New York below). This model gives state regulators the authority to negotiate plan premiums and exclude less affordable plans from the Marketplace even if they otherwise meet minimum standards (see Update for Week of May 27, 2013). Covered California also has reduced rates by providing insurers with utilization data dispelling claims that Marketplace enrollees are sicker and more costly than others (see Update for Week of June 22nd).

As a result, Covered California has largely been able to hold premium increases in check since the opening of the Marketplaces in October 2013, reducing 2016 premiums by about \$200 million below what insurers initially proposed. The four percent average increase for 2016 is roughly in line with the 4.2 percent average for 2015.



Final rates are still pending review by state regulators following a 60-day public comment period. However, based on past experience they are likely to closely follow the preliminary rates released last week.

According to Covered California, roughly 20 percent of existing Marketplace enrollees will actually benefit from a rate decrease, while about two percent will experience premium hikes of more than 15 percent if they do not change plans. Premium changes overall will range from a ten percent drop to a 23 percent increase, while consumers who switch to the lowest-cost plan in their metal tier could cut their premiums by an average of 4.5 percent.

Covered California premiums do vary significantly by region, as do the average increases. Southern California consumers will see an average hike of only 1.8 percent while their counterparts in the northern parts of the state will see premiums rise by seven percent on average. State regulators point to the greater competition in southern California as the reason for the disparity, noting that counties that previously had no more than two competing insurers will see average increases of 9.8 to 12.8 percent.

Covered California will have 12 participating insurers in 2016 with the addition of UnitedHealth Group and Oscar Health Plan of California. However, those two insurers will only operate in a very limited number of counties for 2016 (see Update for Week of July 20th).

Renewal rates remain high for Covered California and Medi-Cal

The majority of Medi-Cal and Covered California enrollees that were eligible to renew their coverage last year opted to do so, according to report released last week by Covered California and the Department of Health Care Services.

According to the report, which is mandated by state law, 92 percent of the 1.1 million Covered California enrollees eligible to renew their coverage in the last quarter of 2014 ultimately did so. Of those re-enrolling in Covered California, 94 percent elected to remain with the same insurer.

The report found that the renewal rate was slightly lower among Medi-Cal enrollees, as 82 percent of the three million eligible Medi-Cal enrollees decided to continue their coverage.

Other findings showed that roughly 46 percent of Covered California applicants were under age 26, with 31 percent under the age of 18. About 86 percent of all Covered California enrollees are receiving Affordable Care Act (ACA) subsidies to offset premium and cost-sharing costs, which is roughly the same ratio for all Marketplaces nationwide.

Blue Shield owes nearly \$83 million in consumer rebates mandated by the ACA

According to the *Los Angeles Times*, Blue Shield of California will have to start paying roughly \$82.8 million in rebates this month to consumers and small employers under the medical-loss ratio (MLR) requirements of the Affordable Care Act (ACA).

The majority (\$61.7 million) will be distributed to about 454,000 individual policyholders who had Blue Shield coverage for 2014. The average rebate is expected to be around \$136 and is due by September 30th.

The rebates are required because Blue Shield spent only 76.8 percent of premium revenue on direct medical care, failing to meet the 80 percent threshold that the ACA set for individual and small group plans. Blue Shield blamed the rebates on uncertainty about the case mix of subscribers during the first full year of ACA implementation. However, two other dominant California insurers (Anthem and Kaiser Permanente) both met the required MLR.



The rebates were mandated by the ACA since the 2011 plan year and have steadily decreased as insurers have adjusted to the market. For 2014, insurers nationwide will pay only \$332 million in ACA rebates compared to \$500 million in 2013.

The Blue Shield rebates only heighten the regulatory scrutiny on the insurers, which lost its non-profit tax exemption earlier this year after the Franchise Tax Board determined that the company was failing to use its unlawful and "extraordinarily high surpluses" of more than \$4 billion to make coverage more affordable (see Update for Week of March 16th). If upheld on appeal, it will force Blue Shield to issue billions of more dollars in consumer rebates.

In the interim, Blue Shield is continuing to operate as a non-profit. State regulators limited its average individual plan premium increase next year to only 4.6 percent and only 2.3 percent inside the Covered California Marketplace, which is well below the four percent average for all Covered California plans (see above).

Kaiser survey shows more than two-thirds of uninsured Californians gained coverage due to ACA

Roughly 68 percent of previously uninsured Californians have obtained coverage since full implementation of the Affordable Care Act (ACA), according to the latest report released this week by the Kaiser Family Foundation.

Kaiser researchers surveyed 2,001 adults in California that were prior to the opening of the ACA Marketplaces in October 2013. Initial results last year showed that 58 percent had signed-up for coverage during the inaugural open enrollment period, while the most recent results show that figure increased by ten percent after the second open enrollment period closed last February.

The survey showed that 34 percent of the newly insured enrolled in Medi-Cal, 14 percent obtained employer coverage, 12 percent signed-up for private Covered California plans, and eight percent had other coverage.

Of those that remained uninsured, 44 percent insisted that it was because plans were unaffordable. However, 41 percent also are undocumented immigrants and are thus barred from obtaining Covered California coverage.

The budget proposed last June by Governor Jerry Brown (D) would expand Medi-Cal coverage to undocumented children (see Update for Weeks of June 8th and 15th), while the Assembly is still weighing Senate-passed legislation that would expand Medi-Cal for children while creating a separate but equivalent program for adults and seek a federal waiver allowing adults to buy into Covered California (see Update for Week of July 13th).

Delaware

Delaware elects not to assume full state control over ACA Marketplace

The Secretary for the Department of Health and Social Services (DHSS) informed the Delaware Health Care Commission this week that state officials will not assume full control over the health insurance Marketplace created pursuant to the Affordable Care Act (ACA).

Delaware is one of seven states that elected to operate a state partnership Marketplace (SPM) jointly with the federal government. As a result, nearly 20,500 eligible consumers in Delaware presumably could have lost their premium and cost-sharing subsidies if the U.S. Supreme Court stripped them from Marketplaces that were federally-operated.

In order to preserve subsidies for their consumers, Delaware (along with Arkansas and Pennsylvania) received conditional approval from the Obama Administration to convert to a state-based



Marketplace should ACA subsidies no longer be available (see Update for Weeks of June 8th and 15th). However, because the U.S. Supreme Court preserved the subsidies for all Marketplace consumers (see Update for Week of June 22nd), DHSS officials have decided to stay with the current SPM model in which Delaware retains control over plan management and consumer outreach, as well as final Medicaid eligibility determinations. Delaware will continue to default to the federal government for the final certification of Marketplace plans.

The DHSS Secretary cited recent surveys showing that the percentage of uninsured adults in Delaware has fallen from 14.3 to 10.8 percent since the SPM opened in 2013. However, she acknowledged that Delaware has lagged behind national averages for enrollment in silver tier plans (upon which premium subsidies are based) and actually saw uninsured rates among Latinos climb from 37.1 to 40.2 percent. As a result, state officials are looking to expand outreach efforts to “hard-to-reach” populations.

State regulators are also actively reviewing sizeable rate increases sought by Marketplace insurers for 2016, including the 25.4 percent average hike proposed by the state’s dominant insurer, Highmark Blue Cross Blue Shield.

New York

Premiums to climb seven percent for the 415,000 enrolled in Marketplace plans

NY State of Health officials announced this week that the Marketplace has now enrolled more than 2.1 million consumers in public or private coverage since opening in the fall of 2013.

Roughly 89 percent of these enrollees were previously uninsured when they applied for coverage, according to the Marketplace’s executive director. Nearly 20 percent of applicants signed-up for qualified health plan (QHP) coverage while nearly 75 percent were enrolled in Medicaid.

Marketplace officials also revealed that they have approved an average premium increase of 7.1 percent for those enrolled in individual QHP plans through the Marketplace. This was below the 10.4 percent average increase sought by participating insurers.

NY State of Health will also add a new "Essential Plan" for 2016 that will be offered to households with annual incomes at or below 150 percent of the federal poverty level.

The report from NY State of Health credited the significant expansion of the in-person assister program for boosting enrollment during the 2015 open enrollment period. Two-thirds of all Marketplace enrollees relied upon navigators, certified application counselors, or brokers, to sign-up for coverage, up from only 49 percent during the inaugural open enrollment period. The most improvement occurred among so-called “hard to reach” populations, as enrollment climbed among the uninsured and those with limited English proficiency.

NY State of Health had increased its number of available in-person assisters by 27 percent prior to the 2015 open enrollment period.

North Carolina

Dominant insurer seeks nearly 35 percent rate hike for Marketplace plans

The largest health insurer in North Carolina announced this week that it has upgraded its requested premium increase for 2016 due to higher than anticipated costs of coverage in the federally-facilitated Marketplace created pursuant to the Affordable Care Act (ACA).

Blue Cross and Blue Shield (BCBS) of North Carolina is now seeking an average rate hike of 34.6 percent, up from the nearly 26 percent increase it had proposed only two months ago. Company



officials insisted that such a huge increase was needed to protect the “sustainability of plans....over the long-term” after claims and expenses for 2014 and 2015 were higher than existing premiums.

State regulators are likely to downgrade the proposed hike, as they did for 2015 when they limited the insurer to only a 13.5 percent increase. They have already cited a recent study from the Kaiser Family Foundation showing that premium increases nationwide for the second lowest-cost silver tier plan are averaging only 4.4 percent (see Update for Week of June 22nd).

In addition to the rate hike, BCBS is also redesigning their plan offerings for 16 counties including the most populous areas around Charlotte and the Research Triangle. Roughly 55,000 consumers in these areas will no longer be able to select the Blue Advantage or Blue Select plans and will be switched to lower cost plans with a more narrow network of providers.

BCBS was the only Marketplace insurer to sell plans in all 100 North Carolina counties for 2014. However, UnitedHealth Care and Coventry Health Care entered the Marketplace in 2015 and will remain for 2016. UnitedHealth is seeking a 12.5 percent average increase in premiums while Coventry proposed rate hikes of 17.2 to 25.8 percent.