



## Health Reform Update – Week of May 11, 2015

### CONGRESS

#### ***House subcommittee advances draft of “21st Century Cures” legislation***

The health subcommittee for the House Energy and Commerce Committee advanced draft legislation this week that would expedite the approval of new medical cures by providing regulatory leeway for drugmakers.

In its current form, the bill would allow the Food and Drug Administration (FDA) to consider “real-world evidence” and shorten clinical trials, while manufacturers would be able to expand a drug's indications based on observational data or registries indicating how it performs in the field. A new “breakthrough device” program would provide a faster path to market for devices that could substantially raise the standard of care, while a separate provision would expand the existing “humanitarian device exemption” for products for rare diseases that affect up to 8,000 patients per year (instead of only 4,000).

The package is the product of the so-called “21st Century Cures” initiative launched last year by Energy and Commerce chairman Fred Upton (R) and Rep. Diana DeGette (D). The full committee is expected to take-up the legislation next week. An approved version would then have to be reconciled with a parallel effort in the Senate Health, Education, Labor, and Pension (HELP) Committee.

The latest measure has largely received bipartisan praise as Democrats support the funding boost provided to the National Institutes of Health (NIH) that was absent from earlier drafts (nearly \$35 billion by fiscal year 2018). (Rep. DeGette continued to push for a concurrent increase for the FDA). Rep. Jan Schakowsky (D) and other Democrats were also pleased that most provisions that would extend drug exclusivity by manufacturers have been removed, including the earlier proposal to add six months to the exclusivity period for drugs with newly added orphan indications.

Other areas of bipartisan support include provisions that would prioritize the review of breakthrough diseases and re-authorize rare pediatric disease priority review vouchers. However, lawmakers identified several areas of disagreement or needed improvement, including those focused on interoperability, telehealth, and enhancing access to rare disease therapies. Rep. Ed Whitfield (R-KY) and other members also want to include “disease-specific” provisions that target chronic and costly conditions like diabetes.

Former FDA commissioner Margaret Hamburg had called the bill “misguided”, insisting that “shortening review times...is the wrong mechanism” to expedite approvals while ensuring patient safety. FDA officials testified during a Senate committee hearing last week that the already “overburdened and underfunded” and the demands for additional agency guidance imposed by the draft legislation would further compromise its ability to efficiently evaluate new and modified drugs.

#### ***Controversial trade deal would delay generic competition for biologic drugs***

Consumer groups such as AARP and Public Citizen are opposing a 12-nation trade deal that would extend the 12-year exclusivity period for biologic drugs under the Affordable Care Act (ACA) to other countries and prevent Congress from reducing it.

The Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Industry Organization (BIO) back the trade agreement, as does President Obama even though his past



budgets proposals have sought to reduce the exclusivity period under the ACA to seven years (see Update for Week of March 3, 2014).

However, all but one Senate Democrat opposed legislation this week (S. 995) that would have given the President fast-track authority to approve or reject such trade pacts, without amending it. Groups such as Doctors Without Borders had lobbied against the Trans Pacific Partnership (TPP), insisting that it had the potential to be the “most harmful trade agreement for access to medicines ever” as it would make it “much harder for generic companies to produce cheaper drugs that are vital to people’s health.”

Exclusivity periods within the 12 countries that would be subject to the TPP vary greatly, while several offer no restrictions on competition.

## FEDERAL AGENCIES

### ***Pioneer ACOs saved Medicare \$400 million over two years***

The chief actuary for the Centers for Medicare and Medicaid Services (CMS) announced last month that a key pilot program created by the Affordable Care Act (ACA) has saved Medicare nearly \$400 million over two years and is the first alternative-payment model certified to cut costs while improving health-care quality.

The report recommends that CMS expand the Pioneer Accountable Care Organization (ACO) to a larger group of Medicare beneficiaries. However, it acknowledges that Pioneer ACOs have met with “mixed” results when using other outcome measures. At least 13 of the original 32 participating hospital systems have already dropped out or switched to other models after failing to meet performance targets.

The ACO demonstration allows groups of hospitals or physicians to share in the savings if they successfully collaborate to meet pre-set quality measures (see Update for Week of October 17, 2011). More than 3.5 million Medicare beneficiaries are currently part of ACOs run by some 400 health systems.

Those participating in the fast-tracked Pioneer program had prior experience delivering such value-based care and were eligible for greater savings but also faced more financial risk if they failed to meet their targets. Two providers wound up paying substantial penalties forcing many complaints that the rules were too complex and the benchmarks set too low (see Update for Week of December 8, 2014).

However, the CMS actuary found that the 600,000 patients in Pioneer ACOs spent, on average, \$36 less per month in 2012 and \$11 less per month in 2013 than comparable non-affiliated patients. They also had fewer hospitalizations, lower utilization, and reported more timely care and better communication compared to other patients.

CMS officials are evaluating whether to include parts of the Pioneer ACO model into new options for the next group of ACOs, including assigning patients to the group prospectively. Other new models would set regional benchmarks, let providers assume full financial risk, and allow Medicare patients to volunteer for ACOs rather than being assigned.

### ***OIG says Medicare should be allowed to obtain greater Part D drug rebates***

The Office of the Inspector General for the Department of Health and Human Services (HHS) issued a new report last month urging Medicare to seek additional rebates for prescription drugs furnished to Part D enrollees.



OIG's review of Medicaid drug rebates in 2012 for both Medicaid and Part D enrollees showed that the rebates helped Medicaid save substantially more money than Part D (Medicaid rebates accounted for 47 percent of Medicaid expenditures compared to only 15 percent under Part D). As with their earlier review in 2009, OIG found that inflation-based rebates (which help protect Medicaid from higher costs due to price increases) are not found in Part D and were the primary reason for this discrepancy.

Overall, the OIG found that the rebate amount for each unit of a Medicaid drug was three times higher than for Part D drugs. After accounting for rebates, Medicaid net unit costs were less than half of Part D net unit costs for 110 brand-name drugs.

Senator Bill Nelson (D-FL), who requested the OIG review, promptly introduced legislation (S.1083) that would require drugmakers to offer Medicare the same rebates available to Medicaid. However, the bill is opposed by the Pharmaceutical Research and Manufacturers of America, insisting that altering the fundamental structure of Part D with "Medicaid-style rebates" would limit enrollee access and increase premiums.

### ***HHS Inspector General to investigate generic drug price spikes***

The Inspector General for the Department of Health and Human Services announced last month that it will review how sudden hikes in generic drug prices are driving-up costs to public health programs.

The investigation was sought by Senator Bernie Sanders (I-VT) and Rep. Elijah Cummings (D-MD) after generic drug makers refused their request to turn over "meaningful records" on pricing. According to the lawmakers, prices have doubled for nearly ten percent of generic drugs in recent years. Both introduced legislation late last year that sought to require generic drug makers pay Medicaid rebates whenever their prices rise more quickly than inflation (see Update for Week of December 1, 2014). The Generic Pharmaceutical Association insisted at the time that "the cost of generics has nearly been cut in half since 2008 [while] brand drug spending has nearly doubled over the same period."

### ***GAO finds that only five percent of Medicaid enrollees account for nearly half of program costs***

A new report from the Government Accountability Office (GAO) determined this week that roughly five percent of Medicaid beneficiaries account for 48 percent of all program spending from 2009-2011.

According to GAO, one percent of these so-called "super-utilizers" are responsible for 25 percent of all healthcare spending. However, researchers stress that this dynamic is not unique as five percent of the overall population in 2010 also accounted for nearly half of all healthcare spending.

GAO notes that 63 percent of "super-utilizers" are considered "disabled" and more than half have costly mental health conditions. Substance abuse and diabetes are other predictors of high utilization.

In contrast to "super utilizers", the least expensive 50 percent of Medicaid enrollees made-up only eight percent of costs during that time period. Roughly 12 percent of enrollees cost the program nothing.

## **HEALTH COSTS**

### ***Number of Americans with more than \$100K in drug costs nearly tripled in 2014***

An annual report released this week by the pharmacy benefits manager Express Scripts found that prescription drug costs have reached new highs for patients with certain conditions.



According to the report, the number of Americans prescribed at least \$100,000 in medications last year nearly tripled from 47,000 to 139,000, with specialty drugs and those used to treat Hepatitis C and cancer accounting more than two-thirds of this cost. For those with drug costs of at least \$50,000 last year, 90 percent used specialty medications and more than a third were being treated for ten or more different medical conditions.

Express Scripts specifically cites new drugs such as Sovaldi for HCV and Yervoy for melanoma for much of this cost, noting that each costs \$84,000 and \$120,000 respectively for a single course of treatment.

The report claims that while “patients are overwhelmingly taking specialty medications”, the share of their total medication costs actually declined in 2014 from 14.9 percent to 13.5 percent.

## STATES

### ***Kaiser study confirms that hospitals are greatly benefiting from Medicaid expansion***

A new report by the Kaiser Family Foundation documents that uncompensated care has fallen dramatically for hospitals in the nation’s largest non-profit health system that are located in states expanding Medicaid pursuant to the Affordable Care Act (ACA).

Researchers found that Ascension Health system hospitals saw a 32 percent drop in uninsured patient visits for facilities in expansion states (as of September 30, 2014) compared to only a four percent decline in opt-out states. This resulted in a 40 percent decline in charity care costs, compared to only 6.2 percent for opt-out states. During the same time, Medicaid revenue increased 8.2 percent while falling 9.4 percent in opt-out states.

#### Alaska

### ***House committee refuses to advance Governor’s Medicaid expansion proposal***

The co-chair of the House Finance Committee refused to hold hearings this week or further consider any action on H.B. 148, legislation introduced at the request of Governor Bill Walker (R) to expand Medicaid pursuant to the Affordable Care Act (ACA).

The Governor’s Medicaid expansion was intended to provide a compromise between the Democratically-sponsored legislation that Republicans refused to consider (see Update for Week of March 23<sup>rd</sup>) and the full opt-out of the expansion demanded by House conservatives. H.B. 148 previously was supported by all but one Republican on the Health and Social Services Committee (see Update for Week of March 30<sup>th</sup>). However, after a week of contentious hearings, Finance co-chair Steve Thompson (R) insisted that the committee could not move forward with expansion legislation since the state’s Medicaid Management Information System (MMIS) database is “broken” and could not accommodate additional program enrollment.

Governor Walker’s Republican predecessor has already sued the lead contractor Xerox over design flaws in the new MMIS, which has hindered the interface with the federally-facilitated Marketplace operated in Alaska. However, Department of Law officials testified this week that the lawsuit appeared to force Xerox to make the required changes and that the MMIS is now operating properly.

Companion legislation in the Senate (S.B. 78) also remains stalled, although the Senate Majority Leader expects that the Finance Committee will at least hold a hearing on the bill in the near future.

#### California

### ***Marketplace cuts spending and enrollment projections, but maintains premium assessment***



Covered California officials released a proposed spending plan this week that would slash spending and lower enrollment projections for 2016.

During the inaugural open enrollment period, Covered California was the most successful of all federal or state Marketplaces created pursuant to the Affordable Care Act (ACA). However, it struggled to replicate that success for the 2015 open enrollment period, falling 300,000 enrollees short of its 1.7 million target, retaining only 65 percent of its 1.4 million total for 2014, and adding only 500,000 new consumers. Its net growth of only one percent made it one of the worst-performing states for 2015.

Because affordability concerns were cited as a major factor inhibiting enrollment, Covered California does not plan on increasing its Marketplace assessment of \$13.95 per month for each policy. However, the assessment is now the Marketplace's primary source of revenue since the ACA requires Marketplaces to be self-sustaining and federal grants can no longer be used to cover operating expenses.

As a result, Covered California's board is proposing to cut spending by 15 percent (or \$58 million), including a 33 percent reduction for outreach and marketing. Consumer advocates had recommended a higher premium assessment in lieu of outreach cuts, noting that Covered California still struggles with long waiting times, erroneous Marketplace information, and technical glitches in online enrollment. However, the California Association of Health Plans had urged the board not to raise the fee.

The board also reduced enrollment projection to only 1.48 million consumers in 2016 and two million by 2019. The lower figures are based in part of the fact that attrition from the Covered California to Medi-Cal far exceeded projections in 2015, while fewer Medi-Cal enrollees than expected moved over to Covered California.

#### Colorado

#### ***Marketplace approves 150 percent increase in premium assessment***

The board of directors for the Connect for Health Colorado voted unanimously this week to increase the assessment on participating insurers from 1.4 percent to 3.5 percent of premiums for the 2016 plan year.

The move increases the fee to the same 3.5 percent level assessed on insurers in the federally-facilitated Marketplace, providing Connect for Health in roughly \$5.8 million in new revenue. For consumers holding a \$4,000 per year plan, the higher assessment translates into about an \$84 per year increase in premiums.

Connect for Health also raised the monthly assessment charged by the Marketplace for private non-Marketplace plans purchased in the individual market (from \$1.25 to \$1.80). This would add another \$2 million in new revenue.

Connect for Health officials had urged the board to quickly decide on the higher assessments as plans must submit proposed premiums for 2016 by May 29<sup>th</sup>. The Marketplace is expected to need as much as \$54 million in operating expenses for 2015-2016.

The fee changes would cover this amount and make Colorado self-sustaining as required by the Affordable Care Act (ACA). More than half of the 15 state-based Marketplaces are not self-sustaining due to higher than anticipated expenses and subpar enrollment (see Update for Week of May 4<sup>th</sup>).

Connect for Health has enrolled roughly 143,000 consumers thus far in 2015 but would need to accelerate enrollment fairly dramatically in coming years in order to remain self-sustaining. Current targets call for 217,000 enrollees by June 2016 and 295,000 by June 2018.





Connecticut

***Board considers slight increase to Marketplace premium assessment***

The finance subcommittee for the board overseeing Access Health CT unanimously recommended this week that the Marketplace modestly increase assessments on all individual and small group plans sold in Connecticut in order to ensure it remains self-sustaining as required by the Affordable Care Act (ACA).

Access Health CT is the best-performing of the 15 state-based Marketplaces (SBMs), leading the nation with a 39 percent growth in enrollment for 2015. While roughly half of SBMs are struggling financially (see Update for Week of May 4<sup>th</sup>), Access Health CT is able to cover its operating expenses solely with premium assessments and according to state officials is “the best positioned [SBM] in the country.” It expects to raise \$3 million next year just by selling its successful software to states with pervasive technical issues (see Update for Weeks of April 6<sup>th</sup> and 13<sup>th</sup>).

Access Health CT has performed so well despite having the nation’s lowest assessment on Marketplace at 1.35 percent. However, now that federal grants can no longer be used for operations, the plan proposed by the subcommittee would increase that fee to 1.65 percent, either all at once or progressively, in an effort to build up a nine-month reserve. For a \$700 monthly premium, the change would increase premiums by only slightly more than \$1.

Hawaii

***Governor seeks federal control over Marketplace web portal in order to release needed grants***

Governor David Ige (D) announced this week that web portal for the Hawaii Health Connector will transfer to federal control as part of a negotiated plan to released additional federal grants to the beleaguered health insurance Marketplace.

The federal Centers for Medicare and Medicaid Services (CMS) notified Connector officials earlier this year that they were not in compliance with the Affordable Care Act (ACA) because the Marketplace was not self-sustaining as required by January 1<sup>st</sup> and not integrated with the Medicaid system. As a result, CMS withheld \$70 million of the remaining \$204 million in federal grants that Hawaii received to build the online Marketplace.

The Governor has been negotiating on a set of reforms that would allow CMS to release the funds, which the Connector needs to cover a projected \$28 million deficit through 2022 (see Update for Weeks of April 6<sup>th</sup> and 13<sup>th</sup>). A lack of full website functionality and lengthy delays in determining Medicaid eligibility greatly limited private plan enrollment in the Connector causing the Connector to be unable to cover the \$15 million in annual operating expenses with simply a two percent assessment on Marketplace premiums. The Legislature has thus far appropriated only \$2 million of the \$9-10 million that that Connector officials insist is needed to continue operations past September 30<sup>th</sup>.

The Governor plans to transfer only some Marketplace functions to federal control in an effort to avoid fully-converting to a federally-facilitated Marketplace (FFM), which would put Affordable Care Act (ACA) subsidies at risk should the U.S. Supreme Court declare them next month to be unauthorized for FFM consumers (see Update for Weeks of March 2<sup>nd</sup> and 9<sup>th</sup>).

The contingency plan developed by Connector officials would also place remaining Connector duties under state agency control by September 30<sup>th</sup>, instead of being only one of two states besides Colorado to operate as an entirely independent, non-profit entity (see Update for Weeks of April 6<sup>th</sup> and 13<sup>th</sup>). New enrollments would stop on May 15<sup>th</sup>, outreach activities would cease on June 1<sup>st</sup>, and the Connector workforce would be completely eliminated by February 28<sup>th</sup>.



The roughly 37,000 consumers enrolled in Connector plans would not lose coverage but would be required to re-enroll through the FFM portal for the 2016 plan year. To be self-sustaining for next year, the Connector would need to enroll at least 70,000 consumers combined with the increase in the premium assessment from two to 3.5 percent starting July 1<sup>st</sup>.

Hawaii will incur a cost of \$30 million in order to migrate to the federal web portal for 2016. Nevada and Oregon both made a similar transition last year (see Update for Week of June 2<sup>nd</sup>).

#### Iowa

#### ***Wellmark stays out of Marketplace despite UnitedHealthcare's entrance***

The state's largest health insurer, Wellmark Blue Cross and Blue Shield, announced this week that it will continue to stay out of Iowa's federally-facilitated Marketplace for 2016 even though industry giant UnitedHealthcare has agreed to join.

The addition means that Iowans will now be able to choose Marketplace plans offered by at least two insurers, no matter where they live in the state. That will be a key change from the past two years when most consumers could only purchase plans from Coventry Health Plans (a subsidiary of Aetna). A new insurance cooperative created with ACA loans, CoOpportunity Health, gained substantial market share in the selected counties where it offered coverage. However, it was unable to pay the claims costs it incurred and was liquidated earlier this year (see Update for Week of January 19<sup>th</sup>).

According to the Kaiser Family Foundation, the absence of Wellmark led to only about 20 percent of eligible consumers receiving ACA subsidies –the lowest rate in the nation. Kaiser officials suggested that consumers in ACA-complaint Wellmark plans are reluctant to switch to an unfamiliar carrier just to receive a subsidy averaging about \$260 per month. They noted that a similar trend was found in neighboring South Dakota, where Wellmark did not participate in the Marketplace and only 21 percent of eligible consumers participated. By contrast, 42 percent of eligible nationwide consumers received the subsidies.

Wellmark also announced this week that it would hike average premiums by 28 percent for the roughly 30,000 consumers that purchased ACA-compliant coverage outside of the Marketplace since 2014. The insurer insisted that it was losing money on that group of consumers since they used far more medical services and prescription drugs than Wellmark projected.

#### New York

#### ***New bill would require drugmakers to disclose production costs for specialty medications***

The Senate Health Committee received proposed legislation this week that would require drug manufacturers submit annual reports detailing the production costs for any prescription drug that has a wholesale acquisition cost of at least \$10,000 per year (or per course of treatment).

Sponsored by Sen. Ruben Diaz (D), S.B. 5338 the reports specifically must include the total research and development costs paid by the manufacturer, the total costs of clinical trials, the total profit attributable to the drug, and the amount of any financial assistance provided through patient assistance programs.

Even though comparable measures have failed in California and Oregon, they have continued to proliferate this session in states like Massachusetts, North Carolina, and Pennsylvania (see Update for Week of May 4<sup>th</sup>).

#### Oregon

#### ***Governor signs bill to ensure adequate provider networks***



Governor Kate Brown (D) signed H.B 2468 into law this week. The measure sets new minimum standards for provider networks used by individual and small group plans in order to ensure consumers have adequate access to care and accurate provider directories.

The initial version of the bill sought by former Governor John Kitzhaber (D) included a provision prohibiting insurers from using affordability or cost-containment measures that discriminate against subscribers based on health status, particularly in the composition of drug formularies (see Update for Week of February 23<sup>rd</sup>). However, that provision was removed in committee.

#### Texas

#### ***House passes bill to impose “scarlet letter” on Marketplace enrollees***

The House passed legislation this week that would require labels to be affixed to health insurance cards issued for consumers in the federally-facilitated Marketplace. Only eight lawmakers objected to H.B. 1514, which would add the label “QHP” designating a qualified health plan consumer or “QHP-S” if the consumer is receiving premium or cost-sharing subsidies provided by the Affordable Care Act (ACA).

Bill sponsor J.D Sheffield (R) insisted that the labels were needed to inform physicians whether patients were part of the narrow provider networks typically used by Marketplace plans and if a 90-day grace period must be offered to patients that fail to make timely premium payments. However, the Texas Association of Community Health Centers, Texas Association of Health Plans, and other insurer and consumer groups were “very concerned” that the intended purpose of the bill was create a “scarlet letter” that would allow providers to avoid Marketplace enrollees, stating that there appeared to be no other “purpose for indicating that people are getting a subsidy....other than creating a group that you’re going to discriminate against.”

#### ***Committee unanimously passes drug transparency bill***

The House Insurance Committee unanimously approved legislation last week that would make Texas the latest state to expand plan transparency for prescription drugs.

H.B. 1624 would require health plans to make formulary information publicly accessible on insurer websites without entering a password, user name, or any other personally identifiable information. As of January 1<sup>st</sup>, insurers would have to follow a template that allows consumers to electronically search by drug name for applicable cost-sharing amounts, in-network and prior authorization requirements, and the specific tier for each drug listed in the formulary. The cost-sharing information must include an explanation as to whether the drug is specifically included within applicable deductibles.

#### Washington

#### ***Plan options for Marketplace consumers may double for 2016***

The Office of the Insurance Commissioner (OIC) announced this week that consumers in the Washington Healthplanfinder will have greater choices for the 2016 plan year while premiums will increase for all individual market consumers by no more than average of 5.4 percent—the lowest requested hike in eight years.

Insurance giants Regence Blue Cross and Blue Shield, United Healthcare, and Health Alliance Northwest have all submitted plans to sell Marketplace coverage for 2016, increasing the number of insurers participating in the Washington Healthplanfinder from ten to 13. If all plans are approved, the number of plan options available to consumers would more than double from 90 to 188.

Commissioner Mike Kreidler (D) insisted that final individual market rates are likely to be even lower than the 5.4 percent average, once they are modified by his office within the next 60 days.





## **Governor signs bill limiting biosimilar substitution**

Governor Jay Inslee (D) signed S.B. 5935 this week making Washington the fourth state this year to enact restrictions on the substitution of lower-cost biosimilar drugs for brand-name biologics.

The legislation was backed by Amgen, Genentech, and other biologic manufacturers in order to promote correct product identification and safety. However, it was opposed by groups like the Academy of Managed Care Pharmacy (AMCP), insisting that the restrictions on the interchangeability of biosimilars and biologics were unnecessary and not place on any other drug category. In addition, they argued that requiring pharmacists to notify prescribers within five days creates undue administrative burdens.

Under S.B. 5935, pharmacists can also only substitute a biosimilar if the prescriber explicitly permits such substitution and the interchangeable biosimilar has a wholesale price less than the reference biologic .

AMCP had urged Governor Inslee to veto the measure, following the argument advanced by former Food and Drug Administration Commissioner Margaret Hamburg that such restrictions are intended to effectively discourage substitution, thereby raising costs for patients and payors (see Update for Week of September 3, 2013).

Similar legislation regulating biosimilar substitution has been introduced in at least 20 states since 2013. However, they were previously rejected in all but five states as most contained restrictions that were so onerous that they were viewed as creating barriers to competition (see Update for Week of January 19<sup>th</sup>). Colorado and Georgia were the latest to enact comparable restrictions, while similar bills are being considered in at least seven other states (see Update for Weeks of April 6<sup>th</sup> and 13<sup>th</sup>).

The FDA approved the first biosimilar product last month under the regulatory pathway created by the ACA (see Update for Weeks of March 2<sup>nd</sup> and 9<sup>th</sup>). However, it has yet to declare it “interchangeable”, which many of the state bills require prior to substitution (see Update for Weeks of April 6<sup>th</sup> and 13<sup>th</sup>).