



Health Reform Update – Weeks of June 29 and July 6, 2015

CONGRESS

House overwhelmingly approves 21st Century Cures Act

The House voted 344-77 this week to pass the *21st Century Cures Act* (H.R. 6), the expansive bill that seeks to expedite “cures” for rare disorders by giving drug manufacturers more regulatory flexibility. The measure would also expedite clinical trials and provide the National Institutes of Health (NIH) with an extra \$8.75 billion over five years while the Food and Drug Administration will receive a \$550 million boost (see Update for Week of May 11th).

Despite the wide margin of passage, several amendments threatened to siphon away Democrat support, including the reduction in NIH funding from \$10 billion to \$8.75 billion. However, in the end only seven Democrats joined with 70 Republicans in opposing the measure.

The House did reject the most contentious amendment from Rep. David Brat (R-VA), which would have made the bill’s funding for NIH discretionary instead of mandatory, thereby subjecting it to the spending caps imposed by the *Budget Control Act of 2011*. Lawmakers also agreed to remove an offset that would have delayed payments to Medicare Part D providers and replace it with a provision increasing the amount of Medicaid drug rebates paid by manufacturers.

Four non-controversial amendments were approved by voice vote, including a provision that allows NIH to award a medical innovation prize for breakthrough research and technologies.

The bill now moves to the Senate, which has been considering a different version of H.R. 6 at a slower pace (see Update for Week of May 11th). It received a general statement of support this week from the White House, although the President expressed concern about the largest piece of the \$13.2 billion in proposed offsets, which would come from selling oil in the Strategic Petroleum Reserve (see Update for Weeks of May 18th and 25th). He also sought changes to a provision extending drug exclusivity by six months for a drug approved for a rare disease, citing concerns over the Congressional Budget Office estimate that it would cost about \$869 million from 2016-2015 by delaying the entry of lower-cost generics and biosimilars (see Update for Week of June 22nd).

GAO urges Congress to eliminate financial incentives for 340B hospitals to over-prescribe

A new report released this week by the Government Accountability Office (GAO) found that Medicare Part B drug spending was substantially higher per beneficiary at 340B Disproportionate Share Hospitals than at non-participating hospitals and recommended that Congress consider eliminating financial incentives for 340B providers to overprescribe.

According to GAO, the discrepancies could not be explained by the case-mix or other characteristics of specific hospitals or by the health status of various patients. As a result, GAO concluded that Part B beneficiaries—including those receiving oncology drugs—were either prescribed more drugs or more costly drugs than were medically necessary.

GAO noted that neither the Health Resources and Services Administration (HRSA) that oversees the 340B drug discount program nor the Centers for Medicare and Medicaid Services (CMS) that oversees Medicare Part B have the authority to correct the adverse financial incentives in the program through regulation.



CMS along America's Essential Hospitals (AEH) and other groups representing 340B providers took issue with GAO's analysis, insisting that it should have also examined whether patients had 340B hospitals had better overall health outcomes than at non-340B providers. AEH insisted that GAO's conclusion that financial incentives fully explain the differences in spending was an "unsupported" leap.

However, Pharmaceutical Research and Manufacturers of America (PhRMA) used the findings as evidence that 340B hospitals are not all "good stewards of the program" and that Congressional reforms are needed to "ensure 340B benefits the vulnerable or uninsured patients it was intended to help."

HRSA has started to issue a package of new rules and guidance that implement the long-standing reforms recommended by GAO and the Office of Inspector General (OIG) for the Department of Health and Human Services (see Update for Weeks of June 8th and 15th). These will not only create a "clear definition" of eligible patients but increase program transparency and oversight regarding how covered entities are spending program savings (see Update for Week of March 23rd). Congress has heavily criticized HRSA since 2011 when OIG claimed that 340B providers were reaping "windfall profits" when using discounted 340B drugs to also treat Medicare or private insurance patients (see Update for Weeks of July 1 and 8, 2013).

Provider groups successfully persuaded Congress not to rush through 340B reforms as part of the 21st Century Cures Act that passed the House this week (see above) These reforms, including requirements that participating hospitals track how 340B drug discounts are spent, are likely be part of a separate legislative package (see Update for Week of May 11th).

FEDERAL AGENCIES

ACA reinsurance fund has \$800 million surplus

The Centers for Medicare and Medicaid Services (CMS) announced that it has roughly \$800 million remaining in the reinsurance fund for health insurers for 2014, which it will carry-over into the next two years.

The Affordable Care Act (ACA) created the temporary reinsurance payments, which were intended to offset the costs of insurers treating exceptional numbers of high-cost patients during the first three years after the guaranteed issue mandate fully went into effect. The majority of payments were set to be issued during the first year, when insurers would be required to accept costlier patients transitioning from state and federal high-risk pools.

According to CMS, it paid out only \$7.9 billion of the \$8.7 billion that were raised for the reinsurance payments through the ACA revenue measures—a sign that initial patients have been less costly than anticipated (see below). The \$800 million surplus means that roughly \$1.8 billion remains available to insurers through 2016. CMS also previously announced that insurers will be reimbursed at 100 percent of their exceptional costs for 2014, instead of the planned threshold of 80 percent (see Update for Weeks of June 8th and 15th).

Only about 50 of the 484 health insurers that paid into the pool will not be receiving reinsurance payments for 2014.

New Marketplace enrollees were healthier and less costly than 2014

Consumers that enrolled in Affordable Care Act (ACA) Marketplaces in 2015 were healthier and spent less on prescriptions drugs than those that signed-up the year before, according to a new analysis released this week by pharmacy benefits manager Express Scripts.



Researchers found that the number of new Marketplace enrollees who used at least one prescription medication declined 18 percent in the first quarter of 2015, while costs were 36 percent lower per member per month compared to the first quarter of 2014.

However, researchers stressed that Marketplace enrollees are still typically sicker and more costly than consumers outside of the Marketplace. Monthly costs were 16 percent higher for each Marketplace enrollee in 2015 (compared to non-Marketplace enrollees), due largely to specialty drug spending for complex conditions, whose costs for Marketplace enrollees jumped 24 percent in 2015 (compared to only eight percent in 2014). Newly-approved Hepatitis C drugs were cited as a major factor in the specialty drug cost increase, as Marketplace spending spiked 96 percent for these medications.

Despite the findings and the surplus of ACA reinsurance payments (see above), major health insurers are claiming that initial patients have been far sicker than expected and consequently seeking to hike 2016 premiums by 20-50 percent. For example, Blue Cross and Blue Shield plans have proposed to increase premiums by an average of 23 percent in Illinois, 25 percent in North Carolina, 31 percent in Oklahoma, 36 percent in Tennessee, 37 percent in Kansas, 51 percent in New Mexico, and 54 percent in Minnesota. Other dramatic increases include the 22 percent average rate hike sought by Coventry in Missouri, the 32 percent average proposed by Scott and White Health Plan in Texas, and the 40 percent average for Geisinger Health Plan in Pennsylvania.

ACA proponents stress that these proposed rate hikes are likely to be substantially reduced in states with effective rate review programs. Analyses by Avalere Health and Kaiser Family Foundation also found that premiums for silver-level plans upon which ACA subsidies are based are likely to increase by only single digits on average, especially if consumers are willing to switch plans (see Update for Week of June 22nd).

However, Oregon is an example of at least one state where the Insurance Commissioner actually increased premiums beyond what insurers proposed in order to ensure “stability” in the individual market (see Update for Weeks of June 8th and 15th). The commissioner insisted that Oregon’s premiums—among the nation’s lowest—were forcing insurers to tap too heavily into reserves in order to cover claims costs and approved average increases of up to 33 percent for LifeWise, 25 percent for Moda Health Plan, and nearly 20 percent for the lone non-profit health insurance cooperative competing in Oregon’s ACA Marketplace.

Medicare physician fee schedule clarifies payment rules for biosimilar drugs

The proposed Medicare physician fee schedule for 2016 clarifies that Medicare payment for a biosimilar product will be set at the average sales price (ASP) of all of National Drug Codes assigned to that product plus six percent. This effectively means that reimbursement is based on the ASP of all biosimilars that reference the same biologic drug in the biosimilar license application.

The Food and Drug Administration (FDA) approved the first biosimilar product earlier this year through the regulatory pathway created by the Affordable Care Act (see Update for Weeks of March 2nd and 9th). Several more approvals are expected later this year.

The Centers for Medicare and Medicaid Services (CMS) also states that they “plan to use a single ASP payment limit for biosimilar products that are assigned to a specific HCPCS code.” The agency will rely on data from “local contractors using any available pricing information, including provider invoices” until sufficient manufacturer data is reported on newly-approved biosimilars.

CMS issued earlier guidance providing more details on how biosimilar drugs will be reimbursed under Medicare Parts B and D (see Update for Weeks of April 6th and 13th).



Study shows slight rise in out-of-pocket health spending since 2014

A new survey of roughly 15,000 physicians released this week by the Robert Wood Johnson Foundation showed that patient out-of-pocket (OOP) spending per visit increased by only 3.5 percent since 2014, or about \$1 per visit including copayments and deductibles.

According to the study's author, the increase is "consistent with low overall price increases for health care services that have been reported elsewhere" and not reflective of the spike in OOP costs that were predicted by opponents of the Affordable Care Act (ACA). However, the study did find that increases were most pronounced for annual deductibles, which increased across all types of physician visits by an average of \$8.

The author credited "the focus on preventative care under the healthcare law and of the insurers' strategy to encourage primary care over more costly specialty care" for holding OOP costs in check.

STATES

California

Senate committee substantially amends bill to limit prescription drug cost-sharing

The Senate Health Committee has scheduled a July 15th hearing on legislation that would limit out-of-pocket costs for prescription drugs, after amending the bill for the second time in three weeks.

The latest changes to A.B. 339 would now place a limit of \$250 for a supply of up to 30 days on a single prescription for an outpatient drug. Earlier versions sought a limit of 1/24 of the annual out-of-pocket limit under the Affordable Care Act (ACA) (see Update for Week of June 22nd).

As amended earlier by the Assembly, the limit will apply only to covered outpatient drugs that constitute essential health benefits under both group and individual plan (see Update for Weeks of May 18th and 25th).

The committee relaxed the controversial prohibition sought by several states that would prevent plans from placing most or all of the drugs to treat a specific condition on the highest cost tiers of a formulary (see Update for Weeks of February 9th and 16th). A.B. 339 now only bars plans from placing "more than 50% of drugs approved by the Food and Drug Administration that are in the same drug class into the two highest cost tiers" of a formulary.

The committee further removed a provision stating that cost-sharing limits for high deductible health plans would not apply until an enrollee's deductible had been satisfied for the year.

A.B. 339 also now includes language that "would require a health insurer that provides coverage for outpatient prescription drugs to provide coverage for medically necessary prescription drugs, including those for which there is not a therapeutic equivalent, and....require[s] copayments, coinsurance, and other cost sharing for outpatient prescription drugs to be reasonable."

Senate advances bill to delay Medicaid managed care for children with rare disorders

The Senate Health Committee unanimously voted this week to delay the move to managed care for California Children's Services (CCS) until January 2017.

CCS is a program for Medi-Cal children with rare or complex disorders, including hemophilia, cerebral palsy, and congenital heart disease. The current CCS program had been set to expire next January and one-third of CCS children transitioned into Medi-Cal managed care by July 2017. However,



A.B.187 sponsored by Assemblyman Rob Bonta (D) would allow CCS to continue operating for an additional year and delay this transition, due to concerns over timely access to specialty care.

According to bill supporters, the delay would give Medi-Cal managed care plans time to add the needed subspecialty providers and therapists to their provider networks, many of which now lack access to appropriate services for rare and specialized diseases.

A.B. 187 now moves to the Senate Appropriations Committee. Health Committee chair Ed Hernandez (D) expects the measure will pass the Senate and head to Governor Jerry Brown (D), but expressed concern this week that it would be vetoed.

Hawaii

New law provides greater consumer transparency for formulary drugs

Governor David Ige (D) signed H.B. 261 into law this week, requiring group and individual health plans starting in 2017 to post and regularly update information on drug formularies on their respective websites. The information must include a dollar range of applicable cost-sharing for each formulary drug and make changes related to the addition or deletion of a formulary drug within 72 hours.

Louisiana

New law sets notification requirements for biosimilar versions of biologic drugs

Louisiana became the latest state this week to enact legislation relating to the substitution of generic biosimilars for brand-name biologic drugs when Governor Bobby Jindal (R) signed H.B. 319 into law. However, unlike measures introduced in most other states, H.B. 319 simply requires pharmacists to notify the prescribing physician within five days (and by any means) whenever a biosimilar defined by the federal Food and Drug Administration (FDA) as interchangeable is substituted for the reference product.

Measures with additional requirements have recently been enacted in Colorado (S.B. 71)(see Update for Weeks of April 6th and 13th), Georgia (S.B. 51), North Carolina (H.195), Tennessee, (S.B. 984), Texas (H.B. 751), Utah (H.B. 279), and Washington, (S.B.5935)(See Update for Week of May 11th). Similar bills have cleared both chambers in New Jersey (A.2477) and passed the Senate in California (S.B. 671), where it unanimously cleared the Assembly Health Committee this week.

Maine

No Marketplace carriers request double-digit rate hikes for 2016

The Bureau of Insurance has confirmed that none of the plans participating in the Affordable Care Act (ACA) Marketplace in Maine have sought to increase premiums by ten percent or more for 2016.

The four insurers are seeking increases for 2016, a departure from 2015 when average premiums remained largely the same as 2014. The Bureau will announce final rates shortly before the November 1st start of open enrollment for 2016.

Enrollment in the federally-facilitated Marketplace in Maine jumped during 2015 to the point where nearly 60 percent of eligible residents used it to purchase coverage (compared to only 36 percent in 2014).

Montana

Newly-released Medicaid expansion plan not likely to receive federal approval

The Department of Public Health and Human Services (DPHHS) released the details this week of Montana's plan to expand Medicaid pursuant to the Affordable Care Act (ACA).



Governor Steve Bullock (D) signed the *Health and Economic Livelihood Partnership (HELP) Act* into law last spring over bitter opposition from House conservatives (see Update for Week of May 4th). It was billed as the “most conservative” of the private-sector alternatives to the ACA expansion that have been federally-approved in six states. However, work requirements and premiums for the lowest-income enrollees that were included to attract the critical support of 13 moderate House Republicans are likely to be stripped out of the final waiver request by the Obama Administration, as they were for states like Indiana, Pennsylvania, and Tennessee (see Update for Weeks of January 26th and February 2nd).

DPHHS will hold two public hearings in August on the plan and leave the public comment period open for 60 days. The proposed start date for the expansion is November 1st.

Consumer advocates ultimately expect the plan to require premiums of up to two percent of income only for newly-eligible Medicaid enrollees earning 100-138 percent of the federal poverty level (FPL) and not for those below 100 percent of FPL—consistent with the federal waivers approved for other states.

Ohio

Budget deal would end Medicaid coverage for enrollees that do not make monthly contributions

Governor John Kasich (R) signed a two-year budget this week that would require about one million Medicaid enrollees to contribute to health savings accounts or lose coverage.

The budget provision would apply to all Medicaid enrollees except pregnant women and force them to contribute the lesser of two percent of household income or \$99. Medicaid coverage would be terminated for those that do not comply.

Federal approval for such mandatory contributions is far from certain given the adverse position that the federal Centers for Medicare and Medicaid Services (CMS) has previously taken to state proposals that terminate Medicaid coverage for non-payment of premiums, particularly for those earning below 100 percent of the federal poverty level (FPL)(see Update for Weeks of January 26th and February 2nd). The director of the governor’s Office of Health Transformation acknowledges that approval of Ohio’s proposal would be unprecedented.

Governor Kasich had sought initially to impose a monthly \$20 premium to non-disabled adults earning more than 100 percent of FPL. House Republicans sought the broader approach contained in the budget, which the governor referred to as “a little clunky” but “in the right spirit.”

The Governor previously expanded Medicaid under the Affordable Care Act (ACA) over the objections of House Republicans (see Update for Week of October 21, 2013).

Utah

Medicaid expansion negotiations will slide past July 31st deadline

Governor Gary Herbert (R) and his working group of six Republican lawmakers acknowledged this week that they will miss their self-imposed July 31st deadline to develop a compromise plan that would expand Medicaid pursuant to the Affordable Care Act (ACA).

Utah is one of 21 states that are still refusing to participate in either a traditional ACA expansion or seek federal approval for an alternative plan. House Majority Leader Jim Dunnigan (R) and other working group members have been consulting with state officials in Arkansas and Indiana regarding their federally-approved alternatives that use ACA funds to purchase private coverage for those that the ACA makes newly-eligible for Medicaid. Governor Herbert (R) had offered a similar model through his Healthy Utah proposal last year that received tentative approval from the Obama Administration (see Update for Weeks of October 20th and 27th) and passed the Senate, but House conservatives are backing their far



leaner Utah Cares plan that includes a work requirement and is not likely to receive federal approval (see Update for Week of February 23rd).

A cost-benefit analysis of the two plans by the Notalys consulting group found that Healthy Utah would cover far more uninsured Utahns, thus recouping six times the return on investment compared to Utah Cares. However, Majority Leader Dunnigan dismissed the conclusions as “biased” since the study was commissioned by local non-profits and insisted that it would not factor into the group’s decision about which plan to pursue.