Health Reform Update –Week of August 4, 2014

CONGRESS

CBO predicts that 90 percent of uninsured will be exempt from individual mandate

The Congressional Budget Office (CBO) predicted this week that nearly 90 percent of the nation's 30 million uninsured will qualify for an exemption in 2016 to the controversial individual mandate under the Affordable Care Act (ACA).

Starting this year, all Americans are required to purchase minimum essential coverage that they can afford or pay a tax penalty. For the 2014 tax year, that penalty is limited only to the greater of $95 or one percent of an individual's taxable income. By 2016, it will be $695 or 2.5 percent of income.

However, there are now a total of 14 different exemptions to the mandate, including those set in statute for affordability or specific religious objections, as well as those later created by the Centers for Medicare and Medicaid Services (CMS). The latter includes exemptions for hardships such as domestic violence, deaths in the family, falling into the "coverage gap" in states that refuse to expand Medicaid, or technological glitches in Marketplace enrollment (see Update for December 16th-January 3rd).

According to CBO, the additional exemptions have significantly lowered the total number of Americans that can be subject to the tax penalty in 2016 (from six to four million). Overall, about 23 million Americans will remain exempt, resulting in the federal government collecting only $4 billion in penalty revenue instead of the $7 billion initially estimated by CBO.

CBO notes that the number of exempt Americans could rise even more dramatically if the U.S. Supreme Court ultimately declares ACA subsidies invalid in federally-facilitated Marketplaces (FFMs)(see Update for Week of July 21st). Roughly four million consumers receive subsidies through FFMs and many may qualify for an exemption if unsubsidized coverage costs them more than eight percent of their individual annual income.

FEDERAL AGENCIES

OIG flags suspicious use of HIV/AIDS drugs under Medicare Part D

A new report released this week by the Office of Inspector General (OIG) for the Department of Health and Human Services (HHS) identified $32 million in "questionable" HIV/AIDS drug costs paid by Medicare Part D during 2012.

Previous OIG reports have blamed lax oversight from the Centers for Medicare and Medicaid Services (CMS) for allowing Part D to be "vulnerable to fraud, waste, and abuse" that cost the taxpayers an estimated $65 billion in 2013. However, OIG notes that while their prior analyses cited "questionable" practices by pharmacies and prescribers, this report (OEI-02-11-00170) focused on utilization by consumers.

The OIG investigation flagged claims for 1,578 Part D enrollees that used HIV/AIDS drugs in 2012 (excluding Truvada for HIV prevention). It found that more than half had no identified diagnosis of HIV/AIDS, nor any records showing laboratory tests to monitor the use of the drugs or receipt of any medical services from the identified prescribers.

OIG concedes that some of the utilization may be legitimate but the aberrant utilization pattern warrants warrant further scrutiny. It also acknowledges that the amount of "questionable" activity involving HIV/AIDS drugs is very small compared to the overall usage of these medications (Medicare paid $2.8 billion to supply HIV/AIDS drugs to 135,500 enrollees in 2012.)

CMS largely agreed with OIG's recommendations to expand drug utilization review programs and oversight for both enrollees and plan sponsors. However, it insisted that only Congress could restrict certain enrollees to a limited number of pharmacies or providers and did not agree to OIG's recommendations to hinder an enrollee's ability to switch Part D plans.

CMS reports that 7.2 million have gained Medicaid/SCHIP coverage since October

Monthly data released this week by the Centers for Medicare and Medicaid Services (CMS) shows that at least 7.2 million Americans have gained Medicaid or State Children's Health Insurance Program (CHIP) coverage since the Affordable Care Act (ACA) Marketplace opened on October 1st.

The figures through June 2014 identify more than 66 million individuals that are now enrolled in both programs (not including Connecticut, Maine and North Dakota that failed to submit data). This represents a 12.4 percent increase since last fall, although CMS notes that states expanding Medicaid pursuant to the ACA experienced an 18.5 percent increase compared to only four percent in non-expansion states.

CMS also points out that Medicaid/SCHIP enrollment has jumped by more than 30 percent in nine states of the 24 states that expanded Medicaid by June (Arkansas, Colorado, Maryland, Nevada, Oregon, Rhode Island, Vermont, Washington, and West Virginia).

CMS delays website launch disclosing physician payments from manufacturers

The Centers for Medicare and Medicaid Services (CMS) announced this week that it will take the agency additional time to verify the accuracy of payment data being reported by drug and device manufacturers pursuant to the physician payment sunshine provisions of the Affordable Care Act (ACA).

Physicians had been allowed to register online until August 27th in order to review and challenge payment data attributed to them, before the website was to be opened to the public on September 30th. However, the American Medical Association and roughly 100 other professional groups have urged CMS to delay the launch by at least six months, insisting that the database contains not only numerous errors but that the information is misleading without appropriate "context" to avoid misrepresentations that can harm a physician's professional reputation. For example, grants provided to a physician in combination with other entities are currently made to appear as if the entire amount was received by the physician (see Update for Week of July 28th).

CMS has agreed to indefinitely take the database "offline" to investigate unspecified issues and pledged to give physicians at least 45 days to review and correct any outstanding errors once the database is back online.

FDA issues guidance on exclusivity period for brand-name biologics

The Food and Drug Administration (FDA) issued a guidance document this week defining how originator biologic sponsors can help the agency determine when to start the exclusivity period for a brand-name biologic.

The Affordable Care Act (ACA) created a new approval pathway for less costly biosimilar copies of brand-name biologics, but gave the reference product 12 years of exclusivity before the competing

product could be approved. Stakeholders and lawmakers have been pressuring FDA to clarify when the clock for this 12-year period could begin or when it would restart, as the ACA does not allow for a new 12-year period for changes such as a new indication, route of administration, or dosing schedule.

After soliciting industry input, the guidance stipulates that modifications to the structure of the reference product would warrant a new 12-year period only if it results in a change in safety, purity or potency. These would be evaluated on a "case-by-case basis" based on data submitted by the sponsor. Otherwise, exclusivity will typically start when the reference product was first licensed in the United States.

FDA notes that it is still reviewing options for how to make exclusivity determinations publicly available. It also stressed that these decisions might not always be based on when the product is licensed.

The guidance document comes in week of the first publicly-announced biosimilar application recently being accepted by FDA (see Update for Week of July 28th).

STATES

Study confirms that rural residents are paying more for ACA Marketplace coverage

An analysis released this week by the Robert Wood Johnson Foundation (RWJF) found that rural residents pay slightly higher premiums for mid-level coverage in the new health insurance Marketplaces created pursuant to the Affordable Care Act (ACA).

Researchers defined urban areas as those that include or are adjacent to a metropolitan area of at least 50,000 people. Under this definition, about 40 million urban residents purchased Marketplace coverage during the inaugural open enrollment period, compared to only 6.6 million in rural areas.

Many studies have previously documented that most rural areas had only 1-2 insurers offering Marketplace coverage. The Department of Health and Human Services (HHS) found that initial premiums were substantially higher in these areas, compared to those with more than two competing insurers.

The RWJF analysis determined that monthly premiums for rural residents average $387 for silver plans—the level to which ACA tax credits are tied. This compared to an average of $369 for urban residents. However, the disparity was greater in states where more than half their residents live in rural areas ($452 for rural residents compared to $402 in states where less than five percent of the population lived in rural areas).

This gap also varied dramatically by state. While 15 states had less than a $10 average difference in rural versus urban premiums, the gap widened to a $200 average in Nevada and $181 in Colorado, where rural counties had the highest average premiums in the nation (see Update for Week of June 2nd).

The higher premiums were directly correlated to fewer plan options offered to rural residents. On average, rural residents could choose from only 14 plans, instead of 17 in urban areas. Only 18 percent of rural counties also offered a less costly narrow-network option to rural residents, compared to 38 percent in urban areas.

Consumer groups weigh lawsuits against Medicaid programs that ration care for HCV "cure"

Consumer groups such as the Global Liver Institute announced plans this week to legally challenge state efforts to limit Medicaid coverage of Sovaldi to only the most severely-ill patients.

Illinois and Oregon are among the states that have already taken action to restrict coverage for the recently-approved "cure" for the Hepatitis C virus (HCV), due to the $84,000 cost per course of treatment that threatens to blow through the budget for most state Medicaid programs (see Update for Week of July 28th). The Global Liver Institute stated that they plan to file a lawsuit modeled on the recent effort by cystic fibrosis patients to block similar restrictions imposed by Arkansas Medicaid on a $300,000 treatment for the less common condition (see Update for Week of July 14th).

The National Association of Medicaid Directors urged consumer groups to direct their efforts to "fighting to reduce the price" for Sovaldi instead of legal challenges, insisting that the lawsuits "don't have a leg to stand on" from either a clinical or legal perspective. NAMD stressed that states have little alternative but to limit coverage given the wide range of patients that could be eligible for Sovaldi, as full coverage for the HCV drug would force them to otherwise pare down coverage for other benefits.

Members of Congress from both parties are demanding that Gilead Sciences provide data justifying the $84,000 cost, arguing that it initially projected Sovaldi would be profitable at $36,000 (see Update for Weeks of June 30th and July 7th). Furthermore, Gilead recently disclosed that Sovaldi would be sold at a mere fraction of that cost (only $900 per treatment) in countries such as Egypt and India.

California

Bill to limit prescription drug cost-sharing heads to Senate floor

The Senate Appropriations Committee passed A.B. 1917 this week, which would prohibit cost-sharing for a 30-day supply of any single prescription from exceeding 1/12 of the annual out-of-pocket limits set by the Affordable Care Act (ACA). For a drug that has a time-limited course of treatment of three months or less, this limit would be set at one-half of the annual out-of-pocket limit for the time-limited course of treatment.

The measure has already cleared the full Assembly and Senate Health Committee (see Update for Week of June 23rd) and is expected to receive a full Senate vote before the legislative deadline later this month.

A.B. 1917 would effectively spread out the cost-sharing for the highest tier specialty drugs over a full year instead of forcing consumers to pay all at once and is backed by consumer groups like Health Access California.

Colorado

Analysts predict only a slight rise in Marketplace premiums for 2015

Updated findings from Pricewaterhouse Coopers (PwC) show that premiums for the state-based Marketplace operated in Colorado could increase by only an average of 3.6 percent in 2015.

Of the 27 states that have already released rate filing data, the overall average rate hike is expected to be roughly 7.5 percent, with average monthly premiums before Affordable Care Act (ACA) subsidies of $384. Colorado's average pre-subsidy premium is expected to be significantly higher at $411. However, more than half of enrollees in Colorado's Marketplace currently receive ACA subsidies, which brought average 2014 premiums down to $277 per month.

If that proportion holds, PwC's review of rates sought by Colorado insurers showed only a modest increase when accounting for ACA subsidies, despite the wide variation in proposed premiums. For example, Denver Health sought a 17.5 percent average increase while the largest Marketplace insurer

(Kaiser Permanente) proposed a seven percent hike. However, two non-profit carriers are seeking 22 and ten percent average rate cut (see Update for Week of June 23rd).

The 3.6 percent average increase in Colorado would be lower than the 4.2 percent announced last week by Covered California (see Update for Week of July 28th). However, a previous PwC analysis of rate filings in 18 states showed that Rhode Island was likely to lead the nation with a one percent average decrease in premiums (see Update for Week of July 21st).

Insurance regulators in Colorado have until September to modify or reject proposed rate hikes.

Florida

Obama Administration disputes that Marketplace premiums will rise by 13 percent average

The Office of Insurance Regulation claimed this week that premiums for the Affordable Care Act (ACA) Marketplace operated in Florida will increase in 2015 by an average of 13 percent.

Among the 11 returning insurers from 2014, eight will increase average premiums from 11 percent to 23 percent (Health First Insurance), according to OIR. Florida Blue, the only carrier to offer coverage in every country, already disclosed last week that it will hike premiums by an average of 17.6 percent (see Update for Week of July 28th) while Humana's rates will jump by 14 percent on average. Three insurers (Aetna Health, Molina Healthcare of Florida, and Sunshine State Health Plan) will actually decrease premiums by an average of five to 12 percent.

The federally-facilitated Marketplace will have 14 total participants in 2015, with three new entrants including UnitedHealth Care.

The average monthly premium for a silver-level plan in Florida's Marketplace will range from $938 to $1,452 (before subsidies) for a family of four earning $51,000. According to the U.S. Department of Health and Human Services (HHS) , about 91 percent of Marketplace consumers in Florida received premium tax credits to offset an average of 80 percent of their 2014 premium cost.

HHS promptly challenged OIR's figures, insisting that the majority of Florida policyholders would actually experience premium decreases. The federal agency argued that it was "misleading" for state officials to average the premiums for all metal tiers because 73 percent of Florida consumers purchased the silver-level coverage to which the ACA's premium tax credits are tied.

When weighting the analysis based on the proportion of consumers purchasing each plan level, HHS found that 75 percent of silver-plan enrollees would see their premiums fall in 2015, including a 17 percent drop in the West Palm Beach area, 12 percent in Orlando, six percent in Miami, and 3-8 percent in counties surrounding Tampa Bay.

The public relations battle over rate increases is complicated in Florida by a new state law that suspended all rate review for two years and directed insurers to notify consumers how much of the resultant increases were due to the ACA (see Update for Week of June 17, 2013).

CMS approves three-year extension for Medicaid managed care demonstration

The Centers for Medicare and Medicaid Services (CMS) has formally approved a three-year extension of the federal demonstration waiver that allows Florida to move nearly all Medicaid enrollees into capitated managed care plans. The new waiver, which had already been tentatively approved (see Update for Weeks of April 28th and May 4th), will now last through June 30, 2017.

The Agency for Health Care Administration completed the transition to managed care last week for the final 13 counties. The initial five-county demonstration had been beset by so many complaints of

an erosion in access and quality of care that CMS imposed new safeguards before allowing a statewide expansion that was enacted in 2011 (see Update for Week of June 17, 2013).

The waiver also extends the Low Income Pool (LIP) for one year, which funnels extra money to hospitals and other health providers that serve large numbers of low-income and uninsured patients. However, CMS' approval is contingent upon Florida moving away from the LIP after June 30, 2015. This deadline is expected to put additional pressure on state lawmakers to expand Medicaid under the Affordable Care Act, as federal disproportionate share funding for indigent care will also start to be phased down in future years (see Update for Week of March 31st).

Illinois

Insurance department makes health insurance rate filings publicly accessible

The Department of Insurance (DOI) announced this week that consumers will now have "direct access to review rate and form filings" so that they can view the justification relied upon by health insurers for increases or decreases in health insurance premiums.

The move was largely praised by consumer advocates, who had been seeking greater transparency in Illinois' rate review process for years. However, they criticized DOI for simply allowing consumers to search through technical lingo and minutia via an online tool provided by the National Association of Insurance Commissioners (NAIC). Instead, they urged DOI to follow Oregon's lead and release the information in a more consumer-friendly format.

DOI insisted that making the actuarial data for rate increases publicly accessible would help foster a "competitive" insurance marketplace, since Illinois regulators lack the authority to modify or reject excessive rate hikes. Under the Affordable Care Act (ACA), they can publicize the data to "shame" insurers that they believe has filed for an "unreasonable" increase of at least ten percent (see Update for Week of August 29, 2011).

Massachusetts

ACA Marketplace will remain under state control for 2015

The office of Governor Deval Patrick (D) announced this week that the federal Centers for Medicare and Medicaid Services (CMS) has approved the commonwealth's plan to keep the Massachusetts Health Connector under state control instead of defaulting to federally-facilitated Marketplace (FFM) for 2015.

Massachusetts was among five state-based Marketplaces (SBM) that scrapped their initial software after persistent technological glitches went uncorrected (see Update for Weeks of April 28th and May 5th). The Connector enrolled only about 32,000 consumers in private plans during the inaugural enrollment period and ranked as one of the worst performing Marketplaces nationwide. Its failure was particularly embarrassing for Massachusetts given that the Connector was first created in 2007 and became the model for all Affordable Care Act (ACA) Marketplaces.

The Patrick Administration elected to replace the information technology infrastructure will new software built by hCentive, which also developed successful state-based Marketplaces (SBMs) for Colorado, Kentucky, and New York. Massachusetts was one of seven SBMs including neighboring Vermont (see below) that relied on the same contractor (CGI Federal) that botched the rollout of the FFMs (see Update for Week of February 17th).

The commonwealth had prepared contingency plans to default to the FFM should hCentive software not be ready before the November 15th start of open enrollment for 2015. However, the Patrick Administration insists that the software passed the "rigorous system testing" required to obtain CMS approval to remain under state control (see Update for Week of July 16th).

A spokesperson for the Governor states that the capability of the Connector now exceeds that of the FFM, as it has automated its interface with billing and enrollment vendors responsible for conducting transactions between Marketplace consumers and insurers. In addition, hCentive now supports State Wrap, the unique Massachusetts program that offers additional state-funded premium assistance beyond that provided by the ACA. The State Wrap program is credited for helping Massachusetts continue to lead the nation with an insured rate of more than 97 percent.

Mississippi

One of two participating Marketplace insurers to lower premiums by 25 percent

Insurance Commissioner Mike Chaney (R) announced this week that Magnolia Health Plan will reduce it premiums in the Affordable Care Act (ACA) Marketplace by 25 percent for 2015, after over-estimating its costs during the inaugural open enrollment period.

The staggering drop could stand at the largest in the nation and is a stark contrast to the six percent average hike in premiums sought by Humana, the only other insurer offering plans in Mississippi's federally-facilitated Marketplace (FFM). The lack of competition caused the Marketplace to have the second highest premiums in the nation for 2014, as both insurers competed directly in only four counties.

The commissioner attributed the high premiums to the fact that only 62,000 consumers signed-up for private Marketplace coverage.

New Hampshire

Insurance department required to accept public comments before approving Marketplace plans

Governor Maggie Hassan (D) signed legislation last month that requires the Department of Insurance to hold a public information session and public comment period before approving any qualified health plans to participate in the state partnership Marketplace created pursuant to the Affordable Care Act (ACA). S.B. 340 goes into effect on August 10th.

Vermont

Vermont dumps contractor responsible for continued flaws in Marketplace web portal

Vermont became the latest state this week to remove CGI Federal as the lead contractor for its state-based Marketplace (SBM) created pursuant to the Affordable Care Act (ACA).

CGI Federal was largely blamed for the failed rollout of the web portal used by the 36 federally-facilitated Marketplaces (FFMs), as well as software flaws that plagued seven SBMs that it also constructed (see Update for Week of January 13th). After an independent review ordered by Governor Peter Shumlin (D), the Health Care Reform office has hired Optum to fix the continued problems with Vermont Health Connect, although CGI will continue to host the website.

The Chief of the Health Care Reform office also announced that Vermont will apply to extend approximately $99 million in its remaining federal exchange establishment grants before the December 31st deadline.

Washington

Marketplace consumers will temporarily be able to pay premiums directly to insurers

Governor Jay Inslee (D) and Insurance Commissioner Mike Kreidler (D) announced this week that consumers in the Washington Healthplanfinder will temporarily be able to purchase coverage directly from participating insurers.

The commissioner had pledged to give consumers in the state-based Marketplace created by the Affordable Care Act such a direct purchase option if outstanding technical glitches were not resolved by August 1st. These problems have prevented some premium payments from reaching applicable insurers, causing roughly three percent of paid subscribers to languish without coverage (see Update for Week of July 28th).

Healthplanfinder officials promised that all coverage will be effective from the proper start dates, even if premium payments have not immediately been sent to or received by the insurer. The commissioner has directed all participating insurers to accept premium payments from subscribers.

Neither the commissioner nor the Healthplanfinder set a termination date for the direct payment option. However, Healthplanfinder officials did state that fixing the payment glitches remains their "top priority" and that they expect to make "significant progress by the end of August."

Several Republican lawmakers have threatened to challenge the commissioner's authority to create the direct payment option.