Highmark's Weekly Capitol Hill Report

Issues for the week ending September 9, 2022

Federal Issues

Regulatory

Updated COVID-19 Vaccine Shot and Plans to Manage COVID-19 this Fall

The Biden Administration announced its plan for getting the updated COVID-19 vaccine to Americans this fall.

Why this matters: The Administration's plan centers on getting Americans the best available protection through free and easy access to new, updated COVID-19 vaccines, ensuring Americans continue to have easy access to COVID-19 testing and treatments, and calling on all Americans to use every tool at their disposal to keep communities safe and schools and businesses open.

Key elements of the plan include:

- Helping people get their COVID-19 shot and flu shot at the **same time in one place**.
- Purchasing **more at-home COVID-19 tests** for the nation's stockpile and bolstering the manufacturing of tests made in America.
- Investing in **testing innovations for at-home tests** accessible to people with disabilities, and

In this Issue:

for next-generation, high-performance COVID-19 rapid tests.

- Strengthening our national readiness and preparedness to respond to whatever may come through **federal table-top preparedness exercises.**

- Calling on Congress to **provide additional COVID-19 funding** to meet critical needs.

- Planning to eventually **transition procurement and distribution of COVID-19 vaccines, tests, treatments to the commercial market.**

Court Issues Ruling on Preventative Services Coverage

Judge Reed O'Connor of the U.S. District Court for the Northern District of Texas issued a decision in *Kelley v. Becerra* finding that a U.S. Preventative Services Task Force (USPSTF) recommendation related to pre-exposure prophylaxis (PrEP) and its corresponding coverage mandate under the Affordable Care Act (ACA) violates the Religious Freedom Restoration Act (RFRA). In making its ruling, which applied to just one claim brought by one of several plaintiffs (Braidwood Management), the court emphasized HHS had failed to articulate how mandating coverage for PrEP furthers a compelling governmental interest or to demonstrate that a mandate is the least restrictive means of furthering any such interest.

Why this matters: The ruling may have far more sweeping implications for whether insurers will have to continue offering a range of no-cost preventive health services, as required by the ACA since 2010. Separately, the court ruled that the USPSTF violates the Appointments Clause of the Constitution. However, it remains unclear what the precise scope of relief will be in that ruling.

Background: A recent estimate from the U.S. Department of Health and Human Services found that more than 150 million people with private health insurance (all non-grandfathered private health plans—including individual, small group, and large group health plans) had access to such free, preventative care in 2020.

What's next? The parties were expected to file a joint status report by Friday, September 9, outlining any remaining issues and to propose a briefing schedule. The case is likely to be appealed to the 5th U.S. Circuit Court of Appeals.

There are also several still unresolved claims raised by other plaintiffs regarding coverage for other mandated preventive services, including contraceptive coverage. The court has reserved ruling on additional issues until the parties have had an opportunity to submit further briefing.

OIG Reports Suggest Minimal Medicare Telehealth Fraud & Urban Beneficiaries More Likely to Use Telehealth

On Friday September 2, the Department of Health and Human Services Office of Inspector General released two reports on telehealth use during the pandemic.

One report titled **"Medicare Telehealth Services During the First Year of the Pandemic: Program Integrity Risks"** evaluated telehealth utilization and high-risk provider billing for telehealth services during the first year of the pandemic. This data brief was based on Medicare fee-for-service claims and Medicare Advantage encounter data from March 1, 2020, to February 28, 2021. They found 28 million – about 2 in 5 – Medicare beneficiaries used telehealth services and beneficiaries used 88 times more telehealth services during the first year of the pandemic than they did in the prior year. They identified a small number of providers (1714 providers out of the 742000) billed Medicare inappropriately for telehealth services, underscoring the success of the protections put in place to prevent fraud, waste, and abuse. **The study recommends CMS:**

1. strengthen monitoring and targeted oversight of telehealth service
2. provide additional education to providers on appropriate billing for telehealth services
3. improve the transparency of "incident to" services when clinical staff primarily delivered the telehealth service
4. identify telehealth companies that bill Medicare
5. follow up on the providers identified in this report

The second, companion report, titled **Certain Medicare Beneficiaries, Such as Urban and Hispanic Beneficiaries, Were More Likely Than Others to Use Telehealth During the First Year of the COVID-19 Pandemic** examined how the temporary telehealth flexibilities improved access to telehealth for Medicare beneficiaries, particularly for those who are medically underserved. They found in total, 45 percent of beneficiaries in urban areas used telehealth during the first year of the pandemic, while only 33% of beneficiaries in rural areas used telehealth. Also, older beneficiaries were more likely to use audio-only services, as were dually eligible and Hispanic beneficiaries. **As the federal government considers permanent changes to Medicare telehealth services, OIG recommends CMS:**

1. take appropriate steps to enable a successful transition from current pandemic-related flexibilities to well-considered long-term policies for the use of telehealth for beneficiaries in urban areas and from the beneficiary's home
2. temporarily extend the use of audio-only telehealth services and evaluate their impact
3. require a modifier to identify all audio-only telehealth services provided in Medicare
4. use telehealth to advance health care equity

CMS Issues New Request for Information on Promoting Efficiency, Reducing Burden, and Advancing Equity

On September 6, CMS issued a request for information (RFI), titled the "Make Your Voice Heard" RFI. The RFI seeks public input on accessing healthcare and related challenges, understanding provider experiences, advancing health equity, and assessing the impact of waivers and flexibilities provided in response to the COVID-19 Public Health Emergency. CMS is specifically requesting information related to strategies that successfully address drivers of health inequities, including opportunities to address social determinants of health and challenges underserved communities face in accessing comprehensive, quality care. CMS is also seeking better understand the factors impacting provider wellness and learn more about the distribution of the healthcare workforce. Comments received in response to the Make Your Voice Heard RFI will be used to identify opportunities for improvement and to increase efficiencies across CMS programs.

Report on Coverage Considerations for COVID-19 Vaccines and Treatments

Last week, the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) published a report detailing coverage considerations for the commercialization of COVID-19 vaccines and treatments, following the announcement that the Federal government is beginning the process of transitioning purchases of vaccines and treatments to the commercial market.

The report provides:

1. An overview of the current coverage and payment of COVID-19 vaccines and treatments;
2. Key considerations for coverage determinations post-PHE;
3. Cost-benefit analysis of covering certain COVID-19 vaccines and treatments; and
4. Potential next steps for health insurance providers as they navigate the coverage and payment process.

Discussion & Recommendations

Based on their analysis, ASPE recommends health insurance providers cover COVID-19 vaccines and treatments to prevent increased costs from unnecessary hospitalizations and protect the health of the population. The report also recommends health insurance providers start coverage decision-making before the government-provided supply of vaccines and treatments run out, or as soon as possible. Furthermore, health insurance providers should start their own coverage determination processes prior to FDA approval to prevent potential gaps in coverage.

Interested in reviewing a copy of a bill(s)? Access the following web sites:

Delaware State Legislation: **http://legis.delaware.gov/.**
New York Legislation: **https://nyassembly.gov/leg/**
Pennsylvania Legislation: **www.legis.state.pa.us.**
West Virginia Legislation: **http://www.legis.state.wv.us/**
For copies of congressional bills, access the Thomas website – **http://thomas.loc.gov/.**