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SELLERS DORSEY DIGEST

Issue 10 | November 19, 2020

NAVIGATION

Summary of Key Updates

The COVID-19 public health emergency (PHE) declaration tied to regulatory flexibilities is set to expire on January 20, 2021 (Inauguration Day), unless the Trump Administration chooses to renew the declaration ahead of time. If the Trump administration does not act to renew the PHE, the Biden administration could choose to make it one of its first health care priorities after being sworn in. When the PHE expires, the following policies will also end:

- Medicare inpatient 20% add-on payment for COVID-19 patients
- Increased Medicaid FMAP and maintenance of effort
- Coverage of COVID-19 testing and treatment without cost-sharing
- Section 1135 waivers and the Medicaid disaster SPAs
- Telehealth flexibilities (Modern Healthcare, November 13)

The expiration of the PHE can impact other important flexibilities, such as Section 1135 waivers and Medicaid disaster-relief state plan amendments (SPAs).

CMS announced Medicare beneficiaries can receive coverage for monoclonal antibodies to treat COVID-19 with no-cost sharing during the PHE. Medicare will not pay for the monoclonal antibody products providers receive for free, but Medicare will reimburse for infusion of the product. CMS anticipates it will set reimbursement at 95% of the average wholesale price for COVID-19 vaccines. Detailed billing guidance can be found here (CMS, November 13).

President-elect Joe Biden chose Ronald A. Klain as his White House Chief of Staff. Klain previously served as a top aide to Biden when he was chairman of the Senate Judiciary Committee and ran Biden's office when Biden was vice president (The Washington Post, November 10).

Congress approved $150 billion in relief funding for state and local governments back in March; however multiple reports show the funding has been slow to be distributed. Many local governments are struggling to provide these relief dollars to residents as evolving rules from the Treasury Department have made the process more difficult. Many leaders are advocating for Congress to extend the deadline for distribution past December 30, at which time any unused funds must be returned to the federal government (The Washington Post, November 15).

From November 10 through November 17, CMS approved two 1915 (c) Appendix K waivers and five SPAs, including two time-limited COVID-19 disaster relief response SPAs.

Federal Updates

News

- In a November opinion piece in *Modern Healthcare*, Jeff Micklos of the Health Care Transformation Task Force rejected CMS Administrator Seema Verma's recent claim that value-based reimbursement models, particularly as construed under multiple initiatives funded by the Centers for Medicare and Medicaid Innovation (CMMI), needed significant "course correction." Micklos contends that not all systemic transformation can be easily quantified and that better evaluation methods are needed to capture work that is underway. He also argues that the focus on the specific savings attributable to each CMMI model misses the larger industry shift toward value-based care, which he asserts has saved billions of dollars. He urges policy makers to focus on the big picture of health care system transformation and points to the need to "cheer on" the advances being made.
- Lowering the eligibility age for Medicare from 65 to 60 is one of President-elect Joe Biden's priorities in addressing health care reform. However, he is likely to face opposition from hospitals as they worry the addition of these newly eligible beneficiaries will cost them billions of dollars in revenue. The reimbursement rate for Medicare patients admitted to hospitals are on average half of what commercial or employer-sponsored health plans pay. According to Cristina Boccuti, Director of Health Policy at West Health, those between 60-65 have the highest health costs and pay the highest rates for individual coverage. Employers providing health coverage could save on health costs because of this change, as would states due to the likelihood of Medicare becoming the primary insurer over Medicaid for certain individuals (Modern Healthcare, November 11).
- As reported by *Modern Healthcare* on November 11, Pennsylvania-based Tower Health is considering selling off its five hospitals, acquired in 2017 from Community Health Systems, as it looks to stem significant financial losses. The company posted a -22.9% margin in fiscal year 2020, although the company had already been losing money before the pandemic.

Federal Regulations

- In its lame duck session, the Trump administration continues to chip away at its regulatory agenda and currently has the OMB reviewing 17 regulations. The proposed rules include changes around severing the ties between collecting social security and participating in Medicare Part A, and a rule on third-party dialysis payments. Democratic stakeholders are concerned about the "midnight regulations" and that the Trump administration will attempt to roll back health protections before leaving office (Inside Health Policy, November 16).
- CMS published a notice announcing the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for CY21 under Medicare Part A. Under the statutory formula, the deductible for CY21 will be $1,484 and the daily coinsurance will be $371 for the 61st through 90th day of hospitalization in the benefit period, $742 for lifetime reserve days, and $185.50 for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period (Federal Register, November 12).

Letters

- In a November 13 letter to HHS, a group of 217 members of Congress expressed concern about the 340B Program. Specifically, the letter cites reports that a third-party vendor called Kalderos "is working with pharmaceutical manufacturers seeking to change how covered entities receive 340B drugs by shifting from a discount to a rebate formula." The letter urges Secretary Azar to take action to ensure manufacturers do not implement new rebate models without Health Resources and Services Administration (HRSA) approval.

- In a November 12 letter to HHS, CMS, IRS, and the Department of Treasury, five members of Congress expressed their disapproval over the recent approval of Georgia's Section 1115 and Section 1332 waivers, which impose work requirements as a condition for Medicaid eligibility for certain beneficiaries and allows the state to exit the federally-facilitated health care marketplace. The authors contend the waivers will impede access to care and violate federal law. The authors also urge administration officials to rescind the 1115 and 1332 approvals.

COVID-19

- An independent data and safety monitoring board (DSMB) overseeing the Phase 3 trial of Moderna's COVID-19 vaccine found the vaccine is safe and effective in preventing symptomatic COVID-19 among volunteers with a 94.5% efficacy rate. This vaccine, the mRNA-1273, was co-developed by Moderna and the National Institute of Allergy and Infectious Disease (NIAID) (NIH.gov, November 16).
- HHS has reached an agreement with major chain drug stores, grocery market pharmacies, and other chains and networks covering about 60% of pharmacies nationally and in Puerto Rico, to distribute free COVID-19 vaccines after they are approved and made publicly available. The initial vaccine supply will be limited and distributed to states for them to allocate to priority groups such as health care workers and first responders (AP, November 12).
- The FDA cleared the first antibody drug (from Eli Lily) for people 12 years of age and older with mild to moderate COVID-19 symptoms not requiring hospitalization. The drug is a one-time treatment given through an IV. Typically, the FDA requires "substantial evidence" to show a drug is safe and effective through one or more studies. However, during a PHE, the agency can, and has, lowered its standards and requires only that the drug's potential benefits outweighs its risk (Modern Healthcare, November 9).
- A new study in the Journal of General Internal Medicine found COVID-19 diagnostic test pricing ranges from one penny up to $14,750; for comparison, Medicare's rate is $51. While the CARES Act caps the prices out-of-network insurers pay for COVID-19 tests at the provider's publicly listed cash charge, the law does not place any similar caps on providers in determining their testing price. This does not have an immediate impact on consumers as providers cannot balance bill them for the test, but costs are ultimately passed down as consumers do end up seeing higher premiums and out-of-pocket costs (Modern Healthcare, September 15).

Waivers

- Section 1915(c) Appendix K
    - Washington
        - Extend waiver reporting deadlines
        - Allow electronic public notice
        - Allow non-traditional providers for home-delivered meals
    - Louisiana (Hurricanes Laura, Delta, and Zeta)
        - Temporarily exceed service limitations
        - Temporarily expand service settings
        - Temporarily provide services in out-of-state settings
        - Temporarily modify level of care processes

SPAs

- Traditional SPAs
    - California (CA-20-0035): Allows nurse practitioners, clinical nurse specialists and physician assistants to order home health services, including durable medical equipment (DME) and

medical supplies within their scope of practice. This SPA has an effective date of October 1, 2020.

  - Massachusetts (MA-20-0005): Updates methods used to determine rates of payment for community health centers. This SPA has an effective date of January 1, 2020.
  - Mississippi (MS-20-0021): Updates the out-of-state transplant rates as published in the Milliman U.S. Organ and Tissue Transplant Cost Estimates and Discussion. This SPA has an effective date of July 1, 2020.

- COVID-19 Disaster Relief SPAs
  - Missouri (MO-20-0021): Waives the requirement for technicians delivering applied behavioral analysis (ABA) services to have the Registered Behavior Technician Credential due to testing center closure or delay related to COVID-19. This time-limited COVID-19 response SPA has an effective date of March 1, 2020.
  - Oregon (OR-20-0017): Reimburses providers for interpreters required for limited and non-English speaking members and/or deaf/hard of hearing members when the services are necessary and reasonable to communicate effectively with members regarding health needs. This time-limited COVID-19 response SPA has an effective date of September 8, 2020.

State Updates

Click here to view Sellers Dorsey's state budget tracking summaries.

- The Texas Health and Human Services Commission (HHSC) scheduled a series of "pre-solicitation" meetings with potential health plans interested in the upcoming STAR Health managed care procurement for children in foster care. The meetings are scheduled for November 12 – November 20.
- New Jersey lawmakers are trying to protect a long-standing bistate tax agreement between southern New Jersey and Pennsylvania. The agreement allows commuters from each state to pay income taxes where they live instead of where they work, which has been praised as a key economic-development tool by South Jersey businesses. The tax deal is considered to be a "net loser" to New Jersey's budget, and can be eliminated with 120 days' notice from either state governor. Although New Jersey Governor Murphy has not indicated he will terminate the deal, last week members of the New Jersey Senate Budget and Appropriations Committee unanimously voted on legislation that would allow state lawmakers to block the governor from taking unilateral action on the reciprocal agreement (NJ Spotlight).
- Over the weekend of November 14-15, Washington reported a consistent increase in daily COVID-19 cases with over 2,000 per day. On November 15, Governor Inslee announced a four-week statewide set of restrictions as a response to the spread of COVID-19. These restrictions are effective Monday, November 16 at 11:59 PM and extend through Monday, December 14. The State of Washington has committed $50 million in aid to mitigate the financial impacts on businesses and their employees. In the near term, the state will focus $20 million in cash assistance for the hardest hit industries.

Private Sector Updates

Insurer Industry Updates

- CMS data published on November 13 indicates more than 11.2 million people will qualify for nearly $2.5 billion in medical loss ratio (MLR) rebates from their insurer this year, which is an increase of more than $1 billion from the year before. Marketplace plans, in part, overestimated their administrative costs after Congress repealed the Affordable Care Act (ACA) individual mandate, and the Trump administration froze payments to insurers to reduce out-of-pocket costs for low-income exchange beneficiaries. Plans can expect to pay larger MLR rebates for next year due to foregone care during the COVID-19 pandemic,

since the MLR calculation is based on the previous three-year average of insurers' spending. However, as MLR calculations start to consider 2020 and potentially 2021 utilization, insurers will likely have a much easier time reaching the MLR thresholds (Modern Healthcare, November 11).

- An Urban Institute study found the uninsured rate has remained fairly stable through the COVID-19 pandemic, despite approximately 3.1 million adults losing their employer-sponsored insurance in the same time period. Among adults who have lost their jobs since March, employer-sponsored insurance coverage dropped by 7.9%, but Medicaid/CHIP coverage increased by 4% and non-group coverage increased by 3.2% (Inside Health Policy, November 11).

Health Plans

- The Franklin County Circuit Judge who previously granted injunctive relief to Anthem allowing the company to re-enter the Kentucky Medicaid managed care program pending further review of the case has now ordered Anthem and the five other contract winners and the government of Kentucky to select a mediator and schedule negotiations within the next 30 days. This order comes days after UnitedHealth Group filed a lawsuit requesting Anthem and Molina Healthcare be removed from the $8 billion Kentucky Medicaid contract. The Medicaid contracts are slated to begin January 1, 2021 (Health Payer Specialist, November 16).
- Humana's CFO Brian Kane announced Humana was planning to participate in upcoming Medicaid bidding rounds, as he sees investment and acquisition potential in Medicaid. Humana was one of the payers contracted by Kentucky for an $8 billion Medicaid program. Currently, Humana and Centene are re-competing for the new Department of Defense managed care contract that will cover more than nine million military-related enrollees (Health Payer Specialist, November 16).
- Optum, part of UnitedHealth Group, has teamed up with Johnson & Johnson (J&J) to assist with COVID-19 vaccine trials. Optum will use data to help J&J recruit 60,000 trial participants in COVID-19 hot spots. J&J told Bloomberg that the partnership with Optum might enable the trial to develop results sooner than expected (Health Payer Specialist, November 13).
- Aetna announced it is expanding a new health plan to Texas in 2021 that offers free care at CVS clinics and discounted premiums. The new plan, called the Aetna Connected Plan, is a partnership with CVS Health. The plan will help members manage their chronic conditions at CVS HealthHUBs and will not require copayments at CVS clinics, including HealthHUBs and Minute Clinics. The premiums will be 10% lower than those of its competitors. Additionally, the plan will offer a 20% discount on some of CVS' drug store products and offer free prescription drug delivery (Health Payer Specialist, November 12).

Sellers Dorsey Updates

- Check out our recent Q&A with John Benz, Senior Consultant, who is a former hospital executive and has over 40 years of experience in the health care industry. Learn more about John and his recent work here.
- Sellers Dorsey is grateful to have been able to participate in and sponsor Learn Serve Lead 2020, AAMC's annual meeting which took place this week. Academic medicine has faced unprecedented challenges during 2020, and there is much to learn and accomplish as we move forward. This event addresses a vital need to connect leaders in academic medicine from across the country, and we wish to express our thanks for the organizers who orchestrated this virtual experience.
- Sellers Dorsey has a keen understanding of the impact of federal policy on state operations and the related implications for Medicaid providers. Our considerable experience has taught us that every state environment is different and requires nuanced solutions to meet regional needs as well as federal regulations. From state Medicaid agencies to large health systems, managed-care organizations, safety-

net providers, and even private equity firms, Sellers Dorsey has worked with and for clients to tackle a broad range of issues on all sides of Medicaid. Read about our client successes here.

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