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NAVIGATION

Summary of Key Updates

On December 11, President Trump signed a continuing resolution that extends government spending one more week through December 18 before another potential federal government shutdown. Congress is aware of the looming expiration of government funding, but thought they could use the spending bill to pass a broader COVID-19 economic relief package (The Washington Post, December 11).

- After Republicans and Democrats refused to support measures included in the $908 billion relief package proposed by bipartisan lawmakers, they now appear to be nearing a deal that would include a second round of stimulus payments and additional unemployment benefits but excludes additional funding for state and local governments and coronavirus liability protections (NYT, December 17).

On December 10, CMS released proposed rule CMS-9123-P which aims to "improve the electronic exchange of health care data among payers, providers, and patients, and streamline processes related to prior authorization to reduce burden on providers and patients" (CMS, December 10).

Democratic states and consumer advocates are urging the Supreme Court not to review a lower court's ruling that paused the Trump administration's public charge policy that denies green cards for immigrants who could benefit from public programs such as Medicaid. Stakeholders believe President-elect Biden is likely to overturn the public charge policy. The Trump administration would like SCOTUS to consider the case at its January 8 conference, noting the Biden administration would have to go through a notice-and-comment process to change the policy. Most recently, the full Court of Appeals for the Fourth Circuit agreed to rehear a three-judge panel's decision that reversed the lower court's injunction on the Trump administration's policy (Inside Health Policy, December 11).

On December 11, the American Hospital Association, along with five other provider associations, filed suit against HHS regarding the agency's enforcement of 340B drug pricing program requirements (Modern Healthcare, December 12; American Hospital Association, December 11).

From December 8 through December 15, CMS approved one Section 1115 waiver, one Section 1135 waiver, one Section 1915(c) Appendix K waiver, and six SPAs, four of which are time-limited, COVID-19 disaster relief SPAs. Note: one Illinois SPA rescinds a previously authorized COVID-19 flexibility.

Federal Updates

News

- Beginning January 8, 2021, HHS will require hospitals to report weekly on COVID-19 therapeutic stock and usage. The requirement, which was included in the recent interim final outpatient prospective payment rule, applies to treatments like the Regeneron antibody cocktail distributed by HHS (Inside Health Policy, December 14).
- Following the Food and Drug Administration's December 11 emergency use approval for the Pfizer COVID-19 vaccine, delivery of initial doses of the vaccine are expected at 636 vaccination sites on December 16. The second dose will ship to these sites 21 days later. Gustave Perna, speaking on behalf of the government's Operation Warp Speed, says he expects 40 million doses will be available by the end of December. Many states have announced distribution plans prioritizing front-line health care workers and residents of long-term care facilities (Inside Health Policy, December 12; FDA, December 11).
- On December 10, CMS released guidance describing best practices for states designing substance use disorder treatment programs under the Section 1945 of the Social Security Act related to the health home state plan amendment option. The guidance describes lessons learned based on the experiences of five states: Maine, Maryland, Michigan, Rhode Island, and Vermont (CMS, December 10).
- A draft COVID-19 relief framework authored by a bipartisan group of lawmakers circulated on December 9 and includes $35 billion in new relief money for providers. The grant funds would include $7 billion for rural providers and $1 billion for tribal organizations. The framework also contains changes to reporting requirements and additional flexibilities regarding moving grant funds within health systems (Modern Healthcare, December 9).

Biden Administration

- President-elect Joe Biden continues to build his governing team with a focus on nominating Obama-era individuals and longtime allies rather than new faces from the next generation of Democratic leaders. The nominations signal the incoming Administration is relying more on established figures, passing on some diverse individuals as well as subject matter experts (The Washington Post, December 10).
    - Biden selects Pete Buttigieg, former presidential opponent and former mayor of South Bend, Indiana, to be his Transportation Secretary (NYT, December 15).
- The Kaiser Family Foundation (KFF) released a brief outlining the potential administrative actions the incoming Biden Administration could undertake. Without majority support from the Senate, President-elect Biden will face challenges passing his major health care proposals, such as a public option and lowering the age for Medicare to 60. Through executive branch authority, however, Biden could move forward a variety of policy changes he advocated. Topics outlined in the brief include responses to the COVID-19 emergency, such as extending the increased FMAP due to the public health emergency (PHE), the Affordable Care Act (ACA) exchange markets and private insurance, Medicaid work requirements, long term care, and mental health (KFF, December 8).

Federal Regulations

- On December 10, CMS released proposed rule CMS-9123-P which would improve electronic exchange of health care data among payers, providers, and patients. The proposed rule is not yet in the Federal Register. Stakeholders have until 5 PM on January 4, 2021 to submit comments. The proposed rule, which builds on CMS' earlier Interoperability Rule, includes the following requirements and provisions, most of which would be effective January 1, 2023:

  - Impacted payers must include information about a patient's pending and active prior authorization decisions in the Patient Access application program interface (API).
  - Impacted payers must build a Provider Access API for payer-to-payer data sharing.
  - Allow providers to look up prior authorization requirements within a payer's API.
  - Electronic prior authorization workflow requirements.
  - Payers must include denial reason on prior authorization requests.
  - Payers (not including QHPs) must send prior authorization decisions within 72 hours for urgent requests and 7 calendar days for standard requests.
  - Payers must publicly report prior authorization metrics.
  - Several requests for information about data exchanges and information sharing (CMS, December 10; CMS, December 10; CMS, December 10; Modern Healthcare, December 10).

- HHS finalized a rule clarifying courts can allow disclosure of confidential communications between patients and substance abuse treatment programs if the communications aid the investigation or prosecution of serious crimes. The final rule corrects a 2017 rule that implemented privacy protection for substance use disorder information, and in the process, blocked information that could help criminal investigations. The rule now relies on the original language HHS used before the 2017 change (Modern Healthcare, December 11).
- On December 10, HHS released proposed regulations amending federal HIPAA requirements. In its press release, HHS characterizes the proposed rule as an effort to "support individuals' engagement in their care, remove barriers to coordinated care, and reduce regulatory burdens on the health care industry." The proposal would allow greater flexibility around information sharing in emergency situations and would make it easier for providers to disclose certain information for family members and other caregivers (HHS, December 10; Modern Healthcare, December 10; HHS, December 10).
- The Trump Administration signed off on a dispute resolution process for the 340B drug discount program, shortly after Community Health Centers sued to force HHS to expedite creating such a process. Under the final rule, the 340B Administrative Dispute Resolution Board will have at least six members – including representation from Health Resources and Services Administration (HRSA), CMS, and HRSA's Office of General Counsel. For each dispute, three of the members will form a panel to review claims by covered entities and manufacturers. The ACA originally directed HHS to establish this process, but the agency did not implement the process until directed by the courts (Modern Healthcare, December 10).
- HHS' latest application of the Public Readiness and Emergency Preparedness (PREP) Act allows doctors to provide certain COVID-19 pandemic-related services via telehealth across state lines, essentially preempting state-specific licensure regulations. The PREP Act Authorizes HHS to provide immunity from liability in certain circumstances, precluding state and local governments from enforcing prohibitions that would keep "qualified persons" from administering countermeasures recommended by a PREP Act declaration. Interstate service provision is allowed when it is a legitimate countermeasure, or else the provider still must maintain a license in the state where the patient is located (Inside Health Policy, December 9).

Federal Legislation

- Surprise Billing legislation has become more provider-friendly as House Ways & Means Committee Chair Richard Neal (D-MA) secured buy-in around an arbitration-driven provision in the legislation. If passed, the bill would hold patients harmless from surprise medical bills by ensuring they are only responsible for the in-network payment rates. Two arbiters would lead dispute resolutions between providers and payers where arbiters would consider median in-network rates and the complexity of services delivered.

The bill also contains a complete ban on air ambulance surprise billing. Lawmakers hope to pass the bill by the end of this year (Inside Health Policy, December 11).

Federal Litigation

- On December 9, the Supreme Court ruled the Employee Retirement Income Security Act (ERISA) does not preempt state laws allowing state regulation of pharmacy benefit managers (PBMs). The ruling upholds an Arkansas state law that regulates rates at which PBMs reimburse pharmacies. The law referenced ERISA in authorizing such regulations. The Court of Appeals for the Eighth Circuit ruled ERISA preempts the state law because it both "related to" and "had a connection with" ERISA-governed employee benefits plans, and moreover made "implicit reference" to ERISA since PBMs administer ERISA plan benefits. The Supreme Court disagreed with the Eighth Circuit and instead found the Arkansas statute amounts to a "cost regulation" and does not "refer to" ERISA since the law applies equally to all PBMs, regardless of whether they administer any ERISA plans. Instead, the law "simply establishes a floor for the cost of the benefits that plans choose to provide." This ruling could lead to additional, state-driven PBM regulation; currently, 40 states regulate some aspect of PBM activity (National Law Review, December 14).
- On December 11, the American Hospital Association, along with five other provider associations, filed suit against HHS regarding the agency's enforcement of 340B drug pricing program requirements. The complaint, filed in the Northern District of California, alleges drug manufacturers have refused to provide 340B program discounts and seeks to require HHS to enforce 340B program rules and require drug companies to issue refunds to impacted hospitals (Modern Healthcare, December 12; American Hospital Association, December 11).

Letters

- In a December 7 letter, CMS urged state governors to take action to support the agency's recently announced Hospital at Home initiative. Specifically, CMS requests governors:
    - Ensure no state-level licensure or scope of practice restrictions would impede health systems from leveraging CMS' Hospital at Home flexibilities.
    - Ensure the Medicaid agency is adapting payment and coverage policies appropriately.
    - Foster coordination among the state's health care system to create the partnerships necessary for effective community surge plans (CMS, December 7).
- In a letter to HHS and the CDC, a group of 10 senators urged Secretary Azar and CDC Director Redfield to ensure equitable distribution of COVID-19 vaccines to "ensure access to the vaccine for communities and populations hit hardest by the pandemic" (Senator Warner, December 9).

Waivers

- Section 1115
    - On December 9, Kentucky submitted an amendment to its KY Health Section 1115 Demonstration Waiver. The amendment will provide substance use disorder treatment services to individuals incarcerated in state and county facilities.
- Section 1135
    - Oregon
        - Allows use of representatives to deliver 1915(k) (Community First Choice) services.

- Section 1915(c) Appendix K
    - Oklahoma
        - Temporarily increases the combined additional cost limit for prevocational services and supported employment services.
        - Temporarily expands allowable service settings for group home, daily living support, and supported employment services.
        - Temporarily increases provider payment rates for residential, vocational, and nursing services (through use of an add-on rate, which is retroactive from April 1, 2020).

SPAs

- Traditional SPAs
    - Connecticut (CT-20-0009): Implements various program changes in Wave 3 of its Patient-Centered Medical Home (PCMH) program and sets forth the total amount available for care coordination add-on payments for FQHC participants in 2020 and 2021. This SPA has an effective date of January 1, 2020.
    - Oklahoma (OK-21-0006): Revises coverage and reimbursement for therapy services rendered by physical, occupational, and speech language pathology therapy assistants and clinical fellows. This SPA has an effective date of February 1, 2021.
- COVID-19 Disaster Relief SPAs
    - Illinois (IL-20-0013): Allows diagnosis and antibody testing in non-office settings (e.g., parking lots), allows laboratory processing of self-collected diagnostic and antibody systems the FDA has authorized for home use, and provides enhanced rates to COVID-19 designated facilities for isolation and quarantine services and ventilator services. This time-limited, COVID-19 relief SPA has an effective date of September 1, 2020.
    - Illinois (IL-20-0013-A): Rescinds the 20% IDF/ID increase authorized in a previous SPA. This time-limited COVID-19 relief SPA has an effective date of September 1, 2020.
    - Massachusetts (MA-20-0020): Updates payment methodologies for acute inpatient and psychiatric inpatient hospital services during PHE. Specifically, the SPA authorizes a $94 per-diem add-on for psychiatric beds in acute and psychiatric hospitals. This time-limited, COVID-19 relief SPA has an effective date of August 1, 2020 and expires on October 31, 2020.
    - Michigan (MI-20-0012): Allows for a temporary increase to durable medical equipment (DME) provider rates for non-sterile gloves. This time-limited, COVID-19 relief SPA has an effective date of October 1, 2020.

State Updates

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

- A joint statement from the governors of Arkansas, Maryland, Massachusetts, New Hampshire, and Vermont called on Congress to move forward with additional state relief funding to support declining state revenues forcing states to consider budget cuts, including state worker furloughs. Revenues on average are down 21% based on a National League of Cities' member survey released this month. According to a Moody's report from September, if no further federal relief funding is granted to states and cities they will face a collective shortfall of $450 billion over the next two years (Modern Healthcare, December 13).
- Payers interested in bidding on Oklahoma's $4.8 billion Medicaid contract are facing opposition from lawmakers and health care providers. Republican representatives and senators wrote a letter to the

governor objecting to privatization of the program citing their belief that the system is fine as is (Health Payer Specialist, December 14).

- The Louisiana Department of Health (LDH) will issue a Request for Proposal (RFP) in Spring 2021 seeking managed care vendors to provide Medicaid services. The public comment period is currently open until December 29, 2020.
- MassHealth is preparing to submit a renewal request of its Medicaid 1115 Demonstration Waiver, which is set to expire June 30, 2022. MassHealth will hold a public stakeholder session to seek comments on December 17 from 12:00 – 1:30pm ET. Prior to submission to CMS, stakeholders will have an opportunity to offer public comments on a draft of the waiver.

Private Sector Updates

- Centene signed a definitive agreement to acquire Pantherx, a specialty pharmacy focused on orphan drugs and rare diseases, solidifying its foothold in the specialty drug market. Pantherx will operate independently as part of the payer's drug management program, called Evolve Pharmacy Solutions, which includes pharmacy benefit management and specialty pharmacy capabilities (HealthcareDive, December 15).
- Tenet Healthcare will acquire up to 45 ambulatory surgery centers from SurgCenter Development in a $1.1 billion deal. The transaction is expected to grow Tenet's ambulatory surgery portfolio to 310 facilities in 33 states and expand its musculoskeletal surgery offerings. As a result of this deal, Tenet stated it will be a "leading provider" of the highly profitable musculoskeletal surgery space. The centers are in nine states, three of which are newer markets for Tenet: Maryland, Indiana, and Ohio (Modern Healthcare, December 10).
- UnitedHealth Group received approval from the Justice Department to purchase Tufts Freedom, operated by Tufts Health in New Hampshire. The deal is expected to close next year (Health Payer Specialist, December 14).
- A report by Health Payer Specialist found the major payer with the largest profit margin year-to-date is Health Care Service Corporation with a $4.9 billion in net income and 14.5% profit margin. Aetna followed with $5.1 billion in operating earnings from its $56.3 billion in total revenue for the 9 months trailing September 30 and a 9% profit margin (Health Payer Specialist, December 14).
- The Ohio Department of Medicaid (ODM) awarded its fiscal intermediary service contract to Gainwell Technologies, a technology solutions provider. The fiscal intermediary is part of the State's efforts to modernize ODM's management information systems (Ohio Department of Medicaid).
- Blue Cross Blue Shield of Michigan has expanded a new financial risk-sharing model, "Blueprint for Affordability," to include seven new health care providers. Blueprint for Affordability aims to improve cost predictability, quality, efficiency, and coordination of care. Providers with aggregate costs below the targets will financially benefit from the program, while those with costs above the targets will rebate Blue Cross a portion of the amount above the target (Health Payer Specialist, December 11).
- A report by the Better Medicare Alliance found Medicare Advantage (MA) outperforms traditional Medicare based on several quality measures including preventive screenings and avoiding hospitalizations. The analysis also found MA beneficiaries had higher rates of vaccinations and lower Part D drug costs (Fierce Healthcare, December 9).
- Bank of America will partner with CVS Health to fund a no-cost flu voucher program for under-resourced communities across the country, particularly focusing on people of color who may not have access to low-cost or free preventative flu shots. The program will initially launch in Detroit, Dallas, Jacksonville,

Oklahoma City, Phoenix, Boston, and Washington D.C. This program is part of Bank of America's $1 billion 4-year commitment to advance racial and economic opportunities (Galveston County Daily News, December 9).

- Henry Ford Health System is partnering with Tennessee-based Acadia Healthcare to open a 192-bed behavioral health hospital in the greater Detroit area. The hospital is expected to open in late 2022. Acadia will staff the hospital's therapists and other ancillary providers. Once the new hospital opens, the system will close inpatient psychiatric units at Henry Ford Macomb Hospital – Mt. Clemens, and Henry Ford Kingswood Hospital (Modern Healthcare, December 9).

Sellers Dorsey Updates

- Meet Leesa Allen: Sellers Dorsey welcomed Leesa Allen to our firm last year following her tenure at the Pennsylvania Department of Human Services, most recently serving as the Executive Deputy Secretary and Medicaid Director for the Commonwealth. Leesa serves as a Deputy Managing Director in the Sellers Dorsey Harrisburg office, where she uses her leadership, Federal and State Medicaid and public policy knowledge and expertise to support the teams and Sellers Dorsey clients. Click here to learn more about Leesa.
- Recently, Sellers Dorsey managers Brian Dorsey, Chief Culture Officer, and Mindy Braithwaite, Vice President of Administration, highlighted the importance of being intentional with your culture in the workplace in the article, "Winning Through Culture." Check it out here.

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