

SELLERS DORSEY DIGEST

NAVIGATION

Federal Updates

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State Updates

Hawaii released a request for proposal (RFP) for a qualified behavioral health plan to manage the state's Community Care Services (CCS) program.

Private Sector Updates

Centene announced its acquisition of Apixio, a data analytics company with a focus on artificial intelligence.

Sellers Dorsey Updates

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Summary of Key Updates

After winning Pennsylvania, former Vice President Joe Biden and Senator Kamala Harris are the President-elect and Vice President-elect of the United States, respectively. The Trump Administration has vocally contested all aspects of the vote counting process and has either already filed suit or intends to file suit in numerous states to force ballot recounts.

Supreme Court justices heard oral arguments in California v. Texas, the case that challenges the penalty-free individual mandate under the Affordable Care Act (ACA) and whether the mandate is severable from the rest of the law. The Justices posed questions focused on the plaintiff's standing to bring the suit and the severability issues. Overall, this bodes well for the ACA's survival, and the Supreme Court is expected to rule on the case by June 2021 (Modern Healthcare, November 10).

Pfizer and BioNTech stated in a press release that their COVID-19 vaccine has demonstrated a 90% efficacy rate at seven days after a second dose and does not have any serious safety concerns. The vaccine's Phase 3 clinical trial began on July 27 and enrolled over 43,000 participants, almost 39,000 of which received a second dose. Based on the current projections, the companies expect to produce globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses in 2021. Pfizer engaged with the Operation Warp Speed for a \$1.95 billion deal in July 2020 under an advance-purchase agreement, meaning the company will not get paid until they deliver the vaccine (Pfizer, November 9; New York Times, November 10).

On November 13, the Centers for Medicare and Medicaid Services (CMS) intends to publish the Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Final Rule in the Federal Register. CMS published the proposed rule, which includes significant revisions to its managed care regulations on November 14, 2018 (83 FR 57264). The majority of the rule's provisions will become effective on December 13, 2020 with the exception of changes to Sections 438.4(c) and 438.6(d)(6), which are effective July 1, 2021. Upon its inauguration on January 1, 2020, the Biden Administration will have the option to further adjust managed care regulations through an executive order, the formal rulemaking process, and sub-regulatory guidance. Read our summary of the final rule here.

From November 4 through November 10, CMS approved nine SPAs, including two time-limited COVID-19 disaster relief response SPAs.

Federal Updates

News

- The Trump Administration enters a lame-duck period during which they are expected to fulfill the following items on their health care agenda.
 - Medicare Physician Fee Schedule Rule: The Office of Management and Budget (OMB) is reviewing Medicare's physician fee schedule rule. If implemented as proposed, the rule will permanently expand telehealth use, simplify billing and coding, boost several bundled payment programs, and revise the Medicare Shared Savings Program for 2020.
 - Medicare Payment Rule for Outpatient Services: The White House budget office is reviewing Medicare's payment rule for outpatient services, which would increase payments to providers, decrease reimbursement for 340-B acquired drugs, expand services allowed in outpatient and ambulatory settings by phasing out CMS' inpatient-only list, and create more flexibility for physician-owned hospitals to expand. Therapists and long-term care providers oppose the rule that proposes to cut reimbursement for therapy services by nine percent.
 - Self-Referral and Kickback Reforms: The White House budget office has been reviewing the reforms to the rule since July and is moving slower than expected due to the COVID-19 pandemic. Under current laws, Medicare providers have been deterred from participating in payment models where physicians and hospitals share in financial rewards due to fear of civil penalties under Stark and potentially criminal penalties under the anti-kickback statute and False Claims Act.
 - o **HIPAA Reform:** Updated regulations would give patients more access to their Protected Health Information (PHI) as a means to shift towards more value-based care by encouraging providers to adopt better care coordination and case management practices. The White House budget office approved the rule.
 - o **Regulatory Reform:** HHS proposed a rule that would implement an automatic sunset for 10-year old rules if HHS does not assess, and if necessary, review the rule. This could be a high priority rule to finalize before President-elect Biden's inauguration as deregulation has been a Trump Administration health care priority.
 - o **Tennessee Medicaid Block Grant**: CMS could approve Tennessee's proposal for a Medicaid block grant, as cost-containment Medicaid reforms have been a high priority for CMS administrator Seema Verma (Modern Healthcare, November 9).
- President-elect Joe Biden's early health care agenda will focus on COVID-19 prevention and vaccination and preserving the ACA.
 - o **Bidencare:** The high level talking points for this plan will include lower premiums, deductibles, and drug prices; a new Medicare-like public option; and maintenance of private insurance for those who wish to use employer backed coverage. Political analysts note titling the plan "Bidencare" reclaims the way Republicans have pejoratively used "Obamacare" when describing the Democratically backed ACA.
 - o ACA Case: Biden has a few legislative options that could invalidate the current legal challenges against the ACA, thereby making it easier for Bidencare to act as an extension of the ACA. As the case rests on the idea that the penalty is legal under the congressional taxing power, Biden could push Congress to repeal the individual mandate (which is a potential ruling in the current Supreme Court case) or reinstate some sort of tax penalty. Practically, the Republican controlled Senate could kill the bills, keeping the fate of the ACA with the conservatively led Supreme Court.

- o **Trump Health Care Policies:** The Biden administration will likely start with interim final rules and executive orders to roll back enforcement of controversial Trump rules. In the later part of the Administration's first year or in the second year, CMS is likely to publish comprehensive regulatory proposals to undo the Trump Administration's changes.
- Public Option: The public option will be broadly available to Americans who are too young for Medicare. The public option will need corporate buy in, which is not likely to come as quickly as it did with the ACA. For example, providers may push back at the risk of commercially insured patients shifting to a plan with lower provider reimbursement rates.
- o **Drug Pricing:** Pricing reform will include pursuing value-based limits on drug prices, a ban on price hikes that outpace inflation, and eliminating the statutory prohibition on Medicare's negotiation of drug prices (Law360, November 8).
- As reported by Modern Healthcare, several health care trade groups, including America's Health
 Insurance Plans and American Hospital Association, have released statements signaling their readiness to
 work with the incoming Biden administration on issues related to COVID-19 and overall health care
 affordability and access.
- At a November 5 news conference, Federal Reserve Chairman Jerome Powell announced the Federal Reserve would keep its benchmark interest rates near zero and signaled readiness to do more, noting the rise of COVID-19 cases and the slowing pace of economic recovery compared to that of early summer. "The path of the economy," Powell said, "will depend significantly on the course of the virus" (The Washington Post, November 5).

Federal Regulations

- On November 9 CMS released its final rule on Medicaid and CHIP managed care, finalizing regulations first proposed in November 2018. The final rule maintains many provisions in the 2018 proposed rule with notable changes made to the following topics:
 - Setting actuarially sound capitation rates
 - o Pass-through payments
 - State directed payments
 - Network adequacy standards
 - o Risk-sharing mechanisms
 - o Requirements for beneficiary information
 - Coordination of benefits
 - o Quality rating system
 - o Appeals and grievances
- The rule will be published in the Federal Register on November 13, with most provisions taking effect 30 days after publication.

Federal Legislation

• Senate Majority leader Mitch McConnell expressed his intention to pass a coronavirus package before the end of the year, which is a shorter timeline than previous statements referencing a 2021 relief package. Democrats and Republicans have stalled in negotiations over the price of the package. Republicans are hesitant to spend more than \$1 trillion, and Democrats have proposed a \$2.5 trillion allocation. Some lawmakers would like to incorporate the relief package into an end of the year spending

bill, which the White House and Congress must agree to by December 11 to avoid a government shutdown (Politico, November 4; Fierce Healthcare, November 4).

COVID-19

- President-elect Biden has created a Transition COVID-19 Advisory Board. Thirteen health experts will
 serve to shape the Biden Administration's approach to infection surges and vaccinations. Former FDA
 administrator Dr. David Kessler, former Surgeon General Vivek Murthy, and epidemiologist Dr. Marcella
 Nunez-Smith will co-chair the panel. Other members include:
 - o Dr. Celine Gounder Infectious disease specialist, New York University
 - o Dr. Zeke Emanuel Center for American Progress, UPenn, former Obama White House aide
 - o Dr. Julie Morita former Chicago Health Commissioner, current Executive Vice President (EVP) at the Robert Wood Johnson Foundation
 - Luciana Borio former Assistant Commissioner for Counterterrorism and Emerging Threats and Acting Chief Scientist at FDA under President Obama
 - o Rick Bright former Biomedical Advanced Research and Development Authority (BARDA) Director under President Trump
 - o Atul Gawande surgeon and public health researcher, Brigham and Women's Hospital
 - o Michael Osterholm Director of the Center for Infectious Disease Research and Policy at University of Minnesota
 - o Loyce Pace President & Executive Director at Global Health Council
 - o Robert Rodriguez emergency medicine physician, Zuckerberg San Francisco General Hospital
 - o Eric Goosby former Clinton and Obama Administration leader on HIV/AIDS
- It is unclear whether the Trump administration will cooperate with the Advisory Board's suggestions while it continues to challenge the election's results (NPR, November 9; UPI.com, November 9).

Waivers

- Section 1115
 - On October 30, Indiana submitted an 1115 demonstration waiver application to CMS titled "Maternal Opioid Misuse Indiana Initiative." The demonstration would extend Medicaid eligibility from 60 days to 365 days postpartum for mothers with an opioid use disorder who meet other program criteria for the Maternal Opioid Misuse cooperative agreement with CMMI. CMS will accept public comments from November 9 through December 9, 2020.
 - On November 2, CMS approved an amendment to Tennessee's TennCare II 1115 demonstration waiver to implement a new Katie Beckett program in the state. The new program has two components:
 - Part A will serve up to 300 children with the most significant disabilities or complex medical needs. Children would receive full Medicaid benefits, and up to \$15,000 a year in home and community- based services.
 - Part B will serve up to 2,700 children with disabilities or complex medical needs.
 Children in Part B will not be enrolled in Medicaid, but families will receive up to \$10,000 a year in services per child.

Section 1135

- o Montana
 - Waive required timeframe for initial assessments and reassessments of functional need, and the annual review of Person-Centered Service Plan for Community First Choice.
- Section 1915(c) Appendix K
 - o West Virginia
 - Temporarily increase provider rates.
 - Temporarily make retainer payments.
 - o Delaware
 - Temporarily make retainer payments.
 - o Connecticut
 - Temporarily make retainer payments.

SPAs

Traditional SPAs

- o California (CA-20-0003): Adjusts the fee-for-service schedule for clinical lab services to no more than 80% of the lowest maximum allowance under Medicare. This SPA has an effective date of January 1, 2020.
- o California (CA-20-0037): Updates the third-party liability section of the state plan to use standard coordination of benefits cost avoidance when processing claims for prenatal services. This SPA has an effective date of October 1, 2020.
- o Kansas (KS-20-0017): Increases certain dental fee-for-service rates. This SPA has an effective date of July 17, 2020.
- o Louisiana (LA-20-0011): Amends the provisions governing reimbursement for End-Stage Renal Disease (ESRD) facilities to allow contracted independent laboratories to bill the Medicaid program directly for non-routine lab services instead of receiving reimbursement from the ESRD facility. This SPA has an effective date of October 20, 2020.
- o Mississippi (MS-20-0016): Increases the fee schedule to 100% of the Medicare urban ambulance fee schedule for emergency ground transportation services and adds a mileage component for emergency transportation services. This SPA has an effective date of July 1, 2020.
- Texas (TX-20-0014): Updates the Early and Periodic Screening, Diagnostic and Treatment fee schedule. This SPA has an effective date of September 1, 2020.
- o Texas (TX-20-0020): Updates the Durable Medical Equipment and vision fee schedules. This SPA has an effective date of September 1, 2020.

COVID-19 Disaster Relief SPAs

- o New Mexico (NM-20-0013): Increases reimbursement for non-hospital providers. This time-limited COVID-19 response SPA has an effective date of April 1, 2020.
- o New Mexico (NM-20-0014): Increases dispensing fees for curbside pharmacy services. This time limited COVID-19 response SPA has an effective date of October 1, 2020.

State Updates

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

- On November 6 Hawaii released a request for proposal (RFP) for a qualified behavioral health plan to manage the state's Community Care Services (CCS) program, which provides behavioral health services to over 4,500 Medicaid-eligible adults with serious mental illness (SMI) or serious and persistent mental illness (SPMI). Proposals are due January 8, 2021. Awards are expected on February 8, 2021, with implementation slated to begin July 1, 2021. Current incumbent Centene/WellCare/Ohana has held the contract since 2013.
- On October 2, Pennsylvania Governor Tom Wolf issued an Executive Order establishing the Interagency
 Health Reform Council (Council). The Council will evaluate the potential alignment of the
 Commonwealth's health care payment and delivery systems to provide efficient, whole-person health
 care that also contains costs, reduces disparities and achieves better health outcomes. The Council is
 required to submit a report to the Governor no later than December 31, 2020 that includes proposals for
 the development and implementation of health care reform and identifies all policy and legislative
 changes needed to effectuate the Council's proposals.
- The Texas Health and Human Services Commission (HHSC) is giving around \$202 million in emergency funds to more than one million SNAP recipients for food benefits for November. The additional benefit will be added to their Lone Star Card. The emergency funds provided by HHSC are in addition to the almost \$1.5 billion in benefits given to Texans between April and October. HHSC got federal approval to extend the maximum amount of SNAP benefits to recipients based on family size. The program gives food assistance to around 1.4 million eligible families and people in Texas (KXAN, November 5).

Private Sector Updates

- Centene announced its acquisition of Apixio, a data analytics company with a focus on artificial intelligence. The acquisition is expected to be closed by the end of this year. Centene providers will be able to use Apixio to compile and analyze threads of patient data, such as physician notes. Centene's President and CEO Michael Niedorff stated, "Apixio's capabilities are closely aligned with our plans to digitize the administration of health care and to leverage comprehensive data to help improve the lives of our members" (Health Payer Specialist, November 9).
- Although major insurers are reducing their real estate footprint due to the COVID-19 pandemic, Medicaid insurers appear to be expanding real estate investments. Investing in real estate in a community is a way to express commitment to a state when competing for Medicaid contracts. In July, Molina Healthcare purchased an office site in Louisville after winning Kentucky's Medicaid contract. With this contract and the new office, Molina announced it will create more than 1,000 jobs in Kentucky. Centene is also building a new office in North Carolina, which it anticipates will bring more than 3,000 new jobs to the state (Health Payer Specialist, November 9).
- As reported in last week's Digest, all 36 members of the Blue Cross Blue Shield Association (BCBSA) reached a \$2.7 billion antitrust settlement with consumers. Previously Blue Cross Blue Shield could not enter other markets in the U.S.; however, one of the agreements under the proposed settlement is to reverse that rule. Health Care Service Corporation (HCSC), a licensee of BCBSA based in Chicago, will be free to enter markets but potentially faces competition with other BCBS-owned payers, such as Anthem. If there are more plans entering new markets, premiums in those markets could drop. Further, the

- settlement lifts a revenue cap on non-BCBS business lines and restraints on acquisitions, allowing new growth opportunities (Modern Healthcare, November 6).
- Kaiser Permanente's (KP) operating margin fell to 2.1% in the third quarter of 2020 as health plan members resumed medical care they delayed because of the pandemic. Because of the resumed procedures, KP's expenses were up almost 6% in the quarter year-over-year. Unlike other health systems, KP's supply and labor expenses have not significantly grown because of coronavirus. KP also lost about 11,000 members during the quarter, primarily due to unemployment (Modern Healthcare, November 6).
- Andrew Bindman, M.D., has joined Kaiser as its new CMO and EVP. Before joining Kaiser, Bindman taught clinical medicine at the University of California, San Francisco. During his tenure, he published 180 scientific articles. Bindman was also an advisor to U.S. Department of Health and Human Services and played a role in the drafting and implementation of the Affordable Care Act (Health Payer Specialist, November 6).
- Karen Lynch, Aetna's chief and future CEO of CVS Health, has led a 36% increase in Medicaid enrollment in the third quarter. Lynch stated, "[Medicaid] is strategically positioned as an important business and we hope to continue to grow that asset." She is scheduled to become the new CEO of CVS Health in February 2021 (Health Payer Specialist, November 6).
- Highmark's population health pharmacy and health analytics teams are partnering to improve medication management for diabetes patients. This initiative focuses on diabetic members enrolled in the True Performance value-based care program. The program involves the identification of members who may have medications that can be adjusted or discontinued. The analytics experts will share this information with Highmark pharmacists who will then work directly with primary care physicians to provide guidance on the medications. Highmark's goal is to avoid adverse drug events, increase medication adherence and reduced costs for both providers and patients (Fierce Healthcare, November 4).

Sellers Dorsey Updates

- Sellers Dorsey team members are excited to attend AAMC's annual Learn Serve Lead virtual conference on November 16-18. See a list of events our team members attend here.
- Check out our Q&A with Joe Madsen, Consultant, who has experience in areas of Medicaid managed care, business development, provider policy, and reimbursement. Joe first joined Sellers Dorsey as a marketing associate and has since transitioned into client servicing. Read more about Joe here.

