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SELLERS DORSEY DIGEST

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NAVIGATION

Summary of Key Updates

On January 7, CMS Administrator Seema Verma tweeted CMS intends to withdraw the Medical Fiscal Accountability Rule (MFAR) from the Federal Register. CMS intended for MFAR to promote transparency in federal funding of Medicaid supplemental payments. However, providers and Medicaid Directors vocally opposed the rule as it would significantly reduce the types of state share eligible for federal matching funds, leading to a sharp decline in supplemental payments. CMS previously delayed MFAR implementation citing concerns with cutting Medicaid funding during the COVID-19 pandemic (Twitter, January 7).

On December 27, President Trump signed the Consolidated Appropriations Act, a comprehensive COVID-19 stimulus package and annual spending bill, thereby avoiding a government shutdown shortly before its December 28 deadline (Modern Healthcare, December 22).

CMS released a reminder that Hospital Price Transparency requirements go into effect January 1, 2021. Under the program, CMS plans to audit a sample of hospitals for compliance starting in January (CMS, December 18).

On January 20, immediately after President-elect Joe Biden's inauguration, the White House is expected to publish a memo to halt or delay any Trump Administration regulations passed during the lame duck session (or "midnight regulations") that have not taken effect by Inauguration Day. Additionally, President-elect Biden pledged to sign several executive actions on his first day in office including rejoining the Paris climate accord and the World Health Organization (CNN, December 30).

- If signed as planned, the regulatory freeze would (at a minimum) delay the federally qualified health center (FQHC) 340B policy outlined in this issue of the Sellers Dorsey Digest.

On December 22, CMS issued guidance to states on requirements and considerations for returning to normal operations after the expiration of the public health emergency (PHE). The guidance allows states four months after the end of the PHE to process pending applications and six months to resolve other eligibility issues, such as processing redeterminations (CMS, December 22; Inside Health Policy, December 23).

From December 23 through January 5, CMS approved one Section 1115 waiver, two Section 1135 waivers, one Section 1915(c) Appendix K waiver, and nine SPAs, two of which are time-limited, COVID-19 disaster relief SPAs.

Federal Updates

News

- On December 30, CMS issued guidance to states on the mandatory medication-assisted therapy (MAT) benefit for opioid use disorders (OUD) which is required under the SUPPORT Act (Act). The letter specifies CMS interprets the Act to require states to cover "all forms of drugs and biologicals that the Food and Drug Administration (FDA) has approved or licensed for MAT to treat OUD." This currently includes methadone, buprenorphine, and naltrexone, in addition to counseling services and behavioral therapy related to the drugs and biologicals covered under the new mandatory benefit. The letter provides coverage and provider considerations for states relating to these existing drugs and information on demonstration opportunities for states to further increase coverage for OUD/Substance Use Disorder (SUD) treatment. While the effective date of the coverage requirement is October 1, 2020, the letter provides guidance to states seeking additional time due to state legislation requirements and delays due to states' need to exclusively focus on COVID-19 (CMS, December 30).
- In a December 30 Advisory Opinion, the HHS General Counsel concluded, "covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price — and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price — even if those covered entities use contract pharmacies to aid in distributing those drugs to their patient." This opinion comes in response to months of complaints from pharmacy providers and hospitals and lawsuits from provider associations. As reported by *Modern Healthcare*, however, some pharmaceutical companies have already voiced their disagreement with the advisory opinion and may continue to limit discounts (HHS, December 30; Modern Healthcare, December 30; Modern Healthcare, January 4).
- On December 22, CMS issued guidance to states on requirements and considerations for returning to normal operations after the expiration of the PHE. Enhanced Federal Medical Assistance Percentage (FMAP) authorized under the Families First Coronavirus Response Act (FFCRA) will expire the first day of the month following the calendar quarter in which the PHE expires, while the continuous enrollment requirement that is currently a condition of the enhanced FMAP will expire on the first day of the month following the end of the PHE. The guidance also allows states four months after the end of the PHE to process pending applications and six months to resolve other eligibility issues, such as processing redeterminations. The guidance does not, however, alter timelines for beneficiary appeals for eligibility loss or other eligibility actions. CMS urges states to return to normal operations as soon as possible. The letter details specific expiration dates of emergency SPAs, disaster relief 1115 waivers, 1915(c) Appendix Ks, and Section 1135 waivers. It also provides guidance to states that are considering making certain flexibilities extended during the PHE (e.g., additional services provided via telehealth) permanent. To ensure compliance, CMS will require states to develop a "Post-COVID Eligibility and Enrollment Operational Plan" to document specific plans around eligibility redeterminations and making flexibilities permanent. States are not, however, required to submit this plan for CMS approval. There has been no action taken to date to terminate or extend the PHE declaration (CMS, December 22; Inside Health Policy, December 23).

Federal Regulations

- The Trump Administration published a final rule that requires FQHCs to pass along discounts earned through the 340B program to uninsured patients or patients with high cost-sharing for insulin or Epi-Pens or those with a high unmet deductible. Specifically, the rule applies to health center patients "who receive in-scope health center services beyond dispensing of drugs that are self-administered or administered at home." While stakeholders recognize the high cost of certain life-saving medications, they oppose this rule and indicate it will make it harder for FQHCs to provide low-cost services to their

patients. The rule goes into effect January 22, two days after President-elect Joe Biden's inauguration (Modern Healthcare, December 22). As described above, it is likely Biden will issue a memo halting implementation of this final rule.

- On December 22, CMS unveiled its 2020 list of quality and efficiency measures under consideration. CMS engages in this annual exercise to remove those that have become less relevant and propose new measures that may be more meaningful based on review by external health care experts. List publication is a part of the pre-rulemaking process and represents a first step in measure approval by CMS and providers. The list features:
    - Five outcome measures (measures that focus on the results of health care provided through Medicare), such as the rate of health care-associated infections requiring hospitalization for residents of skilled nursing facilities.
    - Five process measures (measures that emphasize efforts to promote standardized best practices), such as conducting kidney health evaluations or implementing interventions for patients with pre-diabetes (the medical term for blood glucose levels that are high but not yet high enough for a type-2 diabetes diagnosis). Importantly, the 2020 list includes three process measures for the coronavirus disease 2019 (COVID-19) vaccine. The measures under consideration for inclusion on the list include:
        - Vaccination coverage among health care personnel.
        - Vaccination by clinicians.
        - Vaccination coverage for patients in ESRD facilities.
    - Five cost/resource use measures (measures that evaluate how frequently health care items or services may be used and how much they might cost) – including, for example, episode-based costs associated with addressing diabetes or asthma and chronic obstructive pulmonary disease.
    - Three composite measures, which summarize overall quality of care across multiple measures through the use of one value or piece of information.
    - Two patient-reported outcomes measures (measures where the information comes directly from the patient) (CMS, December 21).
- On December 22, CMS issued a final rule that, among other things, amends the Medicaid Drug Rebate Program (MDRP) by clarifying the interaction of value based payment (VBP) arrangements with average manufacturer price (AMP) and best price. The rule defines VBP and clarifies that a drug can have multiple "best prices" if tied to VBP arrangements. The proposed rule appeared in the June 19, 2020 Federal Register. In the final rule, CMS states it seeks to encourage VBP arrangements among drug manufacturers, state Medicaid programs, and third-party Medicaid payors, as a means to expand access to high-price drugs including newer gene therapies. The sections of the rule pertaining to VBP will not go into effect until January 1, 2022.
    - To participate in the MDRP, drug manufacturers are required to sell their drugs to state Medicaid programs at the "best price" available to wholesalers, retailers, or providers in the commercial market and to report those best prices quarterly. VBP drug pricing programs link payment for a drug to that drug's clinical performance. This could lead to a lack of incentive for Pharma to enter into a VBP arrangement, for example, for a high-priced new genetic therapy where there may be a potential risk of failing to meet specific clinical value criteria. Manufactures may wish to avoid a situation where a poor outcome for a single patient could result in a reduction of the Medicaid Best Price.
    - The rule permits drug manufacturers to report multiple best prices for a drug tied to VBP arrangements based on that drug's various measurable clinical outcomes and to consider the sale of multiple units of a drug under a VBP arrangement as a "bundled" sale. Further, CMS will

permit drug manufacturer revisions to AMP and best price reporting in VBP arrangements beyond the current three-year time limit so that manufacturers have a longer period to revise pricing and reporting metrics.

- The final rule also clarifies the application of the recent Continuing Appropriations Act 2020 and Health Extenders Act of 2019 (Pub. L. 116-59) to the calculation of a manufacturer's brand name drug AMP. This Act changed the calculation of AMP for brand drugs by excluding the sales of authorized generic drugs when brand manufacturers have allowed an authorized generic to be sold under the brand name drug's new drug application (NDA). Prior to the Act, this practice of calculating AMP by brand manufacturers had the effect of lowering AMP, which in turn reduced rebates on brand name drugs. The final rule clarifies sales of authorized generics may not be used to calculate the brand drug's AMP regardless of the relationship between the brand and authorized generic manufacturers.
- The final rule also implements new opioid-related drug utilization review (DUR) standards, which were mandated for states pursuant to section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115-271). As described in this issue, it is likely Biden will issue a memo halting implementation of this final rule (Federal Register, December 31).

Federal Legislation

- On December 27, President Trump signed the Consolidated Appropriations Act, a comprehensive COVID-19 stimulus package and annual spending bill, thereby avoiding a government shutdown shortly before its December 28 deadline (Modern Healthcare, December 22).
  - Congress did not focus on CMS in this spending package and kept the agency's budget flat at $4 billion.
  - However, lawmakers did approve an additional 1,000 Medicare graduate medical education (GME) slots with priority for training programs in rural areas for hospitals that are training residents over their caps, states with new medical schools, and facilities that provide care for underserved communities. These spots provide funding for hospitals that were otherwise responsible for the training costs associated with new residents. Teaching hospitals in need of additional support will have to apply to CMS on an individual basis.
- Lawmakers also extended Medicare sequestration suspension (two percent reduction to all fee-for-service claims) through March 31, 2021. The often extended sequestration was set to expire on December 1, 2020 under the CARES Act (Modern Healthcare, December 23; MLN Connects Newsletter, January 4).
- CMS released a reminder that Hospital Price Transparency requirements go into effect January 1, 2021. Under the program, CMS plans to audit a sample of hospitals for compliance starting in January (CMS, December 18).
- The 117th Congress began in Washington, D.C. at the start of the new year. As part of their immediate legislative agenda, House Democrats will focus on economic assistance for state and local municipalities and potentially a $2,000 stimulus check for individuals. The House version of a much contested spending bill, which President Trump signed late in 2020, included $2,000 relief checks (which President Trump had called for), but Senate Majority leader Mitch McConnell (R-KY) replaced the individual stimulus dollars with a provision for a smaller, $600 check. Democrats plan to draft a new relief bill after President-elect Biden's inauguration later in January (The Washington Post, January 4).
- President Trump is expected to sign HR1418 (Competitive Health Insurance Reform Act of 2020), which amends the McCarran-Ferguson Act to restore application of federal antitrust laws to payers (health and

dental insurers and limited-scope dental benefits). Historically, lawmakers believed payers should be able to share data to better predict rates for products and services (which looks like price-fixing in other industries) and therefore allowed insurance companies to engage in these "restraint of trade" activities. However, lawmakers now see this information sharing as a means for payers to evade oversight, especially as they enjoy record-high profits during the COVID-19 pandemic. Payers have been and will continue to be subject to broader federal antitrust laws that bar mergers and acquisitions the Department of Justice (DOJ) or courts find harm competition and consumer choice (Congress.gov, January 4; Health Payer Specialist, December 23).

Federal Litigation

- On December 29, the U.S. Court of Appeals for the District of Columbia Circuit affirmed the lower court's summary judgement in favor of HHS, thereby allowing the Trump administration's hospital price transparency rule to take effect January 1. Under the final rule, hospitals must start posting their negotiated rates online in a machine-readable format or list in a consumer-friendly manner their negotiated rates for at least 300 shoppable services. Hospitals have argued the new rule is contrary to the Affordable Care Act (ACA), which only gives CMS the authority to require publication of chargemaster rates (not negotiated rates). However, the D.C. Appeals Court disagreed and relied on the ACA's Public Health Service Act in its decision. The American Hospital Association is urging the incoming Biden administration to reevaluate the rule and exercise discretion in enforcing it during the PHE (*AHA v. Azar,* DC Circuit Court of Appeals, NO. 20-5193*;* Modern Healthcare, December 29).

COVID-19

- On December 22, the White House's Office of Management and Budget (OMB) released guidance for audits of CARES Act relief dollars. The guidance extends the audit deadline by three months for certain organizations. This is a positive change for providers, many of whom have not had to participate in a single audit before but are now subject to this audit since they have received more than $75,000 in grant awards. Additional Provider Relief Fund (PRF) clarifications in OMB's addendum are:
    - Grants funding is permitted for preparing for, preventing, and responding to the coronavirus, which encompasses building temporary structures, property rentals, medical supplies and equipment (including personal protective equipment and testing supplies), increased workforce and training, emergency operation centers, retrofitting facilities, and adding surge capacity.
    - Grants distributed under the Skilled Nursing Facility Infection Control Distribution can only be used to administer specific COVID-19 tests, to report those tests to local, state, and federal governments, and to hire staff to provide care or administrative support. They can also reimburse for infection control activities and services for residents, such as technology to connect with family members who cannot visit.
    - As expected, the OMB guidance provides the money cannot reimburse expenses or losses expected to be reimbursed by other sources or that other sources are obligated to reimburse. This includes the Federal Emergency Management Agency, for example.
    - The guidance also includes detailed instructions on when and where to report COVID-related expenses and lost revenues. Providers that keep the grant money for at least 90 days without contacting HHS are deemed to have accepted the terms and conditions (Modern Healthcare, December 22).

Waivers

- Section 1115
    - On December 11, Georgia submitted an application to CMS for a new Section 1115 Demonstration Waiver, "Georgia Postpartum Extension," which will extend postpartum Medicaid coverage from 60 days to 180 days. CMS will accept comments through January 22.
    - On December 22, Arizona submitted an application to CMS requesting a five-year extension to its Section 1115 Demonstration Waiver, Arizona Health Care Cost Containment System (AHCCS), which is currently set to expire on September 30, 2021. Comments will be accepted through February 3, 2021. In addition to extending existing authorities, the waiver seeks to:
        - Allow for verbal consent in lieu of written signature for all care and treatment documentation for Long Term Care (LTC) members.
        - Reimburse traditional healing services provided in, at, or as part of services offered by facilities and clinics operated by the Indian Health Service (IHS), a tribe or tribal organization, or an Urban Indian health program.
        - Reimburse IHS and Tribal 638 facilities to cover the cost of adult dental services eligible for 100% Federal Financial Participation (FFP), that are in excess of the $1,000 emergency dental limit for adult members and the $1,000 dental limit for individuals age 21 or older enrolled in the LTC program.
    - On December 22, CMS announced approval of new Section 1115 SUD demonstration waivers for Oklahoma ("Institutions for Mental Diseases Waiver for Serious Mental Illness/Substance Use Disorder") and Maine ("Maine Substance Use Disorder Care Initiative").
- Section 1135
    - Alaska
        - Extends timeframe for reinstatement of benefits related to fair hearing.
    - Massachusetts
        - Waives clinical facility requirement to permit the state and clinic to temporarily designate a clinic practitioner's location as part of the clinic facility so that clinic services may be provided when neither the patient nor practitioner is physically onsite at the clinic.
- Section 1915(c) Appendix K
    - District of Columbia
        - Temporarily exceeds service limitations for respite and community transition services.
        - Temporarily adds coverage of personal emergency response system services.
        - Temporarily increases payment rates for respite and community transition services.

SPAs

- Traditional SPAs
    - Colorado (CO-20-0022): Implements a maternity payment program that incentivizes obstetricians to promote high quality evidence-based practices to promote improved care. This SPA has an effective date of November 1, 2020.
    - Florida (FL-19-0014): Adjusts reimbursement for nursing facilities for federal fiscal year 2019 and 2020 and makes other technical and editorial changes. This SPA has an effective date of October 1, 2019.
    - Florida (FL-20-0010): Updates the reimbursement rates for multi-visceral and intestine transplants. This SPA has an effective date of July 1, 2020.

  - Florida (FL-20-0006): Updates Enhanced Ambulatory Patient Group (EAPG) reimbursement rates for hospital outpatient services and makes other technical and editorial changes. This SPA has an effective date of July 1, 2020.
  - South Carolina (SC-20-0009): Increases the current home-based private duty nursing service rates, vision services rates, and anesthesia services codes. This SPA has an effective date of July 1, 2020.
  - Washington (WA-20-0036): Removes client copay language because the copayment policy was not implemented. This SPA has an effective date of October 1, 2020.
  - Wisconsin (WI-20-0018): Eliminates cost sharing for individuals under 19 years of age and implements a tracking system that complies with the statutory and regulatory cost sharing tracking requirements in section 1916 of the Social Security Act. Approval of this SPA was accompanied by a companion letter memorializing an agreement that the state will reimburse providers, who in turn will reimburse beneficiaries who were assessed a copay between July 1, 2020 and November 1, 2020. This SPA has an effective date of July 1, 2020.

- COVID-19 Disaster Relief SPAs
  - Oklahoma (OK-20-0043): Allows hospitals to make hospital presumptive eligibility determinations for the non-Modified Adjusted Group Income (MAGI) populations to facilitate discharge into LTC facilities. This time-limited COVID-19 response SPA has an effective date of December 14, 2020, and an expiration date upon termination of the PHE.
  - Virgin Islands (VI-20-0002): Adds and specifies provider qualifications for personal care attendant services under the Personal Care Services benefit and clarifies 15-minute increment payment policy. This time-limited COVID-19 response SPA has an effective date of March 1, 2020, and an expiration date upon termination of the PHE.

State Updates

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

- The Texas Health and Human Services Commission (HHSC) posted the 13th edition of the biennial Texas Medicaid and CHIP Reference Guide or "Pink Book." The Pink Book includes the most up-to-date data regarding the State's Medicaid program, including caseload and cost information and important background regarding the program. All data is for state fiscal year 2019 unless otherwise indicated.
- Texas HHSC also posted an anticipated timeline for the state's Medicaid and Children's Health Insurance Program (CHIP) managed care procurements, beginning with the STAR Health (foster care) procurement in August 2021. Texas HHSC plans to release the largest procurement, for the STAR and CHIP programs, in the first state fiscal quarter of 2023.
- On December 17, Maryland Governor Larry Hogan announced Medicaid behavioral health and long-term care provider rate increases pursuant to Maryland Senate Bill 280 (2019) will go into effect January 1, 2021, rather than July 1, 2021. The Department will make the updates to provider rates included in Maryland's State Plan.
- On January 1, Governor Charlie Baker of Massachusetts signed a new health care bill that requires insurers to cover telehealth visits the same way they cover in-person care and provides a short-term model for how those services will be paid. The bill also expands the scope of practice for advanced practice nurses and optometrists, addresses surprise out-of-network billing by requiring patient notification before non-emergency procedures, and gives community hospitals two years of enhanced Medicaid reimbursements (WBUR).

- On January 5, Governor Greg Gianforte (R) took the oath of office as the State's 25th governor (Montana.Gov).
- On January 4, Governor Spencer Cox (R) was sworn into office as Utah's 18th governor (Salt Lake Tribune).

Private Sector Updates

- UnitedHealth Group's Optum division will acquire Change Healthcare for $7.84 billion in cash and about $5 billion in debt to boost the insurer's digital capabilities and give providers a more simplified payment process. Once the deal is closed, president and CEO of Change Healthcare Neil de Crescenzo will be OptumInsight's CEO (Health Payer Specialist, January 6; Fierce Healthcare, January 6).
- In the midst of the ongoing lawsuits between several managed care insurers and the state of Kentucky, Humana filed a new lawsuit alleging the state government violated the terms of the new state Medicaid contracts when it allowed Molina Healthcare to buy Passport Health Plan's membership in September, thus giving Molina access to the program. As a result of the acquisition, Molina gained 315,000 new Medicaid enrollees. Humana argues Passport's membership should be reassigned to the winning companies based on a process outlined in the 2021 Medicaid contracts (Health Payer Specialist, January 4).
- Centene will acquire Magellan Health for $2.2 billion. Centene plans to use Magellan Health's behavioral health platform as a centerpiece of its larger specialty care strategy since individuals in the U.S. are showing a greater need for mental health services during the ongoing pandemic (Health Payer Specialist, January 4).
- More than 8.2 million people signed up for health insurance for 2021 using HealthCare.gov. Nearly 2 million of the 8.2 million people are new customers, and about 6 million renewed their coverage. CMS stated premiums have declined by an average of eight percent since 2018 across states that use HealthCare.gov (Fierce Healthcare, December 22).

Sellers Dorsey Updates

- Sellers Dorsey is an evolving firm dedicated to maintaining a positive culture that is essential to retaining talent and fostering collaboration. Diversity is our strength, and our employees bring unique perspectives to the workplace. To view and apply for any of our available positions, please visit here.
- Sellers Dorsey wishes you all a happy New Year. We look forward to working with you to find solutions and expand your work in 2021.

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