Health Policy Update – December 22, 2020

Lawsuits and Opposition to MFN Rule Continue to Pile Up

Groups representing patients, specialty care providers, and pharmaceutical manufacturers continue to weigh in against the Department of Health and Human Services' Most Favored Nation (MFN) Model. In an op-ed published in *MedPage Today*, Dr. Debra Patt, Executive Vice President of Policy and Strategic Initiatives at Texas Oncology, and Dr. Lucio Gordan, the President of Florida Cancer Specialists discuss how the rule will end up reducing cancer patients' access to care.

"Oncologists agree that drug prices are out of control and welcome partnership with the government to find solutions. Indeed, many oncologists are enthusiastic participants in payment reform models, clinical trials, and experiments that seek create more efficient care," Drs. Patt and Gordan write. "However, to solve the problem, we need well thought out policies based on evidence. The current evidence points to the MFN model as a misguided and dangerous experiment with very real consequences. If we do not act together to stop this policy now and focus on a meaningful collaborative path forward, patients will suffer, and some will die."

Meanwhile, at least four lawsuits against the MFN have been filed in U.S. district courts around the country seeking to stop the model's implementation. Proceedings in these cases are ongoing. Last week a judge held a hearing in the case brought by the Association of Community Cancer Centers (ACCC), the Global Colon Cancer Association (GCCA), the National Infusion Center Association (NICA), and the Pharmaceutical Research and Manufacturers of America (PhRMA). She is expected to issue a decision on the plaintiffs' motion for a temporary restraining order by December 24, 2020.

Finally, a group of 355 patient and provider organizations led by the Part B Access for Seniors and Physicians (ASP) Coalition sent a letter to Congressional leadership today urging lawmakers to immediately delay the MFN rule. The Network signed onto this letter along with a number of likeminded patient and provider groups.

To view Drs. Patt and Gordan's op-ed in *MedPage Today*, CLICK HERE.

To view the ASP Coalition letter, CLICK HERE.

Congress Strikes Deal on COVID-19 Relief Package, Omnibus Spending Bill

Congress passed a massive bipartisan, bicameral COVID-19 stimulus and government funding bill yesterday after months of wrangling. The combined package, nearly 5,600 pages in length, tops out at more than $2 trillion and covers a broad range of policies.

Included in the deal are several provisions of interest to healthcare providers. The bill mitigates the severity of the Physician Fee Schedule (PFS) conversion factor adjustment. Rather than the -10.2% conversion factor (CF) cut finalized by CMS, the bill lowers the CF reduction to approximately -3%. To offset this shift, the bill delays implementation of the complexity code (G2211) finalized in the PFS rule for 3 years and infuses the Medicare trust fund with an additional $3 billion.

The bill extends Medicare sequestration relief first passed in March 2020. The suspension of the 2% sequester cut will now extend through March 31, 2021. The legislation also freezes Alternative Payment Model (APM) thresholds for 2 years, making it easier for providers to qualify for advanced APM incentive payments. Further, the bill delays the Centers for Medicare and Medicaid Innovation (CMMI) Radiation Oncology (RO) Model for 6 additional months – moving the implementation date from July 2021 to January 2022.

The measure includes a number of policy and programmatic changes to the Provider Relief Fund (PRF) and Paycheck Protection Program (PPP). First, it permits PRF recipients to calculate lost revenue relative to budget, rather than actual, losses – allowing providers to keep more grant dollars. It also extends the PPP, allows for "second draw" loans, and allows borrowers to deduct certain expenses paid for with the government loans.

These are just a few of the numerous provisions in the bill, which also includes significant investments in COVID-19 vaccine, distribution, and testing support, another round of individual stimulus checks, and the insertion of a surprise medical billing compromise.

To read the text of the bill, CLICK HERE.

To read a section-by-section of the COVID-19 relief divisions, CLICK HERE.

To read a section-by-section of the authorizing divisions, CLICK HERE.

To read a section-by-section of the appropriations divisions, CLICK HERE.

Supreme Court Rules in Favor of Arkansas Law Regulating PBMs

On December 10, the Supreme Court issued a unanimous 8-0 decision in favor of an Arkansas law regulating the prices at which pharmacy benefit managers (PBMs) reimburse pharmacies for drugs covered under prescription drug plans. In the case, *Rutledge v. Pharmacy Care Management Association (PCMA)*, the Court overturned the decision of the 8th Circuit Court of Appeals which found that the Arkansas law is preempted by the Employee Retirement Income Security Act (ERISA) of 1974.

Writing for the majority, Justice Sonia Sotomayor noted that the Court made its decision based solely on ERISA preemption. She wrote in part, "State rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage are not pre-empted by ERISA."

The Arkansas law, which was passed in 2015, prohibits PBMs from reimbursing pharmacies for less than it costs to dispense a drug (known as “spread pricing”) and prohibits pharmacies from selling a drug if the maximum allowable cost for a product is too low. The state adopted the law to combat concerns that pharmacies were often being reimbursed by PBMs at rates that were lower than their costs, pocketing the difference. The Court’s ruling opens the door for further state regulation of PBM practices.

To view the Supreme Court’s decision, CLICK HERE.

CMS Unveils Proposed Rule to Streamline Prior Authorization

On December 10, 2020, CMS issued a proposed rule aimed at improving the electronic exchange of health care data among payers, providers, and patients with a heavy emphasis prior authorization (PA) reform. The rule would require Medicaid, CHIP, and Qualified Health Plans offered on federally-facilitated exchanges to build application programming interfaces (APIs) to support data exchange and electronic PA. More specifically, payers would be required to build and implement APIs that would allow providers to know what documentation is needed by the plan to approve PA requests. Payers would also be required to make PA decisions within 72 hours for urgent requests and 7 days for standard requests. CMS proposes implementing these changes on January 1, 2023.

The proposed rule includes 5 sets of proposals and 5 requests for information (RFI). The RFIs request stakeholder input on methods for enabling patients and providers to control sharing of health information, reducing burden and improving electronic information exchange of documentation and prior authorization, and accelerating the adoption of standards related to social risk data, among others. The comment period on this proposed rule closes January 4, 2020.

To read the CMS press release on the proposed rule, CLICK HERE.

To read the proposed rule, CLICK HERE.

HHS Unveils HIPAA Reform Proposal

On December 10, the U.S. The Department of Health and Human Services (HHS) issued a Notice of Proposed Rulemaking (NPRM) outlining a series of broad changes to the HIPAA Privacy Rule.

Included among the changes proposed:

- Expanding HIPAA covered entities’ requirement to disclose protected health information to family members and other caregivers when they believe it’s in the best interests of the individual - moving from a disclosure standard of professional judgement to a good faith belief that the disclosure would help the patient.
- Allowing HIPAA covered entities to disclose health information to social services agencies, community-based organizations, home and community-based service providers, or similar third parties that provide or coordinate health services needed for care coordination and case management of an individual.

- Giving providers 15 days to respond to a individual requests for health information, down from the current 30 days, with the opportunity for a 15-day extension.
- Allowing individuals to take notes or use other personal resources – such as cameras – to view and capture images of their health information, like x-rays.
- Requiring electronic health information to be provided to individuals at no charge.
- Eliminating the requirement that a provider obtain an individual's written acknowledgement that they received a notice of privacy practices and that the provider keep that acknowledgement for six years.

These changes are part of HHS's *Regulatory Sprint to Coordinated Care* initiative which aims to promote value-based healthcare by examining federal regulations that impede efforts among providers and health plans to better coordinate care for patients. Comments on the NPRM are due February 12, 2021.

To view the HHS announcement of the changes, CLICK HERE.

To view the NPRM, CLICK HERE.

HHS Finalizes 340B Dispute Resolution Rule as Hospital Groups Sue Over Program Enforcement

On December 10, 2020, the Health Resources and Services Administration (HRSA) released a final rule implementing an administrative dispute resolution process for the 340B Drug Pricing Program. The final rule establishes Administrative Dispute Resolution (ADR) Panels comprised of HHS officials which will make "precedential and binding final agency decisions" regarding claims filed by 340B covered entities and pharmaceutical manufacturers. The final rule notes the ADR Panel should be considered a last resort in the event that good-faith efforts to resolve disputes have failed.
Congress first directed HRSA to promulgate a 340B dispute resolution regulation over a decade ago in the Affordable Care Act (ACA). While a notice of proposed rulemaking (NPRM) was published in 2016, this is the first final rule associated with the ACA directive. The final rule is effective January 13, 2021.

The dispute resolution regulation has so far received lukewarm support from 340B Health – a trade association representing 340B providers – and the American Hospital Association (AHA). Both organizations want HHS to do more to prevent pharmaceutical companies from limiting discounts obtained through contract pharmacies and argue that this rule does not go far enough.

Separately, the AHA and six other organizations filed a lawsuit on December 12 seeking increased enforcement in the 340B program. The providers claim that HRSA's refusal to stop drug companies from limiting discounts through contract pharmacies violates the law. A group of 27 state attorneys general plus the Attorney General for the District of Columbia sent a letter to HHS last week in support of the hospital groups, urging the Department to take action against "drug manufacturers' unlawful refusal to provide critical drug discounts to covered entities." The letter was spearheaded by California Attorney General Xavier Becerra, who was recently announced as President-elect Biden's Secretary of Health and Human Services nominee.

To view the complete text of the rule, CLICK HERE.

To view the AHA-led complaint regarding 340B program enforcement, CLICK HERE.

To view the letter from the state attorneys general, CLICK HERE.

JAMA Study Analyzes COVID-19 Infection Risk and Racial Disparities Among U.S. Cancer Patients

On December 10, *JAMA Oncology* published a study finding that Americans who have recently been diagnosed with cancer face a significantly higher risk of COVID-19 infection and its adverse outcomes. African American cancer patients are especially at risk, mirroring the structural disparities observed in other areas of the healthcare system.

By analyzing more than 73 million electronic health records using artificial intelligence, the researchers found that patients diagnosed with leukemia, non-Hodgkin lymphoma, or lung cancer in the past 12 months faced the greatest risk for being infected with the SARS-CoV-2 virus compared to those without cancer or patients whose cancers had been previously diagnosed. Alarmingly, African American cancer patients were the most susceptible, as the risk of SARS-CoV-2 infection was highest in patients who had breast, prostate, colorectal, or lung cancer.

Although statistical significance was not achieved, the results suggest that African American patients were more likely than White patients to be hospitalized for cancer alone, COVID-19 alone, or both diseases.

To read the study in *JAMA Oncology,* CLICK HERE.