Health Industry Alert

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Friday Evening Health Care Regulatory Blitz!

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Happy Thanksgiving everyone. In a pre-holiday flurry, the Trump Administration has released four long-awaited health care policies impacting a wide range of health industry participants.

On the drug pricing front, the Administration issued a Final Rule aimed at curbing certain prescription drug rebate practices, and an Interim Final Rule (IFR) implementing a new Most Favored Nations (MFN) model that will base payment for certain Medicare Part B drugs and biologicals on international prices.

On the value-based care front, the Administration issued two Final Rules aimed at advancing the transition to a value-based health care delivery and payment system, and encouraging coordination of care among physicians, health systems, and others in the care continuum.

In this alert, we provide links and brief context for each of the rules rolled out on Friday and offer insights on what to expect in the coming weeks and months.

HHS Advanced New Stark and Anti-Kickback Final Rules Across the Finish Line in Its "Regulatory Sprint to Coordinated Care"

In 2018, leadership at the Department of Health and Human Services (HHS) announced that it would be taking steps to reduce the regulatory barriers to care coordination and accelerate the transition to value-based care. The physician self-referral law (aka the "Stark Law"), the Anti-Kickback Statute (AKS), and Beneficiary Inducement Civil Monetary Penalties (CMP) Rules were identified as potentially inhibiting beneficial arrangements between and among health industry participants that would advance value-based care and improve the coordination of care across case settings. On Friday, November 20, two years after the initiative started in earnest, HHS published two Final Rules expanding legal protections for value-based and care coordination arrangements under these authorities.

Revisions to the Safe Harbors Under the AKS and Beneficiary Inducements CMP Rules

The Final Rule from the HHS Office of Inspector General (OIG) implements seven new safe harbors, modifies four existing safe harbors, and codifies one new exception under the Beneficiary Inducements CMP. Three of the new safe harbors protect

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certain coordinated care and value-based arrangements between and among clinicians, providers, suppliers, and others that participate in “value-based enterprises.” Other new safe harbors include:

- Donations of cybersecurity technology and related services
- Arrangements for patient engagement and support
- CMS-sponsored model arrangements and CMS-sponsored model patient incentives
- Accountable care organization (ACO) beneficiary incentive programs

The Final Rule also modifies existing safe harbors for electronic health records items and services, personal services and management contracts, warranties, and local transportation, and codifies a new exception to the Beneficiary Inducement CMP Rules for telehealth for in-home dialysis.

Click here to access the Final Rule

Click here to access the Fact Sheet

Modernizing and Clarifying the Physician Self-Referral Regulations

The Centers for Medicare & Medicaid Services (CMS) issued a Final Rule “Modernizing and Clarifying the Physician Self-Referral Regulations.” The rule implements new exceptions to the Stark Law regulations that will protect arrangements designed to advance the transition to value-based care and improve the coordination of patient care across care settings. The rule also clarifies and modifies existing definitions and policies, in an effort to ease unnecessary regulatory burden on physicians and other health care providers.

Click here to access the Final Rule

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What to expect: The Regulatory Sprint rules each become effective on January 19, 2021, meaning they would not be affected by a new administration’s order to suspend regulations that have not yet taken effect, should such an order be issued. These effective dates, which occur less than 60 days from the date they are officially published in the Federal Register, may be a technical foul under the Congressional Review Act’s 60-day delayed effective date requirement, but this foul should not threaten their future. The Congressional Review Act does not allow for judicial review, and given the broad support for these rules among industry and on both sides of the aisle in Congress, Congressional review seems unlikely. Therefore, it’s likely that these new permissions are here to stay. However, there may be opportunities to continue to tweak under a new administration.

The CMS and OIG rules are major milestones in the Regulatory Sprint, but one more rule is pending. A proposed rule from the HHS Office for Civil Rights cleared White House review earlier this month, and would seek comment on modifications to HIPAA Rules which may present barriers that limit or discourage coordinated care and case management.

Drug Pricing

HHS issued a Final Rule aimed at curbing certain prescription drug rebate practices, and an IFR implementing a new MFN Model that will base payment for certain Medicare Part B drugs and biologicals on international prices. Both of these actions

fulfill Executive Orders issued by the President earlier this summer, and mark the culmination of the Administration's work to lower drug prices for seniors.

Most Favored Nations Model

The MFN Model was released on Friday as an IFR with comment period set to take effect on January 1, 2021. The IFR is likely to meet significant pushback from affected stakeholders seeking to enjoin the implementation of the rule on both procedural (e.g., there was no notice-and-comment rulemaking) and substantive (e.g., challenging whether CMS has the authority to make such sweeping changes) grounds. If the IFR were to take effect, it would implement a nationwide mandatory payment model (with limited exceptions) applying to certain high-cost drugs from January 1, 2021 to December 31, 2027. The MFN Model would test an alternative payment for included drugs that will be based on global prices and include a flat add-on amount for each dose.

Click here to access the Final Rule

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What to expect: The MFN model is scheduled to take effect January 1, 2021, but the decision to waive notice and comment rulemaking will make the model especially vulnerable to a procedural attack. A successful court challenge could leave a new administration with a temporary injunction and tough decisions about whether and how to defend the model. Recall that the Obama Administration proposed a mandatory Part B drug model in 2016, exploring similar concepts, but declined to go through with the model.

Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection

The Final Rule from HHS OIG revises the existing AKS safe harbor for discounts to explicitly exclude reductions in price offered by drug manufacturers to pharmacy benefit managers (PBMs) and Part D plans from the safe harbor's definition of a "discount." It also creates a new safe harbor designed specifically for price reductions that are passed along to the patient at the point of sale. In the Final Rule, HHS decided to retain protection for rebates offered by manufacturers to Medicaid managed care organizations. This Rule, long thought "dead" after it failed to advance back in the summer of 2019, gained new life through an Executive Order issued on July 24, 2020.

Click here to access the Final Rule

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What to expect: The major provision in the rebate rule—the revisions to the discount safe harbor—will not take effect until January 1, 2022. This delay was intended to allow stakeholders to make any necessary changes to their contracts, and for Part D plans to build new assumptions into the bids they will submit next summer. The delay also creates an opportunity for the Biden Administration to reconsider the regulations prior to their taking effect. Even if the new Administration opts to leave these regulations in place, it is possible the Final Rule could face a court challenge.

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