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Due to the Thanksgiving holiday next week, the Healthsperien Daily Alerts will be on a holiday schedule. We will be releasing our Monday Look Ahead and any breaking news alerts on regulatory developments. Our normal Daily Alert schedule will resume on Monday, November 30th. Happy Thanksgiving!

November 20, 2020

- HHS Releases Finalized Changes to Regulations Governing the Anti-Kickback Statute and Physician Self-Referral Law
- HHS Finalizes Controversial Changes to Part D Drug Rebates
- CMS Finalizes “Most Favored Nation” Model Under CMMI Demonstration Authority

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analysis, strategic insights, legislative and regulatory advocacy. All of our COVID-19 analyses can be found here.

SPECIAL REGULATORY ALERT:

HHS Releases Finalized Changes to Regulations Governing the Anti-Kickback Statute and Physician Self-Referral Law

Today HHS released final versions of changes to its underlying regulations implementing the Anti-Kickback Statute and Physician Self-Referral Law – Stark Law (Anti-Kickback Final Rule here and Stark Law Final Rule here). A fact sheet on the AKS rule can be found here and one for the Stark Law can be found here. The proposed versions of the each of the rules were originally released on October 17, 2019 (Anti-Kickback Statute Proposed Rule here and Stark Law Proposed Rule here).

The rules are also part of a broader set of regulatory changes from HHS/CMS (discussed elsewhere in this alert) intended to be issued prior to the informal "midnight regulation" deadline on November 21, 2020. Rules passed after that deadline may be subject to review by the incoming Biden Administration. It also prevents the incoming Administration from claiming the finalized versions as a potential regulatory victory.

Below we have captured highlights from both rules, including some important changes from the proposed versions. These are not meant to be comprehensive summaries. Healthsperien will continue to review the rules in the coming days. Please do not hesitate to reach out with questions.

Anti-Kickback Statute – effective date 01/19/2021
CMS is finalizing its regulatory terminology associated with the three new safe harbor protections: (1) care coordination arrangements to improve quality, health outcomes, and efficiency, (2) the value-based arrangements with substantial downside financial risk, and (3) value-based arrangements with full downside financial risk:

- **Definition of "Value-Based Enterprise":** HHS declined to provide further guidance on the "accountable body" requirement included in the proposed rule's VBE definition. Instead, HHS stresses several times that they prefer to give parties flexibility in constructing their VBAs and VBEs. HHS does state that "where parties already have a governing body that constitutes an accountable body or responsible person, such parties are not required to form a new [one] for purposes of creating a VBE."

- **Definition of "Value-Based Arrangement"**: HHS is finalizing its definition of a value-based arrangement as proposed with the clarification that only the value-based enterprise and one or more of its VBE participants, or VBE participants in the same value-based enterprise, may be parties to the value-based arrangement.

- **Definition of "Target Population"**: HHS is finalizing the definition of a target patient population as proposed – "an identified patient population selected by the

VBE or its VBE participants using legitimate and verifiable criteria that (A) are set out in writing in advance of the commencement of the value-based arrangement and (B) Further the value-based enterprise's value-based purpose(s)"

- **Definition of "Value-Based Entity Participant"**: HHS is choosing to adopt as inclusive of a definition as possible by choosing to instead define what entities are excluded from acting as a VBE participant. HHS explains each exclusion in the rule and its reasons behind it. Excluded entities are: pharmaceutical manufacturer, distributor, or wholesaler; pharmacy benefit managers; laboratory companies; compounding pharmacy; certain DME manufacturers, distributors and suppliers.

- **Change in definition of "substantial downside financial risk"**: HHS has lowered the bar for meeting the "substantial downside financial risk" safe harbor to "risk equal to at least 30 percent of any loss, where losses are covered by the applicable payor and furnished to the target patient population to a bona fide benchmark designed to approximate the expected total cost of such care." The proposed version required 40% risk relative to specific historical expenditures.

- **Monitoring and assessment requirements of VBEs**: HHS is requiring VBE participants, or a responsible part acting on their behalf, no less than annually monitor and assess the (i) coordination and management of care for the target patient population in the value-based arrangement; (ii) any deficiencies in the delivery of quality care under the value-based arrangement; and (ii) progress toward achieving the legitimate outcome or process measure(s) in the VBA. The findings must be reported to the VBE's accountable body.

- **General relaxing of outcome measures**: HHS is permitting VBEs to have "legitimate outcome or process measure(s)" as opposed to "specific evidence-based, valid outcome measure(s)" as in the proposed rule.

Physician Self-Referral Law (Stark Law)
CMS is finalizing exceptions to Stark Law as it relates to value-based payment arrangements, cybersecurity and electronic health records. In response to stakeholder feedback and other factors, CMS also did not finalize certain exceptions that were proposed. Key finalizations include:

- **Value-Based Arrangements**: The final rule creates permanent exceptions to the Stark Law for value-based arrangements (VBA). Physicians and other health care providers may now enter into VBAs without fear that it would violate the Stark Law. The exceptions apply regardless of whether the arrangement relates to care furnished to people with Medicare or other patients.

- **Price Transparency**: CMS originally proposed the inclusion of price transparency requirements for value-based exceptions to the physician self-referral law. This requirement was not finalized because HHS deemed this rule to be an inappropriate mechanism for price transparency due to the strict liability nature of Stark law.

- **Decoupling Stark from the Anti-Kickback Statute:** In the proposed rule CMS sought to separate Stark Law requirements from those of the Anti-Kickback Statute. In the final version CMS states it no longer believes a decoupling to be

appropriate and is not finalizing the change.

- **Cybersecurity and EHR Exceptions:** Consistent with the proposed rule, the final rule establishes a new exception for donations of cybersecurity technology and related services and eliminates the sunsetting of the exception for electronic health records (EHR) items and services.

HHS Finalizes Controversial Changes to Part D Drug Rebates

As part of today's broader set of regulatory releases, HHS finalized the "Removal of Safe Harbor Protection for Rebates to Plans or Pharmaceutical Benefit Managers (PBMs) Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection" final rule, otherwise colloquially referred to as the "rebate rule" with an effective date of January 1, 2022. The final rule fact sheet can be accessed here.

Rebate Rule Regulatory History
The process and timeline of the rebate rule has caused some controversy. The proposed version of the rule was published in February 2019, but the Administration announced in July 2019 that it was withdrawing the rule from consideration. A year later, President Trump issued an executive order calling for the rebate rule to be finalized so long as the "... action is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs."
When the Office of Management and Budget (OMB) began a review of a finalized version of the rule earlier in November, it was unclear if the administration would release another proposed rule. The fact sheet describing the final rule released today stated there was never an official notice of withdrawal posted to the federal register and the Administration used the year between the proposed rule and the Executive Order to address comments received.

Highlights of Finalized Rule
This rule updates the "Anti-Kickback Statute" discount safe harbor. Under current law, the discount safe harbor allows PBMs to negotiate price concessions from manufacturers on behalf of Part D plans. The final rule changes the discount safe harbor to explicitly exclude reductions in price offered by drug manufacturers to PBMs and Part D plans from the safe harbor's definition of a "discount." Instead, the final rule creates a new safe harbor specifically for point-of-sale reductions in price for products payable under Medicare Part D or by Medicaid managed care organizations (MCOs), and forms a new safe harbor for fixed fees that manufacturers pay to PBMs for services rendered to the manufacturers. Notably in the final rule, Medicaid MCOs are exempt from the safe harbor changes, and rebates offered from manufacturers directly to Medicaid MCOs can continue to be protected by the discount safe harbor if all conditions of the safe harbor are met.

CMS Finalizes "Most Favored Nation" Model Under CMMI Demonstration Authority

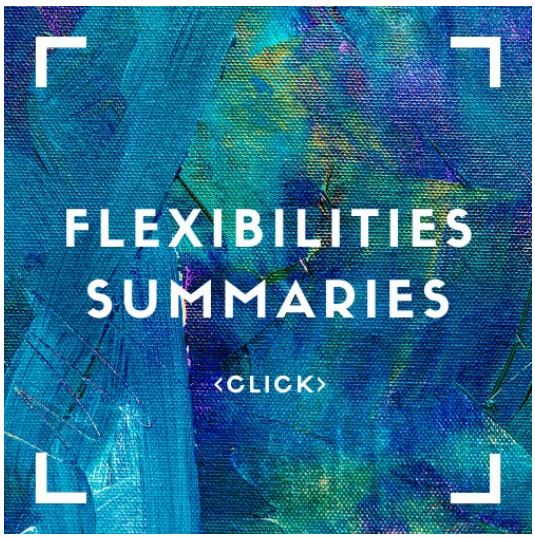
Today, CMS also released an interim final rule (IFR) that details a mandatory "Most Favored Nation" (MFN) model demonstration under the Centers for Medicaid and Medicare Innovation.

Background
The IFR, titled "International Pricing Index Model For Medicare Part B Drugs (CMS-5528-P)", includes provisions similar to the Advance Notice of Proposed Rulemaking (ANPRM) released by the Trump Administration on October 18, 2018, related to a similar "International Pricing Index" model. The IFR follows on the Trump Administration's Executive Order (EO) on September 13, 2020, titled "Lowering Drug Prices by Putting America First." The EO states that "the Medicare program should not pay more for costly Part B or Part D prescription drugs or biological products than the most-favored-nation price." The September EO replaced a July EO of the same title.
Our summary is not intended to be a comprehensive review of the rule. We will continue to review this internally.

Details of the MFN Price for Part B Drugs
The interim final rule ties Medicare reimbursement for 50 separately payable, single source Part B drugs and biologics to international prices. Medicare Part B currently reimburses physicians and hospitals based on a domestic "Average Sales Price" (ASP) and includes a 6% add-on. According to the rule, ASP would be replaced by a new "MFN Price," established based on the lowest prices paid by comparable Organization for Economic Co-operation and Development (OECD) countries.
The MFN Price would apply to a basket of 50 high-cost, brand, physician-administered drugs. The model also replaces the 6% add-on with a flat rate – indicating that the percentage-based add-on can incentivize the use of higher-cost drugs. The rule does not apply to certain vaccines, oral drugs, multiple source drugs (i.e., generics), and intravenous immune globulin products. The model will include all providers and suppliers that participate in Medicare, with some exceptions (notably, cancer hospitals).
The MFN demonstration starts January 1, 2021. The MFN Price will be phased-in over the first 4 years of the 7-year model, phasing in 25 percent per year for years 1-4, and then continuing at 100 percent of the MFN Price for years 5-7.

Comparison to Previous Proposals
When the 2019 proposed rule was released, CMS aimed to reduce Medicare reimbursement by 30 percent on average. The Administration estimated this model would provide $17.2 billion in savings to American taxpayers and patients and lower out of pocket costs by $3.4 billion. However, the proposed rule tied Part B prices to an *average* of prices in OECD countries. The interim final rule released today ties prices to the *lowest* price of the applicable OECD countries. Overall, the Medicare actuary estimates that the MFN Model will result in savings of $85.5 billion, net of the associated change in the Part B premium, in Medicare Part B spending. In addition, the IFR is exclusive to Part B drugs – the July and September EOs on drug pricing indicated that the model could focus on Part B *or* Part D. Importantly, Part D drugs were never considered part of the October 2018 ANPRM.

COVID-19 POLICY & REGULATORY RESOURCES



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