TRUMP ADMINISTRATION ISSUES FLURRY OF LAST MINUTE HEALTHCARE REGULATIONS: WHAT WILL THE INCOMING ADMINISTRATION DO NEXT?

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Health Care Alert

By: Richard P. Church, Karishma Shah Page, Leah D'Aurora Richardson, Victoria K. Hamscho, Laura H. Gregory

On 20 November 2020, the Centers for Medicare and Medicaid Services (CMS) and the Department of Health and Human Services (HHS) Office of Inspector General finalized several rules from President Trump's health care agenda that are considered key parts of his potential legacy. The final rules seek to:

- modernize the physician self-referral regulations (the Stark Law) and the federal anti-kickback statutes (AKS);
- implement new value-based exceptions and safe harbors under the Stark Law and AKS;
- exclude rebates on drugs paid by drug manufacturers to pharmacy benefit managers (PBMs) and Medicare Part D plans from safe harbor protection under the anti-kickback statute;
- implement a new “Most Favored Nation” (MFN) payment model to lower Medicare Part B payments for certain drugs; and
- increase organ supply by revising the requirements for organ procurement organizations.

Except for the MFN rule (effective 27 November 2020), the Stark and AKS rules (effective 19 January 2021), and some of the AKS changes (effective 1 January 2022), the final rules provide that they are set to go into effect 60 days from their publication in the Federal Register. By releasing most of them in pre-publication form in the Federal Register on 20 November—60 days before President-elect Joe Biden takes office—it appears that the Trump administration may be attempting to limit the ability of the incoming administration to impact them. Because the rules are not scheduled to be officially published in the Federal Register until late November or early December, President-elect Biden could rely on the Congressional Review Act (CRA) to try to delay or suspend the rules, though it appears unlikely based on agency experience. Further, the MFN rule seeks to mandate dramatically reduced physician-administered Part B drug reimbursements across wide swaths of the health care provider community through reliance on CMS' normally voluntary payment innovations center. The legality of that approach is also unclear and will likely be litigated based on the early reaction of industry stakeholders.

Based on the above, stakeholders should expect a bumpy ride in the next several months as it relates to these regulations given that the incoming Biden administration may attempt to delay, suspend, or alter each of these rules. In particular, it is worth noting that the MFN rule, though impacting reimbursement on 1 January 2021, is still subject to a comment period. As such, stakeholders may submit comments on the rule by 26 January 2021, and should also be alert to potential litigation immediately upon the MFN rule becoming effective. Otherwise,

stakeholders should be watching for public signals from the Biden administration—particularly as the President-elect makes key appointments within HHS—as to how it may position itself vis-à-vis each of these rules.

This alert provides a brief overview of the rules, the new administration's authority to impact them, and a preview of what to expect from the incoming administration.

OVERVIEW OF THE FINAL RULES

- Modernizing and Clarifying the Physician Self-Referral Regulations, scheduled to be published in the Federal Register on 2 December. The final rule provides guidance on exceptions to the Stark Law, including protections for non-abusive, beneficial arrangements such as donations of cybersecurity technology that safeguard the integrity of the health care ecosystem. The rule also establishes a permanent exception for value-based arrangements to permit physicians and other health care providers to enter into such arrangements to better coordinate and improve the quality of care for patients and lower costs.

- Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, scheduled to be published in the Federal Register on 2 December. The final rule seeks to modernize the AKS and implements new safe harbors, including for remuneration exchanged between or among eligible participants in a value-based arrangement that fosters coordinated and managed patient care.

- Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protections for Point of Sale Rebates and PBM Administrative Services, scheduled to be published in the Federal Register on 30 November. The final rule was a key linchpin in President Trump's drug pricing proposals.[1] Under the new rule, rebates on prescription drugs paid by manufacturers to PBMs and plans related to Part D reimbursable drugs would be excluded from the discount safe harbor under the AKS. The rule also creates new safe harbors. The first is designed to protect discounts on products offered by manufacturers to pharmacies at the point of sale, but only if those discounts are reflected in the price charged to the patient at the pharmacy counter. The second provides a safe harbor for fixed fee payment from manufacturers to PBMs for administrative services.

- Most Favored Nation Part B Drug Payment Model, published in the Federal Register on 27 November. The interim final rule establishes a new drug payment model aimed at lowering Medicare Part B payments for certain drugs. Under the new innovation model, the Part B drug payment amount for the top 50 physician administered Part B drugs (based on CMS 2019 reimbursement data) will be set according to the lowest price available in another Organization for Economic Co-operation and Development (OECD) country with a GDP of 60% of the U.S. GDP per capita. The MFN price will be phased in such that it is blended with the current reimbursement rate of ASP plus 6% over the course of the first three years of the model. In addition, the model will include a flat add-on amount for administration of the drug that will be consistent for each model drug - starting with a reimbursement of $148.73 per administration in Q1 of 2021. The model will operate for seven years, commencing on 1 January 2021.

- Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization, scheduled to be published in the Federal Register on 2 December. The final rule seeks to increase the supply of organs available for transplant in the United

States by revising outcome measures for assessing the performance of Organ Procurement Organizations (OPOs) in order to increase transparency and competition. The revised measures include a donation rate measure, which measures the number of organs an OPO procures from all eligible donors in its donation service area, as well as an organ transplantation rate measure designed to incentivize OPOs to transplant and use all viable organs.

WHAT TO EXPECT NEXT

The New Administration's Authority

When there is a change in administration, the exercise of executive and administrative authority to influence final rules from the previous administration is common. However, the new administration's authority to impact final rules generally depends on their publication in the Federal Register and effective date. A new administration may only rescind or alter a final rule published in the Federal Register that has already become effective by restarting the rulemaking process (akin to any change in regulation), which requires issuing a new proposed rule with notice-and-comment period and providing a rational justification for why the rule is no longer appropriate. In contrast, if a final rule has been published in the Federal Register but not yet become effective by the time the new administration takes office, the new administration may issue an order simply suspending or delaying the final rule. This is quite common when there is a presidential transition, and it is worth noting that both the Trump administration and the Obama administration used this power broadly to delay and ultimately rescind many pending rules.

In this regard, for purposes of determining the effective date of a rule, the Administrative Procedure Act (APA) generally requires that agencies provide a period of at least 30 days after a final rule is published in the Federal Register before the rule becomes effective.[2] The CRA extends the APA's required period for major rules, providing that they “shall take effect on the latest of” 60 days after the date the rule is published in the Federal Register or submitted to Congress (whichever is later) or the date the rule would have otherwise taken effect.[3] The Federal Register distinguishes between filed (pre-publication) and published rules, providing that only the official format of a published document provides public and judicial notice.[4] Given that each of these rules has been deemed by HHS to be a major rule for purposes of the CRA, they are likely subject to the 60-day rule in the CRA.[5]

Accordingly, by issuing the above-mentioned final rules on 20 November—60 days before President-elect Joe Biden takes office—it appears that the Trump administration may be attempting to limit the ability of the new administration to suspend or withdraw them as they are considered key parts of the Trump administration's potential legacy. It is worth noting that, while the rules were released and most of them filed in the Federal Register on 20 November,[6] they are not scheduled to be officially published in the Federal Register until late November or early December. In this regard, while the Trump administration has issued some of the rules with stated effective dates prior to the inauguration, the Biden administration could argue that they will not go into effect until after President-elect Biden takes office because of the CRA as a means to ensure that the new administration will have an opportunity to review the rules.

While President-elect Biden could rely on the CRA to try to influence the rules, it appears unlikely that the new administration may seek to delay or suspend the rules on that basis. Despite the above-mentioned provision requiring that major rules take effect at least 60 days after they are published in the Federal Register and the

Federal Register's differentiation between filed (pre-publication) and published rules, federal agencies have generally relied on the pre-publication date as the date from which the 60 days is counted for purposes of determining when a rule is effective. Given that questioning the effective date of the rules at issue would call into question the effective date of a number of other rules that have been issued in recent administrations, including the Obama administration, it appears unlikely that the new administration may use it as a means to try to suspend or delay them. That said, the CRA remains a tool that President-elect Biden's administration could potentially rely on as a means to influence these rules.

THE NEW ADMINISTRATION'S NEXT STEPS

Regardless of the CRA, as noted above, the MFN rule is subject to further immediate comment period and finalization and each of the other rules can be reopened with a new comment period so each of the rules can be altered if the new administration wants to impact their final form. However, at this point, it is unclear how President-elect Biden's administration may immediately respond to the rules.

Stark, AKS Rules and OPO Rule

At this point, it is unclear how President-elect Biden's administration may respond to the rules. The Stark Law and AKS modernization and value-based rules as well as the OPO rule on organ donations have been several years in the making. Further, efforts to modernize the Stark and AKS regulations have generally received support from stakeholders. The American Hospital Association (AHA) and the Federation of American Hospitals, for example, praised the administration for taking action to modernize the Stark and AKS rules. The AHA said that the rules would “significantly benefit patients by allowing their health care providers to work together to improve their care.” Given the support for the rules and their non-partisan nature, it appears unlikely that the new administration would seek to suspend or immediately alter them.

AKS Rebate and MFN Rules

President-elect Biden has stressed that drug pricing reform is one of his priorities when he takes office. In this regard, the President-elect has favored letting the government negotiate prices with manufacturers and allowing the importation of drugs from abroad. The Trump administration's actions may provide the new administration a pathway to take immediate action on drug pricing by merely allowing the Trump rules to proceed without having to spend political capital advancing its own drug pricing agenda. Accordingly, the new administration could be very open to simply letting the new AKS rebate rule proceed. While the Pharmaceutical Care Management Association, which represents PBMs, has said that the AKS rebate rule “will drastically increase Medicare Part D beneficiary premiums and taxpayer costs,” provider and industry groups have been more circumspect in their reaction to elimination of the AKS rebate rule.

The MFN rule, in contrast, received immediate pushback from provider groups and the pharmaceutical industry since it was initially proposed. In a statement, for example, the Pharmaceutical Research and Manufacturers of America (PhRMA) said that the MFN rule would disrupt patient access to treatments, discourage investment in new medicines, and threaten jobs and economic growth, stressing that it is “considering all options to stop this unlawful onslaught on medical progress.” The AHA also expressed concern about the impact of the MFN rule on the 340B Drug Pricing Program, providing that “by cutting drug reimbursements to hospitals—by an average of 65% when fully phased in—hospitals will have to absorb losses while drug companies are free to continue their trend of charging exorbitant prices.”

Further, the MFN Rule will likely require action by the Biden administration. While it will be implemented as of 1 January 2021—with providers immediately receiving dramatically lower reimbursement—the MFN rule was issued as an interim final rule with comment period, which means that stakeholders may provide comments on the rule and the administration will have an opportunity to respond to those comments and potentially alter the rule based on the comments. Additionally, stakeholders are arguing that the rule may exceed HHS' authority. In this regard, it is worth noting that the rule was issued under CMS' payment demonstration authority through the Centers for Medicare and Medicaid Innovation, but as a practical matter, the rule reduces the statutory Part B payment model for a wide range of provider types on the 50 drugs impacted. Accordingly, the potential for litigation—similar to that challenging CMS' cuts to Part B drug reimbursement to 340B Program-eligible hospitals—is high.

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K&L Gates' health care practice and public policy and law practice routinely assists stakeholders with legal advice regarding Stark Law and AKS compliance matters and on a wide range of pharmacy, 340B Program, and other drug pricing matters. We can advise and engage with Congress and the administration on these matters.

FOOTNOTES

[1]See White House, Executive Order on Increasing Drug Importation to Lower Prices for American Patients, Executive Orders (July 24, 2020).

[2]65 U.S.C. §553(d).

[3]The CRA provides for additional considerations if Congress passes a resolution of disapproval. 5 U.S.C. §801(a)(3).

[4]See Federal Register, Understanding Public Inspection, https://www.federalregister.gov/reader-aids/using-federalregister-gov/understanding-public-inspection (last accessed November 25, 2020).

[5]The CRA provides an exemption if the President makes a determination and submits notice to Congress that the rule is necessary because of an imminent threat, necessary to enforce criminal laws, necessary for national security, or issued pursuant to a statute implementing an international trade agreement. 5 U.S.C. §801(c)(1).

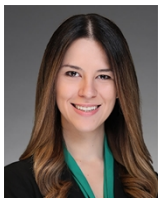
[6]Other than the OPO rule, all rules were filed in pre-publication form in the Federal Register on November 20. The OPO rule was released on HHS' website on November 20 but filed in pre-publication form on November 24.

KEY CONTACTS

RICHARD P. CHURCH
PARTNER
RESEARCH TRIANGLE PARK, CHICAGO
+1.919.466.1187
RICHARD.CHURCH@KLGATES.COM

KARISHMA SHAH PAGE
PARTNER
WASHINGTON DC
+1.202.778.9128
KARISHMA.PAGE@KLGATES.COM

LEAH D'AURORA RICHARDSON
PARTNER
RESEARCH TRIANGLE PARK
+1.919.466.1126
LEAH.RICHARDSON@KLGATES.COM



VICTORIA K. HAMSCHO
ASSOCIATE
WASHINGTON DC
+1.202.778.9137
VICTORIA.HAMSCHO@KLGATES.COM

LAURA H. GREGORY
ASSOCIATE
WASHINGTON DC
+1.202.778.9422
LAURA.GREGORY@KLGATES.COM

