



Trump Administration Regulations on Drug Pricing

Most Favored Nation Rule; Rebate Rule; Drug Importation; and Price Transparency

Most Favored Nation Rule

- Interim Final Rule requires provider groups to engage in negotiations with manufacturers or distributors to obtain prices for Part B drugs in line with new reimbursement rates.
- Mandatory across the country.
- IFR goes further than what was proposed by choose the target price to be the lowest price adjusted for per-capita gross domestic product of any OECD country with a GDP per capita at least 60 percent of that of the U.S.
- IFR acknowledges that 19% of Part B drug utilization may be eliminated because patients can no longer access the drugs from their providers.

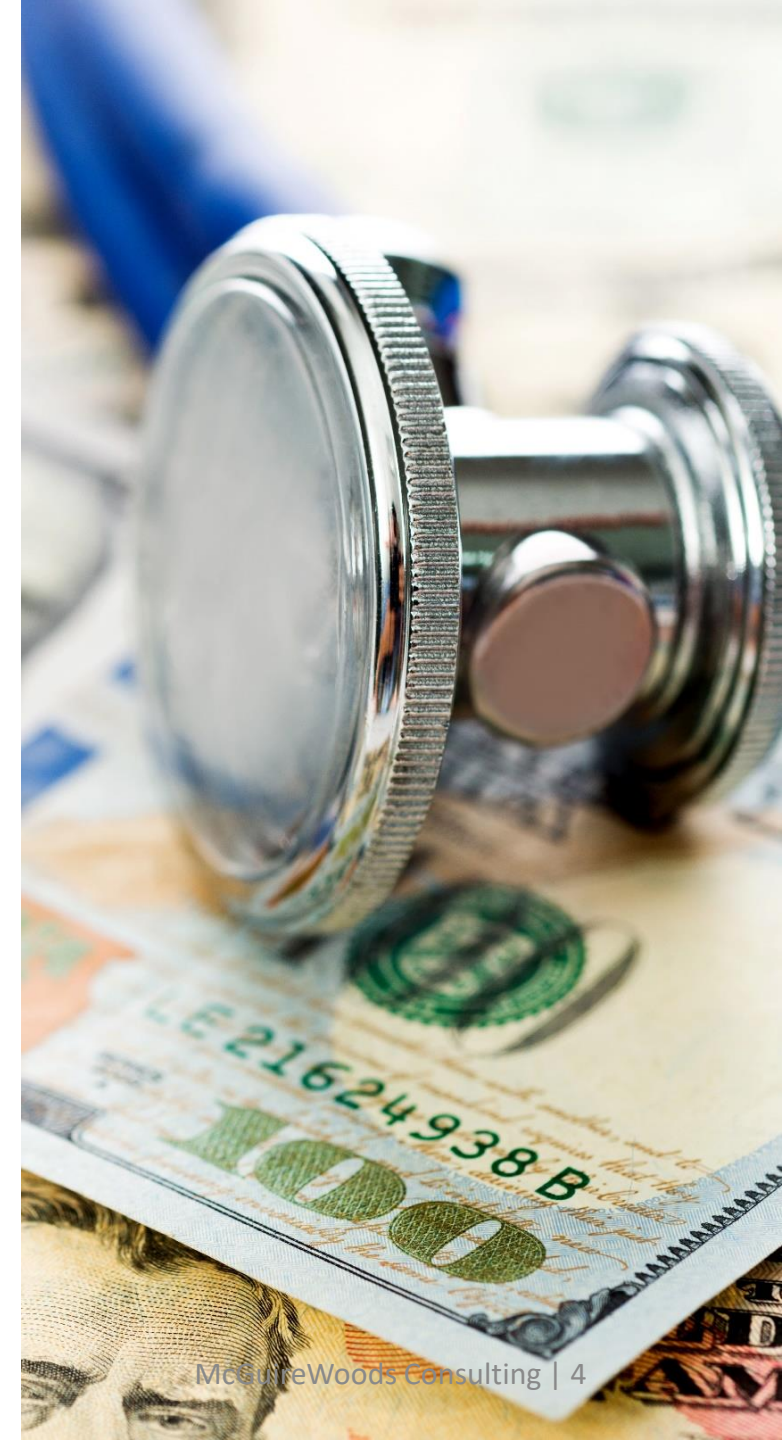


Procedural, Implementation and Policy Issues

- Process: CMS initially issued an advance notice of proposed rulemaking and never issued a notice of proposed rule making.
 - An NPRM was submitted to the Office of Management and Budget but it was never cleared
 - CMS is using the COVID-19 pandemic as an excuse to by-pass the usual rulemaking process, but the existence of an NPRM that OMB did not clear undermines this argument
 - PHARMA is suing to stop implementation stating this was a violation of the Administrative Procedures Act and that the ANPRM said this was a test of a payment model
 - Implementation Problem – CMS may not be able to obtain data that truly reflects the information they need
 - May lower Medicare Advantage payments

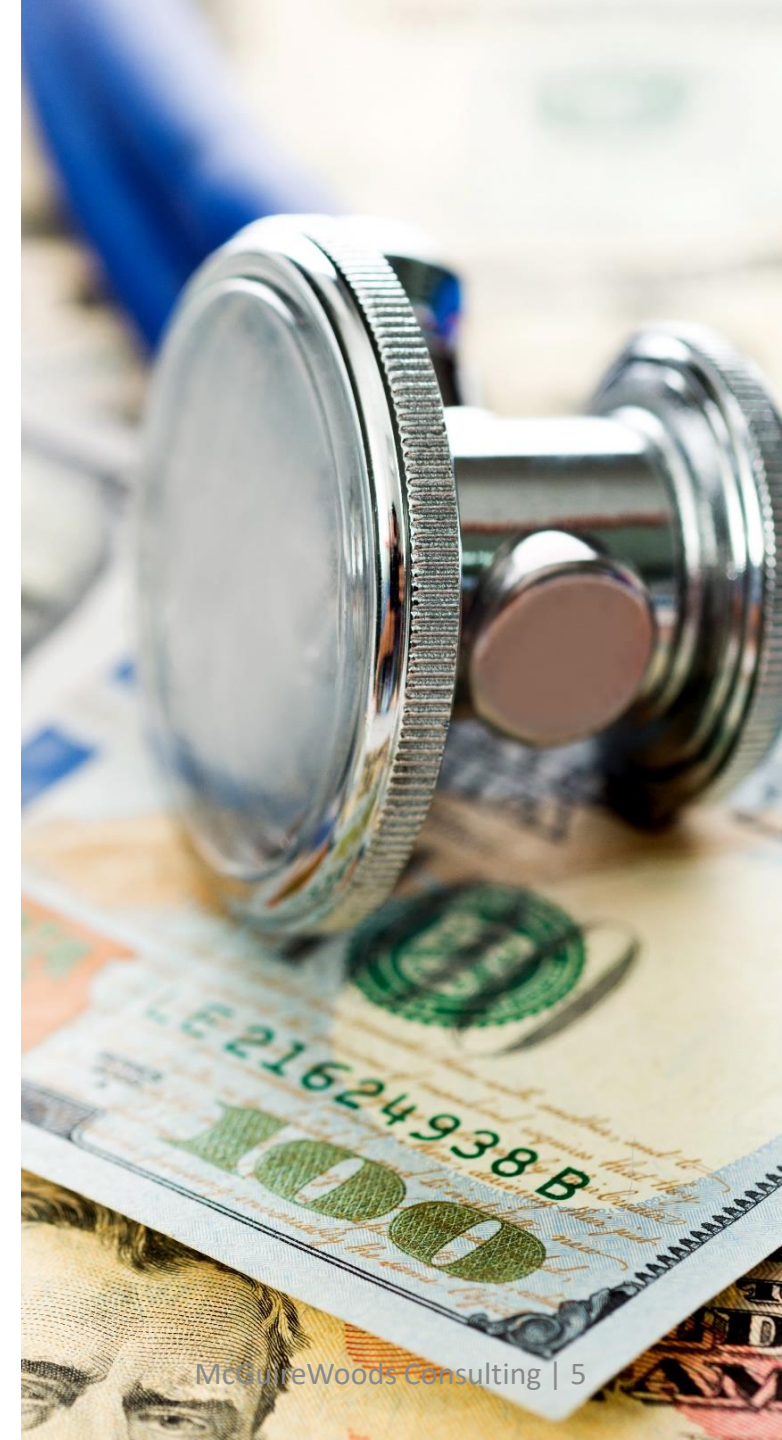
Drug Rebate Final Rule

- Changes the Anti-Kickback regulations to create two narrow safe harbors:
 - To provide discounts for the consumer at the pharmacy counter
 - To protect arrangements between manufacturers and PBs that are fixed fee services – a practice that occurs in government contract bids
 - Removed Medicaid Managed Care Organizations because a number of commenters noted that the projected result of their inclusion would be to increase Medicaid costs for the states and the federal government



Issues with Drug Rebate Rule

- Sec. Azar was required to confirm that Drug Rebate Rule will not increase Federal spending, Medicare beneficiary premiums or patients' total out-of-pocket costs. Yet when he made that confirmation, he did not provide an explanation other than based on his experience in the industry and government. His assertion contradicted several projections to the contrary.
- HHS expects manufacturers will lower their prices.
- Was the NPRM withdrawn? CMS issued a press statement saying it was withdrawing the rule but there was no notice in the Federal Register.
- PHARMA has filed suit.



Drug Price Transparency

- In October 2020, HHS, Labor and Treasury issued a rule concerning transparency in coverage.
- The rule requires plans and insurers to disclose the negotiated rate of the drug, but in general, insurers do not need to disclose discounts, rebates or price concessions for a drug.



Drug Importation

- Current law allows for the importation of certain drugs from Canada under defined, limited circumstances and only if the Secretary of HHS certifies that importation poses no threat to the health and safety of the American public.
- Secretary Azar certified that importation poses no risk to health and safety and would result in significant cost savings.
- In September, HHS issued a final rule and FDA guidance creating two new pathways for the safe importation of drugs.



Issues with Importation

- Canada announced this month that it will take measures to protect their drug supply from bulk importation that could worsen drug shortages and will bar distribution outside their country if to do so would cause or worsen shortages.
- On Nov. 23, PHARMA, and two other organizations challenged the final rule in court alleging the Final Rule disregards key protections of the Food, Drug, and Cosmetic Act related to patient safety.
- The suit also argues that there is no supporting evidence for the Secretary's confirmation that to import drugs is safe and that HHS cannot quantify savings. They also argue the action violates the First amendment and raised questions concerning the Fifth Amendment takings clause.



Biden Administration

- Most Favored Nation Rule and the Drug Rebate rule were published inside the 60 day window before the next Administration so it can be held for review.
- Drug Importation as issue is not likely to go away. The next Secretary may not certify there is no risk to safety and health.
- AHA continues to challenge the health transparency rule in court but has lost most challenges. The drug price transparency is part of that rule.





Questions?

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