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Fast 5: Five Quick Regulatory Takeaways for Pharmaceutical Companies

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Here we are in fourth quarter of 2023 already! As companies start wrapping up 2023 and preparing and modeling for 2024, we thought it was a good time to highlight five regulatory developments, changes, or challenges on the horizon for pharmaceutical manufacturers operating in the US market:

1. The potential for unlimited MDRP rebates begins on January 1, 2024.

One of the “pay fors” buried in a COVID-19 stimulus bill — the

American Rescue Plan of 2021 — was the removal of the Average Manufacturer Price (AMP) cap on Medicaid Drug Rebate Program (MDRP) rebates. Manufacturers that desire for their covered outpatient drugs to be covered and paid by state Medicaid program must agree to participation in the MDRP and pay rebates on state Medicaid beneficiary utilization of their products. Those rebates have a basic component based on AMP for generic drugs with an interplay of Best Price for brand drugs and additional discount component to the extent AMP is rising faster than inflation. Since the Affordable Care Act passed in 2010 those MDRP rebates have been capped at AMP such that a manufacturer never paid a rebate above the drug's AMP. Beginning January 1, 2024, this cap goes away, and a manufacturer could end up paying substantially higher MDRP rebates on certain products. This impacts generics and brand drugs alike. Its important for manufacturers to model for the financial impact of the AMP cap removal in advance of January 1, 2024.

2. The IRA is not just about direct price negotiation. Inflation rebates on drugs reimbursed under Medicare Part B and D are here and will continue to accumulate for brand and generic manufacturers alike.

There has been a lot of articles, discussions and even litigation about the direct negotiation aspects of the Inflation Reduction Act (IRA). The drug pricing provisions in the IRA extend will beyond direct negotiation. Beginning from Q4 2022 for drugs reimbursed under Medicare Part D and Q1 2023 for drugs reimbursed under Medicare Part B manufacturers will be required to pay inflation rebates to the extent the price of the drugs is rising faster than inflation. Unlike Medicaid, which is voluntary and manufacturers elect to participate, the rebates on Medicare reimbursable drugs are due solely because a manufacturer sells a drug that is reimbursed under Medicare.

Under the IRA, the term “Part B rebatable drug” means a single-source drug or biological, including a biosimilar biological product, with some limited exceptions. Certain vaccines and drugs that have an annual average total Part B allowed charge per individual of less than $100 will not be considered “Part B rebatable drugs.” The IRA’s rebate provision also clarifies that a Medicare beneficiary’s coinsurance for Part B rebatable drugs will be calculated as 20% of the inflation-adjusted Part B payment amount. The inflation rebates will be paid on Medicare beneficiary utilization of such Part B rebatable drugs in the applicable quarter unless the utilized drug was sold at the 340B price or subject to a Medicaid Drug Rebate Program rebate. In addition, the Part B rebate is not due or payable on Part B drugs that are not separately reimbursable, but rather reimbursed in a bundled procedural payment.

Similarly, the Act establishes an inflation rebate program for certain Part D drugs that is triggered when the drug’s AMP, as reported under the MDRP, increases faster than inflation. The manufacturer of a Part D rebatable drug shall pay a rebate to HHS to the extent that the drug’s AMP for a given year has increased more than the AMP from a baseline period adjusted for inflation. CMS stated in guidance that if a manufacturer does not participate in the MDRP and, therefore, does not report AMP, no Medicare Part D inflation rebates will apply.

IRA inflation rebates are accumulating even though the Centers for Medicare & Medicaid Services (CMS) has deferred collection until 2025. Its important that manufacturers model and accrue for any financial impact of these inflation rebates today.

3. FDA has ramped up inspections post-COVID-19 and will continue to do so particularly for facilities outside the United States.

The US Food and Drug Administration (FDA) facility inspections

slowed during the COVID-19 pandemic particularly for facilities outside the United States. But 2022 and 2023 has led to a ramp up in FDA inspections especially in facilities outside the United States.

In August 2023, at the **GMP by the Sea Conference** Jennifer Maguire, the director of the Office of Quality Surveillance within the Office of Pharmaceutical Quality in the FDA's Center for Drug Evaluation and Research, stated there were 163 FDA inspections from the beginning of October 2022 to the end of March 2023 conducted at drug manufacturing facilities that were classified as Official Action Indicated (OAI). Twenty-six percent resulted in Warning Letters, 19% resulted in imposition of import alerts (restricting or prohibiting imports into the United States of drugs from a specified facility), 24% resulted in regulatory meetings with the agency, and 29% resulted in FDA exercising "regulatory discretion," which means a decision not to take enforcement action. One inspection resulted in FDA's securing a consent decree to restrict or shut down operations, and two resulted in an "untitled letter," which are not available to the public on FDA's website.

The frequency and volume of FDA facility inspections are expected to continue/increase in 2024 and beyond.

4. Check product country of origin designations in light of the *Acetris* case and recent customs rulings.

Country of origin rulings are important to pharmaceutical manufacturers for a myriad of legal reasons in the United States including FDA labeling rules, customs compliance and as relevant to certifications to the US Department of Veterans Affairs related to federal government contracting. The existing regime for determining proper country of origin has become more complex in the aftermath of the 2020 decision in the case of *Acetris Health,*

LLC. v. United States, 949 F.3d 719 (Fed. Cir. 2020). The *Acetris* court stated a rule that the manufacture of a finished dosage product in the United States qualifies the product as a "U.S.-made end product" for purposes of government procurement – without regard to the place of manufacture of the active pharmaceutical ingredient (API). *Acetris* also cast doubt on the long-standing approach of the US Customs and Border Patrol (CBP) to determine country-of-origin under the substantial transformation test by reference, generally, to the country of API production. The *Acetris* court's analysis of this issue was not necessary to the holding on the "U.S.-made end product" determination, and CPB has continued to issue country of origin rulings that hold the place of API production is the country of origin for a pharmaceutical. This leaves manufacturers potentially in the position of identifying one country of origin for importation purposes and a different country-of-origin for government procurement purposes. Manufacturers are well advised to configure information technology (IT) systems to track country of origin under each standard, and to communicate clearly in government contract documents the origin of APIs and the origin of finished product so a government contracting office has all relevant information.

5. The DSCSA phase II implementation.

The **Drug Supply Chain Security Act** (DSCSA) was enacted in 2013 and contains numerous requirements that become effective in a step-wise fashion over 10 years. Among other things, the DSCSA requirements cover tracing of drug products, first at the lot level and then ultimately at the package level, as the products flow through the supply chain. Full implementation of DSCSA requirements, including package level tracing, was to begin on November 27, 2023; however on August 25, 2023, the FDA issued a "**Stabilization Policy**" — a one-year period of non-enforcement of

certain DSCSA requirements. The FDA explained that it expects drug supply chain trading partners to use this extra time to continue complying with all current DSCSA requirements, while also making efforts to comply with new requirements that become effective on November 27, 2023. Failure to comply with currently effective requirements or failure to make efforts to comply with the new requirements may expose a pharmaceutical company to enforcement action. Coordination with trading partners is essential to ensuring compliance.

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