DRUG PRICING AND DRUG PRICE REPORTING REGULATORY UPDATE

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As the new president and Congress begin their terms, EVERSANA would like to provide this update on recent legislative and regulatory actions that affect drug pricing and price reporting. While these regulations or Executive Orders have been finalized (except where noted), the new administration may take steps to reverse them; if that happens, we will send an update.

Most Favored Nation

The Centers for Medicare and Medicaid Services (CMS) issued this interim final rule on November 20, 2020 (85 Fed Reg 76180-76259), requiring a revised calculation of payments for the top 50 drugs by historic spending under Medicare Part B. The new payment level, to be phased in over four years, is based on the lowest price paid by a member country of the Organization of Economic Cooperation and Development (OECD) with at least 60% of the per-capita gross domestic product (GDP) of the U.S. in a given quarter, thus the Most Favored Nation (MFN) concept. If the revised amount for any of these drugs is greater than Average Sales Price (ASP), then the basis for the Medicare payment amount will revert to ASP. CMS estimates that the reduction in spending will be 65%, or $85 billion over the four-year period.

While the MFN initiative is slated to be a seven-year program before being made permanent, there is a phase-in period in which current ASP pricing is blended with MFN pricing. In the first three years, the Medicare Part B payment rate for one of the MFN drugs will be paid at 75%, 50% and 25% respectively per year, with the balance being paid at the MFN rate. From years four through seven, the payment rate will be at 100% of the MFN price (85 Fed Reg 76205).

CMS also changed the methodology of calculating overhead expenses related to a provider acquiring and administering one of the 50 drugs affected. Instead of an add-on percentage of 6% (4.3% due to sequestration) under the ASP methodology, CMS has instituted a flat dollar rate of $148.73 per administration of each product. This amount, like the add-on percentage, will be paid in addition to the drug administration procedure charge (where applicable in a fee-for-service situation, such as under the Physician Fee Schedule).

The effective date of this regulation was January 1, 2021; however, PhRMA and BIO have filed suit and injunctions were issued in California and Maryland, delaying implementation of the regulation. Until the suits are heard or the new administration withdraws or changes the regulation, it will not move forward.

PBM Medicare Part D Rebate Safe Harbor Elimination/Point of Sale Discount

After CMS issued and subsequently withdrew a proposed rule to allow for Medicare Part D rebates to be directed to patients rather than Pharmacy Benefit Managers (PBMs) in 2019, President Trump issued an Executive Order (EO) in 2020 to eliminate "kickbacks" to middlemen (PBMs) for Medicare Part D. The essence of the order shifts safe harbors for manufacturers, or the ability of the manufacturer not to be in violation of fraud and abuse laws and regulations, from price reductions as a result of moving from Medicare Part D rebates to PBMs to rebates directed to patients.

To avoid the issue that caused CMS to withdraw its proposed rule, the EO also directs the secretary of the Department of Health and Human Services (HHS) to ensure that this safe harbor protection repeal does not increase patient premiums or out-of-pocket costs or other costs to the federal government. In diligence performed around the previous proposed rule, the Congressional Budget Office calculated that the regulation would have increased federal spending by $177 billion over 10 years.

At the end of November 2020, the inspector general of the Department of Health and Human Services issued a final rule (85 Fed Reg 76666-76731) that codified the

EO, with an analysis showing moderate decreases in beneficiary out-of-pocket spending and a $300 million swing of government spending that may result in either a $100 million decrease or a $200 million increase. These calculations are based on assumptions of manufacturer, PBM and patient behaviors that may not come to fruition. Most provisions of this rule begin on January 1, 2022, so the Biden administration may refine or reverse it; however, drug pricing is an issue for the new administration, so even if this rule is reversed or changed, there will still be scrutiny of patient financial burden in Part D.

CMS Final Rule regarding Value-Based Purchasing Arrangements for Drugs

On December 31, 2020, CMS published the final rule regarding Medicaid drug utilization review, drug price reporting regarding payer accumulator initiatives, and drug price reporting when there are value-based purchasing arrangements (85 Fed Reg 87000-87104). CMS clarified and revised some items between the proposed rule in August (EVERSANA's analysis **can be found here**) and this final rule. We will highlight the significant differences in this document.

Value-Based Purchasing Arrangements

Assuming manufacturers decide to enter into Value-Based Purchasing agreements (VBAs) with Medicaid that they make available to commercial insurers, issues remain on reporting payment for the product when it does not meet the VBA thresholds (for example, if a drug did not prevent a future hospitalization for the subject disease state). Presumably, the payment for the significantly lower reimbursement would cause the Best Price (BP) to be reduced dramatically, possibly to zero. To remedy this situation, the final rule provides for multiple best price reporting options so that a single BP does not cause a cascade of untenable reimbursement for the product (i.e., >100% rebate to Medicaid) in a single and/or subsequent quarter. CMS also suggests a method of including the VBA low price as a unit fraction of the overall reimbursement, reducing the BP calculation only marginally. This alternate calculation method may work on high-volume items but could be challenging on low-volume drugs or biologics, which may be the products that manufacturers desire for VBAs. Regardless of the calculation methodology, CMS will not require this BP reporting until January 1, 2022, approximately six months after it expects to release a new Medicaid Drug Rebate Program reporting system.

Coupons, Vouchers and Accumulators

Related to the EO regarding rebates being passed through to beneficiaries, the final rule addresses co-pay coupons and vouchers being exempted from deductibles by PBMs. The intent of the rule seems to be to ensure that the full value of manufacturers' coupon and voucher programs accrue to the enrolled patient, meaning that the portion of the cost of the drug paid by the manufacturer program counts toward a patient's deductible and not be exempted from it, as happens when a PBM (or payer) implements an accumulator program.

While the intent of the final rule seems to help the patient, CMS makes the manufacturer responsible for determining whether a PBM has implemented an accumulator program, which is difficult if not impossible to discern and track. CMS's reasoning for placing the responsibility on manufacturers is their belief that there is constant and open communication between manufacturers and PBMs/payers. We anticipate that to obtain such information, PBMs will add data or access fees to a rebate, thus causing a further increase in the cost of the product to patients. Fortunately, the final rule calls for an effective date of January 1, 2023, for this transparency requirement, allowing time for industry to build technology for such tracking, as well as work with CMS for a more equitable arrangement of responsibility.

Line Extensions/Oral Solid Dosages

To determine whether a line extension remains subject to inflation-based rebates, CMS proposed to expand the definition of Line Extensions, therefore increasing the current reach of the rule that ties inflation penalties of new products to existing products, resulting in a higher unit rebate amount (URA). The proposed rule stated that a new formulation of a drug (except abuse-deterrent

drugs) would be subject to this line extension URA adjustment. In addition, the proposed rule exempted the current language limiting line extensions to oral solid dosages, leaving vulnerable non-oral formulations of a product. CMS also proposed that line extensions (even with different indications, changes in dosage form, route of administration, combination drugs and drug-device combinations) would be subject to the inflation-based penalties. In the final rule, CMS dialed back the inclusion of drug combinations and drug-device combinations. CMS provided a hypothetical example of how the new formulation would go into effect:

CONSIDER TWO SINGLE-INGREDIENT DRUGS, ALPHA AND BETA.

A new combination of these two drugs, AlphaBeta, is not considered a new formulation for the purposes of the line extension alternative rebate calculation. However, a later developed new formulation of AlphaBeta, for example, AlphaBeta XR, is a new formulation with AlphaBeta representing the initial brand name listed drug. (85 Fed Reg 87039)

AMP for Authorized Generics

The final rule puts into effect the portion of the Health Extenders Act related to the treatment of Authorized Generics (AGs) in AMP. An authorized generic is a product that a manufacturer (primary manufacturer) allows another manufacturer (secondary manufacturer) to sell under the primary manufacturer's Food and Drug Administration-approved NDA but under a different National Drug Code (NDC) number. Previously, when the same company sold both the "Brand" and the AG, sales for both products would be combined in the AMP calculation. As the cost of the AG is usually considerably less than the price of the brand, the resultant combined AMP would be less than that of the brand drug alone. Since the Medicaid URA is a function of AMP, the addition of the AG tended to reduce the Medicaid rebate exposure for the brand. In the case where the brand and AG were sold by different companies, the primary manufacturer was permitted to deduct from AMP the "transfer price" of the sale to the secondary manufacturer.

The final rule requires manufacturers calculate separate AMPs for brand products and their AG counterparts, independent of each other. Similarly, the deduction of transfer prices is no longer permitted. Both provisions have the potential for significantly increasing the Medicaid rebate exposure to primary manufacturers.