Insight

The Special Pharmaceutical Relationship: A UK-U.S. Deep Dive on Setting the Best Price

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Executive Summary

- As directed by the Inflation Reduction Act (IRA), the Centers for Medicare and Medicaid Services (CMS) is expected to release on September 1 its first round of drug products to be subject to direct price negotiation under Medicare Part D; this new pricing scheme will be implemented alongside the May 2023 Medicaid Drug Rebate Program (MDRP) proposed rule to change how Medicaid best price is calculated.
- While it remains to be seen what long-term effect the IRA and the proposed MDRP reform will have on the U.S. drug supply chain, the United Kingdom's (UK) current approach to its rebate schemes for branded products highlights potential headwinds to the U.S. drug manufacturing industry.
- The U.S. and UK drug pricing schemes are, contrary to their intent, likely to reduce patient access to the most commonly used drugs – even if they were already offered at a fair price – by placing an inordinate focus on a drug's gross spend, as opposed to medications that are, per-unit, prohibitively expensive.

Introduction

As directed by the Inflation Reduction Act (IRA), the Centers for Medicare and Medicaid Services (CMS) is expected to release its first round of drug products for direct negotiation under Medicare Part D on September 1, 2023, to reduce the cost of the most commonly used drugs.[1] CMS is expected to set prices at 10 percent or below a prescription drug's current net costs (the price after discounts and rebates) to fulfill the Congressional Budget Office's cost-saving projections.

Meanwhile, implemented alongside the IRA's drug pricing reforms is the May 2023 Medicaid Drug Rebate Program (MDRP) proposed rule to change how Medicaid best price is calculated. The proposed rule would make several significant changes to the oversight of the program, as well as require manufacturers to "stack" discounts offered to best-price-eligible entities in the supply chain on a single sale of a drug. Drug manufacturers would be required to combine all discounts (which would include a price concession offered to the wholesaler, a rebate to a provider or payer) on a product within the supply chain for the manufacturer to offer the lowest stacked price to the best-price-eligible entity. While it remains to be seen what long-term effects the IRA and the proposed MDRP reform will have on the U.S. drug supply chain, the United Kingdom's (UK) current approach to its rebate schemes for branded products – which, like the IRA's drug pricing provisions, has set a steep government discount for manufacturers to operate in the country – provides some insights into potential headwinds for the United States. (The UK's next iteration of its current drug-pricing scheme, the Voluntary Scheme for Branded Medicines Pricing and Access (VPAS), is anticipated to take effect January 1, 2024.)

The U.S. and UK drug pricing schemes are, contrary to their intent, likely to reduce patient access to the most commonly used drugs – even if they were already offered at low cost (fair price) – by placing an inordinate

focus on a drug's gross spend, as opposed to medications that are, per-unit, prohibitively expensive.

This insight analyzes the potential negative effects – including drug shortages and long-term industry reductions in research and development of new products – of the IRA's drug-price negotiations under CMS and the proposed MDRP rule on the U.S. drug supply chain. The data consulted in this insight are derived from industry publications and academic sources that speculate on the impact of these newly adopted or proposed laws. [2] The full impact of these rebate-focused reforms from two consistent government payers can only be fully assessed after implementation. Nevertheless, these data are worth exploring to better understand potential impacts to patient access as the federal government and numerous state governments explore price setting for prescription drugs. The UK's comprehensive pricing reforms to its long-standing branded medicine schemes through the statutory scheme and next iteration of the Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) anticipated to begin January 1, 2024, will also provide useful information. Of course, there are instances of certain manufacturers engaging in excessive pharmaceutical pricing or patent delays that postponed new generics or biosimilars from entering the market. Regardless, government-funded programs or systems require dependable and consistent access to pharmaceuticals to treat complex illnesses, improve public health, and vaccinate against communicable diseases.

Although the Congressional Budget Office (CBO) predicts $100 billion in Medicare savings between 2026–2031 from direct negotiations in Medicare Part D, it may be difficult for CMS to generate these savings – especially if manufacturers are able to preserve current pricing practices during the negotiation process. The UK Department of Health and Social Care projects £7 billion in savings from 2018–2023 under its current VPAS scheme. Yet the United States and the UK's new rebate requirements on drug manufacturers may result in the reduction of new medicines brought to market, which could reduce spending in traditional settings such as hospital and outpatient centers.[3] The United States and the UK operate much different pharmaceutical markets (40 percent vs 4 percent of the global pharmaceutical market, respectively), but both are global leaders in research and development of new medicines. Policymakers on both sides of the pond should examine how rebate schemes could discourage new market entrants and place unnecessary pressure on fragile drug supply chains following the COVID-19 pandemic.

Medicare: Inflation Reduction Act

Regulatory Authority: Per IRA requirements, CMS is expected to announce by September 1 the 10 Medicare Part D products selected for the first round of negotiations in 2023 and 2024 with the negotiated price effective in 2026.[4] Eventually Medicare Part B products (medicines administered by a physician in an outpatient setting) will undergo a similar negotiation process. CMS is expected to increase the number of products under negotiation in both Parts D and B by 2029.[5]

Best Price: CMS will negotiate a maximum fair price[6] for the top 10 drugs with the largest gross spend to Medicare (with various exemptions and exclusions). The focus on gross spend may not be the most appropriate metric, however, as these products may be priced fairly but used by a large number of Medicare beneficiaries. For example, the Kaiser Family Foundation reported that 17 million pharmacy claims were filled for Eliquis (anticoagulant also known as a blood thinner) at a gross spend of $739 (excluding rebates) per claim. According to the manufacturer, the average cost to Medicare Part D beneficiaries for the product is $38 and about half of all Medicare Part D beneficiaries pay less than $10 a month. As the rebate amount offered to Medicare Part D plans is not publicly available, public coupons available for beneficiaries that purchase the drug outside an insurance benefit can range widely with out-of-pocket costs ranging from $536.36-$627.42.

Innovation Outlook: CMS will be targeting drugs with the highest gross spend in Medicare—the products

utilized by the most by beneficiaries.[7] Moreover, for CMS to fulfill the savings projected by CBO, the maximum fair price will have to be at least 10 percent or below a prescription drug's current net costs (the price after discounts and rebates). The Pharmaceutical Research and Manufacturers of America (PhRMA), the trade association representing biopharmaceutical research companies, conducted a survey of member companies following the enactment of the IRA and found that "78 percent expect to cancel early-state pipeline projects; 63 percent said they expect to shift [research and development] investment focus away from small molecule medicines; and 95 percent said they expect to develop fewer new uses for medicines because of the limited time available before being subject to government price setting." According to the Kaiser Family Foundation, Medicare Part D is approximately 30 percent of the U.S. total retail prescription drug spend in 2017. Private health insurance has the largest share of the market at approximately 42 percent in the same year. For highly utilized products versus outpatient specialty or high-cost per-unit products, these additional savings through direct negotiation may be hard to realize or make the product no longer profitable. [8]In June 2023, PhRMA, alongside the National Infusion Center Association and the Global Colon Cancer Association, took legal action over the IRA citing constitutional concerns.[9]

Medicaid Best Price

Regulatory Authority: CMS issued a wide-ranging proposed rule on the Medicaid Drug Rebate Program (MDRP) including modifying the ways in which drug manufacturers calculate best price for products.[10]

Best Price: Simplified, best price for products reimbursed by Medicaid meant the lowest price offered by the manufacturer.[11] Following a series of lawsuits on a drug manufacturer's responsibility to stack rebates (which means including all the discounts a product may receive across the supply chain into one rebate) to calculate best price, CMS has proposed that all rebates offered on a single product (whether to the wholesaler, pharmacy benefit manager, or provider) should be stacked (combined) to reflect the lowest realized price and be included in the calculation for best price.[12]

Innovation Outlook: This change in the best price definition is likely to face legal challenges as best price was understood to be the best price the drug manufacturer would offer any one purchaser and not the result of combined discounts across entities in the supply chain. Furthermore, on January 1, 2024, the cap that traditionally limited mandatory Medicaid rebates to 100 percent of the drug's average manufacturer price will be lifted. Potentially, drug manufacturers could end up offering a rebate greater than the cost of the product. For branded products heavily utilized by Medicaid, drug manufacturers may modify their market access strategy if they are likely to pay Medicaid rebates greater than the value of their product.

VPAS 2024

The American Action Forum has published a case study on the UK's 2019 Voluntary Scheme for Branded Medicines Pricing and Access.

Regulatory Authority: VPAS is negotiated between the Department of Health and Social Care (on behalf of England, Northern Ireland, Scotland, and Wales), National Health Service (NHS), and the Association of the British Pharmaceutical Industry. The current scheme ends on December 31, 2023. In July of 2023, the UK government announced a new consultant to review the cost of branded health service medicines which closes on October 10, 2023. If a new iteration of the voluntary scheme fails to materialize, the government recommends updating exemptions to the statutory scheme to facilitate patient access to new innovative medicines and vaccines.

Best Price: In short, the UK has two drug pricing schemes: a voluntary program, in which the majority of manufacturers participate, and a statutory program. In April 2023, the statutory scheme set a rebate amount at 27.5 percent.[13] While the government has yet to agree on the next iteration of the voluntary scheme, it has proposed a rebate amount at 26.5 percent. Subsequently, two high-profile drug manufacturers pulling out of the scheme and other drug manufacturers began removing their products from the market as VPAS negotiations have yet to conclude.

Innovation Outlook: The NHS is a reliable market for drug manufacturers, but setting too high a rebate for the next iteration of the VPAS scheme may inadvertently cause drug shortages by putting strain on already vulnerable supply chains. Celltrion (a South Korean company) withdrew an anti-cancer product from the UK market in June 2023. As one author observed, "Celltrion is far from a minor player in this sector – and the withdrawal of its products alone could put considerable manufacturing and scale-up strain on other generic and biosimilar manufacturers seeking to supply the UK." Additionally, it was reported that "AstraZeneca's chief executive said the UK's discouraging tax rate was behind the company's decision to build a $400 million [Active Pharmaceutical Ingredient] facility" in Dublin, Ireland. AbbVie and Eli Lilly invested €460m on facilities within Ireland.[14] With the NHS under enormous strain following the COVID-19 pandemic to provide frontline care, it is likely short-sighted to discourage drug manufacturers from operating in the market during the VPAS negotiation process for a historically successful drug pricing agreement between the government and industry. Recent increases in hospital prescribed medications have increased overall spending, yet this spike in spending could be related to delays in care due to COVID-19 caused by increased utilization rather than rise in a price of an individual product.

Furthermore, a recent report from the London School of Economics appears somewhat dismissive in its assessment of the usefulness of pharmaceutical research and development investment in the nation.[15] The authors argue that even a substantial reduction in investment from these companies would have little impact on the funding for health care services because 1) the data is self-reported (as discussed earlier, self-reported data is a challenge prior to the implementation and data collection of any new law) and 2) only a small share of jobs and taxable revenue (approximately a £5.7 billion reduction in industry funded research and development would result in a £54.3 billion loss in UK gross domestic product) would be negatively impacted by this reduction of investment by manufacturers.[16] Yet, these projections may not fully capture the long-term impact and knock-on effects to the economy if the parties do not reach agreement on the next iteration of VPAS. [17]

Conclusion

While the United States and the UK are different pharmaceutical markets, both are global leaders in research and development of new medicines. Both also have taxpayer-funded health care programs or systems that support millions of patients. Yet, it is not the most expensive medicines and therapies that face increased government price scrutiny, but branded products with high utilization. Such branded products account for a greater amount of overall gross spend but may, in fact, be priced fairly. Thus, regulatory focus on gross spend could be misplaced.

Policymakers on both sides of the pond should be examining how rebate schemes could discourage new market entrants as well as put pressure on fragile drug supply chains following the COVID-19 pandemic.

[1] Prior to the enactment of the IRA, pharmacy benefit managers directly negotiated with drug manufacturers when creating formularies for Medicare Part D bids as required in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

[2] Aris Angelis, James Lomas, Beth Woods and Huseyin Naci "Promoting Population Health Through Pharmaceutical Policy: The Role of the UK Voluntary Scheme" The London School of Economics and Political Science, June 2023. The authors argue that "claims that increasing VPAS repayment rates would have unintended consequences on industrial strategy are overstated." This author acknowledges the limitations to self-reported industry data but believes the LSE report may be underestimating the potential impact industry could have on patient drug access to new medicines or drug shortages due to the composition of the British national formulary if manufacturers leave the market. The US is the largest pharmaceutical market with increasing drug pricing laws at the state-level which are regulated by state agencies such as the department of insurance or state attorney general (for the fully insured, Medicaid and individual market). For example, insulin price caps have been established for certain payers at the state-level for several years prior to the enactment of the IRA. However, these payers typically have several insulin products covered under the pharmacy benefit reducing the pressure on a single manufacturer and creating competition amongst manufacturers to receive preferred tiering placement by offering products that would be less than the price capped amount.

[3] According to one academic study US life expectancy increased 3.3 years from 1990 to 2015 which 35 percent of this increase could be attributed to pharmaceuticals.

[4] Public Law 117-169

[5] Sean Dickson, Inmaculada Hernandez "Drugs Likely Subject to Medicare Negotiation, 2026-2028" J Manag Care Spec Pharm 2023; 23 (3):229-35. The authors found that "In 2026-2028, we estimate that Medicare will negotiate prices for 38 Medicare Part D drugs and 2 Part B drugs. Combined, the 40 products eligible for negotiation in 2026-2028 accounted for $67.4 billion in gross Medicare spending in 2020."

[6] Juliette Cubanski, Tricia Neuman and Meredith Freed "Explaining the Prescription Drug Provisions in the Inflation Reduction Act" Kaiser Family Foundation, 2023. In terms of the law "[It] establishes an upper limit for the negotiated price (the "maximum fair price") for a given drug. The limit is the lower of the drug's enrollment-weighted negotiated price (net of all price concessions) for a Part D drug, the average sales price for a Part B drug, or a percentage of a drug's average non-federal average manufacturer price: 75 percent for small-molecule drugs and vaccines more than 9 years but less than 12 years beyond approval; 65 percent for drugs between 12 and 16 years beyond approval or licensure; and 40 percent for drugs more than 16 years beyond approval or

licensure."

[7] Of note, new products to treat common conditions, such as blood thinners, which have been around for almost 100 years, performed better than older products in patients. For example, Eliquis performed better than cheaper and older blood thinners such as Warfarin.

[8] Joshua Cohen "For Certain Drugs Medicare Selects for Price Negotiation It May Be a Challenge to Get Deeper Discounts than Current Rebates" Forbes, August 2023. Cohen adds that "…CMS will aim for a price that is below the current net price after rebates. The minimum discount percentages are just benchmarks, not CMS's initial offer. Furthermore, as there is no floor and CMS is a monopsonist or single purchaser it will in all likelihood seek to undercut the present net price. CMS will also be incentivized to do so. This is because in order to reach the CBO savings estimate of $3.7 billion for implementation of fair prices in 2026, CMS would have to attain an average 10 percent discount below the current rebates for the 10 drugs. While certainly possible, this may not be an easy task for CMS. This is partly due to the fact that during the offer and counteroffer process drug manufacturers have plenty of leeway. To justify counteroffer prices, they can provide supportive evidence regarding their drugs' comparative effectiveness evidence, therapeutic advantages, unmet need and R&D costs, among other things. If the data is compelling, it would be hard for CMS to ignore."

[9] Case 1:23-cv-00707. The plaintiffs argue that "Worse still, the law provides for no price floor; HHS could take the position that a selected drug is worth $1 per dose, and the manufacturer must either sell at that price or take on massive liability. The only alternative provided is to exit the Medicare and Medicaid programs altogether, withdrawing not just the drug in question, but all of the manufacturer's drugs. But even that (practically infeasible) choice is constrained by a statutorily mandated delay of 11 to 23 months—during which time the manufacturer is forced to continue participating in the sham 'negotiation.' And providers are caught up in this morass as well, since their reimbursement rates are based on the price HHS imposes on the manufacturer."

[10] PhRMA "Comments of The Pharmaceutical Research and Manufacturers Of America Submitted To The Department Of Health And Human Services Concerning HHS Blueprint To Lower Drug Prices And Reduce Out-Of-Pocket Costs" 2018. "Medicaid rebates for brand medicines have two components: a basic rebate and an additional inflation rebate if the price of a drug rises faster than inflation (based on changes in the Consumer Price Index-Urban). For brand drugs, the basic rebate is the greater of (a) 23.1 percent of the AMP or (b) the difference between AMP and the Best Price (the manufacturer's lowest net price for the drug to any customer with limited exceptions)."

[11] 42 CFR 447.505. The law states that "Best price means, for a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for an authorized generic drug), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the AMP is computed. If a manufacturer offers a value-based purchasing arrangement (as defined at § 447.502) to all states, the lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of that value-based purchasing arrangement."

[12] For clarity, CMS explains that "We interpreted this section expansively as the statute refers to a manufacturer's lowest price 'available' 'to any' entity on this statutory list. That is, if a manufacturer provides a discount to a wholesaler, then a rebate to the provider who dispensed the drug unit, and then another rebate to the insurer who covered that drug unit, CMS has concluded that 'best price' must include (or 'stack') all the

discounts and rebates associated with the final price, even if the entity did not buy the drug directly from the manufacturer. By stacking, best price reflects the lowest realized price at which the manufacturer made that drug unit available."

[13] According to the Department of Health and Social Care "As the update made to the payment percentage in 2023 did not take effect until 1 April 2023, an adjusted payment percentage of 28.6 percent was set for any company that made a payment in the first quarter of 2023 at the lower rate of 24.4 percent. The purpose of this is to give an overall average payment percentage equivalent to 27.5 percent for all scheme members in 2023 regardless of when sales took place during 2023. If the statutory scheme were to remain unchanged this profiling of the payment percentage would not occur again in 2024 and the 27.5 percent payment percentage would apply from 1 January 2024."

[14] Anna Sayburn, "'A global outlier': how drug firms are fighting back against UK tax increases" The Pharmaceutical Journal, April 2023. As noted by Sayburn, tax incentives in Ireland could also be a factor by large drug manufacturers. The author adds that "In 2021, Ireland's corporation tax was 12.5 percent, compared with 19 percent in the UK. However, in 2023, Ireland's rate rose to 15 percent and the UK rate increased to 25 percent."

[15] Rachel Arthur "'Huge boost for biotech companies': UK life sciences industry welcomes new enhanced R&D tax relief rate" Biopharma Reporter, May 2023. Arthur highlights that "There are over 6,548 business in the UK life science industry, and approximately 70 to 80 percent are [small and medium-sized enterprises]. These businesses employ over 282,000 people and generate £94.2bn turnover in 2021…The UK accounts for 35 percent of all life science start-ups crated in Europe since 2012, according to McKinsey data."

[16] The authors highlight key questions around the current threshold of the National Institute for Health and Care Excellence use of quality-adjusted life-year (QALY) and the role these QALY play in NICE's approval process (and their increasing popularity as cost-effectiveness tool at the US state and federal level) is outside the scope of this insight and will be addressed in a future publication.

[17] Recently, the Association of the British Pharmaceutical Industry (ABPI) reported that life science foreign direct investment (FDI) in 2022 dropped almost 50 percent from 2021 to £1 billion from £1.9 billion. The UK departure from the European Union (Brexit) as well as the COVID-19 pandemic may have also contributed to the overall reduction of FDI. According to recent UK government life science competitiveness indicators, the US remains by the far the largest FDI in the UK.