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In this article, Drozdowski and Kachinsky-Bye review the Inflation Reduction Act provisions that have significant accounting and tax implications for the pharmaceutical industry.



President Biden signed the Inflation Reduction Act (IRA, P.L. 117-169) into law on August 16, 2022, following its passage along party lines in the Senate and House. While the IRA was intended to reduce the deficit and provide funding for major investments in healthcare, domestic energy production, and manufacturing, and to mitigate climate change, there are several provisions with accounting and tax implications relevant to the pharmaceutical industry. The act introduces new tax measures as well as Medicare inflation-based drug rebates and a drug pricing negotiation program. It also limits Medicare beneficiaries' out-of-pocket costs for prescription medications to $2,000.

This article provides a practical guide to the financial accounting and tax issues a pharmaceutical company might face in its year-end and first-quarter 2023 financial reporting for drug pricing rebates, the newly enacted corporate alternative minimum tax, the excise tax on stock repurchases, and a variety of tax credits.

## I. Drug Pricing Provisions

### A. Medicare Inflation Rebates

Requiring immediate consideration by the pharmaceutical industry is the IRA provision requiring manufacturers that sell drugs through Medicare to pay rebates to the government for drugs increasing in price faster than the rate of consumer inflation.

More specifically, drug manufacturers must pay the annual rebates if they increase the price of Medicare Part D-covered drugs above an allowable inflation rate benchmarked from a 2021 base period (based on the consumer price index for all urban consumers) for drugs approved before October 1, 2021. Drugs approved after that date are benchmarked from the year after they are first marketed. The program applies to the 12-month period starting on October 1, 2022, and each subsequent 12-month period. Similar to other gross-to-net deductions, the effects of the rebates must be estimated and recorded as a liability and a revenue deduction when the manufacturer sells the drug product. (This provision goes into effect beginning in 2023 for drugs covered under Medicare Part B.)

A manufacturer subject to a rebate is expected to receive a rebate invoice within six months of the end of the rebate quarter, due and payable within 30 days of receipt. While it is possible that the secretary of health and human services will choose to delay sending invoices for calendar quarters in 2023 and 2024 to not later than September 25, 2025, affected companies will need to consider the financial implications of these provisions in the short term.

The financial and tax effects of these provisions could be minimal in the near term given the current state of inflation rates. But

companies should still contemplate the longer-term implications of increased gross-to-net deductions and the effect of the rebate provisions.

### B. Drug Price Negotiation Program

In addition, the IRA establishes a drug price negotiation program for some high-cost, single-source chemical drugs and biological products covered under Medicare Part B and Part D. The HHS secretary is required to negotiate maximum fair prices with drug manufacturers for 10 qualifying drugs in 2026, 15 drugs in each of 2027 and 2028, and 20 drugs in 2029 and each following year. (In 2026 and 2027 the program applies only to Part D.) This provision potentially applies to the highest-priced small-molecule drugs post-FDA approval of at least seven years and the highest-priced biologics post-FDA approval of at least 11 years.

Excluded from this program are generic drugs and biosimilars, along with the respective listed or referenced drugs. In other words, in the event that a branded drug has a generic or biosimilar option, it will be excluded from the program because the focus is on single-source drugs. Other ineligible drugs include plasma-derived products and orphan-designated drugs approved for a single rare disease.

The initial negotiations begin in 2023, when the HHS secretary publishes "a list of selected drugs," culminating in 2026, when the first round of maximum fair prices takes effect. During negotiations with manufacturers, the secretary must consider factors including the drug's cost of production, research and development expenditures (including federal support), and alternative treatments. A negotiated maximum fair price would generally be in effect until the first year beginning at least nine months after the date the secretary determines there is a marketed generic or biological substitute for the drug.

To enforce compliance with the drug price negotiation program, the new law introduces a significant nondeductible excise tax that will apply if a manufacturer does not, within the time required, enter into a negotiation agreement, submit the required information, or agree to a maximum fair price.

### C. Out-of-Pocket $2,000 Cap

Effective in 2025, the Part D benefit is reconfigured to include an annual $2,000 out-of-pocket spending cap for beneficiaries. The IRA also expands subsidies for low-income enrollees and limits annual premium increases. This shifts the pharmaceutical manufacturer's discount from the existing doughnut hole (predetermined range of spend by a beneficiary) to prescriptions for a beneficiary above the $2,000 out-of-pocket limitation. The manufacturer's discount is provided as a government rebate for participating in the Part D program. The patient's cost is based on their Part D plan and the new $2,000 out-of-pocket limitation.

Branded drug manufacturers, biologics manufacturers, and biosimilar manufacturers would provide a 10 percent price discount of the drug cost while a beneficiary is in the out-of-pocket phase (up to $2,000 out-of-pocket), and a 20 percent discount when a beneficiary has exceeded the $2,000 out-of-pocket cap with phased-in liabilities for smaller drug manufacturers.

Similar to other gross-to-net deductions, the effect of these discounts and rebates needs to be estimated and recorded as a liability and revenue deduction when the manufacturer sells the drug product. Companies will have to estimate when beneficiary prescriptions are in the out-of-pocket phase and when they happen after $2,000 of out-of-pocket costs.

### D. Vaccines and Insulin

In 2023 the IRA also introduces a ban on cost sharing or deductibles for vaccines under Part D, Medicaid, and the Children's Health Insurance Program and sets a $35 monthly cost cap for insulin.

### E. Pharmacy Benefit Manager Rebate

The IRA also extended the deferral of provisions in the HHS November 2020 final rule on pharmacy benefit manager rebates and point-of-sale discounts to 2032. That rule focused on the rebate for purchases of prescription pharmaceutical products under Part D by a plan sponsor either directly or indirectly through a

pharmacy benefit manager acting under contract with a plan sponsor.

### F. Financial and Tax Implications

These IRA provisions are being implemented to lessen the cost of medications under certain government programs and to introduce negotiated prices for some of the most costly medications needed by people in the Medicare program. They will put pressure on the overall revenue and gross margins a branded drug may earn over its life cycle, and manufacturers should consider them when establishing launch prices.

Drug manufacturers subject to these provisions of the IRA, as well as those that may be affected by future legislation should they be expanded, have much to consider for revenue and gross margin forecasting purposes. Uncertainty regarding the amount and timing of these potential adjustments introduces new variables into an already complex forecasting process for many companies. This should be contemplated not only by companies performing financial planning and budgeting for their own purposes but also by those conducting due diligence on potential acquisition targets or collaboration partners. For prior and future acquisitions, the potential valuation effect on goodwill and products' intangible value is yet another consideration as the rebates and negotiated prices will affect future product revenue streams.

The drug pricing provisions discussed here may have tax implications as well. For example, accurate forecasts of revenue streams and corresponding profit margins are important in determining the value of intellectual property for tax planning, tax valuation, and transfer pricing purposes. Some companies rely on enhanced charitable deductions to support their health equity initiatives, and the amount or realizability of these deductions could be affected. From an accounting for income tax perspective, projections for sources of future taxable income are often relied on to assess a company's ability to realize deferred tax assets as well, so changes to those projections may require reassessment for financial reporting purposes.

## II. Relevant Tax Provisions

### A. Corporate AMT

The IRA will impose a 15 percent corporate AMT on book income of applicable corporations, which includes U.S.-headquartered corporations with global financial statement income exceeding $1 billion and foreign-headquartered groups with domestic financial statement income exceeding $100 million, both averaged over three years.[1] To arrive at income subject to the corporate AMT, a series of adjustments are made to applicable financial statement income, including adjustments for defined benefit pensions, taxes, depreciation, amortization, and certain items derived from foreign affiliates. The corporate AMT only applies if the 15 percent tax generally computed as described above exceeds the corporation's regular tax liability, and the R&D tax credit does not negatively affect this computation, which is good news for pharmaceutical companies.

Beginning in the first quarter of 2023, calendar-year companies subject to the new corporate AMT should consider the need to reflect it in the determination of their income tax expense and potentially its effect on their future tax liability (given the fact that the corporate AMT may be applied to reduce regular tax liability in subsequent years) for financial and estimated tax reporting purposes.

### B. Stock Buyback Excise Tax

The IRA also imposes a 1 percent excise tax on the fair market value of stock repurchased by a publicly traded corporation. The amount on which the tax is imposed is reduced by the value of any stock issued by the corporation during the tax year. The provision provides for several exceptions to the excise tax that should be assessed, and it is effective for stock repurchased after December 31, 2022.

In addition to the cash flow considerations for the excise tax itself, companies should be mindful of its financial and tax reporting implications. The

[1] For a broader discussion of IRA tax provisions, see KPMG, "Analysis and Observations: Tax Law Changes in the 'Inflation Reduction Act of 2022'" (Aug. 16, 2022).

excise tax is determined on a non-income-based measure, and therefore generally would not be accounted for as an income tax but instead as a direct cost of the repurchased stock and recognized as a component of the price paid.

### C. R&D Payroll Tax Credit

Applicable only to some small businesses with revenues below $5 million, the new law increases the R&D tax credit amount available to offset payroll taxes from $250,000 to $500,000. The change may be beneficial for early-stage life sciences companies awaiting Food and Drug Administration approval on drugs in development and/or with minimal collaboration revenue and is effective for tax years beginning after December 31, 2022. Companies may need to consider the financial reporting implications, such as applying the company's accounting policies for government grants.

### D. Clean Energy Credits

The IRA has introduced incentives for companies constructing new laboratories, drug manufacturing storage buildings, or other facilities that use renewable energy as either a primary or backup power source. Examples of eligible investment include construction projects involving the use of solar panels, fuel cells, combined heat and power system property, and/or waste energy recovery property. An investment tax credit ranging from 6 percent to 30 percent could be available if all requirements are satisfied (and for microturbines, a lesser percentage may be available). To be eligible for the higher percentage, some wage and apprenticeship requirements must be met for the construction project by either the pharmaceutical company or its third-party contractor. Finally, other new provisions are included in the IRA for these clean energy incentives, allowing some of them to be refunded regardless of current tax liability or the ability to sell these credits to third parties.

Another credit that may be relevant to the life sciences industry — especially those companies providing vehicles to their commercial field force — is a tax credit for the purchase of qualified commercial clean vehicles placed in service beginning in 2023. The amount of this credit is determined by a prescribed formula and is capped at $7,500 for vehicles with a gross vehicle weight rating of less than 14,000 pounds, and at $40,000 for all other "heavy weight" eligible vehicles. This provision is applicable beginning after 2022 and before 2033. Related to this is an additional $100,000 credit for charging stations, although restrictions require these charging stations to be installed in certain rural and underdeveloped locations.

These credits may provide some mechanism for life sciences companies to support their corporate social responsibility and related environmental, social, and governance initiatives. In addition to the credits mentioned, many jurisdictions around the world, as well as local jurisdictions in the United States, offer additional statutory as well as negotiated economic incentives that a life sciences company should evaluate in light of planned investment.

Accounting for these clean energy credits is complex. Further, investment credits may affect the tax basis of the underlying assets. Those determinations may require consideration of policy elections and may also require disclosure in the footnotes of the financial statements or elsewhere.

### E. Notably Absent: R&D Expensing Provision

The IRA contains no deferral or repeal of the Tax Cuts and Jobs Act provision that requires R&D costs to be capitalized and amortized over five years (domestic) or 15 years (outside of the United States), which began in 2022. Given the magnitude of R&D expenses for a pharmaceutical company, this has caused significant cash tax implications, as well as myriad other complexities given the number of other tax calculations affected by the R&D expense amount.

## III. Conclusion

The IRA has introduced new provisions to lessen the cost of certain medications, creating pricing pressure for some existing and soon-to-be-launched medications, and introducing complexity for financial planning and tax purposes. Additional revenue raisers within the IRA requiring compliance by larger, publicly traded life sciences companies include the 15 percent corporate AMT and the 1 percent stock buyback excise tax. Newly enacted or expanded

tax incentives may reward life sciences companies undertaking capital investments that rely on renewable energy as a primary or backup power source to fuel their facility's operations. All of these provisions have unique accounting and tax implications, and as of the time of this writing, we are still awaiting the issuance of Treasury regulations intended to provide additional guidance and answers to the many questions taxpayers in the industry have raised regarding these new rules.[2] ■

[2] Some or all of the services described herein may not be permissible for KPMG audit clients and their affiliates or related entities. The foregoing information is not intended to be "written advice concerning one or more Federal tax matters" subject to the requirements of section 10.37(a)(2) of Treasury Department Circular 230. The information contained herein is of a general nature and based on authorities that are subject to change. Applicability of the information to specific situations should be determined through consultation with your tax adviser. This article represents the views of the author(s) only and does not necessarily represent the views or professional advice of KPMG LLP.