IRA Compliance: Getting Quality Right The First Time

A compliant approach to IRA pharma processes beyond “good” practices

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The IRA brings some of the most significant policy changes to the pharma industry in more than a decade. This will have broad implications for pharmaceutical drug and therapeutic companies with far-reaching complexities for pricing, contracts and compliance. Even if your company's drug isn't among the first selected, the ripple effect will touch you in more ways than you may think. So, it's better to be proactive than reactive.

> Download our Inflation Reduction Act Data Placemat to reference the complex components of the IRA as you read this eBook and reference it again to better plan for compliance.

With extensive experience in the Life Sciences industry and government and regulatory decision-making, our Life Sciences Industry Team regularly tracks and closely connects with developing trends around pricing, contracts and regulatory compliance. While it's difficult to know what you can anticipate next from the government because there are constantly moving parts, we have defined specific actions you can take now to prepare for the provisions affecting pricing, contracts, reporting, chargebacks and rebates.

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First things first

Are you already floating around ideas for a compliant approach to the IRA? If not, you will end up in reactive mode, substantially impacting your revenue. The time is now to prepare for the next round of drug selection to strategize, execute and implement your compliance plan so you don't find your team and company in a situation that doesn't meet all your regulatory needs.

There are crucial steps your pharma company needs to take now to best position you for growth in the new era of IRA. This eBook will introduce you to a compliant approach to the IRA, outlining the pitfalls and pain points you will likely encounter and the most compliant ways we can help you solve for them.

> There were 1,216 products whose price increases during the 12-month period from July 2021 to July 2022 exceeded the inflation rate of 8.5% for that period. The average price increase for these drugs was 31.6%.

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The price is (not) right

Pharma manufacturers need to clearly understand how IRA will impact net revenue. These financial impacts include discounts, rebate liabilities, plan liabilities and costs. What you may not be able to see now is how the IRA will change the way you position certain products based on price and market accessibility. With so much data being generated and only more to come, how can you be sure your pricing is right? Likewise, how will your pricing on drugs affected by the new provisions play into your portfolio and pipeline pricing?

These pricing complexities play right into financial impacts on market share and revenue. As value-based pricing and other pricing models gain traction, you will need real-time access to accurate comparative data and evidence to protect your pricing decisions in Medicare negotiations as well as other payer channels.

Beyond a single dimensional view: the path to predictive mode

The trend in Life Sciences to reach predictive mode through AI, data science and analytics is growing at warp speed. Complete visibility into your data beyond a single-dimensional view in real-time and accessible to all once seemed like a pipe dream, but it is attainable to those who plan and have buy-in to a better way of doing business.

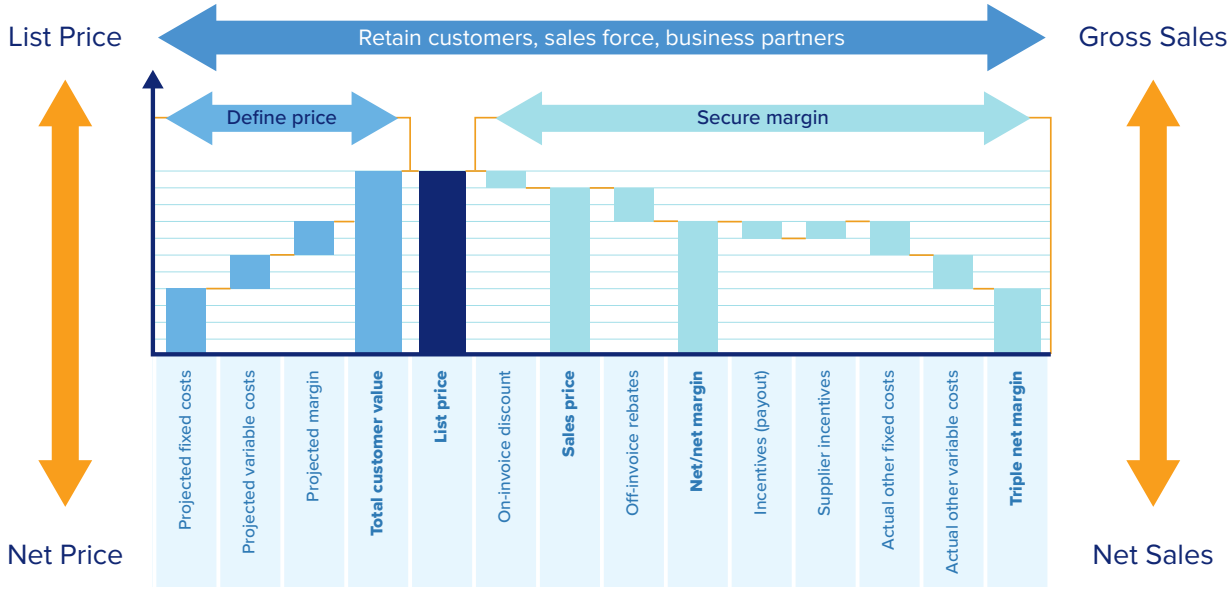
It's important to note that the IRA affects all pharma manufacturers, not only the companies with a drug in question. That's because reducing the price of an expensive drug will have a ripple effect on all competitive drugs. "What-if" scenarios give you the ability to make pricing decisions by simulating the impacts of future events. Additionally, scenario planning considers behavioral responses from partners as well as Medicare drug negotiations. You should be able to assess how payers may change formulary designs and project potential increases in utilization due to affordability.

Manufacturers will be impacted by the IRA at different levels, given the diversity of portfolios. That does not affect the processes you need in place to reassess revenue projections. Once you have a detailed evaluation of potential impacts on revenue for each product under each government program, you can reassess revenue projections. Without an end-to-end solution that provides a single source of truth, the complexities will become overwhelming. The considerations you'll need to account for include how the law applies not only to your own products but also to your competitor's products, which have the potential to affect market share.

Preparing your company with transparency and accuracy with data and analytics allows you to collaborate effectively across teams that can use this knowledge for coherent pricing, contracts, finance and compliance. IRA compliance adds complications to an already heavily regulated industry, and incomplete data will cost your company. Your government reporting needs to be accurate to avoid non-compliance and fines...millions of dollars per day with the new IRA penalties! This would, without a doubt, cut into your profits and possibly leave you dealing with bigger repercussions.

From curiosity to cure: going from HOW to WHY

Do you rely on multiple solutions to manage your processes and wealth of data? If so, you're not alone...yet. Pharma manufacturers who have moved beyond the curiosity of what their data is hiding have discovered that reducing errors and operating efficiently involves operating with a single source of truth. If your data can't tell you about the purpose behind every pricing discount and/or rebate, you're missing valuable information. You need to know what to do, how to do it, and why it needs to be done, and you need this done for you automatically.



You may think that multiple solutions provide benefits autonomously and asynchronously, but increasing complexities mean you need to balance more than just product innovation holistically. More than ever, understanding your pricing, Gross-to-Net, incentives and margins will depend on an end-to-end solution that will provide a single source of truth to all the complexities and provisions that already exist and the ones that are coming soon.

Since the first mandated regulations in the 1960s, Life Sciences manufacturers have discovered that policies and strategies need consistent review to comply. A healthy dose of a commercial policy framework will help direct processes, procedures and profits while remaining compliant.

Increasing complexities means the wealth of data scales synchronically. This is important with increasing complexities in the industry, especially regarding pricing and compliance that demand agility and quick response.

One of the most valuable commodities you have is your data. Yet most Life Sciences companies are drowning in it partly due to manual processing. Your vast amounts of data kept in silos makes it challenging to run reports and analyze to ensure compliance. Without these reports and the ability to apply analysis, it's difficult to know if you're pricing your products to make a profit.

Gross sales	Example
 Mandatory/statutory terms	Mandatory/statutory/ government pricing
 Market access	Negotiated terms
 Tenders	Tenders, price equalization
 Commercial incentives	Product incentive, listing fee, etc.
 Trade terms	Sell-out activation, customer sponsorship etc.
 Incentives for supply chain players	WSD incentives, GPO incentives, etc.
 Net sales	Net sales

A compliant approach: Part D and Part B

For complex pricing models such as IRA Part D and Part B, the ability to focus on execution and analysis rather than managing manual processes provides you with comprehensive visibility, transparency and accuracy. Gaining control of critical processes involved in IRA Part D and Part B is critical not only for your margin but also for the impact on compliance.

By capturing data in a structured way with predictive capabilities, your teams will feel confident they are getting accurate answers and can make informed decisions. In the end, accurate data will lead to insights, and insights will lead to higher profits. A single source of truth provides the capability for full transactional control to minimize revenue leakages due to wrong master data for all moving parts of compliance in IRA.

No tool is going to accomplish this without these fundamentals:

Strategic Planning: Real-time forecasting based on accurate data analytics to determine discounts, special pricing agreements, and rebate strategies

Accruals and Gross-to-Net: Accurate general ledger and accrual account updates and reporting

Strategic Analytics: Data translated into real-time trends and forecasts

Contract Authoring Collaboration: Web-based, dynamically shareable, updateable digital contracts

Managed Markets: Transparency in rebate models and payments for partner longevity

If you participate in any Medicare program, you must generate a transparent and accurate audit trail and prepare for your FDA, CMS or HRAS audits, ensuring compliance. Failure to meet compliance will result in significant penalties. An end-to-end solution with a single source of truth allows you to confidently transact with visibility, transparency and accuracy with pricing, contracts, rebates and chargebacks.

The IRA mandates that drug manufacturers pay rebates for drugs in Medicare Part D whose price increases exceed inflation for the 12-month period beginning October 1, 2022. The IRA is focused primarily on Part D drugs. Ironically, Part B spending has outpaced Part D for the last decade by 3.5 times that of Part D. The Drug Price Negotiation Program will begin to include Part B therapies in the eligible drug pool beginning in 2026, going into effect in 2028.

According to the West Health Policy Center, they estimate that between 2026-2028 only 2 drugs may be eligible for negotiation due to the fact that many Part B drugs fall into the exclusion criteria. Drugs that have been FDA-approved for less than 9-13 years (drug type dependent) or have a biosimilar are excluded.

The law establishes Medicare Part B prescription drug inflation rebates for certain single-source drugs and biologicals with prices increasing faster than the rate of inflation and provides for lower Part B beneficiary cost-sharing on these drugs and biologicals through an adjusted coinsurance rate.

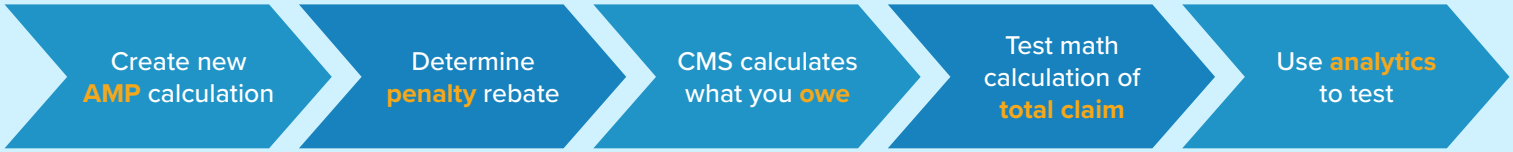
While it's impossible to foresee compliance regulation changes entirely, building an agile platform for revenue growth, pricing, contracts, analysis and compliance can help you meet current requirements in the most efficient way possible while preparing for the future.

The Vistex point of view and solution to Part D and Part B will prepare you for the market today and in the future with an eye toward the market and rule changes. See below for our solutions to lower compliance-related risks and reduced revenue leakage.

Vistex POV and solution for IRA: Part D

1. Create a new annual average manufacturing price (AMP) calculation
2. Utilize the defined baselines and current data to create an annual calculation: this is already being performed monthly and quarterly, so the same methodologies can be used for the new annual calculation
3. Extend these to create an annual calculation
4. Calculate and determine what could be your penalty rebate
5. Perform the calculation against your sales and what we determine the penalty would be for any given period to prepare for what CMS provides
6. Build a new claim type where you would accept a claim from CMS in which they have done their own calculation on what they believe you owe
7. Accept that claim into the system and compare it against what was calculated to determine if the claim is valid
8. Test math calculations of the total claim
9. Use analytics to test trends on units versus rebates

Currently, there is no adjudication process defined for calculation disputes. This will most likely not be acceptable to manufacturers on a broad level. We believe more guidance may be forthcoming as there should be some allowable dispute on the calculation units. The actual first rebate payments have been pushed out, and we expect more guidance before it is finalized. Meet all your regulatory needs and control auditable and transparent solution SoX compliance for government pricing, contracts, reporting, rebates and international reference pricing.



Vistex POV and solution for IRA: Part B

1. Add fields to master data to capture which products/drugs will be reportable for the rebate
2. Create a second variant of the Vistex current ASP to calculate the inflation penalty
3. Include inflation penalty ASP in Vistex posted price types to be used for further claims processing
4. Perform the calculation against our data and units and determine what we believe the penalty would be for any given period to prepare for what CMS provides
5. Accept that claim into the system and compare it against what was calculated to determine if the claim is valid
6. Build a new claim type to accept what CMS calculated is owed and compare them to determine if you owe, how much and if the amount is accurate
7. Use analytics to perform trend line analysis

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Conclusion: Getting it right the first time

While the totality of these impacts is nearly impossible to quantify, it will almost certainly represent a substantial reduction in pharma revenue. The legislation will affect some companies more than others, particularly those with a greater concentration of high-Medicare-spend products in their portfolio. But the ripple effect will be a consideration all pharma manufacturers will need to plan for as well as other scenarios. The right end-to-end solution that provides the best single source of truth will position you to prevail.

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About the author | Bob Steller, Industry Principal, Life Sciences at Vistex

Bob Steller is an expert in Life Sciences revenue management, operational improvement, and information systems. With 28 years of experience, including 21 years with pharmaceutical companies, Bob leverages his deep knowledge of the industry's unique requirements to help clients streamline financial processes and boost overall performance.

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