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IRA: how low will they go?

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The Inflation Reduction Act creates ceilings but does not create floors for prices CMS sets, or "negotiates," with drug companies. It also gives the Medicare agency a great deal of discretion over price-setting policies and limits judicial review of its decisions.

Leaders of companies making drugs that will be subject to the IRA's price-setting provisions assume CMS will crash through the ceiling, establishing rock bottom prices.

Some stakeholders, however, expect CMS to use the price ceilings as guideposts.

While the first prices will not come into effect until 2026, assumptions about the process are already influencing investment and pipeline prioritization decisions.

The ceilings

The IRA requires CMS to select 10 single-source Part D drugs in 2023 that will be subject to regulated prices starting in 2026. The number of drugs increases every year, with Part B drugs added to the mix starting in 2028. By 2031, Medicare prices of up to 100 drugs will be controlled under the IRA.

Drugs will be selected for price-setting from lists of the top 50 Part D and top 50 Part B drugs ranked by Medicare spending. To qualify, drugs must be at least nine years away from having received an NDA or 13 years from a BLA. The drugs will be selected from lists of the drugs that generate the highest costs to the Medicare, but CMS hasn't said how it will decide which drugs it selects from the list.

The formula for determining the highest possible maximum fair price (MFP) for Part D drugs starts by selecting the lowest of the non-federal average manufacturers price (non-FAMP) or the sum of the enrollment-weighted net Part D negotiated prices. For Part B drugs, the starting point is the lower of the non-FAMP, the wholesale acquisition cost, or average sales price.

Those prices are then discounted, by 25% for "short monopoly" drugs that were approved less than 12 years prior to selection for price setting, 35% for "extended monopoly drugs" that were approved 12-16 years prior to price-setting, and 60% for "long-monopoly" drugs that were approved more than 16 years prior to price-setting.

The one exception where there is a floor relates to drugs from "small biotechs."

This involves a two-year exemption for certain "small biotech drugs," followed by a two-year period in which there is a minimum price for small biotech drugs of 66% of the 2021 average non-FAMP, adjusted for inflation.

Because the price-setting only applies to single-source drugs, those with generic or biosimilar competition are excluded. In addition, a biologic is exempt if its manufacturer can demonstrate that biosimilar competition is likely within two years of the time it would otherwise be selected.

Drugs that are approved solely for a single orphan indication and plasma-derived products are also exempt from price-setting.

Criteria for setting MFPs

The IRA specified factors the HHS Secretary must consider when setting the MFP, including the manufacturer's R&D costs; production and distribution costs; data on pending and approved patents and FDA exclusivities; and market, revenue and sales data.

Prior federal financial support for discovery and development of a drug is also among the criteria. Inclusion of government funding addresses concerns from politicians who assert that NIH does most of the heavy lifting in drug development, a claim that greatly exaggerates the contribution of academic research. If CMS explicitly cites federal support as a factor in reducing MFPs, biopharma companies could become less enthusiastic about partnering with academic researchers — an outcome that would slow the translation of fundamental scientific research into medicines.

The Secretary is also instructed to consider the degree to which a drug represents a therapeutic advance over therapeutic alternatives, comparative effectiveness data, and the extent to which it addresses unmet medical needs.

The law prohibits the use of quality-adjusted life years (QALYs) in setting prices.

The IRA requires HHS to develop and use a "consistent methodology and process" for determining MFPs, but it doesn't provide any guidance on how the various factors should be weighed.

Manufacturers that do not accept the MFP are subject to ruinous excise taxes. The only way for companies that are not willing to accept an MFP to avoid these taxes is to withdraw a drug from the Medicare and Medicaid programs.

David Ricks, chair and CEO of Eli Lilly and Co. (NYSE:LLY) compares the IRA negotiations to Mafia extortion. "The government will make an offer, and if you say 'no' they will tax gross U.S. sales by 95%. It is an offer you cannot refuse, à la The Godfather," said Ricks.

"WE HAVE A CEILING, WE DON'T HAVE A FLOOR, SO YOU HAVE TO BE PREPARED FOR DRACONIAN RESULTS." ALICE VALDER CURRAN, HOGAN LOVELLS

A loss of exclusivity event

Ricks and other biopharma CEOs told BioCentury they expect CMS to set MFPs at levels that would be similar to the prices the market establishes when a drug loses exclusivity and is subject to competition from multiple generic drugs.

Alice Valder Curran, a partner at Hogan Lovells, is advising clients to "prepare for the worst and hope for the best" in terms of price-setting. "The reason it makes sense to be prepared for that result is that there is no requirement around negotiation. We have a ceiling, we don't have a floor, so you have to be prepared for draconian results."

There are no legal constraints on CMS's ability to set prices, Lindsay Bealor Greenleaf, VP of ADVI Health, a consulting firm that specializes in commercialization and market access strategies, told BioCentury. "Whether the price stays near the ceiling or is much lower depends on where CMS wants to set it. That's the bottom line. Manufacturers have very little leverage in this process, which is why we refer to it as government price-setting instead of referring to it as negotiation."

While biopharma companies and investors are anxious to see which drugs will be selected for the first round of price-setting, and what prices the HHS Secretary will set, it isn't clear how predictive those datapoints will be.

The extent of the transparency of the negotiations is uncertain, Michelle Klein, a consulting actuary at Milliman Inc., an actuarial consulting company, told BioCentury. "We don't know if it will be publicly disclosed where they started and where they ended up, or if we're just going to know what the final number is."

If CMS doesn't disclose details of the logic behind MFPs, it may not be possible to predict what prices it will set in the future.

One of the most consequential uncertainties about implementation of the IRA involves the nature of the price negotiations. "We won't know until we see it," Klein said. The IRA's framework for establishing MFPs "may help it to be robust and fair, but the considerations are open-ended. CMS

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can consider other factors, so it is really unclear exactly how that will play out for any individual drugs."

The case for moderation

Klein thinks CMS will "want to try to balance making drugs as affordable as possible with avoiding setting prices so low that manufacturers just don't want to play in the Medicare space anymore."

In addition to prompting companies to withdraw from Medicare and Medicaid, CMS may consider the effects of very low MFPs on the generic drug industry.

Driving small molecule drugs to extremely low prices would prevent generic drug manufacturers from profiting during the 180 days of exclusivity the Hatch Waxman Act gives to the first approved generic. Without the ability to make hefty profits during the exclusivity period, it may not be profitable to produce a generic version of a drug.

The threat of manufacturers walking away from Medicare will moderate CMS's appetite for slashing prices, according to some observers.

"Our expectation is that the prices that result from negotiations are going to end up being, in most cases, fairly close to the ceiling price," Scott Briggs, a principal at Putnam, a consulting firm that is part of Inizio Advisory, told BioCentury.

MFPs will not be substantially lower "because manufacturers will have some leverage to negotiate," principally by opting to pull their drugs out of Medicare, Briggs said. "I don't think CMS is going to want to be in a position where products that were previously available are not because they could not come to a resolution in terms of the negotiated price."

CMS is also aware of the need to defend its procedures, if not specific prices.

To withstand legal challenges, the "process has to be fair, and that usually means it has to be transparent," Steve Pearson, president of the Institute for Clinical and Economic Review (ICER), told BioCentury. "The rules of the road will have to be transparent about who gets to submit data, and the role for drug companies and other stakeholders."

CMS has consulted with a number of stakeholders, including ICER and biopharmaceutical companies, but it has ruled out outsourcing the price-setting process to a third party.

CMS will "likely want to have a standard, a consistent, transparent and fair way by which they negotiate something lower than the maximum fair price specified in the statute," Pearson said.

Making it work

The IRA allocates $3 billion for CMS to the law, funds it is using to hire hundreds of staff. CMS has started meeting with stakeholders, including biopharma executives, about the price-setting process.

For stakeholders who need to make decisions based on an understanding of how CMS plans to implement the price-setting provisions of the IRA, "the most critical next step is getting clarity about what it is and what it isn't," Mark McClellan, director of the Duke-Margolis Center for Health Policy, told BioCentury. McClellan serves on the boards of Johnson & Johnson (NYSE:JNJ), Cigna Corp. (NYSE:CI) and other healthcare companies.

"There is room in the legislation for real negotiation, for back and forth with manufacturers, and for a predictable process," McClellan said. "There is also a lot of discretion, which puts a lot of weight on what CMS does from here to actual implementation." He acknowledged the skepticism of biopharma executives about how CMS will exercise its discretion, and whether it will actually engage in a genuine negotiation.

Drug companies and investors have cause to be worried that the best-case scenario may not come to pass. "Especially with such broad language and discretion in the law, I appreciate concerns about the risks that it could lead to very low prices and that the process for negotiations will not be transparent," McClellan said.

"The best way for CMS to get around the skepticism is through transparency," McClellan said. He added that CMS has little time and suggested that it should take advantage of the fact that 2023 is not an election year so there will be less political scrutiny of it actions.

McClellan's reflections on CMS's implementation of the IRA are pertinent because he was responsible, as CMS administrator from 2004-06, for implementing the Medicare Part D program, the only recent change in U.S. reimbursement policy that rivals the IRA in terms of impact and complexity.

When Congress created Part D, "it was quite unclear how and even whether the program would work and be sustainable," McClellan said. "CMS is in the same boat here. There is an intent to get more affordable prices more effectively than we've had in the past – and there is a lot to do to get there."

CMS cannot anticipate all of the potholes and unintended consequences associated with implementing the IRA, so it needs broad engagement with stakeholders, McClellan said. "We got so many good comments about Part D that we ended up hiring some of the people who sent in comments."

A paper trail documenting solicitation of public comments and good faith attempts to consider feedback would "help protect against the inevitable legal challenges that CMS is exceeding its authority or acting in a manner that is arbitrary and capricious," McClellan added. "If the goal is to make this a sustainable program that will survive from one administration to another and not be subject to big political shifts, then there is a reason to go through a very transparent public regulatory process. It would make the program more predictable, but also more solidified so it can stand the test of time."

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