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Stealth Defense: Medicare, IRS Implementation May Weaken Pharma's Arguments Against IRA

by Sarah Karlin-Smith

Flexibility included in guidance issued after many IRA lawsuits were filed put some of the arguments industry has made on shakier footing, legal experts explain.

Key Biden administration decisions on how to implement the US Medicare program's new drug price negotiation authorities could help the government in its attempts to quash the pharmaceutical industry's and other challenges to the Inflation Reduction Act program in court, legal experts say.

These decisions came in recent Medicare and Internal Revenue Service guidance that were issued after many of the industry's challenges were filed in court.

"We're seeing CMS do three things that I think really directly address the pharmaceutical companies, some of their core complaints and make this whole regime look a lot less coercive, if it was ever coercive at all," said University of Michigan law school professor Nicholas Bagley in a *Pink Sheet* interview.

Those three actions include laying out:

1. How easily a company can withdraw from Medicare and Medicaid to avoid the excise tax penalties if it chooses not to participate in the drug price negotiation process;
2. Clarification around how companies can remain participants in Medicare and Medicaid for the rest of their portfolio even if they don't want to engage in drug price negotiation; and
3. The applicability of the excise tax.

"You can tell that CMS is working to minimize the threat that these lawsuits pose," Bagley said.

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Bagley for his part thought the challenges were weak even prior to these Centers for Medicare and Medicaid Services and IRS actions. (Also see "*Merck Suit Against Medicare: Constitutional Arguments Are Scathing, But Are They Persuasive?*" - Pink Sheet, 7 Jun, 2023.)

The Department of Justice is drawing on these actions as it attempts to kill challenges to the law, said Zachary Baron, Associate Director of the O'Neill Institute for National and Global Health Law at Georgetown University, pointing to *DOJ's motion to dismiss* the US Chamber of Commerce's suit against the price negotiation program.

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Oral arguments will be held on 15 September on the Chamber's request for a preliminary injunction that would stop implementation of the program. (*See sidebar for related stories.*)

"Some of the claims that the manufacturers are making in terms of how onerous the excise tax is, or how difficult it is for manufacturers to pull out of Medicare, or how much it will harm their overall business, I think what the government has tried to do in guidance ... is to say actually the impact is going to be much less than some of these companies are saying," Baron said.

Expedited Withdrawal

Two of the decisions Bagley and Baron point to come from Medicare's *30 June final guidance* on the first round of negotiations. (Also see "*Medicare Negotiation Final Guidance: No More 'Gag' Rules, But Other Changes Fall Short Of Hopes*" - Pink Sheet, 3 Jul, 2023.)

First, section 40.1 of the updated guidance provides an expedited process for companies to withdraw from Medicare if they want to avoid the penalties involved in refusing to accept a negotiated price. The guidance also says that manufacturers may terminate their negotiation agreement with CMS at any time as long as conditions for termination are met.

Manufacturers who do not accept the negotiated price would not be subject to one of the law's sticks, excise taxes on the sales of their drug if they terminate their Part D Coverage Gap Discount Program, Part D Manufacturer Discount Program, and Medicaid Drug Rebate Program agreements, and none of their drugs are available under Part D or Medicaid. But companies have argued that to do this they would have to terminate their contracts well before they knew whether their drug was even subject to negotiation.

"The law prohibited participations or appeared to prohibit participants from leaving without giving some pretty extensive lead time, either 11 months or 23 months depending on the time of the year. And in guidance, CMS said, that's generally the case. But if you're withdrawing from the program, because you don't want to negotiate with us, we'll consider that good cause for an

immediate termination from the program. So already, that's some additional flexibility that drug manufacturers said they didn't have," Bagley said.

Per the procedures outlined in the guidance "any manufacturer that declines to enter an Agreement for the Negotiation Program may avoid incurring excise tax liability by submitting the notice and termination requests described herein 30 days in advance of the date that excise tax liability otherwise may begin to accrue. Moreover, any manufacturer that has entered into an Agreement will retain the ability to promptly withdraw from the program prior to the imposition of civil monetary penalties or excise tax liability," the updates say.

A Very Narrow Off-Ramp?

Second, Bagley notes changes made in Section 40.7 of the guidance that may throw a wrench in some of industry's arguments challenging the scope of the new law – such as that the only way to avoid the taxes for refusing to engage in negotiations is to withdraw all of a company's drugs from Medicare and Medicaid. (Also see "*PhRMA Teams With Provider And Patient Groups In Suit Against IRA Filed In Texas District Court*" - Pink Sheet, 21 Jun, 2023.)

The updated guidance provides a way for companies to spin off a drug subject to Medicare negotiations to an independent company that could decline to participate in the negotiation program, while the original pharmaceutical company would keep the rest of its portfolio in the two government programs.

Bagley said it is not clear to him how realistic it would be for a company to pursue this path.

Richard Frank, a senior fellow in economic studies and the director of the Brookings Schaeffer Initiative on Health Policy believes it is unlikely it would make economic sense for a company to do so.

If drugs are "big enough sellers to make it on the CMS list over the foreseeable future, I don't see how it would ever be a good deal for them to just throw it away, unless they got a huge amount of money for it. And then the other guy, you've got to wonder what they're thinking," Frank told *Pink Sheet*.

But for the purposes of a legal defense it may not necessarily matter that this option is unlikely to make economic sense. Instead, what matters is that CMS is giving companies some different on and off ramps, he said.

"It's a very complex story here. And it's complex economically and it's complex politically and legally and the three of those don't overlap much in some cases," he said.

Frank also noted that CMS seems to have written the guidance to ensure this type of carve out of

a drug isn't "gamed" by the industry such that they are able to both avoid negotiation and continue to profit from the drug in the US.

The guidance makes clear that if there's "any hint of some kind of connection," between the transferring manufacturer and the new entity "it's not going to happen," Frank said.

"I think the reason that they wrote whole little section was to cut off most approaches to sort of relicensing, doing joint ventures, having subsidiaries, shifting ownership to subsidiaries or related entities," Frank said.

"Everybody's gonna try to game every provision that they can. That's just the name of the game. But I think what they're doing here is saying, Look, we understand this. And if we're silent on it, then it's an invitation to game it. They're trying to sort of narrow that doorway, so it's hard to get through," Frank said.

IRS Limits Excise Tax

The third recent administrative action on the law comes in the form of an *excise tax guidance document* from IRS issued on 4 August.

In the guidance, the IRS explains that the excise tax will only be imposed on a manufacturer's sales of designated drugs dispensed, furnished or administered to Medicare beneficiaries, not on all US revenues for a drug as industry has said.

Further, while lawsuits such as Merck's argue that the maximum ratio of the tax to the total amount the manufacturer chargers for a drug could be as high at 1900%, the IRS guidance outlines a process where the ratio would actually be capped at 95%, DOJ explains in a *11 September filing to Merck's lawsuit*. This IRS interpretation if effective immediately.

Whether any of the changes were fast enough or deep enough to satisfy the judges that will hold the fate of the program in their hands remains to be seen, but the flexibility embedded in the implementation documents suggests the administration is happy to compromise on numerous aspects of the program to preserve its core functions.