



## The Controversial 340B Rebate Pilot Program Is Moving Forward

In a surprise move in the midst of the federal government shutdown and outcry from safety net health care providers, pharmacies, and wholesalers, the Health Resources & Services Administration (HRSA) has [announced](#) that it has approved plans for nine of the 10 drugs that are subject to pricing under the Medicare Maximum Fair Price (MFP) negotiations for participation in the recently-proposed 340B Rebate Model Pilot Program. The anticipated effective date for the rebate program is January 1, 2026.

For the approved products under the new model, instead of 340B-covered entities receiving the 340B price through an up-front discount at the time of purchase, the covered entities will be required to purchase the products at the manufacturer's list price, known as the wholesale acquisition cost (WAC). The 340B-covered entities will then submit data to the applicable rebate platform after the drug is dispensed and receive a rebate for eligible 340B claims paid within 10 calendar days of data submission. All nine drugs with approved plans are currently leveraging the same rebate platform. The rebate amount will be the greater of (a) the difference between the WAC paid and the 340B ceiling price and (b) the difference between the WAC paid and the MFP, if applicable.

Conceptually, according to the [announcement](#) by HRSA in August that manufacturers could submit proposals for a rebate program, the primary stated goal of the 340B Rebate Model Pilot Program is to provide pharmaceutical manufacturers the data they need to "deduplicate" 340B discounts and MFP prices, since manufacturers are not required to provide access to both – effectively stacking the discounts – for the same dispense. A secondary goal is to give manufacturers more data to prevent duplicate discounts with Medicaid and

diversion (which, for 340B purposes, means providing 340B discounted products to patients who are not eligible to receive them).

Concerns have been raised by numerous stakeholders (e.g., [American Hospital Association](#); [American Medical Group Association](#); [National Rural Health Association](#); and [Ryan White Clinics for 340B Access](#)) and [a bipartisan group of legislators](#) about the significant damage to the financial viability of many 340B-covered entities that the 340B Rebate Model Pilot Program represents by requiring covered entities to float the difference between WAC and the discounted price they are entitled to under the 340B statute. Lawmakers have also expressed concern about manufacturers leveraging aggressive tactics to delay or avoid paying rebates that are owed.

The feasibility of operationalizing this model across over 42,000 covered entities and over 32,000 contract pharmacy locations in just two months is also extremely questionable.

Nonetheless, as of today, the project is still moving forward. While there is still plenty of time for legal or administrative action to pause implementation of the 340B Rebate Model Pilot Program, covered entities that have 340B dispenses of any of the nine approved products should assess what they will need in terms of operational and financial resources to meet the data submission and other implementation requirements of the program and to buffer for a reduction in 340B revenue attributable to the nine implicated products for any errors, delays, or glitches in the rollout of the program.

These are the products with approved 340B Rebate Model Pilot Program plans, along with links to the contact email for each manufacturer and the platform for submitting data.

<b>Manufacturer</b>	<b>Selected Drug Name</b>	<b>Contact email</b>	<b>IT platform</b>
Bristol Myers Squibb	ELIQUIS	<a href="mailto:Linda.kamin@bms.com">Linda.kamin@bms.com</a>	<a href="#">Beacon platform</a>
Immunex Corporation	ENBREL	<a href="mailto:340BRelations@amgen.com">340BRelations@amgen.com</a>	<a href="#">Beacon platform</a>

<b>Manufacturer</b>	<b>Selected DrugName</b>	<b>Contact email</b>	<b>IT platform</b>
Astra Zeneca AB	FARXIGA	<a href="mailto:340B@astrazeneca.com">340B@astrazeneca.com</a>	<a href="#">Beacon platform</a>
Pharmacyclics	IMBRUVICA	<a href="mailto:340Brebate@abbvie.com">340Brebate@abbvie.com</a>	<a href="#">Beacon platform</a>
Merck Sharp Dohme	JANUVIA	<a href="mailto:340Brebate@merck.com">340Brebate@merck.com</a>	<a href="#">Beacon platform</a>
Boehringer Ingelheim	JARDIANCE	<a href="mailto:340brebate@boehringer-ingelheim.com">340brebate@boehringer-ingelheim.com</a>	<a href="#">Beacon platform</a>
	NOVOLOG;		
	NOVOLOG		
	FLEXPEN;		
	NOVOLOG		
Novo Nordisk Inc.	PENFILL;	<a href="mailto:340binfo@novonordisk.com">340binfo@novonordisk.com</a>	<a href="#">Beacon platform</a>
	FIASP; FIASP		
	FLEXTOUCH;		
	FIASP		
	PENFILL		
Janssen Biotech, Inc.	STELARA	<a href="mailto:340B_JJHCS@its.jnj.com">340B_JJHCS@its.jnj.com</a>	<a href="#">Beacon platform</a>
Janssen Pharmaceuticals, Inc.	XARELTO	<a href="mailto:340B_JJHCS@its.jnj.com">340B_JJHCS@its.jnj.com</a>	<a href="#">Beacon platform</a>

These are the data elements covered entities will need to provide to claim 340B rebates for the products approved for the program:

**Pharmacy Claims Data Fields Medical Claims Data Fields**

Date of Service	Date of Service
Date Prescribed	Claim Line Number
Rx Number	Claim Number
Fill Number	Unit of Measure
NDC-11	NDC-11
Quantity Dispensed	Quantity
Prescriber ID	Rendering Physician ID

Service Provider ID	Service Provider ID
340B ID	340B ID
RX BIN	Health Plan Name
RX PCN	Health Plan ID
Group Number ID (optional)	Health Plan ID Qualifier (optional)
	HCPCS Code (optional)
	HCPCS Modifiers (Up to four) (optional)

We will continue to monitor developments in this space.

*This blog post was drafted by [Beth Siemer](#) and [Aurora Kammerer](#), attorneys in the St. Louis, Missouri, and Overland Park, Kansas, offices of Spencer Fane, respectively. For more information, visit [spencerfane.com](http://spencerfane.com).*

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