

Manufacturer Proposed Rebate Models (As of 1/16/2025)

Manufacturer	Platform	Impacted Entities	Required Data Elements	Rebate Upon	Intended Start Date	Status	Lawsuit against HHS/HRSA?	State Exemptions	
								CAD & EO Rx	CRx
Bristol Myers Squibb (BMS)	Beacon (BRG)	All CEs	Not specified in lawsuit	Dispense Unit or Full Package	Early 2025/ Spring 2025	Proposed model to HHS 10/22/24 HHS declined to approve model 11/4/24 and again 11/21/24	Filed 11/26/24	Not specified in lawsuit	
Eli Lilly	Truzo (Kalderos)	All CEs	<u>Utilization Data</u> (CAD, EO Rx, & CRx)	Dispense Unit	11/1/24	Proposed model to HHS 8/2024 HHS declined to approve model 9/18/24	Filed 11/14/24	Not specified in lawsuit	
Johnson & Johnson (J&J)	Beacon (BRG)	DSH	<u>Purchase & Utilization Data</u> (CAD, EO Rx, & CRx)	Full Package	10/15/24	Announced publicly 8/23/24 HRSA threatened to remove J&J from 340B Program on 9/17/24 and 9/27/24 Paused as of 9/30/24	Filed 11/12/24	Not specified in notice	
Novartis	Not specified in lawsuit	DSH	Not specified in lawsuit	Full Package	6/2025	Proposed model to HHS 12/2024 HHS declined to approve model 1/14/25	Filed 1/15/25	Not specified in lawsuit	
Sanofi	Beacon (BRG)	CAH, DSH, RRC, SCH, CH/CHC	<u>Purchase & Utilization Data</u> (CAD, EO Rx, & CRx) <u>Encounter Data</u> (Hospitals only)	Full Package	Hospitals: 1/6/25 CHCs: 3/1/25	Announced publicly 11/22/24 HRSA threatened to remove Sanofi from 340B Program on 12/13/24 Paused as of 12/16/24	Filed 12/16/24	WV (Purch data only)	AR (Purch & util data, and PSA or attestation) KS, MD, MS, MO (Purch & util data) WV (Purch data only)

CAD = Clinic Administered Drugs (aka Physician Administered Drugs)

CRx = Contract Pharmacy

EO Rx = Entity Owned Pharmacy (aka In-House Pharmacy)

Wholly Owned Pharmacies are Considered Contract Pharmacies

Restriction Applies to Hospitals Only	Restriction Applies to Hospitals and FQHCs	Restriction Applies to all Covered Entities
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Rebate Model Impacted Drugs

Bristol Myers Squibb	Eli Lilly	Johnson & Johnson	Novartis		Sanofi
Eliquis	Adcirca	Stelara	Adakveo	Piqray	Admelog
	Alimta	Xarelto	Afinitor	Pluvicto	Ambien
	Amyvid		Aimovig	Promacta	Apidra
	Baqsimi		Alomide	Rydapt	Arava
	Baricitinib		Arzerra	Sandimmune	Avalide
	Basaglar		Beovu	Sandostatin	Avapro
	Bebtelovimab		Betopic S	Scemblix	Doxercalciferol
	Cyramza		Coartem	Simulect	Dupixent
	Ebglyss		Cosentyx	Tabrecta	Enoxaparin Sodium
	Emgality		Desferal	Taflinar	Flomax
	Erbitux		Diovan	Tasigna	Insulin Glargine
	Forteo		Diovan HCT	Tegretol	Ibesartan
	Humalog		Egaten	Tobradex	Kevzara
	Humatrope		Entresto	Tobrex	Lantus
	Humulin		Exforge	Trileptal	Leflunomide
	Insulin Lispro		Exforge HCT	Tykerb	Lovenox
	Jardiance		Exjade	Viojoice	Multaq
	Jaypirca		Fabhalta	Votrient	Plavix
	Jentadueto		Femara	Xolair	Priftin
	Kisunla		Gilenya	Zolgensma	Primaquine
	Lyumjev		Gleevec	Zortress	Renvela
	Mounjaro		Ilaris	Zykadia	Sevelamer
	Olumiant		Jadenu		Soliqua
	OmvoH		Kesimpta		Toujeo
	Retevmo		Kisqali		Zolpidem
	Reyvow		Kymriah		
	Synjardy		Leqvio		
	Taltz		Locametz		
	Tauvid		Lutathera		
	Tradjenta		Mayzent		
	Trijardy		Mekinist		
	Trulicity		Myfortic		
	Verzenio		Neoral		
	Zepbound		Netspot		

BMS, J&J, and Sanofi drugs not listed here still managed in 340B ESP, based on respective Contract Pharmacy Policies

Rebate Process Through Beacon

Entity purchases drug through wholesaler at WAC

Entity dispenses or administers drug to patient of the covered entity

Entity submits data to Beacon for 340B eligible utilizations

- a. Purchase data can be submitted at any time
- b. Utilization data must be submitted:
 - i. BMS: *timeline not specified in lawsuit*
 - ii. J&J: within 45 days of dispense or administration
 - iii. Sanofi: within 30 days of dispense or administration

Beacon confirms 340B eligibility using the following criteria:

- a. Drug ordered by the entity, at WAC
- b. Drug dispensed or administered at entity location, entity owned pharmacy, or contract pharmacy (in line with manufacturer's contract pharmacy policy)
 - i. Contract pharmacies still designated through 340B ESP
- c. Claims data submitted within required time frame
- d. SANOFI, HOSPITALS ONLY (eff. 3/1/25) Drug dispensed or administered to a patient of the entity
 - i. Encounter data used to determine if individual receiving a medication has received medical care from the entity in the last 24 months and the prescription is associated with services provided by the entity
 - ii. Referral prescriptions: Sanofi analyzes data submitted to determine if the prescription relates to the services provided by the entity to the patient

Beacon issues a **credit payment** to the covered entity (WAC - 340B):

- a. BMS: Within 7-10 days after data submission, or sooner if entity shares 340B price directly with patient (at either dispensed unit or full package size)
- b. J&J: Within 7-10 days after accumulation of validated rebate claims (at full package size)
- c. Sanofi:
 - i. Hospitals: Within 7 days after data submission (at full package size)
 - ii. Health Centers: Upon submission & validation of purchase data, with utilization data validated upon submission
 - 1. Credits presumptively paid on a claim that is not validated will be applied to subsequent claims
- d. Denied credits may be disputed through Beacon, which may require additional documentation

Rebate Process Through Truzo

