

# Policy Updates on Accumulators, Maximizers, AFPs and Beyond

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HIV+Hepatitis Policy Institute*

*Copay Congress  
November 18, 2024*

**HIV+HEP**  

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POLICY INSTITUTE

## Summary of Plan Sponsors' Tools for Accessing Manufacturer Patient Support Funds to Offset Drug Spending

### COPAY ACCUMULATOR

- Exclude a manufacturer's copay support from patient's deductible
- Patient responsible for full value of deductible
- Plan can capture the value of two deductibles
- Typically offered directly by the plan's PBM

### COPAY MAXIMIZER

- Patient's out-of-pocket obligation set to maximum value of copay support
- Patient incurs minimal out-of-pocket costs
- Plan can capture the value of a drug's copay offset program (less vendor fees)
- Typically offered by a third-party vendor partnered with the plan's PBM

### ALTERNATIVE FUNDING

- Coverage eliminated for selected specialty drugs. PAP pays for full drug cost.
- Patient incurs minimal out-of-pocket costs
- Plan can capture a drug's list price value (less vendor fees)
- Typically offered by a third-party vendor unaffiliated with the plan's PBM

PBM = pharmacy benefit manager

Source: Drug Channels Institute research. This chart appears as Exhibit 134 in *The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*.

# Comparing Plans: Traditional vs Maximizer vs Accumulator

**Patient Insurance Max Out of Pocket: \$6,500**

**Copay Program: \$0 copay up to \$20,000 Annually**

Traditional	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Cost Share	\$4,500	\$2,500	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$6,500
Copay Funds	\$4,500	\$2,500	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$6,500
Patient ROOP	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0

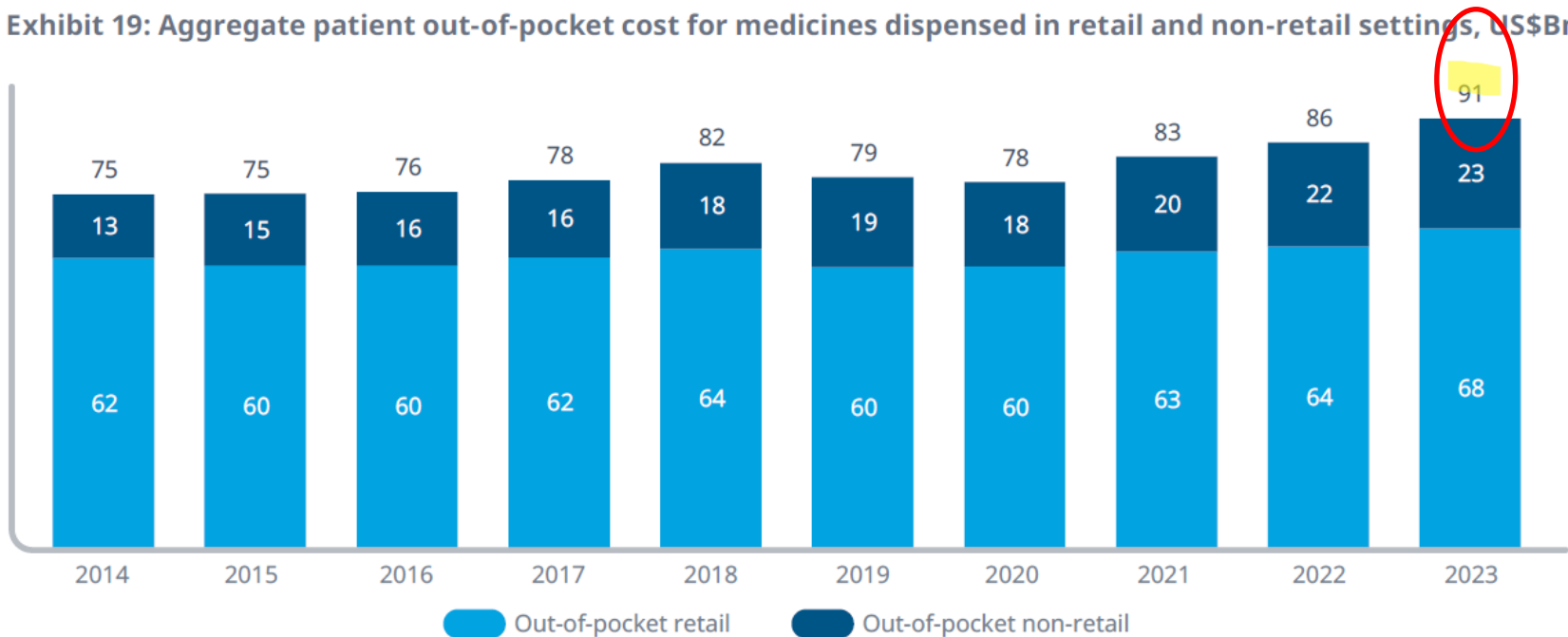
Maximizer	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Cost Share	\$1,666.67	\$1,666.67	\$1,666.67	\$1,666.67	\$1,666.67	\$1,666.67	\$1,666.67	\$1,666.67	\$1,666.67	\$1,666.67	\$1,666.67	\$1,666.67	\$20k
Copay Funds	\$1,666.67	\$1,666.67	\$1,666.67	\$1,666.67	\$1,666.67	\$1,666.67	\$1,666.67	\$1,666.67	\$1,666.67	\$1,666.67	\$1,666.67	\$1,666.67	\$20k
Patient ROOP	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0

Accumulator	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Cost Share	\$4,500	\$4,500	\$4,500	\$4,500	\$4,500	\$2,000	\$2,000	\$0	\$0	\$0	\$0	\$0	\$26,500
Copay Funds	\$4,500	\$4,500	\$4,500	\$4,500	\$2,000	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$20k
Patient ROOP	\$0	\$0	\$0	\$0	\$2,500	\$2,000	\$2,000	\$0	\$0	\$0	\$0	\$0	\$6,500

## PATIENT OUT-OF-POCKET COSTS

**Out-of-pocket costs in aggregate reached \$91Bn in 2023, an increase of \$5Bn, with most of the increases in retail drugs**

Exhibit 19: Aggregate patient out-of-pocket cost for medicines dispensed in retail and non-retail settings, US\$Bn

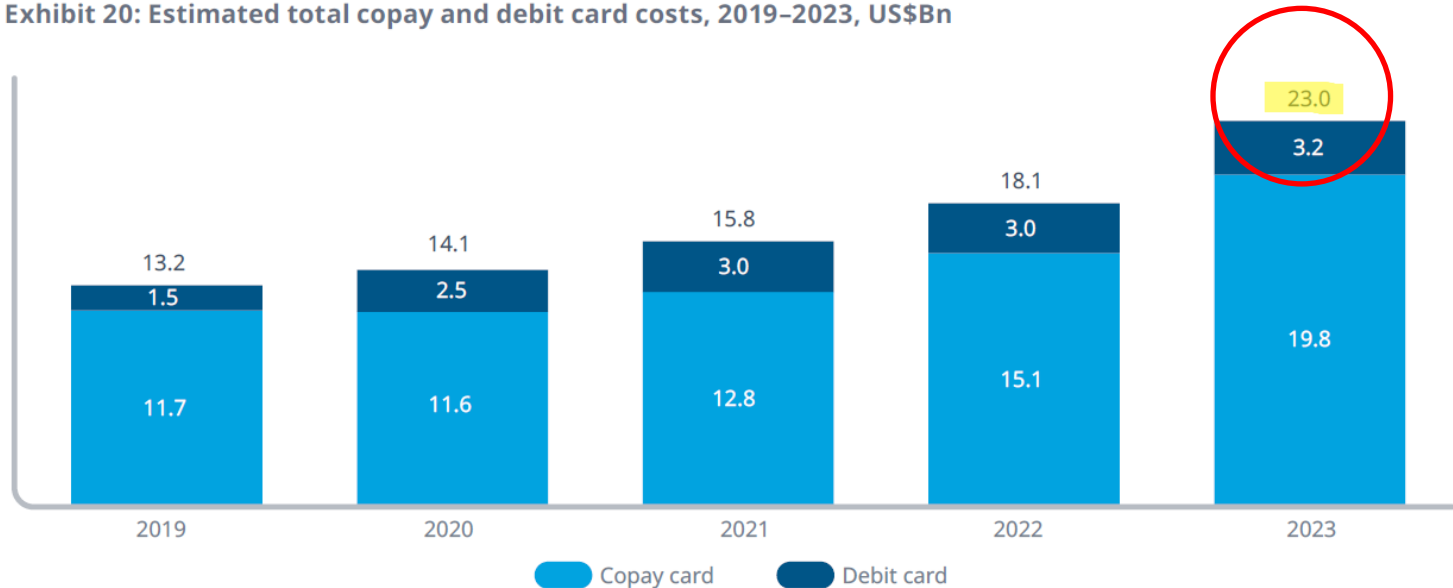


Source: IQVIA LAAD Sample Claims Data, CMS National Health Expenditures, Dec 2023; IQVIA Institute, Mar 2024.

PATIENT OUT-OF-POCKET COSTS

## Manufacturer copay assistance offset patient costs by \$23Bn in 2023 and \$84bn over the last five years

Exhibit 20: Estimated total copay and debit card costs, 2019–2023, US\$Bn



Source: IQVIA LAAD 3.0 Claims Data, Xponent PlanTrak Projected Data, IQVIA US Market Access Strategy Consulting Analysis, Dec 2023.

**Copay accumulator and maximizer programs accounted for \$4.8 Billion of copay assistance in 2023, more than double the amount attributed to these programs in 2019.**



## **Court Strikes Down HHS Rule that Allowed Insurers to Not Count Copay Assistance**

***Copay Assistance for Drugs Must Now Count in Most Instances***

WASHINGTON (October 2, 2023) – In a major victory for patients who depend on prescription drugs, Judge John D. Bates of the U.S. District Court for the District of Columbia [struck down](#) a Trump administration federal rule that allowed health insurers to not count drug manufacturer copay assistance towards a beneficiary’s out-of-pocket costs.

The [case](#) was brought against the U.S. Department of Health and Human Services by the [HIV+Hepatitis Policy Institute](#), [Diabetes Leadership Council](#), [Diabetes Patient Advocacy Coalition](#), and three patients who depend on copay assistance and whose insurers implemented “copay accumulator” policies.

# Next Steps on Copay Assistance

## ▶ 2020 NBPP now in effect

- ▶ Preamble: Copay assistance *must* count as cost-sharing for brands without generic
- ▶ Regulation: Accumulators *may* be allowed for brand name drugs with a generic alternative, *if permitted by state law*

## ▶ Federal Government

- ▶ This administration has said it will issue a rule clarifying definition of cost-sharing
- ▶ In meantime, will not enforce court decision

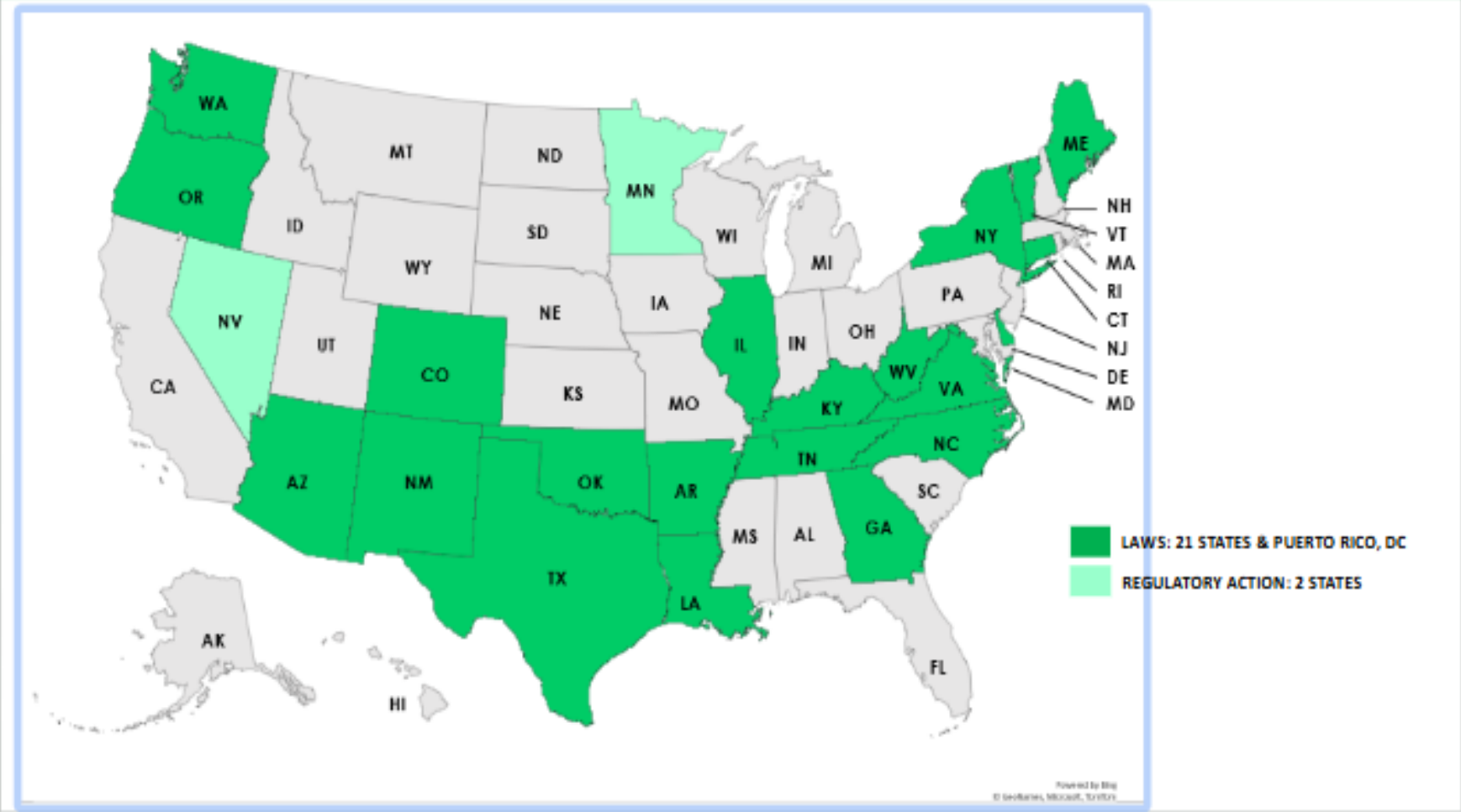
## ▶ Federal & State Enforcement Needed

- ▶ Nevada & Minnesota are enforcing 2020 NBPP

## ▶ Congressional & State legislation

# STATE ACCUMULATOR LAWS

September 2024





# Nevada DOI now enforcing 2020 NBPP

	<p><b>DIVISION OF INSURANCE</b> Protect Consumers, Ensure Solvency</p>
	<p><b>Prescription Drugs (cont.)</b></p> <ul style="list-style-type: none"><li>• Issuers <b>must</b> include a separate tier (Tier 1) for Zero Cost Share Preventive tier in the Prescription Drug Template per NRS<sup>1</sup>.</li><li>• Per Civil Action No. 22-2604 (JDB), HIV &amp; Hepatitis Pol’y Inst. v. U.S. Dep’t of Health &amp; Hum. Servs., the Division is enforcing prior guidance to allow the exclusion of Rx coupons from cost-sharing limits <b>only in situations where a generic is available.</b> <small><a href="https://www.federalregister.gov/documents/2020/05/14/2020-10045/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2021">https://www.federalregister.gov/documents/2020/05/14/2020-10045/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2021</a></small></li></ul> <p><sup>1</sup>NRS 689A.0418(9), NRS 689B.0378(10), NRS 689C.1676(9)</p> <p>52</p>

[https://doi.nv.gov/uploadedFiles/doinvgov/Content/Insurers/Life\\_and\\_Health/ACA\\_Plans/PY25\\_NV MED\\_%20Filing%20Guidance\\_FINAL.pdf](https://doi.nv.gov/uploadedFiles/doinvgov/Content/Insurers/Life_and_Health/ACA_Plans/PY25_NV MED_%20Filing%20Guidance_FINAL.pdf)



PAYERS

# Patient advocates shred Becerra's copay accumulator comments during House hearing

By Noah Tong · Apr 18, 2024 12:18pm

copay coupons

Patient Advocacy

legal

PBM



Xavier Becerra before the House Committee on Energy and Commerce April 17, 2024. (House Committee on Energy and Commerce livestream)

**Becerra repeatedly said in the hearing HHS would comply with the law and protect Medicare beneficiaries.**

“This issue has absolutely nothing to do with the Medicare program,” said Sarraille.

Copay accumulators and maximizers are not used by Medicare patients, he explained. Under the anti-kickback statute, usage of coupons on a federal program beneficiary is illegal.



POLICY INSTITUTE

PRESS RELEASE

April 2, 2024

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## **Federal Government Refuses to Enforce Copay Assistance Court Victory, But Moves to Stop Scheme of Classifying Drugs as “Non-Essential Health Benefits”**

***Will Also Issue Rule to Close Loophole for Large Group & Self-funded Plans***

Washington DC...As part of the [final 2025 Notice of Benefits and Payment Parameters rule](#) issued today, the federal government completely ignored the D.C. District Court [decision](#) that struck down the rule allowing insurers not to count copay assistance for prescription drugs as part of patient cost-sharing. However, they do move to stop a new scheme that insurers and employers are engaged in: classifying certain drugs as “non-essential health benefits.” In the final rule, CMS states that all covered drugs in excess of a state benchmark are essential health benefits.



HIV+Hepatitis Policy Institute 📍 @HIVHep · Sep 26

We ID'd 150+ Employers/Insurers using Vendors that designate Certain #Rx's as "Non-Essential Health Benefits" & pocket #CopayAssistance meant for #Patients. Biden-Harris admin said they'll issue rule to end this but clock is ticking #ProtectACA. Full list: [bit.ly/3XdBkXw](https://bit.ly/3XdBkXw)

✓ Bank of America

✓ Chevron

✓ Citi

✓ Delta

✓ Hilton

✓ Home Depot

✓ NewsCorp

✓ Target

✓ United Airlines

✓ Carnegie Mellon

✓ Duke

✓ George Washington

✓ New York University

✓ Ohio State

✓ Texas A&M

✓ University of Connecticut

✓ Villanova

✓ Yale

✓ Catholic Diocese of Columbus

✓ Cleveland Clinic

✓ New York Teamsters

✓ Screen Actors Guild

✓ State of Connecticut

✓ State of Delaware

✓ State of New Mexico

✓ Mendocino County, CA

✓ Orange County, FL



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- Please note that manufacturer copay assistance may still be available to you without the plan or administrator's support; however, **if you do not consent to SaveOnSP monitoring your pharmacy account, any costs not covered by manufacturer copay assistance may be your responsibility.**
  - Any payments made by you or the drug manufacturer for these specialty medications will not accumulate toward your out-of-pocket maximum. Additionally, copayments for these medications will continue even after you've met your plan's out-of-pocket maximum.

# SaveOnSP Drug List

Effective as of July 1, 2024.



Please call 800-683-1074 to participate. Once you've completed the manufacturer copay assistance program's enrollment process and consented to SaveOnSP monitoring your pharmacy account, your responsibility will be reduced.

The specialty medications included in the copay assistance benefit drug list are specific to your plan's prescription drug benefit and subject to change at any time. Prescription drug benefit plan terms will always take precedence. Medications with prior authorization criteria must be approved in advance by the plan and follow applicable laws and/or regulations. The specialty medications included on this list will have a 30 percent coinsurance, which may be subject to change. By completing the manufacturer copay assistance program's enrollment process and consenting to SaveOnSP monitoring your pharmacy account, your final cost will be reduced. Specialty medications will be filled through your approved specialty pharmacy.

**A**  
Abrilada  
Actemra  
Adalimumab-adaz  
Adbry  
Adstiladrin  
Aleccensa  
Alunbrig  
Alymsys  
Arcalyst  
Austedo  
Avonex  
Ayvakit

Cibinco  
Cimzia  
Columiv  
Cometriq  
**Complera**  
Copaxone  
Copiktra  
Cosentyx  
Cotellic  
Crysvita  
Cuvriol  
Cyltezo  
Cystadrops

**D**  
Daybue  
Dojolvi  
Doptelet  
**Dovato**  
Dupixent

**E**  
**Edurant**  
Egrifta  
Elrexfo  
Empaveli  
Enbrel  
Entyvio  
Epinly  
Erivedge  
Exkivity

**C**  
Cabometyx  
Calquence  
Camzyos  
Cayston  
Cerdelga  
Cholbam

**F**  
Fasenra  
Filspari  
Fintepla  
Firdapse  
Fotivda  
Fulphila  
Fynlentra  
Fynlentra

**G**  
Galafold  
Gattex  
Gavreto  
Genotropin  
**Genvoya**  
Gilotrif  
Glatopa  
Gocovri  
Granix

**H**  
Haegarda  
Halaven  
**Harvoni**  
Hulio  
Hyrimoz

**I**  
Ibrance  
Iclusig  
Idacio  
IDHIFA  
Ilaris  
Ilumya

Imbruvica  
Imcivree  
Increlex  
Ingrezza  
Inlyta  
Inqovi  
Inrebic  
**Intelligence**  
Iwifin

**J**  
Jakafi  
Jaypirca  
Joenja  
**Juluca**  
Juxtapid  
Jynarque

**K**  
Kalbitor  
Kalydeco  
Kesimpta  
Keveyis  
Kevzara  
Kineret  
Kisqali  
Kisqali Femara  
Co-Pack  
Koselugo

**L**  
**Ledipasvir/Sofosbuvir**  
Lenvima  
Litfulo  
Livmarli  
Lonsurf  
Loqtorzi  
Lorbrena  
Lumakras  
Lumryz  
Lupkynis  
Lynparza  
Lytgobi

**M**  
Mayzent  
Mekinist  
Mektovi

**N**  
Nerlynx  
Neulasta  
Neupogen  
Ngenla  
Ninlaro  
Nivestym  
Nourianz  
Nplate  
Nubeqa  
Nucala  
Nuplazid  
Nutropin  
Nyvepria

# SaveOnSP Drug List

[https://networkhealth.com/\\_\\_assets/pdf/pharmacy/saveon-drug-list.pdf](https://networkhealth.com/__assets/pdf/pharmacy/saveon-drug-list.pdf)

**O**  
Ocaliva  
**Odefsey**  
Odomzo  
Ogsiveo  
Ojjaara  
Olpruva  
Olumiant  
Omnitrope  
Omvo  
Onureg  
Opsumit  
Orencia  
Orenitram  
Orfadin  
Ojgavyx  
Orladeyo  
Orserdu  
Otezla  
Oxbryta  
Oxervate  
Ozurdex

**P**  
Palynziq  
Pemazyre  
Phesgo  
**Pifeltro**  
Piqray  
Plegridy  
Ponvory  
**Prezcobix**  
Procysbi  
Prolia  
Promacta  
Pulmozyme  
Pyrukynd

**Q**  
Qinlock

**HIV drugs**

**Hepatitis C drugs**

**R**  
Radicava  
Ravicti  
Rebif  
Retevmo  
Rinvoq  
Rolvedon  
Rozlytrek  
**Rukobia**  
Rydapt

**S**  
Scemblix  
**Selzentry**  
Serostim  
Signifor  
Siliq  
Simponi  
Skyclarys  
Skyrizi  
sodium oxybate  
**Sofosbuvir/Velpatasvir**  
Somavert  
Sotyktu  
**Sovaldi**  
Sprycel  
Stelara  
Stimufend  
Stivarga  
Strensiq  
**Stribild**  
Sublocade  
Sucraid  
Syfovre  
Symdeko  
**Symtuza**  
Synagis

**T**  
Tabrecta  
Tadliq  
Tafinlar  
Tagrisso  
Takhzyro  
Taltz  
Talzenna  
Tasigna  
Tavalisse  
Tavneos  
Tazverik  
Tecentriq  
Tegsedi  
Thalomid  
Tibsovo  
Tobi  
Tremfya  
Trikafta  
**Triumeq**  
Truqap  
Tukyasa  
Turalio  
Tymlos

**U**  
Udenyca

**V**  
Valchlor  
Vanflyta  
Vegzelma  
Venclexta  
Verzenio  
Vijoice  
**Viracept**  
Vistogard  
Vitakvi  
Vizimpro  
**Vosevi**  
Votrient  
Vowst  
Voxzogo  
Vumerity  
Vyjuvek  
Vyleesi  
Vyndamax  
Vyndaqel

**W**  
Welireg

**X**  
Xalkori  
Xeljanz  
Xembify  
Xermelo  
Xolair  
Xospata  
Xpovio  
Xtandi

**Y**  
Yuflyma  
Yusimry

**Z**  
Zarxio  
Zejula  
Zelboraf  
Zeposia  
Ziextenzo  
Zokinvy  
Ztalmu  
Zynzy

# Next Steps on Non-EHB Loophole

- ▶ **Individual market & small group plans**
  - ▶ All covered drugs are EHB
  - ▶ Maximizers & some AFPs no longer allowed
- ▶ **Large group & self-funded plans**
  - ▶ This administration has said it will issue a regulations to do this
  - ▶ But was not included in draft 2026 NBPP
  - ▶ EHB loophole remains open
- ▶ **Non-EHB loophole must be closed & copay assistance must count**
  - ▶ Otherwise maximizers could be changed to accumulators, which are even worse for patients

# **HIV+HEP**

## POLICY INSTITUTE

### **PRESS RELEASE**

October 4, 2024

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## **Biden-Harris Administration Sides with Insurers & Fails to Take Steps to Lower Patient Costs for Prescription Drugs**

### ***Promised Rules Not Included in Notice of Benefit & Payment Parameters Proposal***

*Washington DC...* In a shock to patients who are struggling to afford their prescription medications, the Biden-Harris administration has failed—again—to take steps to lower how much Americans pay for their drugs and instead, by their inaction, are continuing to allow big insurers and PBMs to profit from billions of dollars of drug manufacturer copay assistance that is meant for patients, not for insurers or PBMs.

In the [2026 Notice of Benefit and Payment Parameters rule](#) proposed today, although they state they still intend to do it, the administration failed to include promised new regulations on whether copay assistance will count as part of patient cost-sharing and that all drugs covered by large group and self-funded plans are to be considered essential health benefits.

“Every day these rules are delayed is another day that insurers and PBMs are pocketing billions of dollars meant for patients who are struggling to afford their drugs,” commented **Carl Schmid, executive director** of the **HIV+Hepatitis Policy Institute**. “Coming from an administration that prides itself on supporting patients and lowering their prescription drug costs, this is a huge disappointment. While they have gone on record that they will issue these rules, the clock is ticking and there isn’t much time left.”



# Thank you!

<https://hivhep.org/copay-accumulator-litigation/>

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