



Colorado Prescription Drug Affordability Board  
Colorado Division of Insurance  
1560 Broadway, Suite 850  
Denver, CO 80202

May 30, 2024

Madam Chair and Honorable Members of the Colorado Prescription Drug Affordability Board:

On behalf of the over 45 organizations dedicated to keeping our pharmaceutical supply chain safe, the Partnership for Safe Medicines thanks the Prescription Drug Affordability Board (Board) and Board Staff for the opportunity to present key information on the discussion around the June 7th 2024 Board meeting to discuss the medicine, Stelara. **We recommend that you do not find Stelara unaffordable due to the unintended consequences that will ensue: greater risk of counterfeits, the rise of a black market in Stelara in the secondary wholesale market, and reduced patient access.**

## Overview

PSM is deeply concerned that the suggested policy recommendations that the Board might make on unaffordability and the setting of an Upper Payment Limit (UPL) will create an increased risk of diversion and counterfeiting around Stelara.

We understand that the setting of a UPL for Stelara will create a ceiling for:

- the maximum amount a pharmacy or provider can be reimbursed by an insurance company or PBM for the cost of the Stelara they dispensed or administered; and
- the maximum amount a pharmacy or provider can pay to buy Stelara from a wholesaler.

This strategy presents a big problem for independent pharmacies because UPLs only set a ceiling on the amount a pharmacy can be reimbursed, not a floor. Pharmacies are already losing money on a wide variety of medicines because pharmacy benefit managers (PBMs) reimburse them for less than it costs to buy the products from authorized wholesalers. This situation has created a risk to the drug supply chain as counterfeiters target pharmacies with diverted and counterfeit versions of these under reimbursed medicines.

We are particularly concerned about four scenarios relevant to the Colorado PDAB's consideration of Stelara:

1. Pharmacies that currently break even or better on Stelara might find that the PBMs they dispense for lower their reimbursements to make up for profits they lose as a result of the UPL. Dispensing Stelara will go from being profitable to unprofitable, and criminals will aim to sell diverted/fake versions to these pharmacies.
2. Pharmacies that are currently losing money due to PBM under-reimbursements will face even greater financial pressure, and will become even more attractive targets for criminals selling black market versions of Stelara.

3. Since World War II, price controls have repeatedly been associated with the creation of black markets, and black markets for medicine are particularly dangerous. Should Colorado put UPLs on Stelara, several types of actors will be incentivized to arbitrage medicine out of the state of Colorado, which will harm Colorado patients. Colorado is unprepared to deal with this danger: there is currently no law enforcement authority in the state adequately resourced to prosecute significant diversion of **therapeutic, non-controlled-substance** medicine.
4. Setting UPLs is likely to reduce supply, as many wholesalers won't be able to afford to sell UPL-regulated medicines in Colorado. In situations where medicines are in short supply, patients will order risky drugs from outside the legitimate supply chain. Ordering medicines from overseas will increase the risk of diverted and counterfeit medicine.

## Background: Medicines that are under reimbursed are at a high risk of being diverted and/or counterfeited

As PBMs reimburse pharmacies below cost of acquisition, [criminal counterfeiters have been targeting those medications for fraudulent sale to pharmacies](#). From GLP-1 drugs like [Ozempic](#) to HIV medicines like [Biktarvy](#), [Descovy](#), and [Genvoya](#), counterfeiters have been making and selling dangerous, fake, and diverted versions of these medications to unsuspecting pharmacies.

This danger isn't theoretical: In 2023, two men were jailed and a licensed distributor signed a multi-million dollar settlements for their roles in [a crime ring that bought empty and diverted bottles of HIV medicines like Genvoya; cleaned them up, sometimes putting other, random pills in them; and sold them to unsuspecting pharmacies](#).

**Patients received and were harmed by the counterfeit products in these bottles.** Genvoya was one of the medicines the Colorado PDAB recently considered for a UPL.

When we refer to *counterfeit medicines*, we mean fake pills or the wrong pills placed into convincing packaging that looks just like the correctly manufactured medicine. When we say *diverted medicine* we mean medicine that was dispensed to a patient and then brought back into the supply chain. A diverted medicine might be counterfeit because the criminals may have just bought empty packaging. Ultimately you won't know until you test it. Diverted medicine, even if you know it's real, is not safe to dispense to a patient. Many medicines are temperature or shock sensitive. They become therapeutically ineffective when they are not handled or stored according to clinical requirements even if they are in the same, unopened package that was previously given to a patient.

When a pharmacy discovers that medicine their patients need is being reimbursed at an amount below their prime wholesaler's price, it is only rational that it would look for a lower price from secondary market vendors with wholesale pharmacy distribution licenses. Criminals in several unrelated cases have acquired valid wholesale licenses or worked with pharmacies to do informal wholesaling of diverted and counterfeit medicines through [online pharmacy-to-pharmacy marketplaces](#).

**What is a secondary wholesaler?** Many pharmacies purchase most of their medications from large “prime” wholesalers. Their contracts incentivize them to purchase as much as possible from a single wholesaler to get the largest possible discounts. But sometimes a pharmacy will seek a secondary wholesaler for a medicine because it’s in shortage at their prime, or because the secondary has a better price on a medicine that another pharmacy over-purchased. Sometimes, however, the price is better because the secondary is selling black market (diverted or counterfeit) medicine.

Risk: PBM’s systemic reimbursement of Stelara below cost of acquisition creates a draw for criminals to sell diverted and counterfeit products to desperate pharmacies. Additional pressures from strategies like UPLs will worsen this situation.

We pulled acquisition costs from several pharmacies around the country that dispense Stelara<sup>1</sup>, and compared them to two PBM reimbursement contracts for Medicare Part D plans to demonstrate the problem. We have heard of pharmacies that have dispensed Stelara for a small net gain (<\$20) but we could not obtain documented proof of that fact.

Drug	NDC	Average Wholesale Price	Acquisition cost (what the pharmacy pays)	Top 5 PBM - Medicare Part D 2024 Contract		Different Top 5 PBM - Medicare Part D 2024 Contract	
				Reimbursement (AWP - 25.5%)	Net loss to pharmacy	Reimbursement (AWP - 22%) + 5 cent dispensing fee	Net loss to pharmacy
Stelara IV 130mg SDV 26ml	57894-0054-27	\$2,429.41	\$2,024.51	\$1,809.91	-\$214.60	\$1,894.94	-\$129.52
Stelara 45mg PFS 0.5ml	57894-0060-03	\$16,705.72	\$13,468.99	\$12,445.76	-\$1,023.23	\$13,030.46	-\$438.48
Stelara 45mg SDV 0.5ml	57894-0060-02	\$16,705.72	\$13,921.43	\$12,445.76	-\$1,475.67	\$13,030.46	-\$890.92
Stelara 90mg PFS 1ml	57894-0061-03	\$33,411.42	\$26,937.96	\$24,891.51	-\$2,046.45	\$26,060.91	-\$877.00

<sup>1</sup> A screenshot of a wholesaler’s pricing from their ordering website can be found at the end of this document.

In all these cases the pharmacy loses money dispensing Stelara under Medicare Part D because reimbursement is below cost of acquisition. Because pharmacies that choose to dispense Stelara must find a cheaper source, they become excellent targets for criminals selling diverted or counterfeit products.

**UPLs don't address this problem, and have the potential to make it worse**

UPLs are likely to have a very negative impact on independent pharmacies and their patients because the UPL rule doesn't prevent pharmacies' losses, and PBMs may lower their reimbursement amounts to compensate for lost profits as a result of the UPL.

Using the data in the table above, here is an example of a money-losing dispense on Stelara using the 2024 contract for a [major PBM cited on our website](#).

Money-losing reimbursement before a UPL is put into place.

Pharmacy purchases Stelara from wholesaler	<b>-\$2,024.51</b>
Patient co-pay to be kept by pharmacy	+\$100
PBM reimbursement to pharmacy (no dispensing fee was allowed)	<u>+\$1,809.91</u>
Pharmacy loses money on this dispense	<b>-\$114.60</b>

Example: Prices pulled May 8, 2024 for Stelara IV 130mg SDV 26ml NDC 57894-0054-27. \$100 copay assumed. Actual copays differ for different insurance situations.



No pharmacy can sustain losses like these, and nothing about the methodology of setting UPLs will improve this situation. Faced with these money-losing events, many pharmacies have told us they decline to dispense Stelara. Others will become targets for criminal counterfeiters.

**Won't the UPL prevent PBMs from under-reimbursing pharmacies?**

No. UPLs set a ceiling for reimbursement amounts, not a floor. They don't set fixed prices for medicines. As things currently stand, PBMs will continue to profit on "[spread pricing](#)," pocketing the difference between the price they have negotiated with the manufacturer and what they pay the pharmacies they under-reimburse, even under a

UPL regime. Here is a hypothetical example in which the state has set a \$1,000 UPL for the previously mentioned Stelara.

### Money-losing reimbursement AFTER a UPL is put into place.

Pharmacy purchases Stelara from wholesaler for \$1,000 (the UPL)	<b>-\$1,000.00</b>
Patient co-pay to be kept by pharmacy	+\$100
PBM reimbursement to pharmacy for less than the UPL (no dispensing fee was allowed)	<u>+\$785.40</u>
Pharmacy loses the same amount money on this dispense	<b>-\$114.60</b>

Example: Price of Stelara IV 130mg SDV 26ml NDC 57894-0054-27 reduced from current wholesale cost of \$2,024.51 to a hypothetical \$1,000. \$100 copay still assumed. Actual copays differ for different insurance situations.



As you can see in this example, **the financial impact of the drug is unchanged for the patient** under a UPL. As with before the UPL, **the pharmacy suffers a \$114.60 loss** because the UPL doesn't prevent the PBM from lowering its reimbursement.

The next example shows that the PBM could reduce their reimbursement to the pharmacy even more to recoup some of the profit lost because of the UPL.

## Money-losing reimbursement AFTER a UPL with PBM recouping lost profit.

Pharmacy purchases Stelara from wholesaler for \$1,000 (the UPL)	<b>-\$1,000.00</b>
Patient co-pay to be kept by pharmacy	+\$100
PBM reimbursement to pharmacy for less than the UPL (no dispensing fee was allowed)	<u>+\$485.40</u>
Pharmacy loses even more money on this dispense	<b>-\$414.60</b>

Example: Price of Stelara IV 130mg SDV 26ml NDC 57894-0054-27 reduced from current wholesale cost of \$2,024.51 to a hypothetical \$1,000. \$100 copay assumed. Actual copays differ for different insurance situations.



### But won't the dispensing fee keep the pharmacy from losing money on the dispense?

The rulemaking for Colorado's UPL specifically says that:

An upper payment limit established by the Board **does not preclude a pharmacist or pharmacy** (as defined by section 12-280-103(43), C.R.S.) licensed by the State Board of Pharmacy **to charge reasonable fees**, to be paid by the providing health benefit plan of the consumer, for dispensing or delivering a prescription drug for which the Board has established an upper payment limit.

The rule allows pharmacies to charge fees that cover dispensing costs, but it does not guarantee that they are entitled to receive the fees. Dispensing fees are governed by contracts between PBMs and pharmacies, and current contracts often exclude them or offer token amounts.

This example below is from a redacted top five PBM contract for pharmacies to fulfill Medicare Part D contracts for 2024. In all six instances outlined in red, no dispensing fee is included.



September 25, 2023

**2024 MEDICARE PART D NATIONAL PERFORMANCE AMENDMENT  
 TO THE [REDACTED], INC. PHARMACY PROVIDER AGREEMENT**

Contract Rates			
	<b>BRANDS</b> Up to an Average Discount for Single-Source & Multi-Source <sup>(4, 5)</sup> Brands not paid on <input type="checkbox"/> MAC + Not less than an Average Dispense Fee:	<b>GENERICS – A</b> Up to an Average Discount for Generic Drugs not paid on <input type="checkbox"/> MAC + Not less than an Average Dispense Fee:	<b>GENERICS – B</b> Generic Drugs and Multi-Source <sup>(4, 5)</sup> Brands paid on <input type="checkbox"/> MAC + Not less than an Average Dispense Fee:
<b>30 Day Network Participation</b>			
Year 1	AWP – 25.50% <input type="checkbox"/> <b>\$0.00</b>	AWP – 57.00% <input type="checkbox"/> <b>\$0.00</b>	<input type="checkbox"/> MAC <input type="checkbox"/> <b>\$0.00</b>
<b>90 Day/EDS Benefit Participation</b>			
Year 1	AWP – 30.50% <input type="checkbox"/> <b>\$0.00</b>	AWP – 57.00% <input type="checkbox"/> <b>\$0.00</b>	<input type="checkbox"/> MAC <input type="checkbox"/> <b>\$0.00</b>

Pharmacists have told PSM that these PBM contracts are non-negotiable and we have documented many transactions in which a PBM paid no dispensing fee to the pharmacy or paid a token amount, [such as \\$0.10 on a \\$900 medicine such as Ozempic](#).

The dispensing fee is not a small thing, because pharmacies don't just buy and sell drugs. They also require staff and equipment to properly care for patients and their medicines.

Enbrel, Stelara, and Cosentyx, are all injected specialty medicines that have been or are being considered by the Colorado PDAB. These medicines require significant patient counseling that is more complex than asking a pharmacist whether to take a medicine on a full stomach. There are medicines and medical conditions that are contraindicated for patient safety. Patients who have not been trained to inject themselves will have questions and require significant assistance. All this will be done by a trained pharmacist, and that costs the pharmacy money.

All three of these medications require refrigeration and are sensitive to motion. They need to be handled and stored carefully. These refrigeration units, though shared with other medicines, are also not free.

[Industry analysis from 2020](#) found that dispensing the simplest of medicines costs pharmacies at least \$12. For specialty medicines such as Stelara, that cost is closer to \$73. Pharmacists typically do not get a \$12 dispensing fee to cover these costs, much less one that would cover a loss in the cost of medicine acquisition. Even if a pharmacy were reimbursed at cost for a medicine, they would lose money in the process of dispensing it.



## Have providers of other specialty medicines in the U.S. been defrauded by criminals selling counterfeit medicines before the rise of PBMs?

Yes.

From 2007 to 2012, a Canadian online pharmacy called Canada Drugs trafficked \$78 million in black market and counterfeit oncology products through wholesale channels, almost exclusively to oncologists who administered them in-office. They targeted independent oncologists working outside of hospital systems, presumably because they wouldn't have to deal with purchasing departments concerned with compliance. The Canadian criminals even sold through U.S.-based sales offices and staff, so physicians would think they were buying from American sources. [This PSM publication](#) describes many of the legal cases that encompass this era.

From 2009 to 2013, 39 individuals were prosecuted for the purchase or sale of non-FDA approved intrauterine devices (IUDs). In Texas alone, over 450 black market IUDs were provided to Texas patients. Patients in 7 states were affected. There were six separate lawsuits brought for patient injuries in Arkansas alone. Some patients experienced long lasting medical adverse events.

## Risk: Setting a UPL will encourage arbitrage and diversion of medicine from Colorado

Attempts to control the increased prices for products often distort the market in ways that don't benefit consumers (see "[Why Price Controls Should Stay in the History Books](#)," Federal Reserve Bank of St. Louis). A UPL is a price control, and if a UPL on Stelara creates a guaranteed supply of a medicine cheaper than can be found in every other state besides Colorado, an immediate black market in Colorado-priced medicine would emerge. ***Every supply chain player will be able to make more money selling Stelara outside Colorado than dispensing it.***

Existing examples suggest that pharmacies, which are already facing tremendous financial pressure, would make more money selling Stelara to pharmacies out of state than dispensing it within Colorado. These examples include:

**Arbitrage of medicines in shortage:** PSM has studied the gray market in lidocaine, an injectable anesthetic available from multiple manufacturers that is currently in shortage. Following a tip from a hospital pharmacy in West Virginia that was forced to purchase lidocaine for a 500% markup over its regular wholesale price, PSM found a small community pharmacy in Texas that had adopted an arbitrage model where it purchased lidocaine injections that it never intended to dispense for the purpose of selling them to a licensed gray market wholesaler. This was happening at the same time physicians in Texas were struggling to get lidocaine for orthopedic arthritis patient injections. (See: "[Why pay 500% markup for lidocaine?](#)" on PSM's YouTube channel)

**Pharmacy-to-pharmacy online marketplaces:** Technically, it is legal for pharmacies to sell each other product without track and trace documentation for a *named patient need*. This is an important way for pharmacies to address shortages. Online marketplaces, like Amazon marketplace but for pharmacies,





have sprung up to facilitate these transactions, and are an obvious route that pharmacies and wholesalers with access to cheap UPL-governed medicine could use to sell price-controlled medicine out of state.

Additionally, we have seen examples for over two decades of patients who sell their medicine to criminal diverters who bring it back into the supply chain illegally. This is likely already happening in Colorado for Medicaid patients. (See PSM's video, "[Pharmacists: How to spot a patient fraud](#)")

UPLs for medicine would create the unintended consequence that it is more profitable for any player in the supply chain to sell Stelara outside Colorado than to dispense it. Even if only one or two supply chain participants did this, it would have an outsized effect on patient access. The resulting shortages would worsen access to that medicine, fueling additional risky behavior on the part of patients.

We understand that this is not the intended goal of the Prescription Drug Affordability Boards like Colorado's, and we sympathize with the challenges of making change in a complex economic system. However the warning signs of the unintended consequence of a black market are very clear. Furthermore economists who study black markets created by price controls recommend that the government instituting them create and fund an entity that enforces the rules around these controls. Colorado has no such entity, and even if one may assign that responsibility to an existing entity, there is no funding allocated to protect patients from these unintended consequences.

## Risk: Unsafe patient behavior due to limited supply of Stelara because of the UPL

When patients have difficulty getting the medicine they need, they engage in unsafe behavior to get it. We think that as with many economies that experiment with price controls, setting a UPL for Stelara will ultimately reduce access to it and drive patients to consider purchasing from unlicensed sources. This isn't a theoretical danger, it has occurred very recently.

In November 2021 one of the top five PBMs removed one of two state-of-the-art anticoagulants from their drug formulary. These new products, Eliquis and Xarelto, are successors to warfarin, which requires more monitoring and blood testing.

The formulary change forced nearly 100 million U.S. patients into a non-medical switch. For many medicines, this is a problem. Physicians and patients often work together to find the exact right dosage of a medicine that is therapeutically effective, and once found, any change could result in therapeutic failure. Examples of therapeutic failure for anticoagulants, which include deep vein thrombosis, blood clots, and stroke, are extremely dangerous for patients.

### **Mexican counterfeiters enter the market to meet patient need**

Soon after the PBM removed Eliquis from their formulary, PSM received word that placebo counterfeits of Eliquis and Xarelto had been found in border pharmacies in three cities in Mexico, including Los Algodones. These

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pharmacies cater to U.S. tourists and are often within a short walk or drive from the border checkpoint. Los Agodones, for example, is a twenty-five minute drive from Yuma, AZ and a three hour drive from Phoenix, AZ.

The examples that undercover purchasers working for manufacturer anticounterfeiting teams found were extremely good-looking fakes.



See our PSA

UC purchases of fake blood thinner, photo credit Pharmaceutical Security Institute

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As you can see in the examples, the first two instances of these fakes are labeled in English. The medicines themselves were nothing but filler powder. They contained no active ingredient at all. The third medicine was the same product, but a counterfeiter had translated the label into Spanish to outwit clever Americans who might wonder why an English-labeled FDA-approved product was for sale in a Mexican pharmacy. It, too, contained pills with no active ingredients.

Manufacturers of the legitimate products learned about these fakes when concerned patients called in to their quality hotlines. Patient harm was reported, but not publicly documented. These fakes spread along the Mexican border pharmacies until they finally reached Cancun. In June 2022 the PBM put Eliquis back on their formulary, reducing the need for patients to seek alternative sources. Anticounterfeiting team members told me that after that, the fake anticoagulants were no longer easy to find in Mexican border pharmacies, though you can still find black market versions for sale online.

The criminal black market is absolutely responsive to economic conditions that affect patients. If anything reduces access to Stelara or any other UPL-regulated medicine in Colorado, the black market will step in, likely with unsafe medicine.



Because prosecutions of counterfeit therapeutic medicines are not well-funded or a high priority, it would be wise to tread very carefully when making policy decisions that might result in reduced access to medicine. Colorado does not have adequately resourced law enforcement to address the problem.

## Conclusion

While the goals of Prescription Drug Affordability Boards are laudable, the problems in our healthcare system are complex, and using payment caps in just one part of the supply chain, on the supply chain participants least able to control prices, will yield multiple different unintended consequences.

PSM would be happy to discuss any additional follow-up items with the Board or Board staff at length.





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## Additional materials

### Stelara wholesale pricing capture.

We found remarkably similar pricing all around the country from different pharmacists who shared their wholesale prices with us.

Description	Form	Unit Size	Per Dose	W / Rebate	AWP	Retail Price	Acq. Cost ▲
 <b>STELARA IV 130 MG SDV 26 ML</b> ☆ ASD 10244384   57894-0054-27   701612 JOM PHARMACEUTICAL SERV... ZB	SINGLE DOSE...	26	\$77.8658		\$2,429.41		\$2,024.51
STOCKED <a href="#">View Biosimilar Landscape</a> 1 EA <a href="#">Add to Cart</a>		Requires refrigeration / freezing Ships separately via UPS / FedEx Reference Product					
 <b>STELARA 45 MG PFS 0.5 ML</b> ☆ WHL 10001734   57894-0060-03   016402 J-O-M PHARM SERVICES ZB	PRE-FILLED S...	0.5	\$26,937.9800		\$16,705.72		\$13,468.99
RES 0 <a href="#">View Biosimilar Landscape</a> 1 EA <a href="#">Add to Cart</a>		Out of Stock Back Order Notify Me Requires refrigeration / freezing Reference Product					
 <b>STELARA 45 MG SDV 0.5 ML</b> ☆ ASD 10245657   57894-0060-02   701794 JOM PHARMACEUTICAL SERV... ZB	SINGLE DOSE...	0.5	\$27,842.8600		\$16,705.72		\$13,921.43
RES 12 <a href="#">View Biosimilar Landscape</a> 1 EA <a href="#">Add to Cart</a>		Requires refrigeration / freezing Ships separately via UPS / FedEx Reference Product					
 <b>STELARA 90 MG PFS 1 ML</b> ☆ WHL 10001724   57894-0061-03   016303 J-O-M PHARM SERVICES ZB	PRE-FILLED S...	1	\$26,937.9600		\$33,411.42		\$26,937.96
RES 36 <a href="#">View Biosimilar Landscape</a> 1 EA <a href="#">Add to Cart</a>		Requires refrigeration / freezing Reference Product					