

HHS's proposed modification of pharmacy rebate safe harbors

Implications for Medicaid

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In the Federal Register of February 6, 2019, the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) released proposed modifications to safe harbor regulations in 42 CFR 100.952(h)¹ that protect pharmacy rebates from the federal anti-kickback statute, Section 1128B(b) of the Social Security Act (the Act).

The proposed update eliminates safe harbor protection for rebates provided by pharmaceutical manufacturers to:

- Medicare Part D plan sponsors
- Medicaid managed care organizations (MCOs)
- Pharmacy benefit managers (PBMs) acting under contract with either

The proposed regulations do not explicitly impact the commercial market, although voluntary alignment with Medicare is a possibility,² and HHS Secretary Azar has called for follow-up legislation.³ The regulations also do not change the safe harbor with respect to drugs purchased through Medicare Part B fee-for-service plans, federal rebates collected for Medicaid MCO claims, or federal or supplemental rebates received directly by Medicaid state agencies.

The Medicaid and CHIP Payment Access Commission (MACPAC) has publicly disclosed that it will send HHS a formal letter, asking to protect the Medicaid program's supplemental rebates.⁴

As a potential replacement for removing the safe harbors, the regulation proposes new safe harbors for reductions in price reflected at the point of sale to the beneficiary. The proposed rule also outlines a protected structure for fixed service fees paid by manufacturers to PBMs.

HHS states the goals for the proposal are as follows:

- Align incentives to curb list price increases
- Reduce financial burden on beneficiaries
- Impact federal expenditures
- Improve transparency
- Reduce the likelihood of inappropriate inducements

In this paper we focus on potential implications of the proposal for state Medicaid agencies and the Children's Health Insurance Program (CHIP).

Background and history

ANTI-KICKBACK AND SAFE HARBORS

In 1972, Congress enacted Section 1128B of the Act to fight fraud, waste, and abuse in Medicare and Medicaid. In 1977, violations were upgraded to felonies and the law's definition of kickback was broadened to encompass "any remuneration."

Due to concern that many relatively innocuous commercial arrangements might be subject to criminal prosecution, the Medicare and Medicaid Patient and Program Protection Act of 1987 authorized the HHS OIG to develop safe harbors. This was followed by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which in Section 1128D of the Act established criteria for the safe harbors.

¹ The full text of the proposed rule published in the Federal Register is available at <https://www.govinfo.gov/content/pkg/FR-2019-02-06/pdf/2019-01026.pdf>.

² Manatt on Health (February 14, 2019). HHS proposes revisiting anti-kickback safe harbor on pharmaceutical rebates. Retrieved March 1, 2019, from <https://www.manatt.com/Insights/Newsletters/Manatt-on-Health/HHS-Revising-Anti-Kickback-Safe-Harbor-on-Pharma>.

³ Near the end of his February 1, 2019, speech to the Bipartisan Policy Center, HHS Secretary Alex Azar noted, "Congress has an opportunity to follow through on their calls for transparency too, by passing our proposal into law immediately and extending it to the commercial drug market." The full text of the speech is available at <https://www.hhs.gov/about/leadership/secretary/speeches/2019-speeches/remarks-to-the-bipartisan-policy-center.html>.

Several senators have shown interest in responding. A summary of activity to date is available at: <https://www.modernhealthcare.com/payment/senators-boost-trumps-proposed-ban-pbm-rebates>.

⁴ Modern Healthcare (March 8, 2019). MACPAC wants Part D rule to protect Medicaid supplemental rebates. Retrieved March 17, 2019, from <https://www.modernhealthcare.com/payment/macpac-wants-part-d-rule-protect-medicaid-supplemental-rebates>.

CHANGES TO THE DELIVERY SYSTEM

The OIG developed the current safe harbors during the 1990s. Since then, HHS notes, significant events have affected the delivery of prescription drugs in federal healthcare programs, namely:

- Establishment of Medicare Part D in the Medicare Modernization Act of 2003
- Medicaid drug rebate equalization in the Patient Protection and Affordable Care Act (ACA)
- Comprehensive Medicaid managed care regulations

As an impetus for the proposed regulation, HHS cites the growing market share managed by private plans in the Medicare Part D and Medicaid markets, along with an increase in the cost of drugs that is “unsupported by objective economic criteria,” and “significant distortions in the distribution chain,” including an increase in the “gross to net bubble,” describing a phenomenon of list prices rising faster than prices net of rebates. A Wells Fargo analysis found that the average sale, rebate, and allowance discounts offered to insurers rose from 28% in 2012 to 41% in 2016,⁵ with expectations for continuing percentage growth.

Impact on list price

The impact of proposed regulations on list prices charged by manufacturers, or wholesale acquisition cost (WAC), depends on the manufacturer response. Below are a few possibilities:

1. **Retain rebates:** If manufacturers adopt this approach, there would be little or no change to the list price, and manufacturers would retain funds previously spent on rebates. This response could be untenable from a competitive standpoint, as the drug might appear to be a poor value relative to competing products that either reduce list price or apply rebates at points of sale. It could also increase public pressure on manufacturers to justify prices and pressure on Congress to find another solution to high drug prices.
2. **Reduce list price:** Under this approach, manufacturers reduce list prices, possibly down to the current average discounted price in the commercial market. This approach would impact all markets.

3. **Chargeback:** This approach allows manufacturers to maintain current discounts, individualized by payer, but under full disclosure.⁶ Manufacturers would apply all or most of the rebates previously paid to MCOs or PBMs at points of sale to beneficiaries, paid to the dispensing pharmacy. As chargeback amounts will vary by payer, this could introduce cash flow timing concerns for the pharmacies, if manufacturers and wholesalers are unable to pay chargebacks in a timely fashion. For beneficiaries subject to deductibles or coinsurance, chargebacks may significantly reduce cost sharing. However, due to limited cost sharing in Medicaid, little impact is expected on Medicaid members.
4. **Product shifts:** Manufacturers may have more of an incentive to develop authorized generics, including biologics. An example of this approach is an insulin product being considered by Eli Lilly.^{7,8} Manufacturers may also modify marketing strategy to focus on generics and more competitively priced products.

Manufacturers may employ a combination of the approaches above, depending on the therapeutic class or competitive position (e.g., whether the drug is an innovator offering, the only one in its class, or whether it is in a more competitive situation).⁹ Also, manufacturer responses may depend on whether the drug’s revenue is primarily from government or commercial markets.

There is substantial uncertainty around the *magnitude* of potential changes to list price. However, directionally the regulation is generally expected to have either a neutral or a downward impact on list prices. In addition, without the incentive of rebates on higher-cost brand products, the drug mix has the potential to shift toward more generics and more competitively priced brand offerings.

⁵ ASH Clinical News (April 1, 2018). Report finds drug discounts to insurers continue to rise. Retrieved March 1, 2019, from <https://www.ashclinicalnews.org/news/higher-drug-prices-bigger-discounts/>.

⁶ The transparency will allow for more direct competition, but the impact on pricing is unclear. Some economists argue transparency discourages big discounts. See Manatt on Health, op cit.

⁷ Inside Health Policy (February 19, 2019). Lilly proposes “authorized biologics” to lower insulin list prices. Retrieved March 1, 2019, from <https://insidehealthpolicy.com/daily-news/lilly-proposes-%e2%80%99authorized-biologics-%e2%80%99-lower-insulin-list-prices> (subscription required).

⁸ One possible barrier to authorized generics is their treatment under Medicaid best price and AMP legislation. Under Section 1927(c) of the Act, the lowest price at which an authorized generic is sold is considered the best price for both the brand and the authorized generic, which can expose the manufacturer to higher Medicaid rebates. Under Section 1927(k), the price of both brand and authorized generic are blended in determination of AMP.

⁹ See <https://comm.ncsl.org/productfiles/119423533/AHIP-Milliman-PartD-Rebates-summary.pdf> for more information.

Impact on rebates and net price

The initial price Medicaid pays for outpatient drugs is offset by substantial rebates. In fiscal year (FY) 2016, Medicaid spent approximately \$60.8 billion on outpatient prescription drugs, and collected \$31.2 billion in rebates, for net drug spending of \$29.6 billion.¹⁰ Of total rebates, supplemental rebates are typically in the single digits as a percentage of pharmacy costs, while federal rebates make up the majority of rebate revenue.¹¹

The Office of the Actuary (OACT) of the Centers for Medicare and Medicaid Services (CMS) has estimated the 10-year impact to Medicaid, 2020 to 2029, as follows¹² (in \$ billions):

Price reductions (savings)	-\$18.0
Reduced rebates (cost)	18.5
Higher MCO premiums (cost)	<u>1.3</u>
Net federal impact (cost)	1.7
Net state impact (cost)	0.2

OACT has estimated a net cost to states rather than savings. The amount may seem relatively minor, as \$200 million over 10 years corresponds to an average of \$0.4 million per state per year. Price reductions, though large, will be muted by offsetting reductions in rebate revenue. However, as OACT notes, there is “a significant amount of uncertainty around this modeling.”

The impact may vary significantly by state, depending on managed care pharmacy exposure, whether the state or MCOs control the formulary, and whether the state responds to adjust formulary control to retain the value of supplemental rebates. During initial implementation, as prices shift and MCO rebate revenue dries up, states will need to be agile on adjusting MCO capitation rates to reflect the changing market environment.

In the next sections, potential impacts to Medicaid supplemental and federal rebates are addressed separately.

SUPPLEMENTAL REBATES

The proposed changes do not modify treatment of supplemental rebates paid by manufacturers directly to Medicaid state agencies. As such, the rule has no direct impact on supplemental rebates related to arrangements in which pharmacy services are reimbursed through fee-for-service (FFS). However, the proposed rule would remove the safe harbor protection from manufacturer rebates paid to Medicaid MCOs and their contracted PBMs, impacting many managed care arrangements.

Under current practice, there are three primary ways in which the state may contract with MCOs to retain or delegate drug expenditure risk and control of the formulary:

- **Full delegation:** Under this model, pharmacy services are fully delegated to the MCOs. Each Medicaid MCO develops its own preferred drug list (PDL) and utilization management procedures, with state approval.
- **Single or unified PDL:** Under this model, the state sets a single PDL all MCOs must follow, but MCOs retain risk for pharmacy expenditures for their members.
- **Carve-out:** MCOs have no direct risk for pharmacy services, but may play a role in management through contracted physicians. Drugs for MCO enrollees are paid on a FFS basis using the state PDL.

Medicaid MCOs under full delegation, with control of the formulary for their members, are able to earn manufacturer rebates for preferable formulary placement.¹³ These manufacturer rebates reduce the net price of drugs purchased by the MCO, and rebate savings are generally reflected as reductions to the capitation rates paid by states to the MCOs. If the manufacturers eliminate rebates paid to Medicaid MCOs, it may increase the cost for MCOs to obtain drugs, which may in turn increase the capitation rates (premiums) paid to MCOs. This may be the premise underlying the “higher MCO premiums” line item in the OACT fiscal estimate.

With either a unified PDL or carve-out, states maintain control of formulary placement, consolidating the state’s negotiating power with manufacturers for supplemental rebates. Under the proposed rule, states with pharmacy carve-outs or unified PDLs may continue to receive supplemental manufacturer rebates. However, these states need to be alert and react nimbly to renegotiate agreements as the business paradigms shift amid potential changes to list prices and federal rebates.

¹⁰ MACPAC (June 2018). Chapter 1: Improving Operations of the Medicaid Drug Rebate Program. Retrieved March 1, 2019, from <https://www.macpac.gov/wp-content/uploads/2018/06/Improving-Operations-of-the-Medicaid-Drug-Rebate-Program.pdf>.

¹¹ Klaisner, J., Holcomb, K., & Filipek, T. (January 31, 2019). Impact of Potential Changes to the Treatment of Manufacturer Rebates. Milliman Client Report. Retrieved March 1, 2019, from <https://aspe.hhs.gov/system/files/pdf/260591/MillimanReportImpactPartDRebateReform.pdf>.

¹² CMS OACT (August 30, 2018). Proposed Safe Harbor Regulation, Table 6. Retrieved March 1, 2019, from <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf>.

¹³ Based on available National Association of Insurance Commissioners (NAIC) Supplemental Health Care Exhibit data for 2017 on approximately 25 million Medicaid managed care lives, Medicaid MCO rebates were equivalent to 4.5% of gross prescription drug costs. The 4.5% represents a mix of two types of MCOs: those with formulary control (full delegation) and those where the state has formulary control (unified PDL). Where the state has formulary control, MCOs have less opportunity to earn supplemental rebates, as they cannot offer favorable formulary placement.

States currently supporting full MCO delegation may face higher pharmacy costs due to loss of MCO manufacturer rebates. In some cases, these states may decide to move to unified PDL or carve-out models, which will provide the opportunity to negotiate directly with manufacturers for supplemental rebates.

FEDERAL REBATES

Federal rebates make up the majority of state pharmacy rebate revenue.¹⁴ Although the proposed safe harbor modifications have no *explicit* impact on federal Medicaid rebates, various actions taken by manufacturers could lead to reduced federal rebates.

Section 1927(c) of the Social Security Act provides for Medicaid to receive the larger of the following two types of rebates:

- Minimum percentage rebates
- Best price rebates

Inflationary rebates may be payable in addition to the larger of the above, with the total rebate limited to 100% of the average manufacturer price (AMP).

In formula form:

Unit Rebate Amount (URA) = greater of [Best Price or applicable percent of AMP] + Inflationary rebate

Minimum percentage rebates

Minimum percentage rebates are calculated as a percentage of AMP. The January 2016 Medicaid Covered Outpatient Drug final rule defines AMP as the average price paid to the manufacturer by wholesalers and retail pharmacies in the United States.¹⁵ If manufacturers make no changes in the commercial market, proposed regulations may have a smaller impact on AMP or, by extension, federal Medicaid rebates, than if chargebacks are implemented in all markets. However, if manufacturers reduce list prices or transition commercial rebates to chargebacks, AMP will be reduced for all payers and Medicaid rebates will be reduced proportionately.

Figure 1

Figure 1 below illustrates a few hypothetical scenarios for the change to net price for a single source brand drug on which states receive the minimum percentage rebate of 23.1% of AMP.¹⁶ The hypothetical drug has a WAC of \$100, which we will assume for simplicity is also the average price paid by wholesalers and retail pharmacies (in the real world, these entities may receive small discounts off list).

Current pricing: We assume states have transparency on aggregate rebates received by the MCO. The 5% MCO rebate paid by the manufacturer in this example has been reported as part of aggregate rebates by the MCO, and is reflected in the capitation rates. The state also receives a minimum percentage rebate of 23.1% of AMP, resulting in a net price of \$71.90.

Possible results include these scenarios:

1. **Retain rebates:** Under this scenario, manufacturers choose to retain the \$5 MCO rebate. There is no change to AMP or the Medicaid minimum percentage rebate of \$23.10; however, the loss of the MCO rebate is likely to ultimately result in higher capitation rates. (Although we have not illustrated it under this scenario, states could respond to this manufacturer tactic by moving to a unified PDL or carve-out, which would allow them to negotiate replacement supplemental rebates directly with manufacturers.)
2. **Lower list price:** Under this scenario, manufacturers convert rebates to lower list prices, reflecting discounts across all markets. The average discount across all markets will vary by drug and its competitive environment. However, for a given drug, commercial and Medicare Part D discounts tend to be higher than Medicaid MCO rebates.¹⁷ For purposes of the example in Figure 1, we choose a drug with a lower-than-average discount across all markets, illustrating a reduction in list price of 20%. The lower list price reduces AMP and Medicaid rebates, but could result in a lower net cost to Medicaid, at least before taking into account the potential loss of inflationary rebates.

¹⁶ The minimum percentage rebate of 23.1% is the percentage applicable to most single source and innovator multiple source drugs, as required under Section 1927(c) of the Act. Single source or innovator multiple source drugs clotting factors or drugs approved exclusively for pediatric indications are eligible for rebates of 17.1%, and a percentage of 13.0% is applicable for non-innovator drugs.

¹⁷ Manufacturers tend to place less value on formulary position in Medicaid products, due to the federal rebates they will incur. Where possible, manufacturers attempt to keep commercial discounts for brand drugs below 23.1% to avoid triggering Medicaid best price rebates. Please note that the proposed rule does not provide manufacturers with an explicit safe harbor to provide chargebacks in the commercial market, and in the absence of that imprimatur, manufacturers may be concerned that these practices could be considered price fixing or anticompetitive when applied to the commercial marketplace.

¹⁴ Klaisner et al., Milliman Client Report, op cit.

¹⁵ The full text of the final rule as published in the Federal Register is available at <https://www.govinfo.gov/content/pkg/FR-2016-02-01/pdf/2016-01274.pdf>.

3. **Chargeback:** Under this scenario, manufacturers convert the full \$5 MCO rebate into a chargeback to the pharmacy and the chargeback is included in AMP calculations.
- **3a: Chargeback in Medicare/Medicaid only.** In this scenario, the chargeback is implemented only in the Medicare and Medicaid markets, and chargebacks in the commercial market are \$0. AMP is an average over all markets, so the reduction to AMP in this scenario is smaller than in scenario 3b below, under which chargebacks are implemented in all markets. In this example, we have assumed that, with chargebacks only implemented in Medicare and Medicaid, the impact on AMP is approximately half the impact of implementation in all markets.
 - **3b: Chargeback in all markets, initial.** If the chargeback is also implemented in commercial markets, then the AMP reduction from chargebacks is larger, and could be significantly larger than the MCO rebate, although this might not be immediately apparent to Medicaid payers. This scenario illustrates a possible initial result in which the states and Medicaid MCOs are unaware of the drop in AMP, and initially continue to pay \$95 for the drug, only discovering a few months later that AMP has been reduced along with rebates.
 - **3c: Chargeback in all markets, ultimate.** As soon as Medicaid payers discover the reduction in AMP, they will renegotiate to pay no more than other payers.

States that plan ahead may be able to avoid or minimize losses sustained in scenario 3b by negotiating early for discounts on key affected products.

4. **Product shifts:** We have not illustrated the impact of manufacturer product shifts to the more competitively priced drug mixes in Figure 1, but this would be expected to reduce the net price to Medicaid.

IMPACT OF CHARGEBACKS ON AMP

Federal rebates are determined based on AMP, which makes any changes to AMP of critical interest to Medicaid.

However, the proposed regulations are vague as to how chargebacks might affect AMP. This is conceded on page 2344: “the Department may issue separate guidance if this proposal is finalized to clarify the treatment of pharmacy chargebacks in calculation of AMP and Best Price.”

If chargebacks are not allowed to affect AMP, the net price to the state could be the same as under current pricing.

The other possibility is that chargebacks are reflected as reductions to AMP, and this is illustrated in scenario 3 of the examples shown in Figures 1, 2, and 3.

Chargebacks present some new reporting challenges. In order to receive chargeback payments, pharmacies will have to document each end purchaser and report back to the manufacturer. Manufacturer AMP reporting processes will also have to change for chargebacks to be reflected in AMP. Under current practice, the sales price is determined on the date the drug is sold by the manufacturer to a wholesaler or directly to a retail pharmacy. If manufacturers are required to reflect chargebacks in AMP, however, they will not be able to determine the net price at which the drug was sold until the pharmacy reports the end buyer. Depending on how long the drugs sits on a pharmacy’s shelf, this could be days or weeks after the initial purchase.

Finally, if chargebacks are to be reflected in AMP, it appears the proposed 42 CFR 1001.952(cc)(2)(ii) contains a potential loophole. It requires that the chargeback be made “directly or indirectly by a manufacturer to a dispensing pharmacy,” but does not require that the chargeback be made through the same channels used to purchase the drug. In particular, this allows for a drug to be purchased by a pharmacy through a wholesaler, and then for the chargeback to be made directly to the pharmacy, bypassing the wholesaler. If this should occur, a literal reading of AMP regulations in 42 CFR 1927(k)(1)(A) might exclude the chargeback from the AMP calculation. This issue may be clarified in final regulations.

FIGURE 1: MINIMUM PERCENTAGE REBATE: ILLUSTRATIVE EXAMPLES OF IMPACT ON HYPOTHETICAL DRUG PRICING

Current MCO/PBM rebates fully reflected in capitation

	Current pricing		1. Retain rebates		2. Lower list price	
	Discounts	Pricing	Discounts	Pricing	Discounts	Pricing
List price		\$ 100.00		\$ 100.00		\$ 80.00
Chargeback to pharmacy	\$ -		\$ -		\$ -	
AMP		\$ 100.00		\$ 100.00		\$ 80.00
MCO Rebate	\$ 5.00		\$ -		\$ -	
Cost reflected in capitation		\$ 95.00		\$ 100.00		\$ 80.00
Minimum % rebate - 23.1% of AMP	\$ 23.10		\$ 23.10		\$ 18.48	
Total Discounts	\$ 28.10		\$ 23.10		\$ 18.48	
Net price to the state		\$ 71.90		\$ 76.90		\$ 61.52

	3a. Chargeback - only Medicare/Medicaid		3b. Chargeback - all markets - initial		3c. Chargeback - all markets - ultimate	
	Discounts	Pricing	Discounts	Pricing	Discounts	Pricing
List price		\$ 100.00		\$ 100.00		\$ 100.00
Chargeback to pharmacy	\$ 5.00		\$ 5.00		\$ 20.00	
Avg chargeback impact on AMP		\$ 10.00		\$ 20.00		\$ 20.00
AMP		\$ 90.00		\$ 80.00		\$ 80.00
MCO Rebate	\$ -		\$ -		\$ -	
Cost reflected in capitation		\$ 95.00		\$ 95.00		\$ 80.00
Minimum % rebate - 23.1% of AMP	\$ 20.79		\$ 18.48		\$ 18.48	
Total Discounts	\$ 25.79		\$ 23.48		\$ 38.48	
Net price to the state		\$ 74.21		\$ 76.52		\$ 61.52

Best price rebates

For some drugs, minimum percentage rebates are smaller than best price rebates. Best price rebates are calculated as the difference between AMP and the best price allowed to any eligible U.S. payer, excluding Medicare Part D, Veterans Health Administration (VHA), TRICARE, hospitals, and others listed in 42 CFR 447.504(c). The best price discount (AMP less best price) is larger than the minimum percentage rebate whenever the manufacturer is offering discounts of higher than the applicable percentage (e.g., 23.1% for single source drugs). Where the best price represents a significant percentage discount off list prices (sometimes as high as 70% or more), Medicaid MCO rebates tend to be nominal or nonexistent (illustrated as 1% in Figure 2). This is because, in these situations, Medicaid market share is of less value to manufacturers, due to the substantial best price and/or inflationary rebates payable.

If the drug is currently eligible for best price rebates, any MCO rebates reflected in capitation rates under current pricing will be lost under the first two manufacturer responses to the proposed rule (retain rebates and lower list price), as illustrated in Figure 2.

As with the minimum percentage rebate illustrations in Figure 1 above, the ultimate net price under chargebacks (scenario 3c) is consistent with a lower list price. We should note that scenario 3c is sensitive to the distribution of discounts provided to payers. In the example, the average discount of 45% is materially lower than the best discount of 60%. In cases where most payers get a similar discount, which commonly occurs with the more competitive products such as hepatitis C drugs, the net price to the state could be better than under current pricing. For these products, the state Medicaid program might receive a chargeback that is as good or almost as good as the best price rebate it receives now, and then *in addition* receive a regular percentage rebate of 23.1% of AMP.

However, the important takeaway from Figure 2 is that, over the short term, the potential losses are much greater for states that fail to quickly adjust pricing and/or capitation rates, as illustrated in scenario 3b. If states are able to proactively renegotiate contracts with manufacturers prior to the implementation of the proposed rule, drugs with best price rebates will need to be a priority.

FIGURE 2: BEST PRICE REBATE: ILLUSTRATIVE EXAMPLES OF IMPACT ON HYPOTHETICAL DRUG PRICING

	Current pricing		1. Retain rebates		2. Lower list price	
	Discounts	Pricing	Discounts	Pricing	Discounts	Pricing
List price		\$ 100.00		\$ 100.00		\$ 55.00
Chargeback to pharmacy	\$ -		\$ -		\$ -	
AMP		\$ 100.00		\$ 100.00		\$ 55.00
MCO Rebate	\$ 1.00		\$ -		\$ -	
Cost reflected in capitation		\$ 99.00		\$ 100.00		\$ 55.00
Best price: \$40	\$ 60.00		\$ 60.00		\$ 15.00	
Total Discounts	\$ 61.00		\$ 60.00		\$ 15.00	
Net price to the state		\$ 39.00		\$ 40.00		\$ 40.00

	3a. Chargeback - only Medicare/Medicaid		3b. Chargeback - all markets - initial		3c. Chargeback - all markets - ultimate	
	Discounts	Pricing	Discounts	Pricing	Discounts	Pricing
List price		\$ 100.00		\$ 100.00		\$ 100.00
Chargeback to pharmacy	\$ 1.00		\$ 1.00		\$ 45.00	
Avg chargeback impact on AMP		\$ 22.50		\$ 45.00		\$ 45.00
AMP		\$ 77.50		\$ 55.00		\$ 55.00
MCO Rebate	\$ -		\$ -		\$ -	
Cost reflected in capitation		\$ 99.00		\$ 99.00		\$ 55.00
Best price: \$40	\$ 37.50		\$ 15.00		\$ 15.00	
Total Discounts	\$ 38.50		\$ 16.00		\$ 60.00	
Net price to the state		\$ 61.50		\$ 84.00		\$ 40.00

Inflationary or price protection rebates

In addition to minimum percentage and best price rebates, manufacturers are also required to pay inflationary rebates where the rate of increase in list price has been higher than the consumer price index for all urban consumers (CPI-U), with the total rebate capped at 100% of AMP. Inflationary rebates apply to generic drugs as well as brand drugs, effective January 1, 2017.¹⁸ A 2015 OIG study found that approximately 54% of federal rebates are a result of the inflationary clause (Section 1927[c][2] of the Act).^{19,20}

Inflationary rebates may be significantly reduced under the proposed rule, in situations where the manufacturer opts for a chargeback in all markets (assuming chargebacks are included in AMP) or a lower list price approach.

Medicare Part D Clawback

Medicare Part D Clawback payments are transfer payments from the states to the federal government. The payments are intended to support funding for the Medicare Part D program, and offset the state savings for dual-eligible enrollees that arose from the implementation of Medicare Part D on January 1, 2006.

A state's monthly clawback payment is calculated as the product of its monthly full dual-eligible enrollment and the state's per capita expenditure (PCE) amount. The PCE is adjusted to reflect changes in a state's federal medical assistance percentage (FMAP) and national growth in per capita Part D prescription drug spending.

If Part D prescription drug spending is reduced or grows more slowly under the proposed rule, state Medicaid programs should see a similar percentage reduction in Part D per capita clawback payments.

In aggregate, Medicaid Part D clawback payments total \$12 billion per year,²¹ so a 1% change would have an impact of approximately \$120 million per year. There is no federal matching funding for these transfer payments, so 100% of the costs are paid using state funds, most commonly state general funds.

¹⁸ As required under the Bipartisan Budget Act of 2015.

¹⁹ MACPAC (May 2018). Medicaid Payment for Outpatient Prescription Drugs. Issue Brief. Retrieved March 1, 2019, from <https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf>.

²⁰ Klaisner et al., Milliman Client Report, op cit.

²¹ 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. Retrieved March 1, 2019, from <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/downloads/tr2018.pdf>.

From a state perspective, the change to Medicare Part D payments has the potential to be the most significant fiscal impact component from the proposed rule.

Final thoughts

HHS's proposed modifications to pharmacy rebate safe harbors could significantly affect current business practices in all markets. Due to the complexity of the pharmacy supply chain, there is significant uncertainty over how various stakeholders will react and interact (primarily manufacturers, but also plan sponsors, insurers, and others). States will need to plan ahead to ensure that pharmacy pricing, rebate agreements, and capitation rates anticipate market changes.

For Medicaid, long-term costs have the potential to decline due to lower list prices, chargebacks, or shifts to lower-cost drug mixes resulting from removal of some of the rebate incentives for higher-cost products. However, unlike with Medicare Part D, any Medicaid cost reductions will be significantly dampened by offsetting impacts to federal Medicaid rebates.

With the proposed rule eliminating the safe harbor for MCO rebates, but not for supplemental rebates negotiated by state Medicaid agencies, states currently delegating formulary control to MCOs may consider moving to unified PDLs.

Perhaps most intriguing for Medicaid is the promise of increased transparency, bringing the potential for more effective and direct competition between products. Transparency also may smooth out distortions and inefficiencies in the distribution chain, especially those due to undisclosed agreements that affect costs.

States require increased visibility into the payments between all parties to perform effective oversight.

HHS solicited comments on a large number of significant issues, leaving room for material changes in the final rule. Comments are due April 8, 2019; if passed, the effective date of this proposed rule will be January 1, 2020.

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