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Summary of Draft CY 2025 Part D Redesign Program Instructions

Calendar Year 2025

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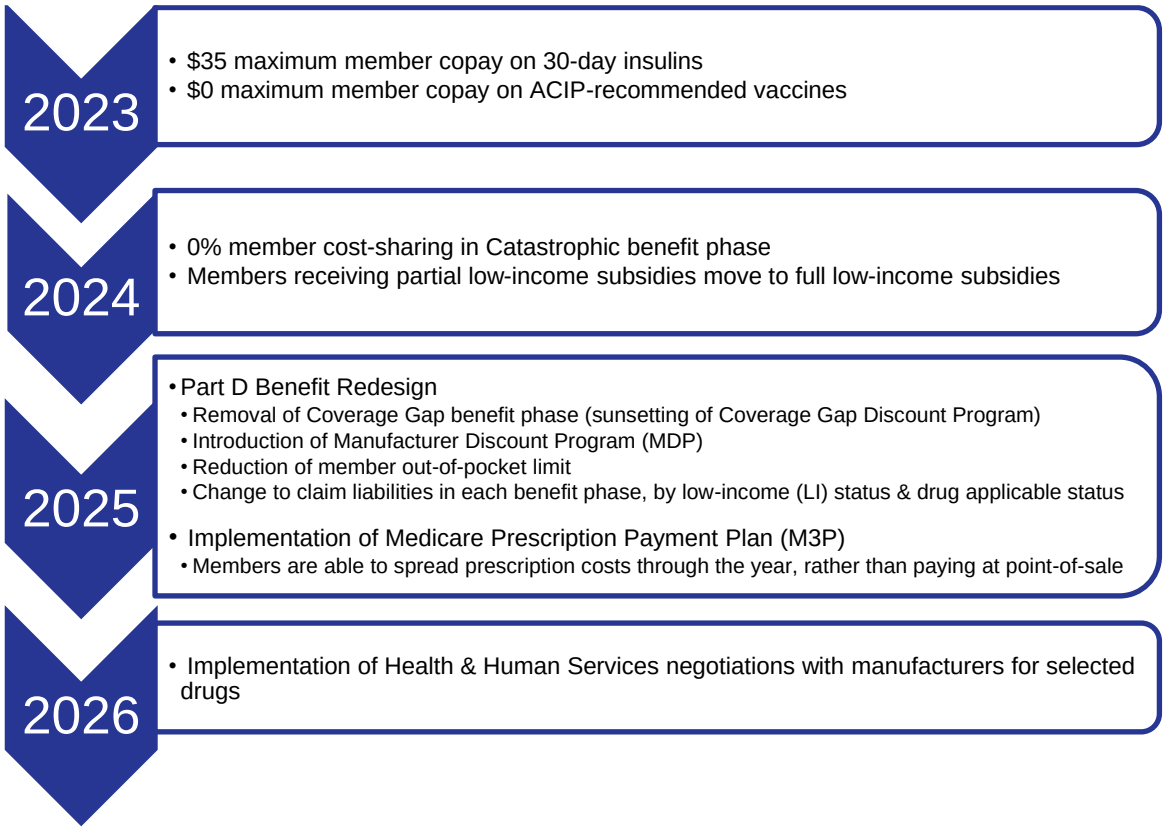
On January 31, 2024, the Centers for Medicare and Medicaid Services (CMS) released draft instructions on the CY2025 Part D Redesign[1]. These draft instructions touch on many of the outstanding Part D benefit adjudication questions that the industry has been asking. It lays out True-Out-of-Pocket (TrOOP)-eligible claims and their application to deductible & out-of-pocket (OOP) thresholds, in addition to reinsurance, medical loss ratio, risk corridor, and Out-of-pocket cost (OOPC)/meaningful difference methodologies. Some guidance on Employer Group Waiver Plans (EGWPs) was also provided.

Inflation Reduction Act (IRA) Changes to Benefit Design

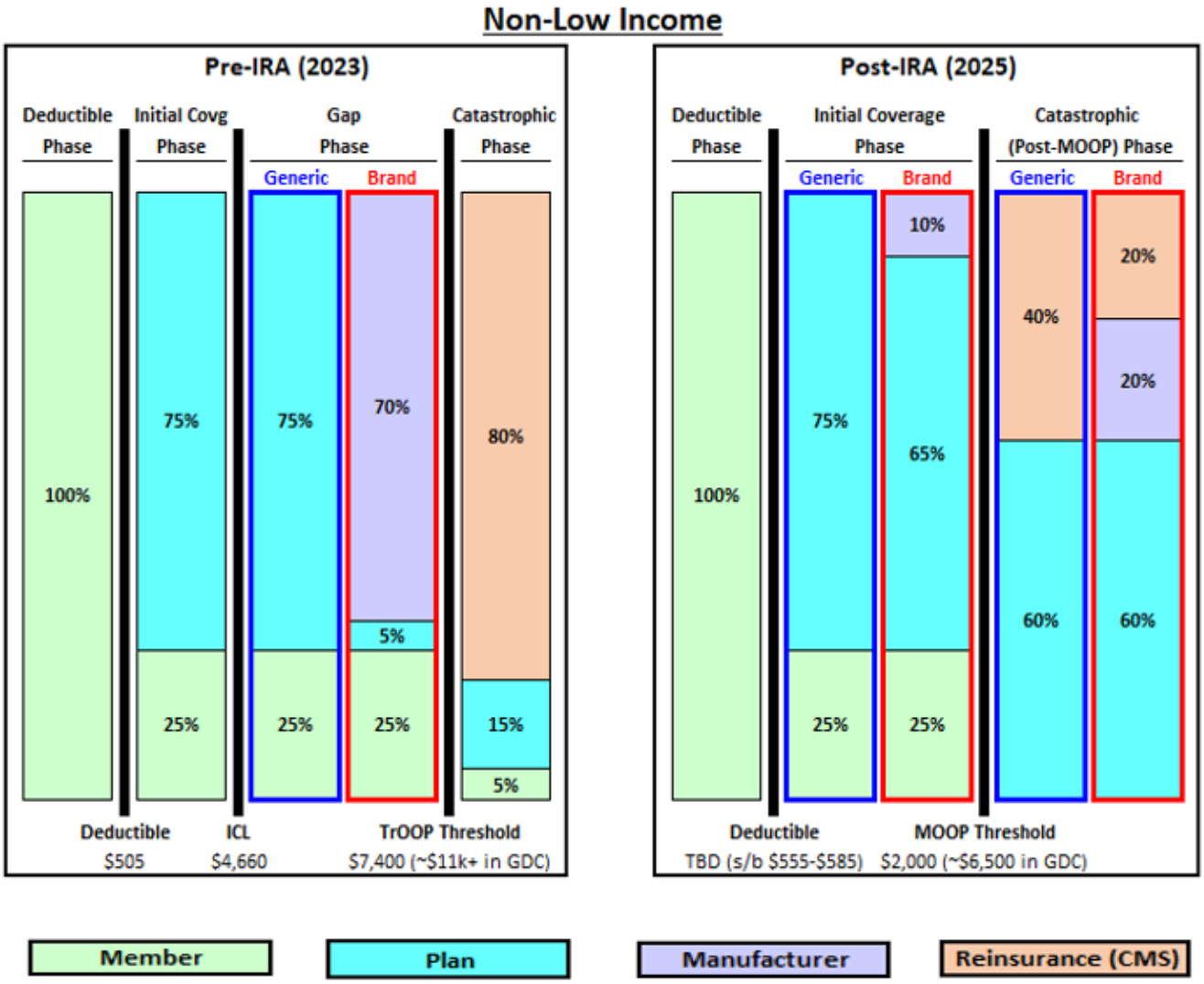
The IRA, signed on August 22, 2022, is a multi-year phase-in of provisions that affect the Medicare Part D cost-sharing of all stakeholders with claim liabilities (beneficiaries, plan sponsors, manufacturers, federal government). The purpose of the IRA is to reduce financial hardships on Medicare beneficiaries and shift more risk to the stakeholders setting prices, rather than the federal government.



In 2025, there are large changes to the benefit design, as shown below, from 2023 to 2025.

[1] Titled 'Draft CY 2025 Part D Redesign Program Instructions'; https://www.cms.gov/files/document/draft-cy-2025-part-d-redesign-program-instruction.pdf

EXHIBIT 1 – 2023 to 2025 Benefit Changes for Non-Low Income Beneficiary



STAKEHOLDER IMPACTS

Members

- Removal of cost-sharing in catastrophic (effective CY 2024)
- Out of pocket maximum of $2,000, based on basic benefits
- Manufacturer discounts do not count towards MOOP

Manufactures

- Removal of coverage gap phase
- Reduction in liability in standard coverage phase compared to previous coverage gap phase
- Introduction of (uncapped) liability in catastrophic phase
- Yearly phase-in of manufacturer discounts for "small specified manufactureres". 2025 liability = 1%

Plans

- Increased liability in the catastrophic phase
- Additional liability during phase-in of "small specified manufactures". 2025 liability = 9% in standard coverage phase, 19% in catastrophic phase

Federal Government

- Reduced liability in the catastrophic phase, differs by brand versus generic
- Not pictured: increased direct subsidy

These changes apply to all Medicare Advantage Prescription Drug Plan (MAPD) and standalone Prescription Drug Plan (PDP) plans, including EGWPs.

Definition of TrOOP is Changing in 2025

Historically, different accumulators were used to reach the Part D deductible (accumulator = member pay), initial coverage limit (accumulator = allowed costs), and catastrophic limit (accumulator = member pay + coverage gap discount program). Starting in 2025, TrOOP will be the accumulator for satisfying all thresholds, i.e. deductible, eligibility for MDP, and the catastrophic phase.

TrOOP will be the amount spent on covered Part D drugs by the beneficiary or on their behalf by certain third parties. Starting in 2025, the TrOOP threshold will be based on the accumulation of both member out-of-pocket expenses and supplemental part D coverage (i.e. cost sharing reductions as compared with Defined Standard cost sharing) provided by Enhanced Alternative (EA) plans or other health insurance (OHI). This also includes supplemental covered provided by EGWPs, as well as Medicare-Medicaid Plan & D-SNP plan reductions in cost sharing for enrollee beneficiaries. No discounts from MPD will count toward TrOOP.

One interesting caveat related to supplemental coverage is that amounts reimbursed by supplemental coverage will be included in the calculation of TrOOP. That is to say that, for EA plans, for any benefit worse than Defined Standard (DS) benefit, the member out of pocket costs will be used. Exhibit 2 shows how a member's claim will accumulate to TrOOP, depending on the benefit's richness compared to the DS benefit. It illustrates two claims of the same value. One has an EA benefit of 10%, the other has a benefit of 33%, while the DS benefit is 25%. It is assumed the defined standard deductible has been meet for both claims.

EXHIBIT 2 – Accumulation to True-Out-of-Pocket (TrOOP) on Enhanced Alternative Plans

Two members in an *enhanced alternative plans* have just hit the defined standard deductible of $590.
Both have a T5 claim of $1,000.
Member A has plan benefit of 10% coins.
Member B has plan benefit of 33% coins.

	Member A	Member B	
Allowed	$1,000	$1,000	*a*
Defined Standard Member Coinsurance	25%	25%	*b*
Alternate Benefit Member Coinsurance	10%	33%	*c*
Defined Standard Member Cost-share	$250	$250	*d = a x b*
Alternate Benefit Member Cost-share (Mbr Pay)	$100	$330	*e = a x c*
Manufacturer Discount Program (MDP)	$100	$100	*f = a x 10%*
Defined Standard Plan Liability	$650	$650	*g = a - d - f*
Alternate Benefit Plan Liability	$800	$570	*h = a - e - f*
NPP or EGWP PLRO	$150	($80)	*i= h - g*
TrOOP Eligible	$250	$330	*j = e + MAX(0 , i)*

Member A, under the defined benefit, would have paid $250. Due to the EA benefit, the member is only paying $100 out of pocket ($1000 x 10%). Based on the IRA, this claim's supplemental coverage of $150 also counts towards TrOOP, for a total TrOOP accumulation of $250 for this claim.

Member B, with a coinsurance of 33%, is paying more than the defined standard (aka the benefit is worse than the DS benefit). This leads to a negative Non-Covered Plan Paid Amount (NPP) amount of $80. Because negative supplemental coverage cannot be counted towards TrOOP, only the member pay of $330 is counted towards TrOOP.

Part D sponsors will be responsible for updating their accumulation methodology for 2025.

EA Plan Satisfaction of Deductible is Nuanced

Many EA plans have a non-uniform deductible (e.g. Tiers 1 & 2 are excluded from the deductible). Any TrOOP eligible costs, including insulin copays, not subject to the deductible still accumulate towards the beneficiary's satisfaction of DS TrOOP for deductible & catastrophic eligibility requirements.

Additionally, members are eligible for the discounts under the MDP once the DS benefit has been met. Until that time, the plan will cover the discount typically covered by the MDP on any non-uniform deductible claims. Exhibit 3 shows the differences in payment liabilities for meeting the plan deductible versus the DS deductible.

EXHIBIT 3 – Rules on Deductible Satisfaction

	DS Deductible	Plan Deductible	Liabilities during Initial Coverage phase
Member Meets:	Yes	No	CMS states plan deductible **is** met at this point; member meets criteria for MDP and receives discounts from manufacturers.
Member Meets:	No	Yes	Member does not meet criteria for MDP. Plan must cover MDP discounts until member reaches DS deductible.

PDE reporting examples & instructions will be provided later in 2024.

Considerations for EA Plan Design & Valuation

The most common feature in EA plans is reduced annual deductible and reduced cost-sharing in the initial coverage phase. With the IRA, these enhancements are still available. Due to the removal of the coverage gap phase, enhanced benefits for that phase are no longer an option, and the IRA stipulates that the member out-out-of-pocket (MOOP) cannot be reduced.

To determine whether an EA plan provides more value than the DS plan, CMS will utilize the CY2025 Bid Review OOPC Model (OOPC Model). The OOPC of an EA will be compared to the DS benefit, using the EA formulary for both benefit designs. For 2025, CMS is not establishing a threshold in the difference of OOPC value between the plans, but rather just that the EA benefit must be better than the DS benefit (i.e. OOPC value is lower for EA plan). A modified OOPC

Model will be available2 to plan sponsors for testing their plans, in which the EA formulary can be run through the tool for EA & DS benefits. Once bids are submitted, CMS will review the results and consider implementing a more rigorous process for following years.

CMS had previously solicited comments on the EA plan moving to a basic benefit, with a "wrap" or "rider". They received overwhelmingly negative feedback in the solicitation and will not re-consider structuring the benefits this way.

CMS Considering Removal of Basic Alternative (BA) Plans

Exhibit 4 shows the plan and member cost sharing that applies to the DS deductible accumulation under the IRA for Basic Alternative and Enhanced Alternative plan designs.

EXHIBIT 4 – Applicability of Cost-Sharing towards DS Deductible Accumulation by Plan Type

	Basic Alternative	Enhanced Alternative
Offers Basic Benefits	Yes	Yes
Offers Supplemental Benefits	No	Yes
Ability to Reduce Deductible	Yes	Yes
Patient Pay Applies to DS Deductible	Yes	Yes
Plan Pay Applies to DS Deductible	No	Yes

As a BA plan only offers basic benefits, any payment by the plan is not considered an eligible expense towards DS deductible accumulation. Because of this, a member would take longer to exceed the DS deductible than a member in an EA plan, as seen in Exhibit 5.

Given the difference in accumulation styles, CMS is considering disallowing a reduced deductible for a BA plan; this would, essentially, remove BA as a plan type, leaving only defined standard (DS), actuarial equivalent (AE), and enhanced alternative (EA) plans.

[2] OOPC Model to be released April 2024, per CMS

EXHIBIT 5 – TrOOP Accumulation Differences between DS/BA/EA Plan Types

3 members are on DS, BA, EA plans.
BA & EA plans have reduced deductible at $300.
BA plan has coinsurance of 29%, while DS & EA plans have coinsurance of 25%.
All 3 members fill a $1,000 Tier 5 drug.

	DS Member 1	BA Member 2	EA Member 3
Plan Deductible Left Before Claim	$590	$300	$300
DS Deductible Left Before Claim	$590	$590	$590
TrOOP Left Before Claim	$2,000	$2,000	$2,000
T5 Claim Allowed Cost		$1,000.00	
Member Coinsurance in Initial Coverage Phase	25%	29%	25%
Member Cost Share	$693	$503	$475
Manufacturer Discount Program	$41	$0	$41
Basic Plan Liability	$267	$497	$267
Supplemental Plan Liability	$0	$0	$218
Plan Liability	$267	$497	$484
TrOOP Eligible	$693	$503	$693

Adjustment to PDP Meaningful Difference

Starting in 2025, two metrics will be used to measure PDP meaningful difference, still using the OOPC Model. CMS will measure the (1) formulary robustness and (2) benefit design/tier placement for EA plans compared to the sponsor's BA plan offered in the same region. The combined difference of these two metrics must be at least 15% lower for an EA plan than for the BA plan, and for both of these metrics, individually, the EA plan must be more favorable (i.e. lower) than the BA plan.

If CMS disallows BA plans, then new guidance on PDP Meaningful Difference will need to be provided.

Reinsurance Methodology Change

In the Part D redesign, the calculation for reinsurance is becoming more complicated. The federal government will take on 20% of risk on applicable (i.e. brand) drugs, and 40% of the risk on non-applicable (i.e. generic) drugs in the catastrophic phase, less an allocation of total plan direct and

indirect renumeration (DIR). This is a marked change from CMS's previous liability of 80% of all spend in the catastrophic phase, net of DIR.

Pre & Post IRA methodologies for Adjusted Reinsurance Costs are as follows[3] [4]:

Pre-2025	Reinsurance DIR = GDCA / GDC x DIR Adjusted Reinsurance Cost = (GDCA – Reinsurance DIR) x 0.8
Post-2025	Reinsurance DIR for Applicable Drugs = (total DIR / GDC) x incurred reinsurance costs for applicable drugs Adjusted Reinsurance for Applicable Drugs = (incurred reinsurance costs for applicable drugs – reinsurance DIR for applicable drugs) x 0.20 ……. Total Adjusted Reinsurance = Adjusted Reinsurance for Applicable Drugs + Adjusted Reinsurance for Non-Applicable Drugs

DIR : Direct and Indirect Remuneration (includes manufacturer rebates, pharmacy price concession (thru 2024), etc)
GDC : Gross Drug Cost; also known as "allowed cost"
GDCA : Gross Drug Cost Above Catastrophic Limit

Exhibit 6 shows a numerical example of calculating post-2025 adjusted reinsurance costs.

[3] "incurred reinsurance costs for (non)applicable drugs" is the allowed costs for (non) applicable drugs above the catastrophic limit

[4] Post-2025 calculation for non-applicable drugs is the same methodology as applicable drugs, with a factor of 0.4 applied instead of 0.2.

EXHIBIT 6 – Post-IRA DIR Allocation for Adjusted Reinsurance Costs

	Applicable	Non-Applicable	
CMS liability for drugs in catastrophic phase	20%	40%	*a*
Incurred reinsurance costs for drugs	$200	$15	*b*
Total DIR	$400		*c*
Total Allowed	$1,000		*d*
Reinsurance DIR	$80.00	$6.00	*e = (c / d) x b*
Adjusted Reinsurance	$24.00	$3.60	*f = (b - e) x a*
Total Adjusted Reinsurance Costs	$27.60		*g = sum(f)*
DIR retained by plan ($)	$314.00		*h = c - e*
DIR retained by plan (%)	79%		*i = h / c*

Risk Corridors

By law, CMS is prohibited from narrowing risk corridor thresholds. In the 2025 Advance Notice, CMS proposed no changes to the current risk corridor methodology.

Implications to EGWPs (TrOOP Eligibility, Prospective Payments, Non-Calendar year Plans)

In 2024 & prior, all EGWPs report the Part D benefit as the DS benefit. Any difference in cost sharing from the DS benefit would constitute OHI. Starting in 2025, OHI, including supplemental coverage provided by EGWPs, will be TrOOP-eligible. CMS will provide PDE reporting examples later in 2024.

CMS will continue to provide prospective reinsurance payments to calendar year EGWPs. Historically, the payment has been based on historical final reinsurance PMPMs paid to EWP sponsors. If CMS followed the same methodology for CY2025, the prospective payment would be overstated, due to the reinsurance liability decreasing substantially between plan year 2024 and 2025. The prospective payment for CY2025 will, instead, be based on the member weighted PMPM average of the Pt D prospective reinsurance amounts submitted for EA plans for 2025. This amount will be released with the national benchmarks in the summer of 2024. CMS will determine how to calculate the EGWP prospective reinsurance payment for 2026 and beyond at a later date.

IRA changes, in particular the MDP, are effective 1/1/2025. At that time, the coverage gap phase will be discontinued, and the coverage gap discount program will be sunset, with no exceptions. With the sunsetting of CGDP, and MDP not being TrOOP-eligible, an EGWP member will be adjudicated through the benefits phases like an individual plan beneficiary, and will not get stuck in a benefit phase, as they had in previous years.

CMS also released draft instructions on how non-calendar year (NCY) EGWPs should transition to IRA adjudication rules. For NCY EGWPs, Part D sponsors must map the EGWP benefit to the 2024 Part D DS benefit for the portion of its NCY plan year that falls in 2024 and to the 2025 Part D DS benefit for the portion of its NCY plan year that falls in 2025. Exhibit 7 spells out how a member should be mapped from a 2024 benefit phase to the equivalent 2025 benefit phase.

EXHIBIT 7 – Non-Calendar Year EGWP Adjudication Rules from 12/31/2024 to 1/1/2025

Enrollee Spending as of 12/31/24	1/1/2025 Map
Did not meet 2024 plan deductible	Enrollee will not have met either the plan or DS deductible thresholds
Met 2024 plan and/or DS deductible, but not 2025 DS deductible	Enrollee has met 2025 plan deductible, but not 2025 DS deductible
Met 2025 DS deductible threshold, but TrOOP eligible costs are less than $2,000	Enrollee will start in the 2025 Initial Coverage phase
Met 2025 DS deductible threshold, and TrOOP eligible costs are greater than $2,000	Enrollee will start in the 2025 Catastrophic phase when their first claim is adjudicated in 2025

Additionally, plan sponsors are not required to offer Medicare Prescription Payment Plan (M3P) to NCY EGWP beneficiaries until their renewal date in 2025.

Considerations for Capitated Payments to PACE Organizations

While CMS indicated that the methodology for calculating the additional payment received by PACE plans to cover nominal copays from low-income subsidy (LIS) members (PACE cost-sharing add-on amount) will not change, the Part D benefit redesign guidance notes two important changes that will impact PACE plans. First, Part D supplemental coverage will count towards the TrOOP accumulator. This change will result in more members reaching the catastrophic phase, where plan liability has been significantly increased due to the IRA. Second, unlike the Coverage Gap Discount Program it replaces, the new Manufacturer Discount Program applies prior to supplemental coverage. This rule change means that many PACE organizations will receive Manufacturer Discount payments for the first time. Additionally, the Manufacturer Discount Program applies to both LIS and non-LIS members.

Considerations for Retiree Drug Subsidies (RDS) and Creditable Coverage (CC)

With the implementation of the IRA, the requirements for a qualified retiree prescription drug plan have not changed. CMS pays a subsidy to sponsors of qualified retiree prescription drug plans that provide equivalent or better coverage than the actuarial value (AV) of standard prescription drug coverage.

The current AV methodology does not consider claims through the coverage gap phase. As the coverage gap phase is removed for 2025+, the AV methodology needs to change. Post-2025, the AV will not consider any discounts provided by MDP, and members do not qualify to participate in the MDP. The AV will include any plan cost-sharing associated with the phase-in of small & specified manufacturers in the MDP. Subsidies, such as LICS & federal reinsurance, continue to be excluded from the AV calculation.

CMS noted that the simplified determination methodology5 will not be a valid methodology to determine creditable coverage moving forward. No information was shared regarding a new methodology for sponsor use.

Implications to Medical Loss Ratios (MLRs)

Minimal changes are being made to the Affordable Care Act MLR calculation as it applies to Part D plans. Exhibit 8 summarizes the similarities & differences in CMS's guidance in the MLR methodology pre- & post-IRA.

EXHIBIT 8 – MLR Rules

	2022 & prior:	2023 & beyond:
Minimum MLR:	85%	85%
MLR Reported at:	Contract level	Contract level
Excluded from calculation:	LICS, CGDP	LICS, CGDP, IRASA[6], MDP
M3P Bad Debt[7] :	n/a	Forthcoming in draft Pt2 M3P guidance

[5] Creditable Coverage Simplified Determination: https://www.cms.gov/medicare/prescription-drug-coverage/creditablecoverage/downloads/ccsimplified091809.pdf

[6] PDE Reporting Instructions for Implementing the Cost Sharing Maximum Established by the Inflation Reduction Act for Covered Insulin Products and ACIP-Recommended Vaccines for Contract Year 2023; https://www.cms.gov/files/document/irasapdeguidance508g.pdf

[7] Draft Part One guidance released August 21, 2023, titled 'Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security

Summary of Future Guidance Items

As noted through the draft instructions, CMS will be offering guidance at a later date on a few items; some of them due to a one-year methodological update, others due to soliciting feedback. Here is the list of items that will be provided from CMS in the future:

For Contract Year 2025:

- PDE examples of deductible accumulation
- Incorporating M3P bad debt into MLR calculation
- Guidance for tiered cost-sharing threshold and formulary tier models
- Decision on removal of BA deductible reduction
- PDE reporting examples for EGWPs

For Contract Year 2026+:

- Methodology for OOPC measurement of enhanced against defined standard benefits
- PDP meaningful difference methodology
- EGWP prospective reinsurance subsidy methodology

CMS is soliciting comments on these draft program instructions. Comment should be sent to PartDRedesignPI@cms.hhs.gov with subject line “Draft CY 2025 Part D Redesign Program Instructions, by March 1, 2024 6pm ET.

Please contact Sarah Legatt (612.900.2196 • sarah.legatt@wakely.com) or Tim Courtney (612.387.3578 • timc@wakely.com) with any questions or to follow up on any of the concepts presented here.