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EVALUATING THE CMS PROPOSED RULE TO PERMIT TWO SPECIALTY TIERS IN PART D

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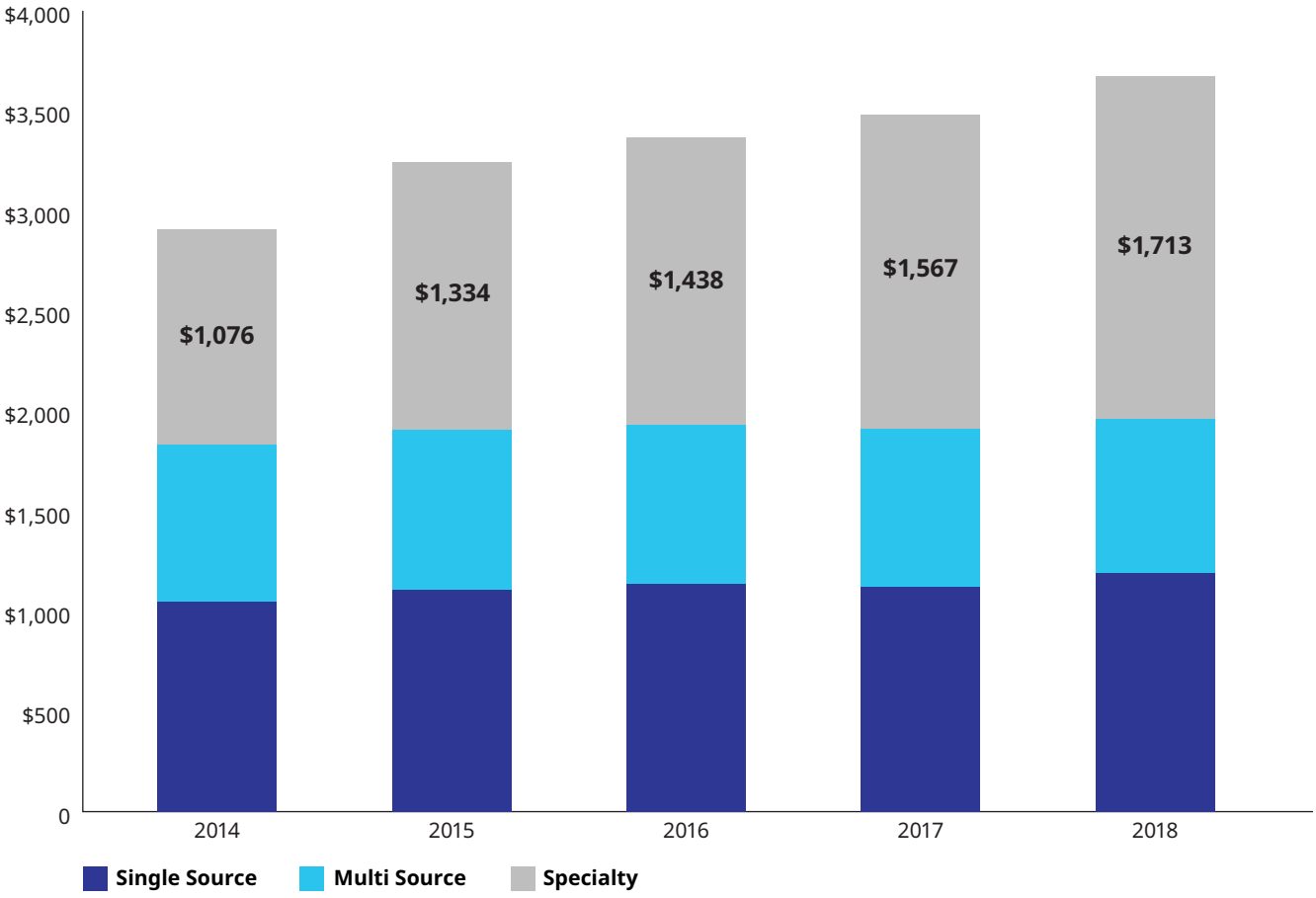
ON FEBRUARY 5, 2020, CMS RELEASED THE CONTRACT YEAR 2021 AND 2022 MEDICARE ADVANTAGE AND PART D PROPOSED RULE.[1]

The proposed rule includes a provision to allow plan sponsors to introduce a preferred specialty tier to their formularies starting in CY2021, which is prohibited under current rules.

The aim of this proposal is to allow plan sponsors greater flexibility to manage the cost and utilization of specialty medications, which have been rising rapidly over the last several years.

Total Average Annual Part D Gross Spend per Member by Drug Type



SOURCE: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD

1. https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-02085.pdf

WHAT IS IN THE PROPOSAL?

The introduction of a preferred specialty tier is intended to **create more competition** among existing specialty drugs, bolster plan sponsors' ability to **negotiate better discounts** and rebates, and promote utilization of **lower-cost generic and biosimilar drugs.**

Under the proposal, plan sponsors would be permitted to have up to **two specialty tiers,** with one being a preferred tier that offers lower cost sharing than the non-preferred tier.

Maximum coinsurance for the non-preferred tier would be limited to 25% to 33%, based on the plan deductible, consistent with current limitations.

Plan sponsors would be able to determine how drugs are classified on the specialty tiers, so long as they meet the definition of a specialty drug and CMS requirements regarding formulary review and approval specified in § 423.120(b)(2).

Current rules around tiering exceptions would not change (i.e., plan sponsors are not required to grant tiering exceptions for specialty drugs to non-specialty tier cost sharing), but plan sponsors would be required to grant tiering exceptions from the non-preferred specialty tier to the preferred specialty tier.

CMS also proposes to **codify several items,** which are currently only updated per CMS' discretion:

- The maximum permissible cost sharing for the specialty tier.
- The methodology to determine the cost threshold for which drugs can be included on a specialty tier, which would allow for the threshold to increase each year. CMS proposes to target the top 1% of claims having the highest 30-day equivalent ingredient cost. Note this calculation is currently based on negotiated price and the current threshold is equal to $670 per script.

WHAT ALTERNATIVES MAY CMS BE CONSIDERING?

In the proposed rule, **CMS has requested comment** on the following alternatives related to these proposals:

- Allowing only generic and biosimilars on the preferred tier
- Excluding all specialty drugs from tiering exception requirements
- Permitting cost sharing on the non-preferred specialty tier that is higher than the current limit
- Setting a maximum allowable cost sharing percentage of 25% for specialty drugs, regardless of the deductible
- Specifying a minimum difference in cost sharing between the preferred and non-preferred specialty tiers

WHAT ARE THE POTENTIAL IMPLICATIONS FOR STAKEHOLDERS?

The overall impact of this proposal is not entirely clear given there are components of the rule that will offset, and the magnitude of the impact will depend on how plan sponsors, beneficiaries, and drug manufacturers react to this new flexibility.

PLAN SPONSORS

- Plan sponsors and PBMs may find it challenging to implement a preferred specialty tier for CY2021. There will be several considerations to balance such as benefits, formulary design, discount and rebate negotiations, and product strategy. Plan sponsors and PBMs will need to **weigh the benefits of more attractive cost sharing and potential rebate improvement against increased plan liability and administrative complexity.**
- **For plans that offer the Defined Standard deductible, it may be challenging to add a preferred specialty tier.** Because coinsurance for the non-preferred tier would not be permitted to exceed 25% for such a plan (per the CMS rule that scales the maximum specialty coinsurance based on the deductible), coinsurance for the preferred specialty tier would need to be lower than 25%. This would put upward pressure on supplemental premiums. Plan sponsors could reduce the deductible for those plans in order to take advantage of the additional specialty tier flexibility, but this would put additional upward pressure on supplemental premiums.
- If net plan costs can in fact be reduced through higher rebates, we would expect a corresponding reduction in basic premiums. However, manufacturers may try to offset higher rebates with higher list prices.
- We would expect enhancement of benefits on the specialty tier to put upward pressure on supplemental premiums. A reduction in plan liability for basic coverage would also allocate more non-benefit expenses and gain/loss to supplemental premium in the bid.
- Reduced cost sharing on some specialty drugs would delay the point at which beneficiaries utilizing those drugs reach the catastrophic cost sharing phase, shifting some costs from federal reinsurance to drug manufacturers and plan sponsors. This would also be expected to put upward pressure on supplemental premiums.

BENEFICIARIES

- Cost sharing on the non-preferred tier cannot exceed current levels, **so beneficiaries would not see an increase in cost sharing for any specialty medications.**
- Any increases in supplemental premium will make plans less attractive to low income beneficiaries. Those members would see an increase in premium, but no reduction in cost sharing since their costs are highly subsidized.

DRUG MANUFACTURERS

- Margins for manufacturers may be tighter due to **payer pressure for greater price concessions** in order to gain more favorable formulary placement. Manufacturer margins may also be tighter due to potentially lower utilization of drugs that are not on the preferred tier.
- **Manufacturers of drugs that are very high cost (e.g., Harvoni) may not have much incentive to negotiate higher rebates for preferred tier placement.** For drugs with such a high price, member behavior would likely not be influenced by the modest reduction in cost sharing on the preferred specialty tier relative to total member out-of-pocket costs.

- Manufacturers of lower-cost specialty drugs would likely have more incentive to offer greater price concessions for more favorable tier placement, since beneficiaries utilizing those drugs may have a larger proportion of their total costs below the ICL.

FEDERAL GOVERNMENT

- Higher negotiated rebates would likely yield **lower direct subsidy payments to plan sponsors** given the expected reduction in the standardized bid, producing savings for CMS.
- Lower member cost sharing would be expected to result in **savings for CMS on the Low Income Cost Sharing Subsidy** (LICS), especially considering low income members generally use a disproportionate share of specialty medications.
- Lower member cost sharing would also be expected to produce a **reduction in federal reinsurance payments** to plan sponsors since beneficiaries would not reach the catastrophic cost sharing phase as quickly, resulting in savings for CMS.

HOW MIGHT PLAN SPONSORS BENEFIT FROM THIS ADDITIONAL FLEXIBILITY?

Plan sponsors will need to evaluate whether the addition of a **preferred specialty tier would be advantageous.** Here are some possible circumstances under which plan sponsors may or may not benefit from using this additional flexibility:

- A change in Part D premiums, whether upward or downward, would have a corresponding impact on the **amount of MA rebates** available to reduce Part C cost sharing or offer supplemental benefits. If the net impact of implementing a preferred specialty tier would be expected to result in lower total Part D premiums, plan sponsors may want to consider taking advantage of this new flexibility in order to make their **MA plan more attractive.**
- If a plan sponsor can identify certain populations with lower loss ratios that typically utilize lower-cost specialty drugs, this additional tiering flexibility could be used to promote those drugs and possibly **attract more beneficiaries** in that cohort.
- For plan sponsors that pair a PDP with a Medigap plan, a decrease in basic premium accompanied by an increase in supplemental premium may **attract a healthier population.** Such plans may be less attractive to low income beneficiaries given the increase in supplemental premium.
- PDPs with basic premiums near the low-income benchmark should be aware of how **basic premiums will change relative to the benchmark.** Plan sponsors specifically desiring to be either below or above the benchmark should consider how the expected reduction in basic premium would impact those pricing objectives, either positively or negatively.

ARE THERE ANY POTENTIAL DOWNSIDES FOR PLAN SPONSORS?

Plan sponsors will also need to weigh any **downside risk** associated with adjusting their benefit structure. Plan sponsors will have to think through the following important considerations:

- The risk corridors only impact the basic benefit. To the extent that specialty claims are underestimated in the bids and thus supplemental premiums are insufficient, **plan sponsors will not have the risk corridors to protect them from potential losses for the additional tier flexibility.**
- If a plan sponsor does not consider which populations may be incentivized to enroll in their plans, some **anti-selection may occur.**
- The comment period for the proposed rule runs through April 6, 2020. Plan sponsors may **not know until late in the bidding process** whether this proposal will be adopted and the specific rules that CMS will implement.

The opportunity to introduce a preferred specialty tier offers plan sponsors **additional flexibility** for benefits, formulary construction, and product strategy. It is difficult to assess how stakeholders in the market will react to this proposal for CY2021 bidding. Beyond CY2021, it will be easier to assess how the market has responded to this additional flexibility and adjust strategy accordingly. For now, plan sponsors will need to be careful to **assess the potential risks and rewards** of implementing a preferred specialty tier for their Part D plans.

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