

## **II. A. Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability**

### **1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) (Pg. 21)**

- CMS Comment – CMS published proposed criteria in the proposed rule. However, we recommend that CMS provide and define the standard criteria for a “Potential at-risk” beneficiary and what “Clinical Guidelines” CMS expects Plan Sponsors to follow for this program to ensure they are uniform across all plans and there is no variation.
- CMS Comment – We appreciate the ability to have flexibility in the number of proposed outreach attempts at 3, but request that CMS define a minimum number of required outreaches as it leaves plans at risk during audits when the minimum expectation is not set by CMS.

### **11. Part D Tiering Exceptions (Pg. 148)**

- CMS Comment – We recommend that CMS leave the Specialty Tier as exempt from Tiering Exception requests and Tier Exceptions should not be allowed for Specialty Tier drugs as the alternatives at lower tiers are not typically therapeutically equivalent and/or appropriate formulary alternatives although they may treat the same medical condition.
- CMS Comment – We recommend that CMS does not eliminate the exclusion of a dedicated generic tier from Tiering Exception requests as this limits formulary management and may drive some generic products to higher tiers to avoid down tier expensive branded drugs negating the potential benefit to beneficiaries.
- CMS Comment – If CMS decides to eliminate the exclusion of a dedicated generic tier from Tiering Exception requests, then we recommend that CMS provide specific criteria and/or guidelines related to review and processing of Tiering Exception requests.
- CMS Comment – These proposed tiering exception changes could limit the flexibility and economics of multi-tier cost shares. If established correctly, brands can still be blocked from Generic but the Generic cost shares would be blended. Ultimately if this is abused by members it will lead to elimination of a low copay generic tier.

### **8. Establishing Limitations for the Part D (SEP) for Dual Eligible Beneficiaries (Pg. 158)**

- CMS Comment – We agree with changing the SEP from open ended to the updated circumstances.

### **14. Changes to the Days’ Supply Required by the Part D Transition Process (Pg. 278)**

- CMS Comment – We do not agree with the change from 30 day transition supply to “Month Supply” as it is vaguer. From an operational standpoint, this makes it potentially more difficult to manage. Prefer a minimum day supply required for a transition supply (i.e. 25 days, 28 days or 30 days). Lowering the days’ requirement would allow drugs commonly submitted for 28 days to meet the transition day supply requirement without making it vaguer as a “Month Supply” makes it.
- CMS Comment – We support reducing the transition supply for LTC from 90 days to 30 days to align with non-LTC membership.

### **15. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (Pg. 282)**

- CMS Comment – We support the proposal to allow plans to immediately remove brand name drugs from the formulary and replace them with generic equivalents at any time during the year.

## **Price Concessions to Drug Prices at the Point of Sale**

- It is assumed that this is based on the individual market. What, if any, exceptions would there be for EGWP? We believe this would have a higher impact to self-funded groups because at the point of rebate reconciliation, they would absorb the estimate to the actual true up. An overstated rebate estimate will give more credit to the plan and less to the member at POS.
- This cannot be accomplished with financial accuracy and is not easily estimated because;
  - Rebate information is provided 6 months out and drugs can be removed in the interim.
  - Over the last 5 years CMS has seen a large difference in rebate dollars for Plan Sponsor bids vs their DIR reporting, validating how difficult estimation would be.
- Generally speaking, we believe the impact of the proposed rule changes will ultimately increase the monthly premiums for Medicare members and reduce the ability of smaller PDP's to be competitive with the largest plans.
- The modeled impact to member premiums in the document is likely understated as well as the increased cost to the government for additional direct subsidies of plan premiums and low income premium subsidies.
- Contrary to observations/comments in the proposed rule, we believe the competitive balance as a result of these changes would be tipped in favor of only the largest of PDPs that would retain the leverage to negotiate the highest rebates and largest pharmacy discounts with manufacturers and retailers.
- These performance based contracts are individually negotiated between plan sponsors and manufacturers or pharmacies. These proposed changes, in essence, inserts CMS into the contractual relationship between the respective parties which historically has been territory that CMS would not/could not insert itself.
- In addition, many of the proposed changes would add administrative and operational complexity and cost to the plans. In particular, we believe this change would cause an undue burden on the plan. It would require a system build-out to manage this process, which would take considerable time and incur significant costs. In addition to increasing member premiums, plan designs may potentially increase co-pays offsetting the proposed potential savings to the member in the EGWP program especially.
- Performance based pharmacy contracts are by nature designed to encourage dispensing of lower cost generic drugs, formulary compliance and medication adherence to improve medical outcomes and lower long term costs. Many of the proposed changes likely will cause the industry to take a step back from performance and quality based reimbursement and return to the inefficient and more costly historical fee for service approach.
- The current structure also encourages preferred and non-preferred arrangements in network pharmacies which ultimately lowers member and program costs through creating a competitive environment for retail pharmacies. We believe a movement away from this network structure, which may be an unintended consequence of the proposed changes would be a negative for all stakeholders except pharmacy providers.
- Cost-Shifting (Pg. 311) "Numerous research studies further suggest that the higher cost-sharing that results can impede beneficiary access to necessary medications..."

CMS Comment- We have seen no indication that the slight differences in cost sharing described in the document are significant impediments to access to medications.

- Transparency and Differential Treatment (Pg. 313) “The resulting competitive advantage accruing to one sponsor over another in this scenario stems only from a technical difference in how plan costs are reported to CMS. Therefore, the opportunity for differential treatment of rebates and price concessions could result in bids that are not comparable and in premiums that are not valid indicators of relative plan efficiency.”

CMS Comment - This allows flexibility within the established guidelines for smaller PDPs to compete with the larger PDPs who maintain competitive leverage in the market. Changes may substantially reduce smaller plans' ability to compete with the larger plans.

- Manufacturer Rebates to the Point of Sale (Pg. 313) “a share of the manufacturer rebates they receive, in order to mitigate the effects of the DIR construct...”

CMS Comment - We recommend no more than 50% of rebates should be included at POS.

- Specified Minimum Percentage (Pg. 315) “and thus, for some sponsors, weaker incentives to participate in the Part D program.”

CMS Comment - Again, we believe this recommendation greatly advantages larger Part D plans. Noting a trend in number of these rules, we respectfully ask if CMS is intending to drive smaller players out of the program. If so, whether intentionally or not, we believe this will ultimately reduce competition and drive higher costs to beneficiaries.

- Plan-Level Average (Pg. 317) “We solicit comment on whether the most appropriate approach for calculating the average rebate amount for point-of-sale application would be to do so at the plan level, using plan-specific information, given that moving a portion of manufacturer rebates to the point of sale would impact plan liability and payments, or if another approach would be more appropriate. Drug Category or Class: We are considering requiring that the manufacturer rebate amount applied...”

CMS Comment - If this is going to be applied, we recommend that it is applied at the plan level.

- Drug Category or Class (Pg. 318) “would help maintain fair competition among drug manufacturers, as well as Part D sponsors, by preventing competitors from reverse engineering...”

CMS Comment - We believe this still highly advantages larger plans due to size and volume advantages in negotiations.

- Point-of-Sale Rebate Drugs (Pg. 321) “percentage of rebates at the point of sale only for specific drugs or drug categories or class.”

CMS Comment - If this change is going to happen, it would be preferred to limit to specific drugs or drug classes. Although more complicated to administer, would still leave some flexibility for smaller plans to compete.

- Pharmacy Price Concessions to Point of Sale (Pg. 329) “Pharmacy Price Concessions to Point of Sale”

CMS Comment - See earlier general comments regarding the fact that these proposed changes favor only the very large PDPs that have the leverage to negotiate deeper discounts and higher rebates.

- All Pharmacy Price Concessions (Pg. 332) “We are considering revising the definition of negotiated price at § 423.100 to remove the *reasonably determined* exception and to require that all price concessions from pharmacies be reflected in the negotiated price that is made available at the point of sale and reported to CMS...”

CMS Comment - See earlier comments but why single out pharmacy price concessions? Performance results will vary greatly.

- All Pharmacy Price Concessions (Pg. 333) “We are considering requiring all, and not only a share of, pharmacy price concessions be included in the negotiated price in order to maximize the level of price transparency and consistency in the determination of negotiated prices and bids and meaningfully reduce the shifting of costs from sponsors to beneficiaries and taxpayers.”

CMS Comment - Pay-For-Performance contracts are designed to improve quality/adherence, encourage use of lower cost generic drugs and increase formulary compliance. All factors that ultimately lower costs and improve outcomes. These changes will discourage use of these mechanisms to accomplish those goals.

- Impacts for Applying Pharmacy Price Concessions at the Point of Sale (Pg. 338) “with no unfair competitive advantage accruing to one sponsor over another based on a technical difference in how costs are reported.”

CMS Comment - Technical differences allows competitive flexibility to smaller Part D plans. Removing them will reduce ability to remain competitive.

## **11. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System**

- e. Contract Ratings (Pg. 186)

CMS Comment - We do not support the idea of PBP-level report of Star Ratings for all of the reasons stated in the Proposed Rule (data reliability due to small sample sizes, administrative burden, etc.). If CMS is looking to report certain measures more specifically than contract-level, we would offer the idea of reporting certain medication-related measures at the Formulary ID level.

- h. Adding, Updating, and Removing Measures (Pg.’s 196-207)

CMS Comment - We support the increased lead time for the addition of new Star Measures. We also support the removal of Measures from Star Ratings when new clinical evidence indicates that measure objectives may be harmful to beneficiaries. In instances when Measures are removed after more than half of the measurement period, we would like CMS to consider calculating a plans Summary Rating both including and excluding the removed measure and assigning the better of the two Summary Ratings.

## **6. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations**

- CMS Comment - We support the increase in the adjudication timeframe from 7 to 14 days for standard redetermination requests for payment. We would also like CMS to consider other measures that would reduce the need to deny other types of requests due to missing information, such as expanding the types of coverage determinations that qualify for tolling the clock.

### **Preclusion List (Pg. 386)**

- CMS Comment - Is the preclusion list on a per script basis or can we preliminarily notify the member that all scripts prescribed by this DR will be rejected?

### **k. Data Integrity (Pg. 219)**

- CMS Comment - We support the scaling of the IRE measure reduction for data integrity issues based on the number of cases not sent to the IRE.