Survey Analysis of January 2014 CMS Medicare Part D Proposed Rule

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Pharmaceutical Care Management Association

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EXECUTIVE SUMMARY

Milliman has been retained by Pharmaceutical Care Management Association to evaluate the effect of the January 10, 2014 CMS Proposed Rule on the Medicare Part D market.[1] To quantify the effect of the Proposed Rule, Milliman conducted a survey of Prescription Drug Plan (PDP) sponsors and pharmacy benefit managers (PBMs) on the effect of key provisions. Survey participants provide coverage to more than two thirds of the 18.4 million individual Medicare PDP beneficiaries.[2]

Expectations of PDP sponsors and PBMs play a crucial role in the decision-making process used to offer particular plans and develop annual PDP bids. As a result, these expectations affect the final plan premiums and the cost of the PDP program. Survey responses provided Milliman with many important assumptions used to estimate the potential effect of the Proposed Rule on Medicare costs and beneficiaries. We applied these assumptions to a set of representative 2015 bids developed from a comprehensive Medicare Part D claims database, survey data, and Milliman trend and formulary research. The major findings from our survey analysis are:

- Approximately 6.9 million non-low income Medicare Part D beneficiaries currently enrolled in preferred pharmacy PDPs may experience material premium and cost sharing increases in 2015 on average based on provisions in the Proposed Rule using assumptions derived from survey responses.

- Federal government subsidies for approximately 6.0 million low income Medicare Part D beneficiaries currently enrolled in preferred pharmacy PDPs may increase in 2015 on average based on provisions in the Proposed Rule using assumptions derived from survey responses.

- Up to 50% of Part D plan choices may be eliminated or materially changed during 2015 and 2016 based on provisions in the Proposed Rule using assumptions derived from survey responses.

- The average bid amount for beneficiaries enrolled in preferred pharmacy PDPs may increase by 10% in 2015 based on Proposed Rule provisions using assumptions derived from survey responses. The average bid amount represents the net cost of PDP benefits, which is funded by federal government subsidies and beneficiary premiums.

- Costs to the federal government may increase by $1.2 to $1.6 billion in 2015 as a result of provisions in the Proposed Rule based on assumptions derived from survey responses. We expect that costs of a similar magnitude will occur in future years as many Proposed Rule provisions will incur costs on an ongoing basis.

This report expands on the analysis described in our October 2013 report titled “The Impact of Preferred Networks on Federal Medicare Part D Costs, 2014-2023” by revising important

[1] The Centers for Medicare & Medicaid Services (CMS) Proposed Rule titled “Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs” may be found on the GPO website: http://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2013-31497.pdf.

[2] Based on January 2014 enrollment published by CMS.

assumptions using survey responses.[3] The remainder of this report includes a discussion of impactful Proposed Rule provisions, a description of our methodology, and important disclosures.

DISCUSSION OF PROPOSED RULE PROVISIONS

The Proposed Rule contains several provisions that have a substantial effect on the Medicare PDP market. In this section, we will discuss how these key provisions affect Medicare PDP beneficiaries and costs.

Proposed Rule effectively eliminates post-point-of-sale pharmacy price concessions

In a preferred pharmacy plan, a PDP sponsor offers reduced beneficiary cost sharing at preferred pharmacies. Reduced beneficiary cost sharing is typically offered in the form of lower copays or coinsurance. The PDP sponsor is able to offer reduced cost sharing because it receives more competitive pharmacy contract terms on prescription drug prices. The preferred terms might be deeper drug discounts, lower dispensing fees and/or a post-point-of-sale (POS) price concession paid to the PDP sponsor. Post-POS price concessions are considered to be direct/indirect remuneration (DIR) under federal requirements.

In §423.100 of the Proposed Rule titled, "Pharmacy Price Concessions in Negotiated Prices," CMS clarifies the definition of negotiated prices in a manner that effectively eliminates post-POS pharmacy price concessions. Post-POS pharmacy price concessions typically cannot be reflected in the negotiated price since they depend on specific metrics such as overall volume and generic dispensing rates that are determined retrospectively and not tied to the price of individual prescriptions.

Survey participants indicate that the elimination of post-POS price concessions reported as DIR will increase bids for PDP sponsors that use such contracts by 2.5% to 10.0%. Increased bids may result in increased federal government subsidies and increased beneficiary premiums. This is true for low income and non-low income beneficiaries.

While all non-low income beneficiaries may be affected by increased bid amounts, the impact on their out-of-pocket costs varies depending on their annual prescription drug spending level and the extent to which POS discounts equivalent to post-POS price concessions could be negotiated. Survey participants do not expect that pharmacies will negotiate discounts at an equivalent level to current post-POS price concessions due to other key provisions in the Proposed Rule, which are discussed below.

Require that "any willing" pharmacy be included in preferred pharmacy networks

The Proposed Rule provision §423.120(a)(8) titled "Any Willing Pharmacy Standard Terms & Conditions" requires that Part D sponsors publicize standard terms and conditions for network participation that list all combinations of cost sharing and negotiated prices possible for every type of similarly situated pharmacy under the plan. PDP sponsors would be required to contract with any willing pharmacy able to meet the terms and conditions offered by the plan.

All survey participants expect that this provision may increase pharmacy costs since expanding networks to include any willing pharmacy may reduce the volume of sales that each pharmacy

[3] For a detailed description of methodology and other important assumptions, please refer to the October 2013 Milliman report on PCMA's website: http://www.pcmanet.org/images/stories/uploads/2013/milliman%20preferred%20pharmacy%20networks.pdf.

participating in the network can expect. If PDP sponsors can no longer partner with preferred pharmacies, survey participants are concerned that the pharmacy may have less incentive to offer more competitive discounts.

Prohibit sponsors from using the term "preferred pharmacy networks"

The Proposed Rule provision §423.100 and 423.120(a)(9) "Preferred Cost Sharing," prohibits Part D plans from using the term "preferred pharmacy network" among other limitations. The term "preferred pharmacy network" is currently used by PDP sponsors that account for more than 70% of total PDP beneficiaries. Many PDPs use this term to help beneficiaries differentiate between preferred and non-preferred out-of-pocket cost options that vary by pharmacy. Prohibiting plans from using the term "preferred pharmacy networks" may confuse and potentially disrupt beneficiaries.

Survey participants anticipate that this provision may increase drug costs due to a loss of contracting leverage with pharmacies. Increasing drug costs may result in increased beneficiary premiums and federal government subsidies.

Reduce the number of plans per region that sponsors can offer

In §423.265 of the Proposed Rule, "Limit Stand-Alone Prescription Drug Plan Sponsors to Offering No More Than Two Plans Per PDP Region" CMS envisions restricting the number of Enhanced Alternative plans that a PDP sponsor can offer to one per region starting in 2016. As of January 2014, 7.9 million beneficiaries are enrolled in Enhanced Alternative plans, which represent 50% of the total individual PDP plan offerings in 2014.

CMS acknowledges in its cost estimate that there are "no cost savings accruing from this proposal" because any such savings would be offset by "the burden associated with consolidation activities and the legal work necessary to implement the change," (p. 2038). Survey participants indicate that this provision may cause beneficiary disruption due to either plan terminations or beneficiary premium increases.

Limit the use of mail-service pharmacies

In §423.120, "Timely Access to Mail Order Pharmacy Services," CMS proposes that it directly regulates mail order pharmacies by requiring mail order prescription delivery times of five business days (from the date the pharmacy receives the prescription order to when it is shipped) for prescriptions requiring intervention beyond filling (e.g., checking back with physicians or resolving third-party rejections) and three business days for prescriptions not requiring intervention.

As CMS notes in the Proposed Rule, the industry standard for mail order pharmacy delivery times is currently approximately 7-10 business days, which is greater than the 3-5 day standard proposed in the rule. CMS also proposes requiring that 99% of all mail order pharmacy prescriptions must be filled within the 3-5 day standard.

Survey participants generally expect a decrease in mail order utilization as a result of the Proposed Rule. A 2013 CMS analysis found that overall costs at mail-service pharmacies were 16% less than retail pharmacies ($1.26 per pill at mail vs. $1.50 at retail) across all drugs.[4] Therefore, costs to the

[4] Centers for Medicare and Medicaid Services, "Part D Claims Analysis: Negotiated Pricing Between General Mail Order and Retail Pharmacies," December, 2013.

Part D program may increase based on the CMS study and the survey result that the Proposed Rule is expected to decrease the use of mail-service pharmacies.

Expand medication therapy management (MTM) programs

Requirements outlined in §423.153(d) of the Proposed Rule, "Medication Therapy Management Program under Part D," significantly expand eligibility standards for Medicare Part D Medication Therapy Management (MTM) programs by redefining the definition of "multiple" chronic diseases, reinterpreting "multiple" Part D drugs, and reducing the annual cost threshold for MTM participation from $3,000 to $620. In the Proposed Rule, CMS estimates that that these changes would increase MTM eligibility from less than 8% of Part D enrollees in 2011 to 55% of enrollees in 2015.

All survey participants believe that the net effect of MTM program eligibility expansion will result in a net cost increase to the PDP. The estimated net cost increase is primarily driven by increased outreach costs, which may lead to increased beneficiary premiums and federal government subsidies.

Change requirements for the maximum allowable cost (MAC) pricing of generic drugs

In §423.505(b)(21), "Prescription Drug Pricing Standards and Maximum Allowable Cost," CMS proposes to clarify that the definition of "prescription drug pricing standard," which is subject to a 7-day updating requirement, applies to Maximum Allowable Cost (MAC) pricing. In addition, CMS proposes requiring PDP sponsors to disclose all individual MAC prices to pharmacies in advance of their use for reimbursement of claims.

Currently, MAC pricing is widely used by health plans, PDP sponsors, and PBMs for Medicare, Medicaid, and commercial plans. MAC pricing lists specify reimbursement limits for particular strengths and dosages of generic drugs that are available from multiple manufacturers but sold at different prices. The intent of MAC pricing is to encourage pharmacies to dispense the lowest-cost FDA-approved version of a given drug and protects plan sponsors from overpaying for prescriptions since generic prices often vary widely by manufacturer.

Aggregated survey results suggest that this provision may result in additional administrative costs with generally no material drug cost improvement. Higher administrative costs may lead to increased beneficiary premiums and federal government subsidies.

Modify the six protected drug classes of clinical concern

In §423.120(b)(2)(v) and (vi)), "Drug Categories or Classes of Clinical Concern and Exceptions" the Proposed Rule outlines new criteria for determining categories and classes of clinical concern, to update the exceptions for such categories and classes, and to apply the new criteria to the classes that are currently treated as such categories and classes. The anticipated effect of the proposal will be to reduce the number of protected classes.

Aggregated survey results indicate that this provision may decrease Medicare PDP costs for the federal government and beneficiaries. With fewer protected classes, PDP sponsors may reduce drug costs by using formulary management tools across a greater portion of drug therapy options. Reduced drug costs also reduce federal government costs and average beneficiary costs.

METHODOLOGY

We distributed a survey to PDP sponsors and PBMs to evaluate the anticipated effect of Proposed Rule provisions on various aspects of the Medicare PDP market. We applied survey responses to the preferred pharmacy scenarios described in the October 2013 Milliman report to estimate the effect of the Proposed Rule based on industry practitioner analysis and expectations for 2015. Please refer to the October 2013 analysis for a detailed explanation of underlying projection assumptions.

Survey participants operate PDPs that provide coverage to over two thirds of the 18.4 million total PDP beneficiaries and administer other Part D plans as PBMs. We have assumed that survey participants are a representative sample of the entire PDP market. As a result, we extrapolated survey responses to the entire PDP market to develop the major findings of our analysis assuming that the remainder of the market would have responded to survey questions in a similar manner.

Similar to the October 2013 analysis, we assume the current PDP market is comprised of three distinct plan types: plans with no preferred pharmacies, preferred pharmacy plans that negotiate lower POS unit costs, and preferred pharmacy plans that negotiate post-POS DIR. We assume that 30% of PDP beneficiaries are currently not enrolled in a preferred pharmacy plan. We assume that 30% of PDP beneficiaries are enrolled in a preferred pharmacy plan that negotiates lower POS unit costs. We assume that the remaining 40% of PDP beneficiaries are enrolled in a preferred pharmacy plan that negotiates post-POS DIR. PDPs may also use a hybrid preferred pharmacy approach in practice, which relies on a combination of improved POS costs and DIR.

We applied survey responses to the post-POS DIR preferred pharmacy scenario from our October 2013 analysis. To estimate the effect of the Proposed Rule on federal government spending and beneficiary spending, we relied on the distribution of plan types described above.

A database comprised of 2012 Medicare Part D experience compiled by Milliman was used as the foundation for this analysis. We also rely on CMS data files which itemize PDP and PD average utilization and allowed costs per member per month and overall generic use rates by region. Our pricing approach relies on separate low income and non-low income claim probability distributions that provide allowed spend levels based on the average price by drug tier (generic, preferred brand, non-preferred brand, and specialty) and distribution method (retail and mail order).

CAVEATS AND LIMITATIONS

Stephen Kaczmarek and David Liner are actuaries for Milliman, members of the American Academy of Actuaries, and meet the Qualification Standards of the American Academy of Actuaries to render this opinion. To the best of our knowledge and belief, this information is complete and accurate and has been prepared in accordance with generally recognized and accepted actuarial principles and practices.

This report has been prepared for the specific purpose of evaluating the effect of the January 10, 2014 CMS Proposed Rule on the individual Medicare PDP market. This information may not be appropriate, and should not be used, for any other purpose. Milliman does not endorse any policy.

This report has been prepared solely for the internal business use of, and is only to be relied upon by, the management of Pharmaceutical Care Management Association. While Milliman has agreed that this report can be shared by the Pharmaceutical Care Management Association, Milliman does not intend to benefit or create a legal duty to any third party recipient of its work. This report must be read in its entirety.

The results presented herein are estimates based on carefully constructed actuarial models, with some assumptions based on the responses to the survey described above. Differences between our estimates and actual amounts depend on the extent to which future experience conforms to the assumptions made for this analysis. It is certain that actual experience will not conform exactly to the assumptions used in this analysis. Actual amounts will differ from projected amounts to the extent that actual experience deviates from expected experience.

Milliman does not provide legal advice, and recommends that any reader of this communication consult with its legal advisors regarding legal matters.