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Taking on Medicare Part D risk: Provider perspective

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Background

On January 30, 2019, the Centers for Medicare and Medicaid Services (CMS) released Part II of the 2020 Advance Notice and Draft Call Letter,[1] which contains the proposed methodological changes for the 2020 Medicare Advantage (MA) capitation rates along with Part C and Part D payment policies.

On page 171 of the Draft Call Letter, CMS issued a request for comments on the potential use of risk-based arrangements for pharmacy benefits in contracts between MA plans and contracted providers. CMS noted that risk-based arrangements in contracting for pharmacy benefits may be another tool to drive down the cost of Part B drugs in MA and Part D drugs for Medicare Advantage and Part D (MA-PD) plans. CMS requests information on the barriers, feasibility, benefits, and drawbacks for these types of arrangements between MA plans and contracted providers.

This is not the first time CMS has requested information regarding the integration of Medicare risk-sharing arrangements and Part D. As part of its August 2018 proposed rule, CMS asked how accountable care organizations (ACOs) and Part D sponsors in the Medicare Shared Savings Program (MSSP) could "structure the financial terms of these arrangements to reward Part D sponsors' contributions towards achieving program goals." There was also a request for information (RFI) in that rule regarding "barriers to developing these relationships." This request for information was met with a number of responses, one of which notably "expressed concern regarding the capability of prescription drug plans (PDPs) and ACOs to undertake information sharing."[2]

This article provides a summary of the key issues providers need to consider before taking on Part D risk, an increasingly common ask from MA organizations, and highlights some of the complexities and common barriers we observe when we advise provider clients on their strategies for Part D risk.

Barriers and challenges for providers taking on Part D risk

PROVIDERS HAVE LIMITED AND SOMETIMES NO CONTROL OVER MANY OF THE LEVERS THAT AFFECT THE PART D NET COSTS

In a risk-sharing arrangement, a provider in theory improves its performance metric (net cost and/or quality of care) through better care management, care coordination, improved coding, and other activities. Because of the complexity of the Part D program, it may be quite difficult for a provider to affect performance measures. This is because, for Part D, the net cost is a function of many things outside the provider's control. Contracting terms between the health plan and the pharmacy benefit manager (including discounts and rebates), cost sharing, formulary, coverage gap discount, federal reinsurance, and other important items will have material effects on the net cost, and the calculation of these amounts is complex. Furthermore, the introduction of new specialty and branded medications, as well as the launch of new generic medications, have material impacts on Part D net costs. In recent years, the introduction of costly hepatitis C treatments, oncology treatments, and treatments for autoimmune diseases have significantly affected net costs per beneficiary in a way providers have had little or no control over.

The marginal change in net cost for the member's next prescription depends on which phase of the Part D benefit the member is in, the cost-sharing parameters (which vary by plan), and possibly numerous other variables such as rebates. Therefore, it will likely be difficult for a provider to fully understand how the performance measure is calculated. Furthermore, the complexity of the cash flows for the Part D program are disproportionate to the amount of revenue Part D would contribute to a performance metric in a risk-sharing arrangement, relative to Part C.

[1] The full text of the CMS Call Letter is available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf.

[2] Federal Register (December 31, 2018). CMS Final Rule: Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017, p. 68031. Retrieved March 17, 2019, from https://www.govinfo.gov/content/pkg/FR-2018-12-31/pdf/2018-27981.pdf.

THE MEDICARE PART D BENEFIT IS COMPLEX

Risk-sharing arrangements are often based on a change in the net cost to the plan sponsor. If the net cost decreases relative to a preset target, the provider shares in the difference as a "gain." There are a number of different ways to view the net cost of the Part D benefit, because there are a number of different stakeholders paying for the benefit. The net cost to the plan sponsor is a function not only of allowed costs and member cost sharing, but also of manufacturer rebates, other direct and indirect remuneration, federal reinsurance, low income cost-sharing subsidies, manufacturer payments during the coverage gap, risk corridors, and other financial items. In order to determine the loss ratio for the adjudication of a risk-sharing arrangement, each of these items will either be accounted for or excluded from the loss ratio calculation.

Therefore, it is important for a provider taking risk to understand how each of these items might affect the outcome of the risk-sharing arrangement. Determining how these items may interact to produce a gain or loss share for the provider is not intuitive and requires specialized knowledge and significant time. In addition, the delayed cash flows for final adjudication (i.e., settlement) of Part D financial items such as low income cost-sharing levels, coverage gap discount, risk-adjusted revenue, and risk corridors means that providers entering into a risk-sharing arrangement may have to wait a long time for the gain share or risk share amount to be determined (or the final settlement that will include estimates).

Figure 1 shows the percentage of the standard Part D benefit paid by various parties, which depends on the accumulated allowed and out-of-pocket costs year to date. The net plan liability for the member's next prescription depends on the member's accumulated allowed dollars for the year to date, and whether the member's out-of-pocket spend has exceeded the true out-of-pocket (TrOOP) amount. Not all Part D plans have the same parameters. The parameters shown in Figure 1 are for the Part D Defined Standard Benefit proposed for contract year 2020.

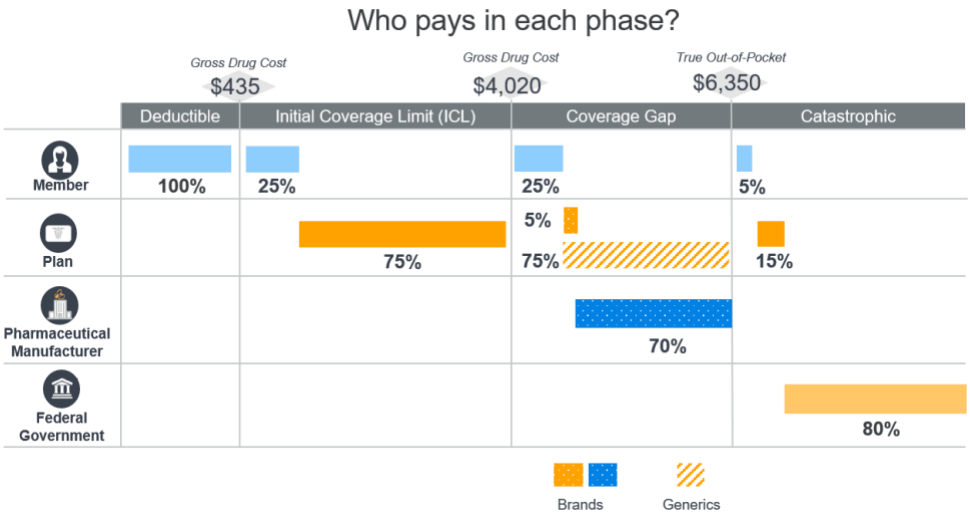
It should be noted that, while Part D plans are often (but not always) sold as packages with Part C plans, the benefit is never integrated. Part D benefits are always priced and adjudicated separately from Part C benefits. This stands in contrast to many benefit plans offered to the under-65 population, where the medical and drug benefits are often combined. Therefore, if Part C and Part D costs are combined in a risk-sharing arrangement, there are two completely independent sets of financial information to be tracked and adjudicated.

REBATES CREATE OPAQUE AND OFTEN CONFLICTING INCENTIVES

Currently, rebates for many branded medications are paid by manufacturers to pharmacy benefit managers (PBMs), and a portion or all of those rebates are passed on to the drug plan sponsor. In 2016, rebates were approximately 20% of total drug costs for Part D.[3] As a result of these rebate arrangements, the PBM and/or drug plan sponsor may have an incentive to provide easier access to rebatable drugs (e.g., better placement on the formulary) for its members. Thus, there is a potential for the plan sponsor to incentivize (via formulary and/or cost sharing) members to take rebatable drugs rather than lower-cost non-rebatable drugs. Depending on the specifics of the risk-sharing arrangement, rebatable drugs may be detrimental to the performance metric used.

[3] 2018 Medicare Trustees Report, Table IV.B8. Retrieved March 17, 2019, from https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf.

FIGURE 1: PROPOSED PART D DEFINED STANDARD BENEFIT PARAMETERS FOR CONTRACT YEAR 2020



Rebates may or may not affect the net cost used as the performance measure for a risk-sharing arrangement that includes Medicare Part D. If rebates are excluded, the performance measure will not be reflective of the true net plan liability, and plan and provider incentives will likely differ. However, if rebates are included, the resulting performance metric will reflect rebates not just for members attributed to the risk-sharing arrangement, but likely also for other members. That is because manufacturer rebates are often not tracked separately for each member. So, if rebates are included, the performance measure used is influenced by the utilization of all members, not just those attributed to the risk-sharing arrangement.

Plan sponsors often have little or no visibility into rebate arrangements between drug manufacturers and PBMs. Consequently, these arrangements are often completely opaque to providers. Given how much rebates can affect net plan liability, this blind spot can pose a significant risk to providers in a risk-sharing arrangement that incorporates Medicare Part D.

A portion of rebates for Medicare Part D drugs is also retained by the federal government. The proportion of rebates retained by the federal government is yet another financial consideration over which providers have no control and it can have a material impact on the performance metric for a risk-sharing arrangement.

Additionally, the U.S. Department of Health and Human Services (HHS) proposed rule removing the safe harbor for rebates from the federal anti-kickback statute will significantly change the financial structure of Part D, if implemented as proposed.[4] The numerous and unknown changes to the rebate landscape from the proposed regulation, including the possibility that bid projections may be based on incomplete information about the proposed rule, make the inclusion of Part D in Medicare risk-sharing arrangements potentially even more risky for providers in the short term. In the long run, these proposed changes to how rebates are handled in Part D could provide more transparency, thus removing one of the most important barriers to including Part D in a risk-sharing arrangement for MA members.

FEDERAL RISK CORRIDORS PROTECT THE PLAN SPONSOR BUT NOT THE PROVIDER

The Part D program includes risk corridors that protect the plan sponsor from adverse deviation. If a plan's liability for the basic Part D benefit significantly exceeds the estimated liability in its bid, the federal government will share in a portion of the resulting loss. Conversely, if a plan's liability for the basic Part D benefit is lower than the estimated liability in the bid, the federal government will share in a portion of the resulting gain. The risk corridor settlement is calculated after allowing for any risk-sharing settlement with providers. Thus, providers are not able to get the benefit of the risk corridor.

The risk corridor offers significant risk protection for the plan sponsor in the event of adverse deviation from bids. This has been particularly important for plan sponsors in the past, for example when high-cost medications for hepatitis C were introduced to the market and the actual cost may not have been fully accounted for in a bid. Risk corridors create an asymmetry of risk for plan sponsor and provider, which can work to the detriment of providers in risk-sharing arrangements.

PART D DATA CAN BE DIFFICULT TO MINE

There are numerous operational hurdles to overcome, one of which is related to claims data. Plan sponsors or PBMs receive regular feeds of prescription drug event (PDE) claims data from CMS. These files are complex and require significant amounts of summarizing and processing before they can be used. Once in possession of processed PDE data for members attributed to the risk-sharing arrangement, there would still be significant work to be done to determine what benefit phase each member is in (due to the complex nature of the Part D benefit), which would affect the plan sponsor's liability for the next prescription. This makes it difficult to project how the next prescription will affect the performance against the target in the risk-sharing arrangement, aside from the problems with rebates already mentioned above.

Additionally, due to the complexities of the Part D benefit, benchmarks for Part D in terms of net plan liability are difficult to come by, especially when compared to medical benchmarks. For Part D, medication adherence and generic dispensing rate are commonly used efficiency metrics, but won't necessarily give a provider "low hanging fruit" for identifying problems the way medical benchmarks do (e.g., readmissions).

CAN PROVIDERS MITIGATE RISK BY CHANGING PRESCRIBING PATTERNS?

There may be less ability for providers to influence costs due to generic dispensing rates (GDR) potentially reaching maximum attainable levels. Overall generic dispensing rates are reaching upwards of 90%. The remaining utilization in brands has limited opportunity to be converted to generics. Certain drug classes have historically had greater potential for cost reductions and optimization of prescribing due to patent loss of brand-name drugs. The number of classes with patent loss opportunity is decreasing over time as highly utilized drugs have increasingly faced generic competition. This leaves providers few, if any, classes they can truly influence with prescribing patterns.

4 For more information on this proposed rule, see http://us.milliman.com/insight/2019/Changing-the-rebate-game-A-primer-on-the-HHS-proposed-rule-to-shift-drug-rebates-to-POS/.

A provider may focus efforts on prescribing only low-cost generic medications rather than higher-cost branded drugs. Given the current financial incentives in place as mentioned above for high-cost branded drugs with high manufacturer rebates (which may lead to negative marginal plan liability), a provider could increase average net plan liability per member per month (PMPM) by prescribing generic medications.

Additionally, Part D formularies designate what medications are (or are not) covered, including clinical management programs, step therapies, and prior authorizations. These clinical management programs provide another layer of influence already accounted for within the Part D pharmacy costs that would form the baseline period for a risk-sharing arrangement.

A well-managed population would also likely observe higher rates of prescription adherence, which could actually increase pharmacy costs. A provider would need to be sure that medical cost savings would partially, if not completely, offset these increased pharmacy costs.

Lastly, the conflicting financial incentives could in theory lead to circumstances where the patient's treatment risks are dictated by the patient's insurance. In other words, in a Part D risk-sharing arrangement, the best treatment from a clinical perspective might differ from the best treatment from a financial perspective. This is clearly an uncomfortable and unacceptable position for a provider to be in. A provider's management of a patient is, and should always be, dictated by the best form of treatment for the patient.

What are the viable alternatives?

Some provider organizations may feel comfortable taking on Part D risk. Providers who are able to obtain deeper insight into the payer's strategy around key risk components, such as formulary, rebates, discounts, and bid pricing assumptions, may attain sufficient levels of comfort with the financial risk. The likelihood of success for both provider and payer is greater when both parties collaborate and readily share information. A provider may also be more comfortable taking on Part D risk if it perceives that the likely opportunity in Part C, or the contract as a whole, is more than sufficient to offset the potential risk in Part D. For example, a provider may believe the potential increased Part D cost from improved medication adherence is more than offset by reduced Part C costs. Market dynamics, competitive positioning, contracting strategy, population health management initiatives around Part D, and other factors may also drive a provider's decision to take on Part D risk.

However, it will not be the optimal strategy for all providers. In many situations, we see Part D carved out completely (i.e., no upside savings and no downside risk). That said, if the provider's desire is to exclude Part D risk, but Part D cannot be negotiated fully out of the arrangement, it is important that the arrangement is structured so that providers are incentivized to manage Part D utilization and cost without passing on undue and potentially unmanageable Part D risk. Common viable alternatives include:

1. Many arrangements include Part D as shared savings only (i.e., no downside risk). From the MA plan's perspective, a financial incentive remains for providers to manage Part D costs. If a plan sponsor strongly believes the upside opportunity is significant—and more likely than any downside risk—then why not offer a carrot in place of the stick? In these upside-only Part D arrangements it is important to have Part D settled separately from Part C in the final calculation, to avoid a significant Part D loss offsetting gains on Part C.
2. Where downside risk in Part D is included in the arrangement, it is typical to include downside risk caps (i.e., maximum losses the provider will sustain in the Part D arrangement). Even with caps in place, we still recommend settling Part D separately from Part C in the final settlement calculation.
3. Most arrangements still incentivize providers to succeed in the Part D star ratings metrics. Consequently, it is customary to see certain Part D metrics—particularly those related to medication adherence—included in any quality incentive payments within the value-based arrangement. Succeeding on these metrics often also translates to improved efficiency (i.e., lower Part C costs, but higher Part D costs). While not a star ratings metric, we also commonly see a generic dispensing rate target included as an efficiency measure.

Taking on Part D risk needs to be an informed decision

As with any value-based arrangement, there is no one-size-fits-all approach to Part D risk. The individual circumstances of healthcare providers and MA organizations will determine whether it is appropriate to incorporate Part D into a risk-sharing arrangement, as well as the appropriateness of specific contractual details. However, a provider should only enter into a risk-sharing arrangement incorporating Part D after careful consideration of the details of the arrangement, its advantages and disadvantages. Therefore, we strongly recommend provider organizations seek advice before taking on risk in Part D.

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