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January 16, 2018

VIA ELECTRONIC SUBMISSION TO www.regulations.gov

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Centers for Medicare & Medicaid Services
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Re: CMS-4182-P/CMS-4182-CN: Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2019

To Whom It May Concern:

Cigna welcomes the opportunity to respond to the proposed rule “Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2019” (CMS-4182-P and CMS-4182-CN). We appreciate the Centers for Medicare & Medicaid Services’ (CMS or the agency) efforts to improve the Medicare Advantage (MA) and Part D programs for beneficiaries, increase flexibility for plans to better target needed services and benefits in order to improve health care quality, outcomes, and value for our members, and reduce the regulatory burdens on plan sponsors so that resources and focus can be redirected to patient care.

Cigna Corporation, together with its subsidiaries (either individually or collectively referred to as Cigna), is a global health services organization dedicated to helping people improve their health, well-being and sense of security. Our subsidiaries are major providers of medical, dental, disability, life and accident insurance and related products and services. Worldwide, we offer peace of mind and a sense of security to our customers seeking protection for themselves and their families at critical points in their lives.

Cigna serves approximately 1.5 million people through our MA, Medicare Prescription Drug Program and Medicare Supplemental products. Our focus on this market has allowed us to develop a unique approach to health care coverage. We have a deep understanding of the needs and challenges facing both patients and physicians, and thus have developed an evolving collaborative model that provides greater access to high quality preventive care for our customers while offering physicians what they need to deliver that care.

Cigna supports the majority of provisions in the proposed rule. In this comment letter we identify those provisions about which we have concerns or do not believe would be in the best interest of beneficiaries or the Medicare program, and identify areas where greater clarity or additional information, including with regard to timing, will help plans understand CMS’ intent and be ready to implement final provisions as needed.

Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions

CMS offers proposals to meet requirements under the Comprehensive Addiction and Recovery Act of 2016 (CARA), which requires Part D plan sponsors to establish processes that will “lock in” a member to a single pharmacy and/or prescriber in cases where the member has been identified as being at high risk of misuse or abuse of certain prescription medications including opioids.

Cigna is committed to helping solve the opioid crisis. We have an initiative underway to reduce our customers’ opioid use by 25 percent by 2019, while ensuring that those at greatest risk of death due to opioids get the care they need. With that commitment in mind, we support the proposed implementation of CARA lock-in requirements, though we have concerns that several of the proposed timeframes would reduce the effectiveness of the lock-in program and cause beneficiaries to remain at risk of harm. We also offer suggestions for improving the process, including:

- **Integrating the drug management provisions of CARA with the current Drug Utilization Review (DUR) and Overutilization Monitoring System (OMS) policy:** Cigna supports the integration of lock-in with OMS. CMS has indicated that OMS has been successful since its inception and we would encourage building on an existing program that has decreased opioid use rather than creating a separate program that would require additional oversight and add administrative burden for plan sponsors.
- **List of frequently abused drugs:** Cigna recommends that CMS limit the Part D lock-in program to opioids for the first year of the program. We encourage the agency to take a step-wise approach when developing the Part D lock-in program, especially in regard to drugs impacted and eligibility for lock-in. We support the regulations that allow for all controlled substances to be considered and believe that the annual Call Letter process is the best way to identify the type of drugs to be included on the frequently abused drugs (FAD) list. We believe that opioid management is still relatively new and that plan sponsors are continuing to identify best practices. We ask that CMS allow for flexibility in identifying at-risk beneficiaries over time.
- **Clinical guidelines:** We support CMS’ proposed use of clinical guidelines as described in the proposed rule. The criteria align with recommendations from the Centers for Disease Control and Prevention (CDC) and would identify a reasonable number of beneficiaries at potential risk at the program’s start. We encourage a step-wise approach when developing the Part D lock-in program. Requiring plans to have aligned eligibility criteria as defined in the Call Letter each year will minimize customer and provider confusion, as well as administrative (operational) burden when submitting and receiving OMS quarterly reports.
- **Chain pharmacies and group practices:** Cigna asks that CMS offer health plans flexibility in how they count prescribers and/or pharmacies for enrollment into drug utilization programs. We are unable to identify chain pharmacies as a single entity in the adjudication system, as each individual pharmacy is registered with a separate National Provider Identification number. To accomplish grouping pharmacies we recommend an industry-wide solution be explored, which would also ensure the pharmacy chains are able to manage the newly-developed regulations across store locations.

- **Identifying at-risk and exempted beneficiaries:** Cigna recommends a uniform approach for identifying beneficiaries at risk and any exemptions from the lock-in program at its inception. We agree that beneficiaries in long-term care and hospice facilities should be excluded, as residents of these facilities are often contracted with a single pharmacy, and existing care coordination services within the facilities reduce the risk of inappropriate medication use. We support excluding beneficiaries receiving palliative and end of life care as well. However, we seek further clarification of how CMS expects plan sponsors to identify these enrollees proactively. We are concerned with the timeliness of plans receiving information that a beneficiary is receiving palliative and end of life care. We suggest that the program address plan requirements if retroactive notification is received by the plan sponsor. Additionally, we support exclusion for beneficiaries with an active cancer diagnosis.
- **Prescriber agreement and verification:** We support a prescriber agreement prior to implementing the prescriber lock-in provision. However, we recommend that if a prescriber fails to respond to a plan communication in a timely manner or does not agree with enrollment into a drug utilization program despite supporting data that indicates the beneficiary is potentially engaged in overutilization behavior, we believe plans should be permitted to take action in order to protect the health of the beneficiary and the integrity of the Part D benefit. Additionally, we support plan efforts to coordinate with all prescribers for a given beneficiary but reaching each prescriber and receiving consent that all agree will likely take an extended period of time and be administratively burdensome, especially if a prescriber is not responsive. Therefore, we support allowing plans to receive a prescriber agreement with at least one prescriber prior to the prescriber lock-in taking effect.
- **Written notices and timelines:** Cigna believes that the proposed six-month waiting period for implementing lock-in for a beneficiary identified as being at risk for substance abuse or misuse via OMS is too long, and would expose beneficiaries to continued risk of harm. We believe that once the notification requirements and timelines outlined in the rule have been carried out, the plan should be free to implement lock-in so as to reduce the risk of harm to an at-risk member. We also encourage CMS to allow plans some flexibility to coordinate with the prescriber so that a lock-in can be implemented safely and effectively for an individual member. This would include allowances for situations where a member moves while they are under lock-in and requires a new prescriber or pharmacy location. Finally, in cases where there is documented evidence of egregious and potentially dangerous overutilization and in cases involving an active criminal investigation, Cigna supports an exemption to the 30-day notification timeline.
- **Appeals process:** Cigna supports using the existing appeals process, as proposed. Additionally, we recognize that lock-in provisions have the potential to lead to an increase in customer grievances and complaints. We recommend that complaints that result from being in the Part D lock-in program be excluded from the Complaint Tracking Module measurement that is included in plan Star ratings as the intent is to reduce harm to an at-risk beneficiary.
- **Termination of at-risk status:** Cigna does not support automatically terminating a beneficiary's at-risk determination and the lock-in after 12 months. If the drug management program is offering benefit to the beneficiary without increasing the burden to the beneficiary, plan sponsor, prescriber or pharmacy we recommend not enforcing a maximum enrollment period. We suggest that CMS offer flexibility to

plan sponsors to collaborate with prescribers and/or pharmacies to assess enrollment after 12 months but that plan sponsors be allowed to extend enrollment beyond the 12-month period.

Flexibility in the Medicare Advantage Uniformity Requirements

CMS proposes to permit MA organizations to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, as long as similarly situated enrollees are treated the same and CMS determines that the plan design is not discriminatory.

Cigna supports the proposed flexibility, but has several questions about how CMS would implement the provision if finalized:

- Will CMS define the permitted therapeutic conditions that can be offered additional benefits, or will plans have flexibility in identifying the conditions and associated benefits to be available?
- How will requirements criteria (i.e., definition of a diabetic member) be determined? If plans are free to set their own definitions, there may not be uniformity across MA organizations (MAOs), leading to beneficiary confusion or perceptions of discrimination.
- Will there be any reporting requirements for this change in uniformity, such as the reporting requirements under the value based insurance design demonstration?
- Through our experience with employer health coverage, customer engagement can have a very positive impact on a beneficiary's behaviors around prevention and high risk conditions. Will plans be allowed to establish annual incentives linked to specific medical criteria to encourage beneficiaries to engage in their healthcare – for example, if a diabetic customer achieves targeted blood sugar levels, sees an endocrinologist quarterly, and/or is compliant with diabetic medications?
- How will information on tailored benefits be reflected in member materials such as the annual Evidence of Coverage (EOC) and Summary of Benefits (SOB) documents? Can specific therapeutic programs be included in the same EOC or SOB? For example, could a single SOB identify different primary care provider (PCP) copays as: PCP copay - \$10 Non-diabetic member, \$0 Diabetic member?
- Will marketing of this program be permitted pre-sale? We would encourage CMS to allow plan sponsors to communicate the availability of such programs to ensure consistent awareness between new and existing members, and to avoid member frustration if an incentive program changes in a subsequent year without being communicated to members during opportunities for re-enrollment.

Segment Benefits Flexibility

CMS proposes to permit MA plans to vary supplemental benefits, in addition to current law flexibility for premium and cost-sharing, by segment within a plan's service area, as long as the benefits, premiums, and cost-sharing are uniform within the segment.

Cigna fully supports the proposed flexibility to vary supplemental benefits by segment. We believe this flexibility will make additional benefits available to more beneficiaries and enhance the value of MA for members. We raise several questions for CMS to consider as the provision is finalized:

- Are there any restrictions to the benefits that may vary? Are all supplemental benefits and services eligible or is this specific to a set of supplemental benefits?
- Is the maximum out-of-pocket (MOOP) amount one of the elements that may vary?

- Are both medical and prescription drug benefits included in the services that may vary by segment?
- May one benefit/service be offered in a specific segment, but not in other segments?

Meaningful Differences in MA Bid Submissions and Bid Review

CMS proposes to eliminate the meaningful difference requirement beginning with MA bid submissions for the 2019 plan year. Cigna supports the proposed elimination of meaningful difference requirements. We believe this will lead to more affordable options for beneficiaries and encourage greater competition among plans to design offerings that meet the needs of beneficiaries.

Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage

CMS proposes to codify the seamless conversion rules and establish new limits on use of seamless conversion, limiting its use to dual-eligible beneficiaries, who could be seamlessly converted only into D-SNPs under certain conditions. CMS also proposes to establish a simplified opt-in election process that would be available to all MAOs for purposes of converting eligible enrollees from existing non-Medicare coverage to MA coverage offered by the same organization.

While Cigna supports the codification of seamless conversion rules, we do not support the proposal to allow the use of seamless conversion only for dual-eligible beneficiaries who are enrolled in an affiliated Medicaid managed care plan. Allowing dual-eligible beneficiaries to be passively enrolled in D-SNPs that are affiliated with Medicaid managed care plans will lead to reduced competition and fewer D-SNPs offerings for beneficiaries, resulting in higher costs and fewer benefits over time. Dual-eligible members (and the state Medicaid programs that support them) benefit most from the vigorous competition that is the hallmark of the MA program, in the form of greater supplemental benefits and services along with lower cost sharing and premiums. Reducing that competition will reduce the value MA offers to these vulnerable beneficiaries, which we believe is preserved by allowing beneficiaries to proactively elect the benefit plan most appropriate for their health care needs. We also know that communication with dual-eligible members can be challenging, making it difficult to ensure that the beneficiary has received sufficient notice of the enrollment decisions that could have significant consequences for their care.

While we support efforts to improve care for dual-eligible beneficiaries, Cigna strongly urges CMS not to finalize the proposed seamless conversion rules for dual-eligible beneficiaries, because we do not believe this benefit would be consistently realized and believe the unintended consequences far outweigh any potential benefits. Instead, we recommend that CMS develop a simplified enrollment process that would apply to all beneficiaries transitioning from existing group coverage – commercial, individual, or Medicaid managed care – into MA coverage with the same organization. Continuity of coverage is important for all beneficiaries, and all should have access to simplified enrollment.

Further, our analysis of 2018 Star ratings shows numerous geographic regions where D-SNPs managed independently of a Medicaid managed care plan have higher Star ratings than D-SNPs managed by Medicaid managed care plan affiliates. For instance, in Southeast Pennsylvania there are nine plans that offer D-SNPs with higher Star ratings than the plan linked to one of the three Medicaid managed care plans selected to participate in Pennsylvania's Community HealthChoices Program. In Tennessee, there are four plans offering a D-SNP

independently of any Medicaid managed care plan with higher Star Ratings than the plan affiliated with a Tennessee managed Medicaid plan. As these examples show, D-SNPs affiliated with Medicaid managed care plans may not offer the best clinical quality or beneficiary satisfaction. It cannot be in the best interests of Medicare beneficiaries or the Medicare program to force enrollment into lower quality plans or to push higher quality plans from the market.

In the proposed rule, CMS identifies the issue of ensuring equal access for Medicare beneficiaries who become eligible due to age versus those who become eligible due to disability. It is more difficult to predict in advance when a person will become eligible due to disability than for age. Cigna agrees that this would make a simplified enrollment process more difficult to implement for disabled beneficiaries. We would urge CMS to develop a process that works for aged beneficiaries and use lessons from its implementation to inform development of the process for disabled beneficiaries. A simplified enrollment process also needs to account for differences in geographic footprints between pre-Medicare and MA plans. Differences in geographic footprint that result in beneficiaries in some areas having access to simplified enrollment while beneficiaries in other areas do not have such access could be viewed as discriminatory. Overall, CMS should develop a simplified enrollment process that recognizes variation in different types of coverage.

Passive Enrollment Flexibilities to Protect Continuity of Integrated Care for Dually Eligible Beneficiaries

CMS proposes new authority for the agency to passively enroll full-benefit dual-eligible beneficiaries who are currently enrolled in an integrated D-SNP into another integrated D-SNP in certain situations.

The same concerns noted above with regard to the proposed new seamless conversion rules for dual-eligible beneficiaries apply to the proposed passive enrollment provisions. Cigna strongly opposes CMS' proposed new authority to passively enroll beneficiaries in selected MA plans. The hallmark of the MA program, and the basis of the tremendous value it offers to beneficiaries and the Medicare program, is vigorous competition and the ability of beneficiaries to choose among plans on the basis of benefit design and cost. Replacing beneficiary choice with CMS' assessment of what is 'best' for an individual threatens to erode the role of competition as a means of driving greater quality and value in the program.

Further, it is inappropriate for CMS to ignore the choices beneficiaries have already made by moving members who are already enrolled in an MA plan and have not expressed dissatisfaction with their current enrollment. CMS has considerable evidence from the financial alignment demonstration program that making enrollment decisions on behalf of dual-eligibles contributes to member confusion, and is likely to cause greater disruptions in care, which is clearly not the outcome CMS intends.

In looking for ways to improve integration and care coordination for dual-eligibles, we urge CMS to focus on the majority of individuals who are not enrolled in MA at all, but remain in the fee-for-service Medicare program with no access to the care management and coordination that MA offers.

Part D Tiering Exceptions

CMS proposes several clarifications to guidance on the process for approving Part D tiering exceptions, including specifying how tiering exceptions for brand or biologic products and generic drugs should be considered and approved.

Cigna appreciates CMS' effort to clarify the standards and process for approving tiering exceptions. The proposed language clarifies several areas of ambiguity and serves to streamline the overall process. In particular, we find the language under "Alternative Drugs for the Treatment of the Enrollee's Condition" to be helpful, allowing for some degree of appropriate clinical judgement. We believe, however, it would be helpful if this were formally codified in the guidance, perhaps with examples. We foresee difficulty across all plan sponsor reviews to maintain consistency in defining just how broadly this might apply.

Utilizing drug categories (generic, branded, or biologic) to help define applicable comparators is likewise a useful proposal. However, we are particularly concerned with the proposal to allow exceptions to the "lowest applicable tier", rather than the next lowest tier. The proposed language would allow high-cost Tier 4 generic products to potentially be provided with a Tier 1 cost-share, rather than a more limited reduction of one-tier level. As CMS is no doubt aware, the price of many generic products has risen dramatically in recent years, with a number of egregiously-priced generic medications. This in turn undermines formulary and benefit design.

This change CMS is proposing would result in significant disruption to formulary integrity, a hallmark of the Medicare Part D program, and would make it more difficult to design formularies that provide access to members and efficiency to the program. Additionally, we believe there will be several downsides to this proposal:

- To maintain benefit design, plans may be incentivized to remove many generic medications from formulary as approved non-formulary exceptions are exempt from tiering exceptions, resulting in even higher cost-sharing for many beneficiaries.
- Generic drug manufacturers will have less incentive to market at competitive prices, knowing that many members will pay lower cost-sharing via the tier exception process, regardless of ultimate plan sponsor formulary tier placement.
- While individual beneficiaries may see lower cost-sharing for specific drugs, all beneficiaries will see higher premiums that result from the consequences described above.

In summary, there is much in the proposed language that will improve the process for both members and plan sponsors. We agree with comparing brand-to-brand, generic-to-generic, and biologic-to-biologic. However, we ask CMS to consider modifying the tier exception from "lowest applicable tier" to the "next lower tier, if applicable." This would allow the possibility of reduction in cost-sharing for affected members, while maintaining the savings to all members that the Part D program now offers.

CMS notes that it is not proposing to change the definition of specialty tier, which will still be based on cost and still ensures "that very high cost drugs remain accessible to enrollees at cost-sharing equivalent to the defined standard benefit."

However, if specialty tier cost-sharing is more preferable than another tier, then CMS proposes to clarify that a drug on that non-preferred tier is eligible for specialty tier cost-sharing if an alternative drug is on the specialty tier. While in theory we understand what CMS is seeking to accomplish here, we believe that executing this will be extremely problematic for plan sponsors. For example, for non-preferred brand tiers, some plans apply a coinsurance and others apply a copayment. A plan would need to determine whether the alternative drug in the specialty tier is a brand, generic, or biologic and then figure out the difference between the coinsurance and copayment. Traditionally, the lower the tier, the lower the cost, whether the cost is determined as coinsurance

or a copayment. But when a specialty tier is added to the tiers being considered, determining the appropriate beneficiary payment becomes much more complicated, as it is no longer a simple calculation and will be very administratively burdensome. Given CMS's stated intent to streamline the tiering exceptions process, we suggest that CMS not to make this proposed change now.

Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries

CMS proposes to change the current rules allowing a continuous special enrollment period (SEP) for dually-eligible enrollees to a more limited opportunity to change plans.

Cigna supports the proposed changes. The more limited SEP provisions will maintain protections for dual-eligibles while promoting continuity of care.

MA and Part D Prescription Drug Plan Quality Rating System

CMS proposes a number of changes to the MA and Part D Stars quality rating system, including the codification of core elements of the methods and rules around measures and ratings, establishing standards for removing existing measures, introducing new measures, and implementing changes to existing measures. CMS also proposes changes to the way that Star ratings are calculated for consolidated contracts.

Cigna supports many of the proposed definitions and standards, and appreciates CMS' efforts to bring greater transparency and accountability to the Stars program. The establishment of valid and reliable measures of plan performance offers beneficiaries valuable information on which to compare plans and understand the value that the MA program offers. In particular, we welcome the proposed regulatory definitions and standards, which will offer greater certainty to plans as they work to improve performance and deliver ever-higher quality to their members. Cigna also supports CMS proposed rules for adding, updating, and removing measures, including the proposal to announce new measures in advance of the measurement period and through the proposed rulemaking process.

We disagree, however, with the assertions in the preamble that rulemaking is not required for the Stars program. The Stars program plays a key role in determining the amount of funding that MA plans receive, which in turn influences the type and amount of supplemental benefits that can be provided to enrollees. The rules governing the Stars program establish substantive legal standards with significant real-world consequences and must be established through notice and comment under both the Administrative Procedure Act (APA) and the Medicare statute. While it is true that quality bonus payments modify the benchmarks that CMS must establish each year, we do not think it is accurate for CMS to contend that the Stars program can be subsumed within the agency's processes for setting benchmarks and capitation rates.

In the remainder of this section, we comment on specific components of the proposals around Stars:

- **Survey of physician experiences:** CMS is considering the development of a survey tool for collecting standardized information on physician experiences with health and drug plans and adding these measures to the Star Rating System.

Cigna strongly disagrees with this approach. First, consistent with CMS principles guiding the Stars program, the goal and the focus should remain on improving the quality of care for Medicare beneficiaries, and there is no direct correlation proven to exist between beneficiary quality of care and physician experience with health plan. Second, CMS already collects information on the physician experience through several measures in the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey, including the Getting Needed Care, Getting Appointments and Care Quickly and Care Coordination measures. Third, the turn-over in contracting physicians may add complexity and bias to the survey results. Finally, an additional survey would add more cost and administrative burden to plans and to CMS.

Cigna strongly recommends that CMS remain focused on the quality of care received by the beneficiary as the ultimate consumer of Medicare and not get involved in the provider-health plan relationship. We do not support the addition of a physician survey to the Star Rating System.

- **Technology-based measures:** CMS has requested stakeholder feedback specific to the addition of “measures that evaluate quality from the perspective of adopting new technology (for example, the percent of beneficiaries enrolled through online brokers or the use of telemedicine) or improving the ease, simplicity, and satisfaction of the beneficiary experience in a plan.”

Cigna is generally supportive of efforts to advance the use of technology to improve beneficiary experience and health outcomes – especially as a higher rate of tech-savvy individuals continue to age into Medicare. At the same time, we urge the agency to be patient and use caution in the development of such measures. In order to be successful, the agency must allow adequate time for MAOs to adopt required technology and for enrollees to become accustomed to using such technology. Current Medicare Marketing Guidelines, such as the requirement that MAOs obtain an opt-in agreement from beneficiaries prior to communicating through platforms such as email, text messaging, or social media, limit the use of technology to communicate with beneficiaries. As such, it will take time for stakeholders to adapt to the use of technology. Further, it is imperative for the agency to recognize and account for different plan populations with varying levels of access to and comfort with the use of technology. Beneficiaries with lower socio-economic status or older members may not find it as easy or convenient to use technology to engage with their health plan as more affluent beneficiaries. To the extent that some plans serve a disproportionate share of low-income members (for example, Part D plans with a large share of LIS enrollees or MA contracts with a large share of D-SNP enrollees), or older members, CMS should ensure that they are not disadvantaged in technology-based measure ratings.

In its development of technology-based measures, we also ask CMS to ensure that the measures are reasonable. If measure performance for all contracts cannot be easily validated, the integrity of the measure and impact to a contract’s overall Star rating could be questionable.

- **Contract ratings:** CMS proposes to continue the practice of calculating the Star ratings at the contract level, with all plan benefit packages (PBPs) under the contract being assigned the same rating. Cigna supports this proposal and agrees with CMS’ assessment that the administrative burden and data issues related to the size of PBPs outweigh the benefits of PBP-level Star ratings.

Specific to CAHPS, achieving the minimum survey response and reliability requirements necessary to

receive a Star rating is at times challenging at the contract level. Meeting the current minimum requirements at the PBP level would be even more challenging due to lower enrollment volume, resulting in many plans not receiving a Star rating for CAHPS measures.

CMS has also requested comments and suggestions about “requiring reporting at different levels (for example parent organization, contract, plan, or geographic area).” Specifically, CMS discusses exploring “market area reporting when a contract covers a large geographic area.” Cigna is concerned that this practice may encourage MAOs to abandon geographic areas with more vulnerable and higher-need populations that tend to result in lower Star ratings. As such, Cigna recommends not pursuing market area reporting in order to avoid limiting health care options for higher-need populations.

- **Contract consolidations:** CMS is proposing a change in how contract-level Star ratings are assigned in the case of contract consolidations. CMS states “there has been a continued increase in the number of enrollees being moved from lower Star rating contracts that do not receive a QBP to higher Star rating contracts that do receive a QBP as part of contract consolidations.” CMS further states it is “worried that this practice results in masking low quality plans under higher rated surviving contracts” and that “this does not provide beneficiaries with accurate and reliable information for enrollment decisions.”

Cigna is concerned CMS’s proposed changes to how contract-level Star ratings are assigned in the case of contract consolidations will actually have an adverse impact on beneficiaries by limiting the marketplace to already consolidated plans and limiting beneficiary options to enroll in plans with richer benefits. We believe this will result in decreased beneficiary satisfaction and poorer health outcomes in cases where beneficiaries would be dependent on richer benefits to obtain the care they need – especially impacting lower income beneficiaries. Contrary to CMS’ belief that current contract consolidation practices result in “masking low quality plans under higher rated surviving contracts”, Cigna believes that current rules actually create a sustainable platform for MAOs to move beneficiaries into higher performing plans with stronger benefits that lead to improved access to care, beneficiary satisfaction, and health outcomes. In cases where contract consolidation is used with ill intent to mask low quality plans under higher rated surviving contracts, that intent will be reflected in future Star ratings as new ratings for the surviving contracts reflect the full contract population.

Cigna recommends the Star rating assigned in instances of contract consolidation be based solely on the performance of the surviving contract until post consolidation performance data is available for inclusion in the Star rating. For instance, if a contract consolidation occurs effective January 1, 2018, the first reflection of the consolidated contract(s) in the surviving contract Star rating should be based on 2018 performance data. As an example, HEDIS results for the newly consolidated contract in the 2018 performance year should be reported in 2019 and reflected in the 2020 Star ratings.

If CMS feels additional controls are needed to prevent MAOs from using contract consolidation to “mask low quality plans under higher rated surviving contracts”, we suggest CMS explore controls around frequency of consolidation or dissolution involving a particular contract.

A second concern around the proposed change to the calculation of Star ratings in cases of contract consolidation involves the timing. While it seems clear from the language in the preamble that CMS intends for this provision to take effect on the same timetable as other proposed changes to the Star rating system – beginning with the 2019 measurement year and the 2021 Star ratings – information

provided in the impact analysis section of the rule suggests that CMS may intend for this change to take effect beginning with the 2019 plan year, based on a recalculation of 2018 ratings.

Should CMS go ahead with the proposed change to the treatment of Star ratings in cases of contract consolidation, we strongly urge that the changes not take effect for the 2019 plan year, but be implemented on the same schedule as other changes to the Star Rating System. To do otherwise would be to violate the principle of transparency that CMS lays out at the start of the Stars section of the proposed rule. Plans that make decisions around contract consolidation in anticipation of the 2019 plan year should be able to rely on a set of rules that will not change after the fact. MAOs will need to notify CMS of any planned contract consolidations for the 2019 plan year by early April 2018. Changing the rules for how contract consolidations are to be treated with regard to Star ratings after MAOs have made business decisions and filed required notifications to CMS would be unfair and run counter to CMS' stated goals of increasing transparency and stability in the Stars program and the MA program more generally.

- **Adding, updating, and removing measures:** CMS proposes to introduce new performance measures to the Star rating calculation as they are developed and adopted. According to the proposed rule, CMS would incorporate the new measures to the display page for at least two years before adding to the official Star rating measurement. This could be longer, should CMS find issues with validity and reliability of such measures. Cigna fully supports the proposed timelines and criteria for introducing new measures. The timeline would allow plans to prepare for implementation of new measures and ensure quality outcomes for their customers.
- **Data integrity:** CMS proposes to “codify specific rules for the reduction of measure ratings when CMS identifies incomplete, inaccurate, or biased data that have an impact on the accuracy, impartiality, or completeness of data used for the impacted measures.” Specifically, CMS proposes a continuation of current policy to reduce measures to 1 Star based on biased data, not reporting, or scoring less than 95 percent on validation audits. CMS further proposes a scaled reduction in Part C and Part D appeals measures ratings for incomplete data or when the agency has concerns about the data based on audits or monitoring activities.

Cigna agrees with CMS that “data underlying a measure score and rating must be complete, accurate, and unbiased for it to be useful.” Cigna also agrees that “data validation is a shared responsibility among CMS, CMS data providers, contractors, and Part C and D sponsors.” However, we are concerned that the proposed policy may be implemented in ways that are unintentionally punitive. For instance, the preamble states that the policy is intended to “reflect[] the underlying *fault* of the sponsoring organization.” Yet, in our experience, CMS sometimes has asserted “data integrity” problems based on highly questionable interpretations of MA program requirements. We therefore recommend the policy be revised to state that data integrity determinations must be based on unambiguous requirements that have been set forth in the Part C or D program regulations, as appropriate.

In addition, we do not share the agency’s belief that excluding an affected measure is insufficient to prevent gamesmanship. Therefore, we encourage the agency to consider a hybrid approach. For example, the agency could exclude the measure if the “earned” score was 4 or 5 stars (to minimize the punitive impact of the data integrity policy), but downgrade the measure to 1 star if the “earned” score

was 3 stars or less (to avoid the possibility of gamesmanship.)

We are also concerned that despite CMS' acknowledgement that data integrity is a shared responsibility, the agency's proposals focus solely on punitive actions to Part C and D sponsors for data issues and neglect to address how CMS will manage its own data responsibilities or those of its contractors. For instance, CMS has previously stated that when the agency or its contractors introduce data integrity problems, the appropriate response is to exclude the affected measures from the star rating calculation. We believe this is a critical aspect of the existing policy that should be continued and added to the regulation.

Specific to Part C and D appeals measures, Cigna has long had concerns with the quality of data and decisions managed by the independent review entity (IRE), on which these measures are based. Cigna has on numerous occasions provided CMS with examples of inaccurate or flawed IRE data. It is clear that CMS shares data integrity concerns associated with Part C and D appeals measures, based on the diligence it has placed on the development of its proposed scaled reduction methodology. In light of these concerns and to CMS' point that "data underlying a measure score and rating must be complete, accurate, and unbiased for it to be useful", Cigna recommends that CMS remove the Part C and D appeals measures from Star ratings until it can adequately address the underlying data integrity issues associated with both the IRE and plans.

- **Measure-level Star ratings:** CMS has requested comments related to proposed methods for determining cut points for specific rating levels. With the elimination of the fixed 4-Star cut points following the 2014 Star ratings, the ability of plans to develop clear, achievable goals has been limited. Cigna recognizes the intent of driving continuous improvement for beneficiaries through the use of the cluster methodology. However, the lack of transparency into national performance throughout the measurement year likely results in inconsistent outcomes for beneficiaries from plan to plan. In order to overcome these obstacles, Cigna recommends that CMS release fixed cut-points for all Star levels prior to each measurement year based on the historical cluster methodology outcomes. The continued use of the 5x weighted Part C and Part D Improvement Metrics ensures that plans have the right incentives to drive continuous quality improvement for members and the program.
- **Measure weights:** CMS is proposing to "continue the current weighting of measures in the Part C and D Star ratings program by assigning the highest weight (5) to improvement measures, followed by outcome and intermediate outcome measures (weight of 3), then by patient experience/complaints and access measures (weight of 1.5), and finally process measures (weight of 1)." Further, CMS is "considering increasing the weight of patient experience/complaints and access measures" and has requested stakeholder feedback.

Cigna is concerned that the current weights do not place enough emphasis on preventive health care metrics, many of which are single weighted process measures. While we are supportive of CMS' desire to put Medicare beneficiaries first, and as an organization strive to deliver an outstanding experience to our customers, we do not agree that a beneficiary's assessment of the care received by plans should be more heavily weighted than the evidence-based clinical care they actually receive. We are concerned that CMS' proposal to further increase the weight of patient experience and access measures further deemphasizes the importance of actual clinical care.

There is still no consensus in the health care industry regarding the relationship between patient experience measures and the quality of delivered care and health outcomes. The inconsistent results of these measures, even within the same health plan year-over-year, are attributable to the general nature of the surveys asking patients to assess all care provided over a six-month experience period, leaving patients to factor in which interactions they prioritize in their evaluations. The timeliness of the survey is also a factor. The CAHPS survey is performed annually and asks patients to evaluate interactions that occurred within the last six months, which can introduce recall inaccuracies and bias.

Cigna recommends that CMS consider giving equal weight to clinical measures and beneficiary experience metrics in the Star ratings. To that end, we do not support CMS increasing the weight of patient experience and access measures, as we feel it minimizes the importance of clinical measures and patient health.

CMS also proposes “assigning new measures to the Star ratings program a weight of 1 for their first year in the Star ratings.” Cigna is fully supportive of this proposal as it will allow plans time to adjust to the measure and better understand national performance under the existing cluster methodology prior to seeing a significant impact to Star ratings.

- **Categorical Adjustment Index (CAI):** CMS proposes to “codify the calculation and use of the reward factor and CAI” while it considers alternatives for the future. The CAI was recently added to the Star ratings in response to concerns raised by plans about disparities in the ratings based on the population served. Additional work is ongoing. As CMS notes, various entities including the National Committee on Quality Assurance (NCQA) and the Pharmacy Quality Alliance (PQA) are engaged in efforts to better account for the role that socio-economic status (SES) plays in beneficiary health and health outcomes, and the resulting impact on quality measurement. The Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE) is examining the impact of SES on the Stars Rating System and other performance measurement systems in Medicare.

Cigna is supportive and appreciative of the work CMS is doing with NCQA and PQA to examine measure specifications used in the Star ratings to determine if re-specification is warranted, and supports the work in which ASPE as well as other external entities are engaged. We are concerned that by codifying the existing CAI methodology, implementation of any additional changes to Stars resulting from these efforts would be slowed. We suggest that CMS not codify the CAI until additional work that better specifies the impact of SES on Star ratings is completed and appropriate methods for accounting for SES are developed.

The CAI is intended to adjust for differences in the populations served by different plans and to reduce the bias in the Star Rating System attributable to disparities in the share of low-income beneficiaries. Cigna continues to believe that the current CAI does not adequately account for the disparity. In 2017, the CAI had very little impact on the ratings of plans with disproportionate shares of low-income beneficiaries. Making matters worse, CMS reduced the number of measures included in the index for 2018. Moreover, the decision to base the index only on those measures where the dual-eligible/low-income subsidy eligible (LIS) population performed better than the non-LIS population by five percent or more is wholly arbitrary, especially given that this percentage exceeds the difference between a rating

threshold for some metrics.

More generally, Cigna is disappointed that CMS has not acted sooner on the results of the report released in late 2016 by the ASPE. That ASPE report found that beneficiaries with low SES have poorer quality outcomes, and that those outcomes are not the result of lower plan quality. The report also found that the best indicator of poorer outcomes is dual status. Managing this population consumes more financial and administrative resources because of the distinct model of care that is required by CMS. Without plans that choose to serve this population, their options for quality care are highly limited.

Based on the ASPE report, Cigna believed that CMS would expand the adjustments made to account for serving low-income beneficiaries in 2018. Instead, CMS scaled back the index and the adjustments. Until ASPE completes additional studies mandated by Congress and CMS incorporates any recommendations into the Star rating program, Cigna recommends that rather than codify the existing CAI methodology, CMS immediately increase the adjustment to Star ratings to account for disparities in ratings that result from serving a disproportionate share of low-income beneficiaries for the 2019 Star rating year and beyond. Those disparities should be based on observed differences in outcomes and ratings both within and across contracts based on the populations served.

In addition, closing gaps in care for low-income beneficiaries requires a larger amount of administrative resources than for non-low-income beneficiaries. Cigna's experience is that it is much more difficult to contact and engage low-income beneficiaries when attempting to address their care needs. Medicare Advantage plans that currently receive quality bonus payments can use these additional resources to help them close these gaps in care, and thus this artificially and systematically deflates the average measureable difference in Star measures between low-income and non-low-income beneficiaries. For this reason, CMS should also investigate this external effect on the CAI adjustments and determine whether the CAI should be calculated and applied separately for contracts receiving a quality bonus payment and those that do not.

- **Plan preview of Star ratings:** CMS proposes to continue offering plan preview periods, but not to codify the details of each period since the process and data continue to evolve. CMS also states the importance of Part C and D sponsors regularly reviewing their underlying measure data and raising issues in advance of plan preview.

Cigna recognizes the evolving nature of the plan preview process and agrees with CMS' decision not to codify the details at this time. Cigna is also in agreement with CMS on the importance of regularly reviewing underlying measure data and when possible, raising issues in advance of plan preview. We do not believe that this waives a sponsor's right to raise issues or problems during the plan preview period.

Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types

CMS proposes definitions for different types of pharmacies, including mail order and retail pharmacies along with requirements around the provision of terms and conditions to pharmacies requesting to be in a plan's network.

Cigna supports the proposed definitions for retail and mail order pharmacies. We note that it is common for pharmacies to be contracted for multiple types of practice such as: retail and home infusion; retail and long-term care (LTC); or retail and specialty pharmacy. We request that the definition also include what the expectation is, possibly a percentage of claims filled in one setting. It is common practice for retail pharmacies to mail a small number of prescriptions as part of their normal course of business, such as to a home bound beneficiary or when a beneficiary is traveling. We would support a threshold to define when mail is a large portion of their business. Additionally, we are aware of some business models that involve convenient packaging that ship one-month supplies at a time. Therefore, we recommend also defining extended day supply, because some pharmacies that mail all prescriptions may do so at frequencies other than three months in order to minimize waste.

Regarding specialty pharmacies, Cigna urges CMS to allow plans the freedom to select specialty pharmacies for management of complex disease states requiring use of high touch specialty medications. Specialty pharmacies play a critical role in helping patients understand and use specialty medications, and plans must be free to contract with only those specialty pharmacies that deliver high-quality patient care and service. While Cigna understands that the ability of a pharmacy to dispense medications for specific disease states should not be a condition for inclusion (or reason for exclusion) in a health plan's pharmacy network, Cigna urges CMS to allow plan sponsors autonomy in selection of quality pharmacies as designated condition-based specialty pharmacies within their networks.

Specialty pharmacies possess the resources and infrastructure that equip them to handle the advanced clinical support and monitoring necessary for complex disease states such as multiple sclerosis, rheumatoid arthritis, cancer and other immunologic conditions. Medicare beneficiaries with serious conditions such as these require specialized and targeted therapies, often in the form of injectable medications that necessitate frequent patient outreach and support for training; clinical monitoring by qualified pharmacists and nurses for safety and effectiveness; collaboration with providers to optimize therapy; case management referral and adherence counseling. In our experience, not every pharmacy in the network would be able to appropriately manage specialty medications utilized by the Medicare population. The designation of specialty pharmacies as preferred providers within the network to manage complex disease states will ensure that beneficiaries are provided with the clinical services and safeguards necessary to receive a high quality of care.

Finally, with regard to the proposed deadlines for provision of standard terms and conditions, although we acknowledge that current CMS guidance set forth a deadline of two business days as a reasonable deadline, we recommend that CMS allow more time so that plans are able to conduct preliminary due diligence and assess the appropriate terms and conditions to be sent. A more reasonable timeframe would be 15 days.

Changes to the Days' Supply Required by the Part D Transition Process

CMS proposes to change the required outpatient days' supply from "30 days" to "a month's supply". CMS also proposes to change the transition days' supply for LTC settings from 91 days or more to the same "month's supply" as proposed for the outpatient setting.

Cigna supports limiting the transition supply members in a LTC facility to a month's supply. We recommend that CMS include this transition fill change in the Transition Fill Letter and ANOC templates so that plans may communicate this change to beneficiaries and prescribers uniformly.

Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

CMS proposes to permit Part D sponsors to immediately remove or change the preferred or tiered cost-sharing of brand drugs and substitute or add therapeutically equivalent generic drugs to plan formularies.

Cigna supports the added flexibility in formulary design and implementation that CMS is seeking to allow with these adjustments, and thanks CMS for proposing this change, which will reduce costs for beneficiaries and the Medicare program. We would suggest that CMS allow the proposed substitution of generic for branded products not only at the time of generic launch but also at the end of patent exclusivity or successful patent challenge. Additionally, we recommend that substitution of the generic for the brand be allowed to take place the first day of the month following the generic release or the first day of the month following the end of patent challenge exclusivity.

We also ask that as CMS finalizes this provision, the agency offer clarification on several related points:

- How would this change apply to future contract years for new generics released after the final open window for the future contract year? For example, if a generic is released in October and the brand is on both the current year and the next year's formulary, could the sponsor remove the brand from following year's formulary, but leave the current year formulary unchanged?
- Does the exemption of these substitutions from the transition fill policy only apply to those multi-source drugs removed based on this process? Does the exemption last the entire plan year? Finally, would new enrollees joining a plan during the plan year be subject to the same requirement?

Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings with Meaningful Differences

CMS proposes to eliminate the threshold differentials to distinguish two enhanced alternative plans offered by the same parent organization in the same region.

Cigna supports removing the meaningful difference requirement and allowing plan sponsors to determine what should constitute a difference between enhanced alternative plans offered. We believe this will lead to more affordable options for beneficiaries and encourage greater competition among plans to design offerings that meet the needs of beneficiaries.

RFI Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at Point of Sale

In what it terms a Request for Information (RFI) rather than a proposed change to existing program rules, CMS requests comments on considerations related to "requiring sponsors to include at least a minimum percentage of manufacturer rebates and all pharmacy price concessions received for a covered Part D drug in the drug's negotiated price at the point of sale." CMS seeks comments on how to most effectively design a policy to require pass-through at the point of sale (POS) of a share of rebates in order to mitigate effects of the direct and indirect remuneration (DIR) construct.

Manufacturer rebates: CMS is considering setting the minimum percentage of what must be passed through at less than 100%. This percentage would not change by drug category or class by year. CMS acknowledges this would result in larger premium increases for all beneficiaries and less plan flexibility. CMS also recognizes that this may result in weaker incentives for plans to participate in Part D. CMS is looking for an appropriate balance, and seeks comment on the minimum percentage and how often, and based on what factors, it should be updated, as well as the impact on competition for rebates under Part D.

CMS hypothesizes that the rebate at POS policy would likely apply only to rebated drugs. CMS is also considering a more targeted approach which would require POS rebates only for drugs or classes that most directly contribute to increasing Part D drug costs. CMS wants comments on the more limited approach and criteria for determining which drugs to target.

CMS also seeks comment on how to do this without increasing government costs, or reducing manufacturer payments under the Coverage Gap Discount Program. CMS notes that feedback received will be used for consideration in future rulemaking on this topic.

Cigna strongly opposes the proposed rebate at POS policy that CMS describes for several reasons. First, such a policy would do absolutely nothing to address the problem of high drug costs; in fact, it would likely lead to higher drug prices. Excessively high manufacturer pricing is the reason that Medicare beneficiaries and the Medicare program face ever-higher costs for prescription drugs. The proposed rebate policy would lead to rebate levels being commonly known, which would likely lead to manufacturers being less likely to offer discounts that exceed those offered by competitors for similar products. For example, where there is only one drug subject to rebate in a given class, the average POS rebate would equal the rebate of that individual drug, and could easily be determined by knowing the price of the drug at the POS. A class with two drugs subject to rebate would also readily allow rebates to be known, especially where a manufacturer has one of the two drugs and knows the exact rebate amount for its drug.

Second, the suggestion that members do not benefit from the rebates that Part D sponsors negotiate is simply wrong. Today, Part D sponsors have a choice: pass through rebates to a subset of members at POS via reduced cost-sharing for affected drugs, or pass through rebates to all members through lower premiums and cost-sharing structures across all drugs. Should a plan sponsor choose not to share the savings derived from negotiated rebates with members in any way, it would quickly find itself in an uncompetitive position and lose membership to lower-priced plans. This reliance on the competitive marketplace to drive lower costs and better value for Part D enrollees and the program is the hallmark of the Part D program, and has delivered consistently low costs to enrollees since its inception more than a decade ago.

Third, the policy CMS proposes will increase premiums for Part D enrollees and lead to higher program costs for the government. As discussed above, Part D premiums today typically reflect savings from negotiated rebates. Requiring those savings to be reflected at POS rather than at point of premium will cause premiums to rise in direct proportion. A small share of enrollees would see lower overall costs because their higher premiums would be offset by lower cost-sharing for affected drugs. The vast majority of enrollees would see higher overall costs because they do not take high cost drugs that would benefit from POS rebates, but would see higher premiums. These higher premiums for all Part D enrollees would also result in higher government costs since direct subsidy payments to plans are based on average premium amounts.

CMS also requests feedback on the impact that requiring Part D sponsors to apply some manufacturer rebates at the point of sale would have on the EGWP market and the retiree drug subsidy (RDS) program. Based on our experience with the RDS, it would be operationally difficult to implement a POS rebate in the program for several reasons. First, employer plan sponsors, not pharmacy benefit managers (PBMs), are responsible for applying and reporting for RDS payments. Second, RDS claims are typically administered and paid on PBMs' non-Medicare platforms with no requirements to identify RDS eligible members and claims at POS. PBMs do not collect and/or store this information today; non-Medicare PBMs would need to enhance their systems to make this possible. Third, the PBM does not flag the claim as Part D eligible at POS, so there is no way to adjudicate the rebate at POS. Fourth, the list of covered retirees is not known upfront and is subject to change throughout the year.

Administering manufacturer rebates at POS would increase administrative costs to employers that use the RDS program to provide retiree drug coverage and to PBMs that support the RDS program. Employer groups would need to create additional structure to separate their RDS eligible membership from their non-RDS membership. This would increase administrative costs charged to RDS employer groups by the carrier. In addition, non-Medicare PBMs would need to make significant systems changes in order to identify Part D claims at POS, to collect information needed to identify RDS-eligible members and claims at POS, and to make covered retiree lists available at POS. Higher administrative costs may lead to higher premiums charged to retirees by the employer.

Another consideration is that requiring rebates to be reflected at POS would likely lead to differences in cost-sharing between RDS and non-RDS beneficiaries. Final rebate amounts paid to PBMs and plans may not be known at POS as they may have utilization or other requirements to be eligible. This has the propensity to cause differences in participant cost shares when often the employer's intent is to offer the same plan design to their RDS and non-RDS plan participants.

Pharmacy DIR: CMS seeks comments on how to update requirements to better reflect current pharmacy payment arrangements "to ensure that the reported price at POS includes all pharmacy price concessions." CMS puts forth a possible approach and seeks comments on the merits. CMS is considering removing the reasonably determined exception and requiring that all price concessions be applied at POS, even if they are contingent. CMS lays out the case that it has legal authority to do this because the statutory language on rebates does not address entities other than manufacturers. Plus, the approach would still allow plans to "take into account" at least some price concessions (e.g., those from manufacturers). CMS is considering requiring the negotiated price to include the lowest possible reimbursement that a network pharmacy could receive. The price at POS would exclude any additional contingent payments to pharmacies (e.g., incentive fees). Any such amounts ultimately paid to pharmacies would be reported as negative DIR.

Cigna strongly opposes the proposed changes to the treatment of DIR. First, we believe that the proposal violates the Part D statute, which states that CMS is explicitly prohibited from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and Part D plan sponsors."¹ The proposal would put CMS in the middle of negotiations between Part D sponsors and pharmacies, directing how reimbursements could be set and paid, which is exactly what the non-interference language of the statute is intended to prevent.

¹ 42 U.S.C. § 1395w-111(i)(1).

Second, it is difficult to see how the proposal would benefit pharmacies because it would lead to lower reimbursement to them at the POS with the potential for additional lump sum reimbursement at the end of the contract year.

Third, the proposal would reduce the value of preferred pharmacies. The innovation of preferred networks has significantly reduced Part D program costs, including government costs and enrollee premiums, and provided enrollees access to reduced cost-sharing at preferred pharmacies. Post-POS DIR is a key driver of preferred network savings for many plan sponsors. The “lowest possible reimbursement” pharmacy price concession proposal would eliminate DIR payments from pharmacies to the plan sponsors, resulting in preferred network arrangements based on discount differentials alone. The elimination of pharmacy DIR may deteriorate the value of preferred networks, which may result in reduced cost-sharing differentials between preferred and non-preferred pharmacies (i.e., reduced enrollee access to lower preferred cost-sharing). In addition, some plan sponsors may realistically no longer be able to offer preferred network arrangements.

Finally, similar to the POS rebate proposal, this proposal would raise beneficiary premiums and government costs. CMS’ own impact analysis estimates that premiums would increase by \$5.7 billion over 10 years and government spending would increase by \$16.6 billion over 10 years if this proposal were implemented.

Cigna strongly urges CMS not to move forward with the proposals outlined in the RFI. Instead, we suggest that CMS focus on addressing the main driver of high drug costs for Part D enrollees and the Medicare program: excessively high drug prices set by manufacturers. Looking to Part D sponsors to somehow solve the problem of high drug costs through required POS rebates and DIR will exacerbate the problem, not fix it. Beneficiaries and taxpayers alike will suffer the consequences of higher costs, not lower, while manufacturers will reap the benefits of having better information on competitor discounts when negotiating with Part D sponsors.

Revisions to Timing and Method of Disclosure Requirements

CMS proposes changes to the timing of certain disclosure information such as the evidence of coverage (EOC) and the annual notice of change (ANOC) document.

Cigna supports the proposed changes, and asks that CMS provide additional guidance on how the new requirements would work once finalized. Our questions include:

- Will plans be afforded more flexibility around the ANOC contents? Currently only the required model materials can be in the ANOC mailing. For example, will plans be allowed to include a summary of network changes or a summary of significant drug list changes, as the complete directories are not required, but plans may want to inform customers about major changes?
- Will the website deadline to include the plan documents be changed? The EOC, directories, and formulary are currently required by October 1, but with this proposal the documents now have a later deadline of the first day of the annual enrollment period.

Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations

CMS proposes to increase the timeframe for issuing decisions on payment redeterminations and IRE reconsiderations from seven to 14 calendar days from the date the plan sponsor receives the request. Under the CMS proposal, the coverage determination payment timeline would remain at 14 days.

Cigna supports the proposed changes to the timeline for IRE reconsiderations, but recommends that CMS align the coverage determination payment timeline with the existing redetermination timeline of 30 calendar days. This will increase the probability of getting needed information from the prescriber and eliminate untimely payments on the coverage determination side.

E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards

CMS proposes to update e-prescribing standards for certain transactions covered under Part D. While Cigna supports the adoption of updated standards, we are concerned that it will be operationally impossible to implement the changes by January 1, 2019. We recommend that CMS implement the updated standards 18 months after the change is finalized. Second, we are concerned that post implementation of the new standards plan sponsors will not be able to accept transactions using the previous standards. Finally, we support the inclusion of electronic prior authorizations in the updated standards.

Reduction of Past Performance Review Period for Applications Submitted by Current Medicare Contracting Organizations

CMS proposes to reduce the past performance review period from 14 months to 12 months. The new past performance period would be March 1 of one year through February 28 or 29 of the following year.

Cigna supports the proposed reduction in past performance period because it reduces the likelihood that a plan will be penalized in two separate measurement periods for the same performance issues. Under a 14-month past performance period, a plan may see past performance points assigned in two different measurement periods because CMS took action related to a performance issue during January or February. CMS action related to the same performance issue taken during a different month would result in past performance points assessed against a plan in only one performance period. By reducing the past performance period, CMS will eliminate the double penalty associated with actions taken against a plan during January or February.

While we support a reduced performance period, we recommend that CMS use the calendar year to measure past performance. The proposed use of March 1 – February 28th/29th is unnecessarily complex and would not fix one problem with the current period: plans not having complete information about their past performance status at the time they make final decisions and file applications for expansion. Making the prior calendar year the past performance period would allow plans to assess their status as part of deciding whether to submit applications for expansion.

Preclusion List – Part D Provisions

CMS proposes to eliminate the prescriber enrollment requirements, which were scheduled to take effect on January 1, 2019. Instead, CMS would require plan sponsors to reject claims for Part D drugs prescribed by providers on a preclusion list.

Cigna welcomes the proposed elimination of the prescriber enrollment requirements, and thanks CMS for recognizing the operational difficulties that would have accompanied those requirements. Cigna also shares

CMS' commitment to reducing fraud, waste, and abuse in Medicare spending, and recognizes the need for continued effort to identify and reject providers who are not permitted to receive Medicare payments.

While we support the move toward the use of a preclusion list for identifying prescribers, we are concerned a January 1, 2019 implementation date is not realistic. We recommend CMS set an implementation date that is 12 months after the provision is finalized. Additionally, we strongly encourage CMS to provide detailed information about file layouts, the frequency of updates, and other operational details as soon as the proposals are finalized, to allow plans sufficient time to make the necessary systems changes. Without close coordination and sufficient advance notice, implementation of a preclusion list for Part D will lead to beneficiary confusion and delays in getting needed medications.

We would also recommend CMS take steps to ensure the list is available to prescribers so they are able to confirm inclusion on the list independent of notification by a plan sponsor. It will also be important CMS notify prescribers when they are placed on the list, and handle any appeals. These administrative duties should not be the responsibility of plan sponsors. We request CMS clarify how the appeal process would work and when reinstatements would occur. If there is a reinstatement, we recommend it occur when the next file is released, not mid-term. We ask that CMS not allow retroactive reinstatements.

In addition, we request CMS provide additional clarification about the relationship between the proposed preclusion list and other exclusion lists CMS uses to determine eligibility for payment, such as the LEIE, MED, GSA/SAM, Medicare concerns, and Medicaid exclusions. We ask CMS to explain how plans sponsors should address situations where a prescriber is on one list, such as the LEIE list, but not on the preclusion list, or where a claim for a dual-eligible beneficiary comes from a prescriber on the Medicare preclusion list but not the Medicaid excluded list.

Finally, we support the proposed requirement that plans offer a provisional fill to beneficiaries affected by the preclusion list requirement. We believe one fill of up to a 90-day supply would be acceptable, as opposed to three 30-day fills.

Preclusion List – Part C/Medicare Advantage Cost Plan and PACE

CMS proposes to eliminate the provider enrollment requirements, which were scheduled to take effect on January 1, 2019. Instead, CMS would require MAOs to ensure that payments are not made to providers on a preclusion list.

Cigna welcomes the proposed elimination of the provider enrollment requirements, and thanks CMS for recognizing the operational difficulties that would have accompanied those requirements. Cigna also shares CMS' commitment to reducing fraud, waste, and abuse in Medicare spending, and recognizes the need for continued effort to identify and reject providers who are not permitted to receive Medicare payments.

While we support the move toward the use of a preclusion list for identifying providers who should not receive payment, we are concerned a January 1, 2019 implementation date is not realistic. We recommend CMS set an implementation date that is 12 months after the provision is finalized. Additionally, we strongly encourage CMS to provide detailed information about file layouts, the frequency of updates, and other operational details as soon as the proposals are finalized, to allow plans sufficient time to make the necessary systems changes. Without

close coordination and sufficient advance notice, implementation of a preclusion list for Part C will lead to beneficiary confusion and delays in getting needed medications.

We would also recommend CMS take steps to ensure the list is available to providers so they are able to confirm inclusion on the list independent of notification by a plan sponsor. It will also be important CMS notify providers when they are placed on the list, and handle any appeals. These administrative duties should not be the responsibility of MAOs. We request CMS clarify how the appeal process would work and when reinstatements would occur. If there is a reinstatement, we recommend it occur when the next file is released, not mid-term. We ask that CMS not allow retroactive reinstatements.

Finally, we request CMS provide additional clarification about the relationship between the proposed preclusion list and other exclusion lists CMS uses to determine eligibility for payment, such as the LEIE, MED, GSA/SAM, Medicare concerns, and Medicaid exclusions. We ask CMS to explain how MAOs should address situations where a provider is on one list, such as the LEIE list, but not on the preclusion list, or where a claim for a dual-eligible beneficiary comes from a provider on the Medicare preclusion list but not the Medicaid excluded list.

Removal of Quality Improvement Project for Medicare Advantage Organizations

CMS proposes to remove the Quality Improvement Project (QIP) requirements for MAOs to reduce redundancies with similar plan efforts.

Cigna supports the removal of the requirement of QIP submissions in order to reduce overlapping regulatory requirements. Cigna intends to continue development and implementation of Quality Improvement Projects based on customer-specific needs identified through data collection sources. It has been our practice to identify not only process improvement needs internal to our organization, but to place emphasis on improvement projects that will improve the overall health outcomes of our members.

Reducing Provider Burden – Comment Solicitation

CMS solicits stakeholder feedback on the nature and extent of the burden on providers of producing medical record documentation for risk adjustment purposes, including risk-adjustment data validation audits (RADV), medical record attestation, and other purposes. CMS asks for ideas to address the burden.

The RADV audit process is an intensive process for all involved, including plans and providers. Cigna recognizes the burden responding to requests for medical record documentation imposes on providers, and works to ensure providers are given adequate time to respond. At the same time, because we have no control over which contracts or records are selected for a RADV audit, we cannot offer any guarantees about the number of medical records or other documentation any particular provider will be required to produce.

In our experience, providers who use electronic medical records (EMRs) spend less time and experience less burden in providing medical records and documentation in a timely manner. Therefore, one step CMS could take to ease provider burden would be to require all physicians to adopt EMR technology, and require that health plans have appropriate record access to the EMR to allow for health plan review of necessary information. Access to the EMR could be granted on a temporary basis during a RADV audit and restricted as allowed by the EMR.

A second approach would be for CMS to take provider burden into account when selecting contracts and/or records for RADV audit. CMS could use provider information during the selection and sampling processes to limit the number of selected records associated with an individual provider.

Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements

CMS proposes to reduce the number of data elements MAOs would be required to submit as part of medical loss ratio (MLR) reporting, and proposes several changes to the calculation of the MLR for MA plans.

Cigna supports the proposed changes to MLR calculations and reporting. We especially appreciate CMS' proposed inclusion of medication therapy management (MTM) efforts as quality improvement activities for purposes of the calculation. MTM programs have demonstrated an ability to close therapy gaps (i.e., improve care quality) and improve outcomes, and are considered an important quality improvement program for plan sponsors.

Changes to Agent/ Broker Requirements

CMS proposes to give plans more discretion in handling agents and brokers who become unlicensed. Cigna supports the proposed change, which would allow MAOs to determine the level of disciplinary action to take against unqualified agents who make a sale without proper licensure. We ask that in finalizing this provision, CMS clarify whether MAOs would still be required to submit unqualified agent information to CMS.

In summary, Cigna supports CMS' efforts to improve the MA and Part D programs through greater flexibilities and customization of benefits and services to meet member needs along with reduced regulatory burdens on plans. We believe the concerns and suggestions offered in this letter will ensure provisions in a final rule will offer the best opportunity to realize these goals for members, plans, and the Medicare program.

Thank you for your consideration of these comments.

Respectfully,



David Schwartz