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Centers for Medicare & Medicaid Services
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Re: CMS-2017-0163-0007: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for the Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter

To Whom It May Concern:

Cigna welcomes the opportunity to respond to the advance notice of methodological changes to the Medicare Advantage and Part D payment rates and policies for the 2019 payment year (CMS-2017-0163-0007). 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 and ensure appropriate payment to plans that provide benefits and services to more than 20 million seniors and persons with disabilities. Our comments in this letter are limited to the proposals and policies set forth in Part II of the advance notice and call letter published on February 1, 2018; Part I of the notice is addressed in a separate letter. Overall, we believe the payment rates and policies in the advance notice and draft call letter ensure beneficiary access to the high value benefits and services MA and Part D plans offer. However, we believe changes to specific provisions, as described in this letter, would improve access to care for members and increase competition among plans.

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.

Changes in the Part C Payment Methodology for CY 2019

ESRD Model

CMS proposes to recalibrate the End Stage Renal Disease (ESRD) model using 2014/2015 diagnosis and cost data (the model as first implemented used 2006/2007 data). Because of the large time lag between the prior and updated data periods, the proposed recalibration would result in very large changes in model factors that will affect plan payments significantly.

While Cigna supports using the most current data available to determine payments, we are concerned the large shifts in risk-adjusted payment factors for the ESRD model will create instability for plans, especially small plans with a relatively large ESRD population. These patients consistently have very high costs which are not adequately accounted for by the ESRD risk adjustment model.

We urge CMS to phase-in the new model over three years to mitigate the impact of the changes and ensure plans and the ESRD members they serve do not face sharp declines in payments or benefits in 2019. We also urge CMS to undertake additional analysis of the costs associated with providing care to patients with ESRD and make changes to the ESRD model to more appropriately account for these costs.

Medicare Advantage Coding Pattern Adjustment

CMS proposes to apply the statutory minimum MA coding adjustment factor of - 5.90 percent for 2019. In addition, CMS is soliciting comments on alternative methodologies the agency is considering with regard to its final decision. CMS references these methodologies as follows:

- “The methodology discussed in the Payment Year 2010 Advance Notice and Rate Announcement, found here: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html>
- The methodology discussed in the Payment Year 2016 Advance Notice and Rate Announcement, also found at the same Web page.
- The methodology discussed in MedPAC’s March 2017 Report to Congress: Medicare Payment Policy. The report can be found here: http://medpac.gov/docs/default-source/reports/mar17_medpac_ch13.pdf?sfvrsn=0”

Cigna supports the proposal to apply the statutorily-mandated minimum coding intensity adjustment for 2019. Further, we strongly encourage CMS not to finalize any alternative methodologies that have not been fully described with an opportunity to offer comment. Without more information from CMS about how any alternative methodologies would be applied, we cannot fully evaluate or meaningfully comment on them.

However, to the extent CMS may consider future changes to the mandated coding intensity adjustment, we have additional concerns with two of the methodologies referenced. First, the methodology discussed in the Payment Year 2016 Advance Notice and Rate Announcement would effectively cap payments to MA plans at the payment amount that would have been calculated using the adjusted average per capita cost (AAPCC) methodology in effect prior to 2000, which only included demographic risk adjustment factors. However, section 1853(a)(3)(C) of the Social Security Act (SSA) requires a risk adjustment methodology that “accounts for

variations in per capita costs based on health status..." Therefore, we believe the 2016 Advance Notice methodology would be inconsistent with that section of the statute.

Moreover, we note that in the 21st Century Cures Act, Congress directed CMS to incorporate further refinements to the risk adjustment model that account more fully for variations in health status: namely, that the model account for the total number of diseases or conditions of an individual.

We also note numerous peer-reviewed, academic evaluations have determined that incorporating clinical conditions into the MA risk adjustment model has been highly successful in better aligning enrollment of high risk beneficiaries with expected health care spending.^{1,2} Eliminating the use of clinical information in determining risk scores would dramatically underestimate costs for individuals with multiple chronic conditions by ignoring any use of diagnoses, and would reverse substantial progress made in MA risk adjustment.

Cigna also has serious concerns with the methodology discussed in the Medicare Payment Advisory Commission (MedPAC's) March 2017 Report to Congress: Medicare Payment Policy. The methodology discussed by MedPAC (the "2017 MedPAC methodology") has three distinct components: 1) develop a risk adjustment model that uses two years of fee-for-service (FFS) and MA diagnostic data, 2) exclude diagnoses that are only documented on health risk assessments from either FFS or MA, and 3) apply a coding adjustment that fully and equitably accounts for the remaining differences in coding between FFS Medicare and MA plans.

It is unclear whether CMS's reference to the 2017 MedPAC methodology was intended to incorporate all three components. However, we note the risk adjustment model CMS proposed in Part I of the CY 2019 Advance Rate Notice did not include two years of FFS or MA diagnostic data.

With respect to the second component, Cigna has previously offered comments on the important role such assessments play in quality of care, especially for members with chronic illness. Cigna opposes any limits on the use of diagnosis codes based on health risk assessments, though we support guidelines for the conduct of such assessments, such as requiring they meet guidelines for Medicare's annual wellness exam and be conducted by qualified health care providers.

Finally, with respect to the third component, neither MedPAC nor CMS has described in sufficient detail how a coding adjustment that "fully and equitably accounts" for differences in MA and FFS coding patterns would be calculated or applied to MA plans. No potential changes of this sort should be considered absent a detailed methodology for how the adjustment would be calculated and applied, and analyses of the impacts on enrollee premiums and benefits, made publicly available with substantial time for review and comment.

Because we think these proposed clarifications and refinements can only be evaluated in the wider context of the various outstanding risk adjustment issues, we think it is important to make the following, broader comments, reflective of some of our and other stakeholders' concerns about the risk adjustment process generally.

¹ McWilliams, J. Michael, Hsu, John, Newhouse, Joseph P. New risk-adjustment system was associated with reduced favorable selection in Medicare Advantage. *Health Affairs* 31(12):2630-2640. December 2012.

² Newhouse, Joseph P., McGuire, Thomas G. How successful is Medicare Advantage? *Milbank Quarterly* 92(2): 351-394. June 2014.

Cigna supports a risk adjustment model that appropriately accounts for the expected costs of treating enrollees whose health conditions and needs lead to higher health care spending and that accurately compares FFS and managed Medicare costs. While Cigna does not support changes to the risk adjustment model that are inconsistent with section 1853(a)(3)(c) of the SSA, which requires a risk adjustment methodology that includes variation in cost based on health status, Cigna has serious concerns that the current risk adjustment model fundamentally fails to ensure actuarial equivalence between FFS and managed Medicare costs, as required by statute. See 42 U.S.C. §§ 1395w-23(a)(1)(C)(i). CMS has not addressed coding issues associated with the FFS system, which is a substantial reason the existing system fails to achieve the statutory requirement of actuarial equivalence. Until these and other defects are addressed, after notice and comment rulemaking, it will be impossible for MA organizations (MAOs) to identify the sums that plans are and are not entitled to under the program. See 42 C.F.R. § 422.326.

Draft CY 2019 Call Letter Section 1 – Parts C and D

Enhancements to the 2019 Star Ratings and Future Measurement Concepts

Reminders for 2019 Star Ratings: CMS comments that, “Part C and D sponsors should regularly review their underlying measure data that are the basis for Part C and D Star Ratings and immediately alert CMS if errors or anomalies are identified so any issues can be resolved prior to the first plan preview period.” CMS further states that, “any necessary changes to the Independent Review Entity (IRE) data must be made by June 30 of the following year in order for the changes to be reflected in a contract’s Star Ratings data.”

Cigna agrees Part C and D sponsors should regularly review their underlying measure data and make reasonable best efforts to alert CMS of errors ahead of the plan preview period, but we do not believe this should waive a sponsor’s right to identify and raise issues during the plan preview period. For example, during the 2018 plan preview period, Cigna was able to use plan preview data to identify instances where the IRE had incorrectly categorized Part C Appeals cases as untimely. Due to limitations with the reports shared by the IRE throughout the year, which do not explicitly specify whether cases are categorized as timely or untimely, Cigna would not have known the cases were incorrectly designated as untimely without the use of plan preview data.

Removal of Measures from Star Ratings: CMS proposes to remove the current Beneficiary Access and Performance Problems (BAPP) measure and introduce a new BAPP measure based solely on Compliance Activity Module data. The new measure would be on the display page for 2019. Cigna fully supports removing the current BAPP measure and removing audit and enforcement actions from a new BAPP measure, as we believe audits and enforcement actions should be decoupled from Star ratings. We recommend before putting a new BAPP measure on the display page, CMS share additional information with plans about how scores would be determined for the new measure.

Proposed Scaled Reductions for Appeals IRE Data Completeness Issues: CMS proposes using statistical criteria to reduce a contract’s Star rating for data that are not complete or lack integrity, based on Timeliness Monitoring Project data or audit findings. Cigna recognizes the value of creating controls to prevent a plan from intentionally failing to forward appeals to the IRE for the purpose of artificially improving Star ratings. However, we are concerned that the scaled reduction penalizes Part C and D sponsors yet fails to address data concerns associated with the IRE. We further believe this proposal highlights broader data integrity concerns associated with the Part C and D Appeals Star measures.

Cigna has frequently expressed concerns to the agency regarding the quality of IRE data. Most recently, during the 2018 plan preview period, Cigna identified instances where the IRE has incorrectly designated several Part C Appeals cases as untimely, which would have had an adverse impact on Cigna's Part C Appeals rating had we not identified the errors. Further, comments and proposals in this Advance Notice and in the Contract Year 2019 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule highlight additional data integrity concerns associated with plans. Examples include the proposed scaled reductions methodology, which is intended to prevent plans from failing to send complete data to the IRE, and the proposed Part C Timeliness display measure which will include cases dismissed by the IRE because the plan has subsequently approved coverage or payment. CMS states that the current measure "exclude(s) all cases dismissed/withdrawn by the IRE" and a "plans' performance may be artificially improved as a result, especially if the dismissals were directly related to the plans' (untimely) approval." Until the broader data concerns can be adequately addressed, Cigna recommends the Part C and D Appeals measures be removed as Star measures.

2019 Star Ratings Program and the Categorical Adjustment Index: CMS proposes to continue using the Categorical Adjustment Index (CAI) for the 2019 Star Ratings Program. Cigna appreciates the work and collaboration that CMS is engaged in to review and address the disparities that exist in Star ratings based on a plan's percentage of beneficiaries receiving the Part D low-income subsidy and dual-eligible (LIS/DE) and disability status. We further appreciate CMS increasing the maximum CAI adjustment to 0.14 for the 2019 Star year. We are concerned, though, the current CAI methodology still does not do enough to account for the disparities associated with a high volume of LIS/DE and disabled beneficiaries and recommend CMS provide additional relief for plans with a high percentage of LIS/DE beneficiaries in 2019.

Based on the Pharmacy Quality Alliance (PQA's) recommendations that adherence measures be risk adjusted and the National Committee for Quality Assurance (NCQA's) proposal to stratify certain measures based on whether beneficiaries are LIS/DE and disabled, it is apparent that industry experts recognize plans with a high percentage of LIS/DE and disabled enrollees will see lower Star ratings than a plan with a lower percentage of LIS/DE and disabled enrollees. CMS states PQA and NCQA's proposed adjustments will be accounted for in future years. In the interim, however, without a temporary adjustment that more directly corrects the disparity in ratings, beneficiaries enrolled in plans with a large share of LIS/DE and disabled members will see reduced benefits and services as a result of lower rebates and quality bonus payments. Until these measure adjustments and/or a more comprehensive plan are in place, Cigna recommends CMS apply a temporary adjustment to Star ratings for plans with a high percentage of LIS/DE enrollees that more fully accounts for the ratings disparity.

Additionally, as CMS works to determine how PQA and NCQA's proposed adjustments are incorporated into future Star ratings, we encourage the agency to work towards consistency between measure adjustments. For instance, all measure adjustments should be either risk-adjusted or stratified, but not a mix of both as it creates inconsistencies in the Star rating methodology.

Cigna also recommends periodic reviews of disability status be conducted rather than relying solely on the original reason for entitlement code (OREC), as beneficiaries can become disabled after the OREC.

Disaster Implications: CMS proposes providing Stars relief to plans with enrollees in an emergency area during an emergency period. Cigna generally agrees with this proposal but seeks further clarification. The proposed adjustment states that contracts with at least 25 percent of enrollees meeting requirements for disaster relief

will be eligible to receive the better of the 2019 rating and the 2018 rating for individual measures. We would like clarification on how CMS plans to address new measures where no Star rating is available for the 2018 rating year.

Changes to Measures for 2019: CMS proposes changing the methodology of the MPF Price Accuracy measure for 2019 based on the changes finalized for 2018. Based on the data issues which precluded the methodology changes from being used in the 2018 ratings, Cigna recommends CMS monitor the new methodology for another year on display to ensure there are no further data issues which could skew the measure ratings.

Plan Finder Civil Money Penalty (CMP) Icon or Other Type of Notice

CMS proposes, beginning with the 2019 Annual Election Period, an icon be added to the Medicare Plan Finder (MPF) identifying plans that have been issued a civil monetary penalty (CMP). While Cigna supports CMS' intent to provide beneficiaries with as much information as possible to guide plan selection, we are concerned the CMP indicator would capture a broad range of issues and could confuse beneficiaries. Further, the amount of a CMP depends on several factors, including the plan's enrollment. Beneficiaries may attribute the size of a CMP solely to the severity of the infraction, which could lead to serious misunderstandings about plan performance. We also encourage CMS to be mindful of when and how the CMP indicator is displayed to beneficiaries, as it could adversely impact customer perception and survey-based measures. Finally, as with the BAPP measure, which is being retired for 2019, CMS should be purposeful about ensuring enforcement actions are decoupled from Star ratings.

Section II – Part C

MA Uniformity Flexibility

CMS proposes to permit MAOs to reduce cost-sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees who 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, and appreciates CMS' continued efforts to ensure MA plans are able to deliver high value, high impact services and benefits to members with varying health care needs. We request CMS issue additional guidance on uniformity flexibility to address the following:

- 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 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 health care – 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.

MA Segmented Service Area Options

CMS is revising its interpretation of existing regulations 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 encourage CMS to publish additional guidance to ensure plans are implementing segmented supplemental benefits fairly and appropriately. We request CMS address the following in such guidance:

- 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?

Section III – Part D

2019 Formulary Reference File (FRF)

CMS is in the process of updating the FRF to remove drugs that are more commonly covered under Medicare Part B than Part D. Cigna generally supports the effort to update the FRF, and looks forward to CMS releasing a draft updated file for public comment. As CMS prepares the updated draft, we request the agency clarify how the following issues will be addressed:

- What threshold for utilization is CMS planning to use for deletion of drugs from the FRF?
- Are any protected class drugs, such as IV Chemotherapy, being reviewed for removal from the FRF?
- If so, would the expectation be that all plans continue to have these drugs on formulary regardless of the ability to submit through the formulary submission process?

CMS proposes to allow plan updates for Part D formularies at several points through the year, including the existing summer update window and two new windows, one in late fall (when plans could enhance formularies) and a January window.

Regarding the summer open window for formulary updates, Cigna believes the ideal time for holding the summer update is the *final week of July*, as was done in 2017. Due to the time needed to prepare documents for

Annual Notice of Change (ANOC) mailing, any later date could make it difficult to meet deadlines for printing and mailing ANOC documents.

We have several questions regarding the proposed new submission windows:

- Will the additional late fall enhancement only window occur prior to open enrollment period?
- Will an updated FRF be available for that submission window?
- Would the submission window be open the first three business days of the year?
- When would the FRF be released?

Finally, we are concerned the proposed January update window could impede plan efforts to ensure a smooth transition to the new plan year. Therefore, we encourage CMS to allow plans additional time between the FRF release and the submission window closure.

Changes to 2019 Formulary Submissions

Non-Extended Day Supply (NDS) file: CMS proposes to eliminate the NDS file. Cigna supports this proposal.

Over-the-Counter (OTC) Validation File: CMS proposes to issue an OTC reference file that uses proxy codes to represent unique drug ingredients, rather than relying on the National Drug Codes currently submitted by plan sponsors. We request CMS clarify whether CMS expects that all products with a given proxy code ingredient be covered.

Tier Composition

CMS proposes a maximum threshold of 25 percent generic composition for the non-preferred brand tier for 2019. Cigna has several questions about how CMS will apply this threshold:

- How is CMS defining generic for this purpose?
- Will it include all abbreviated new drug application (ANDA) drugs?
- How will authorized generics filed under a new drug application (NDA) be viewed?
- Is the threshold applied at an RxCUI level or some other level such as drug name?

Part D Opioid Overutilization Policy

Overutilization Management System (OMS) Metrics: CMS proposes to include a second opioid daily dose rate on quarterly OMS reports that would report on 90 morphine milligram equivalent (MME) Opioid Daily Dose rates in addition to the current 120 MME rates, beginning with the April 2018 quarterly OMS report. CMS also proposes to discontinue reporting the 120 MME Opioid Daily Dose rate in the 2019 OMS reports. Cigna supports the shift to reporting the 90 MME Daily Dose rate as proposed.

Opioid Potentiator Drugs: CMS proposes to enhance the OMS by adding additional flags for high risk beneficiaries who use “potentiator” drugs (such as gabapentin and pregabalin) in combination with prescription opioids. OMS already flags concurrent benzodiazepine use.

Cigna supports expanding OMS to flag additional potentiators for the purpose of inclusion in a Part D plan sponsor's retrospective drug utilization review (DUR) program. If a beneficiary meets OMS criteria, concurrent

use of potentiators is included in the medication review and adding a flag could be helpful in identifying claims for those beneficiaries new to the plan and communicating with prescribing physicians when deemed clinically appropriate. We also encourage CMS to offer more flexibility for plans to leverage existing programs such as concurrent DUR to address safety concerns that are not included in drug package labeling, but supported in the literature.

Concurrent DUR

Hard Edit for Daily MME > 90mg: CMS proposes to require all Part D sponsors implement a hard edit in 2019 that is triggered when a beneficiary's cumulative daily MME reaches or exceeds 90 milligrams. This would align with guidelines from the Centers for Disease Control and Prevention (CDC), which recommends to generally avoid increasing the daily dosage of opioids to 90 MME. These hard edits would be implemented at the point-of-sale (POS) at the pharmacy at a dosage level of 90 MME per day, with a seven-day supply allowance, and could only be overridden by the plan sponsor.

Cigna understands and appreciates the intent of this provision, but we are concerned with the operational challenges and potential access to care issues, administrative burden and unintentional consequences that may result from a hard edit at 90 MME. Our primary concern is that these drugs do not have FDA-imposed maximum recommended dosing; further, CDC guidelines suggesting 90 Morphine Equivalent Dosage (MED) as the maximum are intended to guide PCP prescribing decisions only, and are not intended for all prescribers. Beneficiaries who exceed this threshold need to work with their health care provider to determine an appropriate plan (e.g., non-opioid therapy, inclusive of decreasing utilization of opioids over time or non-medication related therapy.) Introducing an edit at this level could result in potential adverse events, disrupt beneficiary access to care, and is limited to the prescriber submitting a coverage determination stating the prescriptions are medically necessary.

If CMS moves forward with this requirement, we encourage limiting the edit to new starts only with an additional criterion of prescriber count of two or more to focus on opportunities for better care coordination in addition to asking the prescriber(s) to verify doses exceeding 90 MME are necessary. To obtain coverage determinations on this edit, we encourage CMS to follow current policy as it relates to hard edits and coverage determination requirements, with an added provision that plan sponsors be permitted to require more than an attestation by the physician for approving a coverage determination to maximize the value of this process.

Regarding the one-time seven-day allowance, we have concerns this is not an existing functionality and will take time to build. We request CMS specify the requirements in the same way it has specified transition fill requirements. We also recognize the seven-day allowance would create operational challenges for pharmacies and prescribers, as partial fills or additional prescriptions that comply with state prescription laws may be required if the original prescription(s) is written for greater than a seven-day supply. For current beneficiaries with a daily MME greater than 90, Part D plan sponsors can leverage existing programs to balance access while working with prescribers to coordinate care.

Additionally, we encourage CMS to analyze the impact of the current MED edits before finalizing this policy, as this data should give insights across the industry with regard to impact of various MED levels as well as level of intervention.

Days' Supply Limits for Opioid Naïve Patients: CMS intends to establish a days' supply limit for initial fills of prescription opioids (e.g., seven days) for the treatment of acute pain with or without a daily dose maximum (e.g., 50 MME per day). Cigna supports this provision as one strategy for reducing the number of patients who become dependent on opioids after an initial exposure to them via an acute health care event.

If implemented, we request CMS define "acute pain" so Part D sponsors can apply the definition uniformly. We request the definition address situations where a beneficiary is new to a plan and therefore the plan has no prescription history. Additionally, we request CMS address the issue of how PDPs and pharmacy benefit managers can identify patients with cancer or other conditions that may require an exemption from the limit, so as not to impede access to care for these members.

We note any limit could result in partial fills. To accommodate this, we need CMS to immediately adopt the 'Quantity Prescribed' field that the National Council for Prescription Drug Programs has proposed to continue to prevent the claims appearing as refills during recovery audit contractor audits. Additionally, we request CMS include how plan sponsors should process resultant coverage determinations received after a claim rejects for the days' supply limit, including if the reject is also for another utilization management edit such as a quantity limit.

Opioid Duplicative Therapy Safety Edits: In the draft call letter, CMS states that it expects all sponsors to implement soft POS safety edits (which can be overridden by a pharmacist) based on duplicative therapy of multiple long-acting opioids, and requests feedback on concurrent prescription opioid and benzodiazepine soft edits.

Cigna supports the soft edits described. Through these edits, our dispensing pharmacies are able to obtain appropriate information from and coordinate with prescribing physicians to address long-acting opioid duplications in therapy and potential drug-drug interactions to ensure safe and appropriate use.

Access to Medication-Assisted Treatment (MAT)

CMS continues to expect Part D sponsors to include products used in MAT in preferred formulary tiers, and to avoid placing generic drugs indicated for MAT in brand tiers.

Cigna appreciates and understands the intent to focus on beneficiary access to MAT therapy. We encourage CMS to clearly lay out requirements for plans to follow so all sponsors are uniformly complying with CMS' requirements. We also ask CMS to clarify whether the non-preferred drug tier would be considered a brand or generic tier for this purpose.

Part D Mail-Order Refill Consent

CMS solicits feedback on the existing Part D mail-order refill consent policy, which currently requires all plans (except Employer Group Waiver Plans) and their pharmacies to obtain patient consent prior to each and every home delivery of a refilled prescription.

Cigna continues to believe the current policy is overly-restrictive and interferes with our goal to ensure our members have adequate supplies of their life-saving medications on hand via automatic refill shipments. We

also agree with other stakeholders who, CMS notes, believe the existing policy creates an “unnecessary burden and interferes with improving medication adherence.” Cigna believes the current policy must be modified to assist members who forget to re-order their mail-order refills and may potentially be without their prescription medication for several days while their order is being processed and shipped.

While we agree with CMS that Medicare beneficiaries should not be involuntarily opted-in to receiving automatic shipments of medication refills, we believe they should be able to opt-in to such a program once and not be required to provide affirmative consent for every subsequent refill shipment. Therefore, Cigna recommends CMS require an annual beneficiary confirmation to receive automatic deliveries with an opt-in on a per drug basis, combined with a required advanced notification shipping reminder that provides sufficient time for a beneficiary to cancel an order.

We understand CMS has concerns about the potential for waste associated with auto-shipments of refills, but we believe our proposed change protects Medicare beneficiaries from receiving medications they do not want while ensuring they receive the medications they need in a timely manner.

In summary, the provisions of the advance notice and draft call letter, in aggregate, support continued beneficiary access to the high quality, high value care provided through the MA and Part D programs. We encourage CMS to make the recommended changes described in this letter in setting final payment rates and policies for the 2019 payment year.

Thank you for your consideration of these comments.

Respectfully,


David Schwartz