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Centers for Medicare & Medicaid Services Department of Health and Human Services P.O. Box 8016 Baltimore, MD 21244-8016

RE: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model; Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter

Dear Principal Deputy Administrator Kouzoukas:

WellCare Health Plans (WellCare) is pleased to submit the enclosed comments in response to the comment opportunity "Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model," released on December 27, 2017 by the Centers for Medicare & Medicaid Services (CMS) as well as the comment opportunity "Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter," released on February 1, 2018.

WellCare Health Plans focuses exclusively on providing government-sponsored managed care services, primarily through Medicaid, Medicare Advantage, and Medicare Prescription Drug Plans, to approximately 4.3 million families, children, seniors, and individuals with complex medical needs. WellCare's vision is to be a leader in government sponsored health care programs in partnership with our members, providers, and government partners. We have a long-standing commitment to our federal and state partners to deliver value, access, quality, cost savings, and budget predictability. It is from this vantage point that we offer these comments.

Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model

21st Century Cures Act (page 4)

WellCare would like to again express our support of the change in structure of the risk adjustment model that CMS implemented in payment year 2017. Developing a risk adjustment model that



includes separate community segments for the specified six populations allows the model to more accurately predict the actual cost of caring for each individual subgroup.

However, WellCare remains concerned about the impact of imposing such a significant decrease in the premium for partial benefit dual eligibles. WellCare is concerned with the model's failure to differentiate between various groups of partial benefit dual eligibles. Specifically, we question the inclusion of Qualified Medicare Beneficiaries (QMBs) in the same classification as other partial benefit dual eligibles. Medicare benefit utilization by dual eligibles is impacted not only by their health care conditions and social circumstances, but also by Medicaid cost sharing protection. QMBs, like full benefit dual eligibles, are fully cost share protected which makes care essentially "free" to them. As a result, in our experience, QMBs utilize services in a manner nearly identical to the full benefit dual eligibles. WellCare asks CMS to study the utilization patterns of QMBs. If the data validate these utilization practices, we ask CMS to consider creating a separate model segment for this category of partial benefit dual eligible.

Encounter Data as a Diagnosis Source for 2019 (page 23)

For PY 2019, CMS is proposing to increase the percentage of risk scores calculated using encounter data from 15% to 25%. CMS is also proposing to supplement encounter data risk scores with Risk Adjustment Processing System (RAPS) inpatient data. WellCare is concerned with CMS' proposal to increase the percentage of risk scores calculated using encounter data to 25%. Specifically, CMS continues to update the filtering logic via the MAO-004 report, and without a consistent and accurate report, plans are unable to definitively determine which diagnoses will be used by the agency to calculate risk scores. Given the technical and operational issues we are experiencing with the filtering logic, we recommend that CMS postpone the increase in the use of encounter data. We recommend CMS maintain the use of 15% encounter data, and we also recommend CMS allow RAPS data to supplement the inpatient data in order to improve completeness of the data. As CMS noted, on page 23, "Encounter Data inpatient submissions are lowcompared to corresponding RAPS inpatient submissions. Amending inpatient diagnoses from Encounter Data with inpatient diagnoses from RAPS will improve the completeness of the data for payment in 2019."

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

Attachment II. Changes in the Part C Payment Methodology for CY 2018 (page 9)

Section B. Calculation of Fee for Service Cost (page 15)



B1. AGA Methodology for 2019 (page 15)

In the "Advance Notice of Methodological Changes for Calendar Year (CY) 2017 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies," CMS noted that there are a disproportionately high percentage of beneficiaries who enroll in MA in Puerto Rico and a large percentage of beneficiaries who do not opt in to Medicare Part B. The agency outlined an alternative methodology for calculating payment rates for MA enrollees in Puerto Rico. On page 15 of this year's Advance Notice, CMS again notes the unique enrollment situation in Puerto Rico and re iterates its continued belief in the importance of adjusting the fee for service (FFS) rate calculation in Puerto Rico so that it is based on beneficiaries who are enrolled in both Part A and Part B.

WellCare continues to be concerned about counties outside of Puerto Rico experiencing the same challenge of high penetration rates of Medicare Advantage and low FFS Part B enrollment. Like Puerto Rico, counties in Hawaii, for example, have a high level of MA enrollment and a low level of Medicare Part B enrollment. We ask CMS to consider a uniform solution to more accurately calculate payment rates for such counties. Specifically, we ask CMS to consider modifying their geographical index calculations for all counties by including only members with Part A and B coverage. This guarantees that counties that have a disproportionate share of members with only Part A coverage, such as those in Hawaii, are not penalized in their FFS rate development.

Section K. Medicare Advantage Coding Pattern Adjustment (page 28)

The Advance Notice states that CMS is proposing to apply the statutory minimum coding pattern adjustment of 5.90%. WellCare supports CMS' decision to not increase the coding intensity adjustment beyond the statutory minimum.

CMS also notes that it is considering other methodologies to inform the final decision regarding the factor for plan year 2019 and provides hyperlinks to three possible methodologies. CMS states they are seeking comments on the outlined methodologies and any other alternative methodologies for the final adjustment factor. WellCare has concerns with CMS' approach to proposing a final coding pattern adjustment for plan year 2019. Specifically, the provision of links to previously proposed methodologies does not give plans enough data or information to adequately assess the proposals and calculate impact. Any proposed changes to the coding pattern adjustment should be fully developed by the agency, and CMS should provide plans with relevant data on the effect of the proposed adjustments. Doing so allows plans to assess the methodologies and provide meaningful feedback.

If CMS wants to substantially change the methodology for the coding pattern adjustment for future years, WellCare recommends CMS adopt a process similar to that used for the changes to the community segments of the risk adjustment model. Here, the agency included background, presented research and findings, discussed how the model was developed, and provided information on alternative proposals. CMS solicited this feedback in the fall of 2015 and noted that comments



would inform the agency's proposal for the following year's advance notice. This process provided transparency to plans regarding the agency's proposal development. It also allowed plans to fully assess the proposal's impact and provide CMS with specific feedback to help inform the policy. WellCare supports a similar process for any changes to the coding pattern adjustment, including simulations of the effects of different proposals.

Attachment VI. CY2019 Draft Call Letter (page 97)

Section I. Parts C and D (page 100)

Enhancements to the 2019 Star Ratings and Future Measurement Concepts (page 106)

Members Choosing to Leave the Plan (page 111)

WellCare supports CMS' proposal to expand the exclusions for this measure to include plan benefit package (PBP) service area reductions (SARs) that result in the unavailability of PBPs for beneficiaries to move into within a contract. Currently when a plan sponsor reduces its service area, beneficiaries have to involuntarily leave the plan if there is no other similar PBP available within the contract. While this choice is involuntary, it is reflected as a voluntary decision in the "Members Choosing to Leave the Plan" measure, thus negatively impacting a plan's Star Ratings. For this reason, we support expanding the exclusions outlined on page 112 of the CY 2019 Draft Call Letter to more accurately reflect members choosing to voluntarily leave the plan.

2019 Star Ratings Program and the Categorical Adjustment Index (page 122)

WellCare appreciates CMS' ongoing commitment to studying the low income and disabled populations and the effects of serving these populations on plan payment and performance under the Star Ratings system. We continue to believe that individual beneficiary socio-economic status characteristics impact plan performance under the Star Ratings methodology, and that the Star Ratings should account for differences in populations.

We appreciate CMS' consideration of the Assistant Secretary for Planning and Evaluation (ASPE) study on the effects of social risk factors on health outcomes of Medicare beneficiaries. We support CMS' continued dialogue with ASPE to discuss potential options for future MA Star Ratings. WellCare would like to take this opportunity to note that plans that perform below three Stars for three consecutive years will be eligible for termination in 2019. We urge CMS to thoroughly consider the findings in the second ASPE report before the agency commits to terminating plans with low star ratings. We also continue to encourage CMS to examine the impact of adjustment on all measures: process, intermediate outcome, outcome, and administrative to determine where any differences in performance based on low income and disability status exist, as we believe there may be additional measures that are affected by population differences that were not included in the initial analysis and subsequently, not included in the Categorical Adjustment Index (CAI).



Again, WellCare would like to thank the agency for its work surrounding the impact of socio-economic and disability status on Star Ratings, and reiterate the need for a meaningful solution to inequities in the Star Ratings methodology. While we appreciate the proposal to continue the use of the interim analytical adjustment, we believe that more meaningful adjustments are needed to appropriately account for the challenges plans undertake when serving the dual eligible, low-income subsidy (LIS) and disabled populations, and we look forward to partnering with the agency on these efforts.

CMS notes the Pharmacy Quality Alliance's (PQA) draft recommendations on the risk adjustment of the three current medication adherence measures. WellCare is pleased to hear that the PQA is providing these recommendations on risk adjustment. We look forward to seeing how CMS will implement the PQA recommendations in the future for these Star Ratings measures.

On page 126, CMS notes the measures selected for the CAI. WellCare asks CMS to provide additional detail regarding selection of the Medication Adherence for Hypertension for adjustment while not providing an adjustment on the other two medication adherence measures. In our experience, beneficiaries do not selectively choose which medications to which they will adhere. We are interested in the data differentials between the three Medication Adherence measures, and the rationale for selecting only one of the three measures for adjustment.

Disaster Implications (page 133)

Identification of Affected Contracts (page 134)

WellCare appreciates CMS' consideration of the impact of the 2017 natural disasters on Star Ratings. The unforeseen disasters of Hurricanes Harvey, Maria, and Irma, and the California wildfires have left devastating and enduring effects on affected areas. We note that CMS is choosing to exclude certain measures from the proposed adjustments such as call center measures and the appeals and grievance measures. While these measures may not directly affect members, plans may under perform in these measures for the 2019 ratings if their call centers or administrative offices are located in a disaster area. We recommend that CMS include these measures in the disaster relief adjustments to further mitigate the disasters' effects on Star Ratings. We also encourage CMS to consider including the early 2018 disasters such as the California mudslide that took place in January in its disaster implications adjustments. Though this event occurred in 2018, the effects of this disaster and other potential disasters that occur in early 2018 can impact 2020 Star Ratings, particularly if a disaster zone endured two or more disasters in a short period of time.



Changes to Existing Measures (page 141)

Hospitalizations for Potentially Preventable Complications (Part C) (page 141)

Due to concerns raised by experts and stakeholders, the National Committee for Quality Assurance (NCQA) is considering updating the specifications of this measure to include "observation stays." Stakeholders noted that including observation stays in this measure improves the completeness of the measure because these stays can represent failure to prevent serious complications. WellCare feels that observation stays do not always capture and represent failures to prevent serious complications. Frequently, members appear at a hospital rather than their primary care provider out of convenience or preference. Because these cases are not always suitable for inpatient admission, they often turn into observation stays. For this reason, we do not support including observation stays in this measure.

Potential Changes to Existing Measures (page 145)

Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D) (page 147)

The PQA updated the MTM Program Completion Rate for Comprehensive Medication Reviews (CMR) measure to include a new denominator exception for patients that are eligible for CMR with fewer than 61 days of continuous enrollment in the MTM program. WellCare supports this change as it more accurately captures the number of patients who complete the MTM program.

Potential New Measures for 2020 and Beyond (page 148)

Transitions of Care (Part C) (page 148)

CMS states that it plans to include the new Transitions of Care (Part C) measure with the following four indicators on display for 2020: notification of impatient admission, receipt of discharge information, patient engagement after inpatient discharge, and medication reconciliation post-discharge. For the notification of impatient admission indicator, CMS explains that documentation of a primary care practitioner of an inpatient admission on the day of admission or the following day is needed to calculate this measure. WellCare asks the agency for clarification on the party required to provide this documentation. Specifically, we ask if this documentation would need to be provided by the patient's primary care provider or if other professionals such as nurse practitioners and care coordinators could provide this documentation as well.



Depression Screening and Follow-Up for Adolescents and Adults (Part C) (page 150)

WellCare supports the addition of this depression measure to the display page. Adding a behavioral health measure fills a measurement gap, as there are relatively few measures that address behavioral health processes and outcomes. However, WellCare recommends an alternative instrument be used to gather data for certain populations. WellCare agrees that adults should be measured using the PHQ-9, a reliable and valid measure of depression severity. Adolescents should be measured using the PHQ-A, a slightly modified version designed for use in adolescents aged 12-17.

Anxiety (Part C) (page 151)

CMS explains that NCQA is exploring the feasibility and acceptability of developing quality measures that assess care for those with anxiety disorders. While we support CMS' and NCQA's initiatives to better measure care quality for those with behavioral health diagnoses, anxiety may be particularly challenging to assess. For example, an individual facing a variety of social risk factors may report feelings of anxiety due to his/her life circumstances. Improving quality of care for this individual may entail improving the individual's living situation as opposed to taking special precautions to care for the individual's anxiety disorder. We are concerned that anxiety measures may not fully reflect an individual's clinical status because the reported anxiety stems from non-clinical factors such as social determinants of health.

Additional PQA Medication Adherence Measures (Part D) (page 154)

WellCare is concerned about CMS' desire to add additional medication adherence measures to the Star Ratings. While we agree that medication adherence is important and leads to improved outcomes, we do not think the Star Ratings should focus so heavily on adherence measures. A member may affirmatively choose not to take his/her medication, may try to control the medical diagnosis with diet and exercise, and may still achieve his/her therapeutic goals. Medication adherence is a proxy for a medical outcome, but it is not a true indicator. It is more appropriate to look at health outcomes, such as the accompanying outcome measures included in the Part C Star Ratings, rather than examining claims to determine whether or not a member is taking a medication. WellCare encourages CMS to consider the adoption of more outcome measures as a way to accurately capture clinical quality.

Validation Audits (page 159)

Threshold for Requiring Validation Audit (page 160)

CMS currently requires sponsoring organizations that have more than five program audit conditions in their final report to hire an independent auditing firm. Per stakeholder feedback, CMS is proposing to exclude Compliance Program Effectiveness (CPE) conditions from the program audit conditions



threshold because they do not directly and adversely impact beneficiaries. WellCare understands CMS' goal to improve and enhance the program audit validation process to promote consistency and decrease burden on sponsors. While we support CMS' intentions, we feel that CMS should not exclude CPE conditions from the threshold calculation. The CMS CPE conditions were established to assist sponsoring organizations in evaluating the effectiveness of their Medicare compliance programs. Plans may excel or fall behind in different auditing areas. By excluding this audit condition, plans that do not do well on CPE may not be held accountable, because these conditions are not accounted for in the threshold. To ensure that each plan is assessed thoroughly and fairly for all of its compliance efforts, we recommend that CMS continue to include the CPE conditions audit area for threshold assessment.

Validation Audit Work Plan Template (page 162)

WellCare supports CMS creating a validation work plan template for sponsoring organizations undergoing an independent validation audit as it provides guidance to sponsoring organizations and promotes consistency in the auditing process. We encourage the agency to allow for some flexibility in the work plan so sponsoring organizations can tailor the template to their organization's conditions. We appreciate CMS' intention to submit a draft of this template in an upcoming Federal Register information collection, and we look forward to providing feedback on this template.

Plan Finder Civil Money Penalty (CMP) Icon or Other Type of Notice (page 164)

While WellCare recognizes CMS' goal of promoting transparency between enrollees and sponsoring organizations, we are concerned that the proposed Civil Money Penalty (CMP) icon to be displayed next to a plan sponsor's name on the Medicare Plan Finder will cause confusion for beneficiaries. Plan sponsors already undergo comparisons via the Star Ratings. Adding an additional level of comparison may further complicate a potential enrollee's decision-making process because of competing measurement systems. For example, plans may have a low-performing icon and not a CMP icon or visa-versa, which may not help a beneficiary understand his/her best option.

We also are concerned about auditing frequencies and the impact they may have on the CMP icon. When audits are not consistent, certain plans will be competitively disadvantaged. We understand that it is the agency's intention to audit all contracts over the course of a 3-year period. If some plans have a higher audit frequency than others, the more frequently audited contracts will likely accrue more penalties than those less audited. This will affect the frequency at which the CMP icon could be displayed next to the plan on the Medicare Plan Finder. Lastly, we would like to note that while CMPs indicate negative audit outcomes, they are not an uncommon for a plan undergoing an audit. Labeling plans with a CMP icon may not fully and accurately display the quality and caliber of a plan sponsor given the frequency of receiving a CMP from an audit.



Section II—Part C (page 168)

Health Related Supplemental Benefits (page 182)

CMS states that it intends to expand the scope of the primarily health related supplemental benefit standard to include benefits that, "diagnose, prevent, or treat an illness or injury, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and health care utilization." We support CMS' intention to expand this supplemental benefits definition as proposed in in the CY 2019 Draft Call Letter.

On February 9, 2018, The Bi-Partisan Budget Act of 2018 (BBA 2018) was signed into law. It included a provision allowing MA plans to offer a wider array of targeted supplemental benefits to chronically ill enrollees beginning in 2020. We ask CMS to clarify how its proposal is impacted by the BBA 2018 legislation. Allowing newly expanded supplemental benefits to be extended to all beneficiaries, and not solely beneficiaries with chronic conditions would better serve the Medicare population. All beneficiaries can benefit from health related supplemental benefits. Extending these health related supplemental benefits to all enrollees, and not just the chronically ill, may also reduce avoidable emergency department utilization and the development of chronic conditions for this population

Supplemental benefits under this broader interpretation "must be medically appropriate and ordered by a licensed provider as part of a care plan if not directly provided by one." We ask CMS to clarify its definition of a "licensed provider." Specifically, WellCare would like to know if a licensed provider would include clinical staff such as social workers and care managers that are employed by a sponsoring organization.

Lastly, in the section "Medicare Advantage Uniformity Flexibility" on page 184, CMS proposes to establish a mailbox where plan sponsors can submit inquiries on whether or not targeted supplemental benefits for certain beneficiary groups are allowable. We encourage CMS to adopt this idea for health related supplemental benefits as well so that sponsoring organizations can easily submit questions and receive feedback on their supplemental benefit ideas.

Rewards and Incentives (RI) for Completion of a Health Risk Assessment (HRA) (page 186)

Beginning in CY 2019, MA plans may include the completion of an HRA as a permitted health-related activity in an RI Program. WellCare applauds CMS for proposing to include completing the HRA as a health-related activity in the RI Program. As a sponsoring organization, WellCare strives to deliver the best care tailored towards each individual beneficiary. We know that personalized care begins with the completion of HRA. For this reason, we thank CMS for allowing plan sponsors to incentivize completion of the HRA so that sponsors can improve their ability to provide individualized care to their beneficiaries.



Section III—Part D (page 193)

Expanding the Part D over the Counter (OTC) Program (page 196)

We are encouraged that CMS is considering allowing sponsors to include additional OTC products such as dietary supplements and cough medicines in a Part D plan's coverage. CMS explains that for sponsors who elect to cover OTC products, the funding for the products would be covered in the Part D plan premium and would not result in any direct cost-sharing at the point-of-sale. Access to OTCs can redirect beneficiaries from high cost drugs, and in some cases save a beneficiary an emergency department trip. Because OTCs are cost effective drugs that can improve the conditions of an ill beneficiary, we recommend that these drugs be included in Part D bids as opposed to covering OTC drugs through administrative expenses.

Improving Drug Utilization Review (DUR) Controls in Medicare Part D (page 202)

Part D Opioid Overutilization Policy (page 202)

WellCare supports CMS' efforts to fight the opioid epidemic and to make sure plans are maintaining appropriate monitoring activities for their members receiving prescriptions for opioids. Under the Drug Utilization Review (DUR) program, sponsors are expected to reduce beneficiary overutilization of opioids and maintain access to needed medications using tools including appropriate plan-level claim controls at point-of-sale (POS) for opioids. These POS edits include: safety edits and quantity limits, improved retrospective drug utilization review to identify beneficiaries at high risk of an adverse event due to opioids, and case management with the identified beneficiaries' prescribers followed by beneficiary-specific POS edits to prevent Part D coverage of opioid overutilization.

In the CY 2019 Draft Call Letter, CMS proposes newstrategies to more effectively address the opioid epidemic in the Part D population. Specifically, CMS proposes to enhance the Overutilization Management System (OMS) by adding additional flags for high risk beneficiaries who use "potentiator" drugs such as gabapentin and pregabalin which are known to increase the likelihood of an adverse event when combined with an opioid. WellCare supports this proposal and recommends that CMS further extends these flags to all controlled substances due to the numerous negative interactions these drugs can have when combined with opioids.

CMS also proposes that all sponsors must implement hard formulary-level cumulative opioid safety edits at POS, at the pharmacy, and at a dosage level of 90 MME per day, with a 7-day supply allowance. While we recognize CMS' goal to mitigate the opioid epidemic by improving DUR controls, we believe that plans may be fulfilling CMS' intention with soft POS edits such as Drug Interaction, Drug Dosage, Ingredient Duplication, Age Precaution, Pregnancy precaution, and Therapeutic Duplication soft edits. If a plan sponsor is preventing opioid overutilization with their soft edits, then it would not be necessary for the plan to implement a hard edit. For this reason, we ask



CMS to maintain some flexibility for plan sponsors so they can assess their own opioid overutilization process to determine if hard edits are needed.

Days Supply Limits for Opioid Naïve Patients (page 212)

CMS proposes that it "intends to establish a days supply limitation policy for "opioid naïve patients" and seeks comment on implementing this limitation at 7 days or an alternative amount, such as 3 or 5 days. CMS also seeks comment on whether it should implement a days supply limit with or without a daily dose maximum (such as 50 MME per day). WellCare asks CMS to clarify the definition of an "opioid naïve patient". This phrase is very broad and could include anyone that has ever been prescribed an opioid, a person that has not had an opioid prescription for a given amount of time, or a person that has only had a brief history with opioid prescriptions in the past. Having a clear definition for this term is important because it affects howsponsors will need to implement this policy. For example, depending on the definition sponsors may be presented with some barriers to tracking an individual's past opioid use history. Beneficiaries that do not have well documented medical records may appear to be opioid naïve when in fact they may have had a period with an opioid prescription. We look forward to better understanding CMS' definition of opioid naïve patients.

We recommend that CMS implement a supply limitation of 7 days. We recommend a 7 day limitation because this is consistent with the Centers for Disease Control and Prevention's (CDC) Guideline for Prescribing Opioids for Chronic Pain recommendations. We recommend that CMS start with a 7 days supply limitation for 2019 but examine opioid pilot program data across states to support a final decision on the number of days that should be permitted. Lastly, we believe that an MME maximum dosage is needed for this policy to be effective. Not including an MME maximum dosage limit will nullify the implementation of a days supply limitation because prescribers could increase the dosage when faced with a shorter days supply limitation.

Opioid Duplicative Therapy Safety (page 213)

In effort to improve opioid drug safety, CMS proposes that all Part D plan sponsors implement a soft POS edit for duplicative long-acting (LA) opioid therapy beginning in 2019. The agency requests feedback from Part D sponsors on this proposed expectation to implement a soft duplicative LA opioid therapy POS edit. While we recognize and support CMS' goal to mitigate the opioid epidemic, we ask CMS to consider the number of edits it is proposing as it may lead to provider abrasion. When multiple POS edits for different scenarios exist, it may be challenging for providers to keep track of which edit applies in a given case, not to mention difficulties that may arise when two or more POS edits conflict with one another. We recommend that CMS work alongside the National Council for Prescription Drug Programs (NCPDP) to better assess how conflicting edits would interact with one another, particularly from a claims perspective. The NCPDP can help create standardized processes for submitting claims that may trigger multiple POS edits on both the provider and pharmacy side. We believe that with the help of the NCPDP, CMS will be able to successfully execute the proposed POS edits it presents in the CY 2019 Draft Call Letter.



Using the Best Available Information when making B vs D Coverage Determinations for Immunosuppressants and Inhalation Durable Medical Equipment (DME) Supply Drugs (page 218)

CMS proposes new guidance on how Part D sponsors should determine whether a drug is included under Part B coverage versus Part D coverage for immunosuppressants in the setting of an organ transplant. To make this determination, CMS proposes that plan sponsors would now rely solely on information available from CMS via the Medicare Advantage and Prescription Drug (MARx) system. In order for plan sponsors to successfully use the MARx system to determine immunosuppressant coverage, CMS should expand the organ transplant indicators listed in MARx to include immunosuppressant indicators for lung, liver, and cardiac transplants.

Part D Mail-Order Refill Consent Policy—Solicitation for Comments (page 220)

Currently, beneficiaries need to provide prior consent for mail-order refills prior to shipping. If beneficiaries report that the drugs are unwanted or unneeded, plans are expected to provide a full refund for any refills auto shipped. CMS is considering replacing the affirmative prior consent for refills with a refill shipping reminder which will provide sufficient time for a beneficiary to cancel an order. Fromour experience, we encounter beneficiaries at both ends of this spectrum—beneficiaries that expect their medicines and do not desire to provide an affirmative prior consent, and beneficiaries that want to know what is being delivered to them and when it will be delivered. We support CMS' consideration of replacing the affirmative prior consent with a refill shipping reminder. We encourage CMS to explore permitting Part D sponsors to use text reminders or mobile application notifications to promptly remind beneficiaries of their mail-order refills so that they can choose to accept or cancel the order as needed.

Conclusion

WellCare appreciates the opportunity to provide comments on these important policy issues and to partner with CMS. If your staff would like further detail on any of our recommendations, please feel free to contact me at (813) 206-5606. Thank you for your consideration.

Sincerely,

Michelle G. Turano

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