March 6, 2015

VIA Electronic Filing: AdvanceNotice2016@cms.hhs.gov

Mr. Andrew Slavitt, M.B.A.
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Dear Mr. Slavitt:


MAPRx brings together beneficiary, family caregiver and health professional organizations committed to improving access to prescription medications and safeguarding the well-being of beneficiaries with chronic diseases and disabilities under the Medicare prescription drug benefit (Part D). On behalf of millions of Medicare beneficiaries with chronic conditions who rely on Part D for essential medications, the MAPRx Coalition appreciates this opportunity to submit comments in response to the proposed rule regarding “Advance Notice of Methodological Changes for CY 2016 for MA Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter,” hereafter referred to as the Advance Notice and Draft Call Letter, issued by the Centers for Medicare & Medicaid Services (CMS) on the February 20, 2015.

Specifically, MAPRx would like to address the following issues raised in the proposed rule:

- Exceptions and Appeals Process
- Star Ratings and Dual-Eligibles
- Formulary Oversight
- Drug Utilization Review Controls
- Tier Labeling and Composition
- Specialty Tiers
- Use of Multiple Tiers with Coinsurance Cost-Sharing Rates

Exceptions and Appeals Process

In the CY 2016 Draft Call Letter, CMS reiterated its concern with Medicare Advantage Organization (MAO) and Part D plan sponsor non-compliance with exceptions and appeals requirements. In response, CMS clarified the denial notice and pharmacy notice plan requirements. In addition, CMS proposed changes to enhance the beneficiary
experience when a claim is denied at the point-of-sale and to improve the data available regarding exceptions and appeals.

MAPRx strongly supports CMS efforts to improve Part D appeals process. MAPRx supports CMS' clarifications regarding denial notices and pharmacy notices and strongly supports the future improvements proposed by the Agency.

**Denial Notices**

CMS reiterates that for denial notices, plans are required to ensure that enrollees and providers receive “accurate, clear, and detailed information related to the specific reason(s) for denial.” This must include a description of the relevant Medicare coverage rule or plan policy (which includes formulary requirements) that resulted in a denial. Furthermore, the Agency clarifies that MAOs and Part D plan sponsors that need clinical information to assess a coverage request must conduct and document outreach efforts to obtain the necessary clinical documentation from the provider. Documentation should ensure that outreach efforts are conducted where necessary and the number, type, and timing of such outreach efforts should be also be recorded.

Lastly, CMS proposes changes to the standard Part D denial notice to ensure that enrollees and providers receive accurate, clear, and detailed information regarding the reason for the denial. The denial notices will include a new section that provides the clinical reasoning for the denial, any relevant coverage policy language, and any additional information that would be needed to cover the service or medication. Plans will populate the new section with detailed clinical information about the basis for the denial, relevant coverage policy and, if applicable, the information/documentation that is needed to cover the item, service or prescription drug. Plans will be encouraged to excerpt directly from plan or Medicare rules and guidance.

MAPRx applauds CMS' efforts to reiterate the denial notice requirements incumbent on MAOs and Part D plan sponsors. It is essential that plans are compliant with these requirements to ensure transparency and fairness for Part D beneficiaries. We also support the specific changes to the Part D denial notice proposed by CMS. We believe that such changes will meaningfully improve the information available to beneficiaries and their ability to access the care to which they are entitled in the Part D program.

**Improved Information at the Point-of-Sale**

Currently, Part D plans are required to arrange for network pharmacies to provide enrollees with a written copy of the standardized pharmacy notice when the enrollees' prescriptions cannot be filled under the Part D benefit and the issue cannot be resolved at the point-of-sale. As of today, pharmacy notices do not include any personalized information that would help a beneficiary understand why a prescription could not be filled. In response to feedback from beneficiary advocacy groups, CMS is exploring ways to improve the standardized pharmacy notice provided to beneficiaries.

To ensure that beneficiary access to appropriate medications is not compromised, CMS proposes two possible approaches to improve the standardized pharmacy notice. First, CMS proposes that the pharmacy notice be required to contain personalized, actionable information such as the reason for the denial. This would allow beneficiaries to make more informed decisions about whether to seek a coverage determination. Second, CMS proposes that a rejection at the pharmacy counter be treated as an adverse
coverage determination and immediately trigger the processing of an appeal by the plan. CMS expresses their intent to explore the feasibility of this proposal, including creating new transaction codes that could enable this sort of communication.

MAPRx is strongly supportive of CMS efforts to improve the pharmacy notices provided to beneficiaries at the point-of-sale. We recognize that there remain several outstanding operational issues that must be resolved to come to decision on how best to achieve the necessary reforms. We recommend that CMS arrange a multi-stakeholder discussion to continue the dialog and ensure beneficiary views are incorporated.

Expanded Data Collection for Part D appeals

CMS acknowledges that data currently available to the Agency, which consists of aggregate quarterly data submitted by plans annually, “do not provide sufficient information to allow [the Agency] to determine whether plans are providing appropriate access to Part D drugs through their coverage determination process.” In support of this argument, CMS notes that in 2013, less than 17 percent of all Part D coverage determinations that were denied by plans were appealed for redetermination, a percentage the Agency indicates it thinks is likely too low.

In response, CMS proposes developing an appeals tracking system to follow appeals. According to CMS, the tracking system would follow appeals from “beginning to end.” CMS defines the beginning of the appeals process as the initial coverage determination and the end as the final Independent Review Entity (IRE) decision. Data that CMS suggests for possible use in the tracking system includes case-level data, which itself includes the beneficiary, drug, and dosage. Including case-level data will allow CMS to link to PDE, IRE and other program data.

On the whole, MAPRx is strongly supportive of CMS’ proposal to implement an appeals tracking system in Part D. We have long argued that the Part D exceptions and appeals process was unacceptably opaque. However, while MAPRx is supportive of expanded data collection, we propose that the beginning of the appeals process should be defined as instances in which beneficiaries are denied coverage at the pharmacy counter (i.e., all prescriptions not filled). In addition, we believe the end of the appeals process would be better defined as decisions by either an Administrative Law Judge (ALJ) or Medicare Appeals Council (MAC). Lastly, MAPRx would like to see CMS collect more plan level data to capture the full range of beneficiary appeals and exceptions experiences.

Star Ratings and Duals-Eligibles

Recently, CMS has been engaged in an effort to determine whether dual status has a negative impact on MA and Part D Star Ratings scores. In the fall of 2014, CMS issued a Request for Information (RFI) on this topic and received input from external stakeholders. Based on CMS’ internal research and input from external stakeholders, the Agency concluded that the analyses had mixed results and additional research is required. However, CMS also concluded that since it is possible that Star Ratings scores may be impacted by dual-eligible / low-income subsidy (LIS) beneficiaries, it is necessary to reduce the weight of six Part C measures and one Part D measure (see measures listed below) by half. In the case of the Part D measure, CMS proposes only to down-weight the measure for stand-alone Part D plans (PDPs).
<table>
<thead>
<tr>
<th>Measure</th>
<th>2015 Weight</th>
<th>2016 Proposed Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast Cancer Screening (Part C)</td>
<td>1.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Colorectal Cancer Screening (Part C)</td>
<td>1.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Diabetes Care – Blood Sugar Controlled (Part C)</td>
<td>3.0</td>
<td>1.5</td>
</tr>
<tr>
<td>Osteoporosis Management in Women who had a Fracture (Part C)</td>
<td>1.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Rheumatoid Arthritis Management (Part C)</td>
<td>1.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Reducing the Risk of Falling (Part C)</td>
<td>1.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Medication Adherence for Hypertension (RAS antagonists) (Part D)</td>
<td>3.0</td>
<td>1.5</td>
</tr>
</tbody>
</table>

We would like to reiterate that CMS has not made a final determination regarding whether dual-eligible / LIS status have a material impact on MA and Part D plan performance on Star Ratings. The Agency itself highlights that its proposal to reduce the weights for seven Part C and D measures is only an interim policy that is subject to future revision based on forthcoming research and findings from CMS.

First and foremost, MAPRx applauds CMS for the exhaustive review of the existing evidence linking dual-eligible / LIS enrollment and plan performance. In addition, we commend the Agency for its transparent release of the research it has commissioned and received from external stakeholders to date. We share CMS’ interest in this issue and both want to ensure that plans that provide coverage to the most vulnerable Medicare beneficiaries are not inappropriately penalized and that such plans are providing the highest quality care possible to beneficiaries.

However, we remain unconvinced that differences in plan performance are caused by dual eligible or LIS enrollment and, more importantly, do not believe holding plans to a lower standard on essential quality measures is the appropriate response. We believe that CMS’ proposed action is premature and encourage the Agency to withhold changes to the Star Ratings until both NCQA and CMS have completed studying the issue. We are aware of plans that enroll high numbers of dual-eligible and LIS beneficiaries that perform well on the Star Ratings measures and are concerned that plans that provide lower quality care to beneficiaries will inappropriately benefit from this proposal.

Furthermore, we strongly urge CMS to reconsider its proposal due to the potential impact on beneficiary outcomes and quality of care. Multiple measures included in CMS’ list are outcomes-based measures, including the Diabetes Care – Blood Sugar Controlled measure and the Medication Adherence for Hypertension (RAS Antagonists) measure. These measures are essential to improving the population health of dual-eligibles and LIS beneficiaries, many of whom suffer from multiple chronic conditions like diabetes and high blood pressure. By implementing this proposal, CMS risks that patients will receive lower quality care and may ultimately have worse outcomes.
Formulary Oversight

MAPRx is concerned about reduced coverage of drugs on the formularies of low-income subsidy (LIS) benchmark plans. According to data provided to MAPRx by Avalere Health, the percent of available drugs included on LIS benchmark plans declined each year from 2013-2015. In addition, the share of brand drugs on LIS benchmark plan formularies also declined each year over this period.

<table>
<thead>
<tr>
<th>Year</th>
<th>Average Percent of Drugs Covered</th>
<th>Average Percent of Drugs that Are Brands</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>59.2%</td>
<td>44.8%</td>
</tr>
<tr>
<td>2014</td>
<td>58.0%</td>
<td>44.0%</td>
</tr>
<tr>
<td>2015</td>
<td>54.9%</td>
<td>42.2%</td>
</tr>
</tbody>
</table>

MAPRx believes that this trend in which the percentage of available drugs covered on benchmark plan formularies is reduced each year is very troubling, especially given the vulnerable population affected. We have historically supported CMS’ stringent review of formularies offered in Medicare Part D and urge CMS to use its authority to ensure that LIS beneficiaries are not faced with skinnier and skinnier benefits each year. We also strongly urge CMS to analyze formularies to determine whether appropriate access is afforded to needed drugs and classes of drugs. In general, we would like to see more oversight by CMS to ensure robust formularies and would welcome a dialogue with the Agency to help ensure that its approach to formulary oversight results in meaningful access for Medicare beneficiaries.

Drug Utilization Review Controls

In 2016, CMS proposes to require that Part D sponsors implement soft-formulary edits based on cumulative daily morphine equivalent dose (MED) to continue the reduction of opioid overutilization. CMS expects sponsors’ P&T committees to develop the specifications for a cumulative MED soft point-of-sale (POS) edit to prevent opioid overutilization while minimizing false positives. In addition, CMS recommends a POS edit threshold of 200mg cumulative MED when ordered by two or more prescribers of the overlapping opioid prescriptions. In addition, CMS proposes edits to the Opioid Monitoring System (OMS) and indicates that it is interested in revisiting whether to expand the Part D overutilization policy to other drugs or classes of drugs and clinical treatment issues.

MAPRx commends CMS for its efforts to reign in fraudulent and overutilization of opioids. Opioid abuse is one of the most challenging public health issues we are faced with today. However as CMS implements its policies, the agency must maintain a balanced approach that ensures beneficiaries have access to medications in accordance with their needs. While heightened scrutiny of drug use may be warranted with respect to those who over-utilize opioids, CMS should avoid drastic measures that severely restrict access to needed prescription drugs; general “rules of thumb” should not be used to restrict utilization. For example, a beneficiary who has side effects from one medication may be restricted from obtaining a medically appropriate alternative due to plan restrictions. As CMS considers expanding current policy to additional categories, MAPRx urges CMS to study the experience with opioids and proceed with caution. We
believe that beneficiary protections must be put in place to ensure that Medicare beneficiaries are not unduly prevented from receiving necessary care.

**Tier Labeling and Composition**

CMS notes that many stakeholders have expressed concern regarding increasing cost-sharing amounts for generic drugs. Stakeholders also expressed concern about the perception that certain generics are “non-preferred” based on the current tier labeling structure. In response, CMS proposes to alter the tier labeling for generic tiers in 2016 by merging the generic and non-preferred generic tiers into one “Generic” tier. Should plans wish to have a lower cost-sharing tier for certain generic drugs, the tier should be labeled the “Preferred Generic” tier.

Furthermore, CMS itself notes that it is observing “a growing trend of generic drug products being shifted to non-preferred brand tiers.” The Agency is right to recognize that this shift results in substantial increases in beneficiary out-of-pocket costs for generic drugs. For clarification in the short-term, CMS reiterates that the maximum available coinsurance for plans with any generic drugs is 38 percent, rather than 65 percent for tiers that exclusively contain brand drugs. Looking ahead, CMS commits to evaluating the trend toward increasing out-of-pocket costs for generic drugs as part of the bid review process and suggests that it will communicate concerns to outlier plans.

MAPRx shares other stakeholders’ concerns regarding increasing beneficiary costs for generic drugs and we appreciate CMS’ initial steps in addressing concerns about generic drug cost sharing. However, we believe this must only be a first step and urge CMS to monitor generic drug cost sharing trends closely going forward. We encourage CMS to continue to update stakeholders on this area of concern in future Advance Notice and Call Letter documents.

**Specialty Tiers**

The Draft Call Letter notes that the threshold drug price for inclusion on a specialty tier will remain at $600 for CY 2016. In addition, CMS notes that it has become aware that some plan sponsors are offering plans in which decreased or no deductible features apply only to certain tiers or to the specialty tier exclusively. CMS clarifies that the specialty tier may employ a coinsurance above 25 percent when a plan features a reduced deductible if and only if the reduced deductible applies to all tiers.

MAPRx remains very concerned about CMS’ specialty tier policy. CY 2016 marks the ninth year in which the specialty tier threshold remains at $600 despite significant increases in drug prices over the same period. Even if accounting only for inflation, as opposed to specific pharmaceutical price increases, one would expect some rise in the threshold for inclusion on the specialty tier. It is particularly surprising that CMS would opt to retain the $600 minimum after the release of the GAO study “Medicare Part D: Spending, Beneficiary Cost-sharing and Cost-Containment Efforts for High Cost Drugs Eligible for a Specialty Tier” (GAO-10-242) in January 2010 that found the median price of drugs included in specialty tiers, based on 2007 data, was $1,100 per month. This data alone supports the need to increase the threshold to reflect the higher price point for drugs and biologics in particular.

In past Call Letters, CMS has noted the possibility of discriminatory cost-sharing by plans. We believe this issue is particularly relevant to the specialty tier, where
discrimination would most likely be prevalent due to the high costs of specialty tier medications. Recent analyses have shown that on the exchanges, plans are increasingly placing all drugs in a class on the specialty tier. We are concerned that this trend will become prevalent in Part D as well and believe this is yet another reason for CMS to reevaluate the low threshold for inclusion on this plan formulary tier.

MAPRx strongly urges CMS to increase the specialty tier threshold for the first time since CY 2008. In addition, MAPRx continues to urge CMS to establish a cost-sharing exception and appeal process for drugs included on the specialty tier. Though not addressed in the Draft Call Letter, the issue remains exceptionally important for beneficiaries with conditions that have limited treatment options, all of which are included on the specialty tier. For all other plan formulary tiers, beneficiaries may file an exception for a drug to be placed on a lower cost-sharing tier, if that medication is the only therapy available. Specialty tier drugs are the sole exception to this, despite these drugs often having the most burdensome cost-sharing requirements simply because they are on the specialty tier. There is no justification for the lack of an appeals process in these cases. MAPRx respectfully asks CMS to reconsider this policy and implement an exceptions and appeals process immediately.

Despite our concerns about the continued use of $600 as the specialty tier threshold and the lack of a cost-sharing exception and appeal process for drugs included on the specialty tier, MAPRx would like to express its support for CMS’ efforts to increase transparency around its specialty tier decision making. In addition, we wholeheartedly support CMS’ clarifications regarding the requirement that plans apply the Part D deductible to all formulary tiers, and not just a select few tiers.

**Use of Multiple Tiers with Coinsurance Cost-Sharing Rates**

MAPRx is alarmed by the increasing use of high coinsurance cost-sharing on tiers other than the specialty tier. A recent data analysis by Avalere Health found that 66 percent of PDPs in 2015, representing nearly two-thirds of covered PDP lives, apply coinsurance to more than one tier. In 2014, only 32 percent of PDPs (representing 35 percent PDP lives) did the same. In total, enrollment in PDPs with more than one coinsurance tier increased from 6.4 million in 2014 to approximately 11.1 million in 2015. As CMS is aware, non-specialty tiers can employ coinsurance rates as high as 50 percent. In addition to our concerns about the increased cost-sharing burden that the growth in the use of coinsurance will create, we are also concerned about the potential for consumer confusion related to use of multiple tiers with coinsurance cost-sharing rates.

We are particularly concerned about the ability of the Part D program to continue to meet its goal of shielding beneficiaries from the high prescription drug cost burden of their care. According to a recent Health Affairs study, the affordability of prescription drugs has actually declined for some members of the Part D program in recent years. Specifically, the study found that elderly beneficiaries with four or more chronic conditions observed an increase in the prevalence of cost-related nonadherence from

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2009 to 2011, reversing previous downward trends.\textsuperscript{3} We believe that the growing use of specialty tiers and the expansion of numbers of beneficiaries in plans with more than one coinsurance tier is an important component in the trend toward increasing out-of-pocket costs in Part D.

MAPRx requests that CMS conduct a comprehensive review of Part D formulary designs to determine ways to lessen the burden of cost sharing on Part D beneficiaries. CMS should also use this opportunity to determine if Part D plans are engaging in discriminatory coverage practices that would not be recorded by CMS’ standard formulary review process. We believe that increased CMS monitoring is required to ensure that the Part D benefit is not eroded and transformed into an empty promise for America’s Medicare beneficiaries.

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MAPRx appreciates the opportunity to comment on the CY 2016 Advance Notice and Draft Call Letter. Thank you for consideration of our input. For questions related to MAPRx or the above comments, please contact Bonnie Hogue Duffy, Convener, MAPRx Coalition, at (202) 429-4017 or bduffy@quinngillespie.com.

Sincerely,

Allergy & Asthma Network

Alliance for Patient Access

American Autoimmune Related Diseases Association

Arthritis Foundation

Cancer Support Community

Caregiver Action Network

Epilepsy Foundation

GIST Cancer Awareness Foundation

International Foundation for Autoimmune Arthritis

Lupus Foundation of America

Men’s Health Network

National Alliance on Mental Illness

National Community Pharmacists Association

National Council for Behavioral Health

\textsuperscript{3} Nacl, et al. “Medication Affordability Gains Following Medicare Part D Are Eroding Among Elderly With Multiple Chronic Conditions.” Health Affairs. August 2014. \url{http://content.healthaffairs.org/content/33/8/1435.abstract}
National Council on Aging
National Organization for Rare Disorders
National Psoriasis Foundation
RetireSafe
The AIDS Institute
The ALS Association
The Arc of the United States
The Leukemia & Lymphoma Society