

March 4, 2016

VIA Electronic Filing: AdvanceNotice2017@cms.hhs.gov

Mr. Andrew Slavitt, M.B.A.

Acting Administrator

Centers for Medicare & Medicaid Services

7500 Security Blvd.

Baltimore, Maryland 21244

Dear Mr. Slavitt:

**Re:** **Advance Notice of Methodological Changes for Calendar Year (CY) 2017 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2017 Call Letter**

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 “Advance Notice of Methodological Changes for CY 2017 for MA Capitation Rates, Part C and Part D Payment Policies and 2017 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 19, 2016.

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

* Specialty Tier Threshold
* Tier Labeling and Composition
* Generic Tier $0 Copay Plans
* Formulary Oversight
* Drug Utilization Review Controls
* Coverage Determination Timelines
* Access to Preferred Cost-Sharing Pharmacies

**Specialty Tier Threshold**

The Draft Call Letter proposes to increase the negotiated price threshold for inclusion on a specialty tier from $600 in CY 2016 to $670 in CY 2017. Specifically, CMS found that the percent of 30 day equivalent fills that exceed $600 surpassed one percent in 2015. Combined with the significant increase in the cost of Part D drugs since 2008, CMS believes this finding necessitates an increase in the threshold. To finalize a new threshold, CMS applied the annual percentage increase for the Part D benefit parameters to the existing $600 threshold.

MAPRx strongly supports CMS’ proposal to increase the threshold for the first time since 2008. We have been deeply concerned about the lack of increases in the specialty tier threshold. We believe that a policy of holding the specialty tier threshold constant not only fails to take into consideration the effects of inflation on drug prices, but also the growing number of high cost specialty drugs that are reshaping the nature of the Part D benefit. We applaud CMS’ decision to take this step and appreciate the agency’s continued transparency in its specialty tier threshold decision-making process.

While we support and applaud CMS’ proposal to increase the specialty tier threshold, we encourage CMS to take additional steps to protect beneficiaries from the financial distress that beneficiaries can face when prescribed specialty medications. First, MAPRx strongly urges CMS to formally require that the specialty tier threshold be increased by, at a minimum, the same rate as the benefit parameters each year. We believe that applying the same rate of growth to the specialty tier threshold as applied to the Part D benefit parameters sets an important precedent that should serve as a foundation for a more dynamic specialty tier policy in future years.

Second, we continue 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. 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.

**Tier Labeling and Composition**

In the CY 2016 Call Letter, CMS noted that many stakeholders had expressed concern regarding increasing cost-sharing amounts for generic drugs. CMS itself noted that it was observing “a growing trend of generic drug products being shifted to non-preferred brand tiers.” Consistent with these findings, Avalere Health provided MAPRx with data showing that, on average, 23 percent of covered generic drugs are placed on standalone prescription drug plan (PDP) non-preferred brand tiers in 2016. For Medicare-Advantage prescription drug (MA-PD) plans, the figure is 22 percent.[[1]](#footnote-1) However, in the 2017 Draft Call Letter, CMS is proposing to add a non-preferred drug tier option for use in plan formularies. The non-preferred drug tier will be distinct from the non-preferred brand tier and plans will be required to select one or the other in their bids. The maximum cost sharing amounts for the two tiers will be the same but CMS will only assess the brand/generic composition of the non-preferred brand tier, if selected. CMS states that it is proposing to use this tier in response to plan requests for a tier option that will allow for a drug mix regardless of generic/brand status. CMS views the adoption of such a tier as part of its continued efforts to provide tier label options that provide flexibility and transparency in benefit design.

MAPRx remains concerned about increasing beneficiary costs for generic drugs and we are not convinced that CMS’ proposal will alleviate these concerns. In particular, we are concerned that by establishing a non-preferred drug tier, CMS is tacitly accepting the shift toward coverage for generic drugs that is undistinguished from brand drug coverage and leads to higher out of pocket costs. Should a large number of generic drugs shift to coverage on a non-preferred drug tier next year due to the lack of a generic/brand composition assessment, beneficiaries could face significant cost sharing increases that could result in interruptions in care.

Despite our misgivings, we applaud CMS’ commitment to increased transparency and agree that if plans are to be permitted to cover both brand and generic drugs on the same tier in large numbers then those tiers should not be labeled brand tiers. Consistent with this push for greater transparency, we urge CMS to employ more stringent restrictions on the number of generic drugs permitted to be covered on brand tiers. We believe the requirement that the majority of drugs on a brand tier be branded drugs is insufficient. The inclusion of large numbers of generic drugs on such tiers is misleading, increases generic drug cost sharing, and artificially lowers average cost sharing for the tier, allowing plans to achieve higher cost sharing for high cost brand drugs. As plans increasingly employ coinsurance amounts in excess of 40 percent of the negotiated price of the drug on non-preferred tiers[[2]](#footnote-2), it is essential that CMS rigorously review their composition to ensure appropriate access and prevent discrimination.

In the Draft Call Letter, CMS states that it will conduct an outlier test for those Part D sponsors who choose a copay for the non-preferred drug tier to determine if beneficiaries will receive a benefit for the majority of drugs on this tier at the proposed copay. MAPRx urges CMS to implement an outlier test to assess whether beneficiaries receive a benefit for all covered drugs placed on non-specialty tiers. We believe beneficiaries should not be required to pay cost sharing amounts that exceed the negotiated price of the drug at the very minimum.

**Generic Tier $0 Copay Plans**

In the Draft Call Letter, CMS encourages plans to develop formularies that provide beneficiaries with access to both vaccines and generics at $0 cost sharing rates. With regard to vaccines, a recent analysis from Avalere Health found that only 4 percent of overall Medicare Part D enrollees had access to ten recommended vaccines in 2016 without out-of-pocket costs.[[3]](#footnote-3) CMS acknowledges that adult immunization rates still remain low and encourages Part D sponsors to consider offering $0 or low cost sharing for vaccines.

With respect to generics, CMS includes details of analysis of 2012 prescription drug event (PDE) data which found that generic substitution rates were 1.2 to 3.0 percentage points higher among plans with generic-tier $0 copays as opposed to plans without. CMS further notes that this finding was applicable to both low-income subsidy (LIS) beneficiaries and non-LIS beneficiaries. In light of these findings, CMS encourages plans to implement generic tiers with $0 copays as both a cost saving measure and a way to improve access to low cost treatment options. In lieu of such tiers, CMS encourages plans to exempt generic medications from the deductible to provide first dollar coverage for such treatments.

MAPRx supports CMS’ efforts to encourage plan sponsors to utilize $0 cost sharing for both vaccines and generic drugs. Access to vaccines remains critically important to adult public health and yet very few Medicare beneficiaries enjoy the same level of coverage most employer-sponsored and state-based exchange plans are now required to provide. In addition, access to generic drugs is increasingly in jeopardy as prices increase and plans continue to cover generics on higher cost sharing, non-generic tiers. In light of these concerns, we encourage CMS to consider requiring plans to include a $0 cost sharing tier for certain vaccines and generic drugs in future years.

**Formulary Oversight**

MAPRx remains concerned about diminished drug coverage on low-income subsidy (LIS) benchmark plan formularies. According to data provided to MAPRx by Avalere Health, the percent of available drugs included on LIS benchmark plans declined each year from 2013-2016. In addition, the share of brand drugs on LIS benchmark plan formularies also declined each year over this period, until 2016 (see Table 1 below).

**Table 1. Average LIS Benchmark Plan Drug Coverage, 2013-2016[[4]](#footnote-4)**

| **Year** | **Average Percent of Drugs Covered** | **Average Percent of Covered Drugs that Are Brands** |
| --- | --- | --- |
| 2013 | 59.2% | 44.8% |
| 2014 | 58.0% | 44.0% |
| 2015 | 54.9% | 42.2% |
| 2016 | 53.7% | 42.5% |

MAPRx believes the 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 more limited access to needed drugs 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.

In addition to concerns about LIS benchmark plan coverage generally, MAPRx continues to be concerned about the possibility of discriminatory cost-sharing by plans, an issue that CMS has raised in past Call Letters. 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. Indeed, considerable focus has been trained on the practice employed by some state-based exchange plans of 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 encourage CMS to exercise its authority to prevent plans from offering discriminatory formularies to the fullest possible extent.

**Drug Utilization Review Controls**

In 2017, CMS continues to focus on opioid overutilization in Part D and is proposing a number of policies. First, CMS discusses three potential Pharmacy Quality Alliance (PQA)-endorsed measures on opioid utilization. CMS will develop patient safety reports related to the measures, and after a year of experience with the measures, the agency will consider adding them as display measures for 2019. Second, CMS is proposing to revise the criteria that would be considered potential opioid overutilization. Lastly, CMS is proposing new expectations for plans to develop specifications for cumulative point of sale (POS) edits to prospectively prevent opioid overutilization and to implement a POS edit when an opioid is prescribed following initiation of buprenorphine (i.e., opioid addiction) therapy.

MAPRx commends CMS for its efforts to reign in fraudulent use 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, MAPRx urges CMS to 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.

**Coverage Determination Timelines**

CMS is contemplating rulemaking that would allow extensions to Part D coverage determination adjudication timeframes in certain limited circumstances, including all coverage determination requests for drugs that require utilization management (UM). CMS is concerned that the need to obtain information from providers to adjudicate a coverage determination may cause plans to decline coverage due to lack of information and therefore push the final decision into the redetermination process which has longer adjudication timeframes. As a result, CMS believes that some beneficiaries may be waiting longer than is necessary or appropriate to obtain needed medications. In particular, CMS believes that in cases where the adjudication timeframe includes a weekend or holiday (or both), plans may be less likely to reach the prescriber to obtain necessary information before the adjudication timeframe expires.

CMS is soliciting comments from stakeholders regarding potential proposed regulatory changes that would permit Part D plans to extend the adjudication timeframe for coverage determination requests for drugs subject to UM where the plan has been unable to obtain needed clinical information from the prescriber despite reasonable efforts to do so, and the adjudication timeframe has been impacted by a weekend or holiday.

MAPRx shares CMS’ concern regarding potential access delays when Part D plans are unable to obtain the necessary information to make a coverage determination. We believe that adjudication timeframe extensions may be an appropriate way to address these concerns. However, we are deeply concerned about the possibility that the option to extend adjudication timeframes could be abused. We agree with CMS that any proposed extensions must be limited in nature and carefully defined. In addition, we recommend that if a plan exercises the option to extend, CMS should require the plan to provide a short term supply to the beneficiary during the adjudication. We urge CMS to work closely with stakeholders over the coming months to gather detailed feedback and suggestions to ensure that any proposal does not have unintended consequences. Furthermore, we urge CMS to use this opportunity to also build on efforts to improve both the functionality, transparency, and timeliness of the appeals process generally.

**Access to Preferred Cost-Sharing Pharmacies**

In the CY 2016 Call Letter, CMS announced that it would post information about 2016 Preferred Cost-Sharing Pharmacy (PCSP) access levels on the CMS website and require plans who were outliers with respect to access to PCSPs to disclose that their plan’s PCSP network offered lower access than other plans. Based on results of recent CMS analysis of outlier access rates, CMS does not plan to make significant changes for 2017.

MAPRx recommends that CMS require plans to prominently display their designation as a PCSP outlier. Currently, it is challenging to locate the required information in some of the plan marketing materials. CMS should provide greater oversight of marketing materials given that the PCSP outlier language can be difficult to find.  In addition, CMS should include information regarding PCSP access in the Plan Finder so that beneficiaries can make a more informed choice when shopping for drug plans.

MAPRx appreciates the opportunity to comment on the CY 2017 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) 540-1070 or bduffy@nvgllc.com.

Sincerely,

American Association on Health and Disability

American Autoimmune Related Diseases Association

Arthritis Foundation

Asthma and Allergy Foundation of America

Caregiver Action Network

Epilepsy Foundation

GIST Cancer Awareness Foundation

International Foundation for Autoimmune Arthritis

Lupus Foundation of America

Mental Health America

National Alliance on Mental Illness

National Kidney Foundation

National Psoriasis Foundation

RetireSafe

The Amyotrophic Lateral Sclerosis Association

The Arc of the United States

1. Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features. 2016 plan data were released in October 2015. For data provided here, Avalere only reviewed plans with 5-tier formularies. [↑](#footnote-ref-1)
2. An Avalere Health analysis of standalone PDP formularies in 2016 found that the enrollment-weighted average coinsurance was 42 percent for the most common formulary structure (5-tier formulary with two coinsurance tiers). The Avalere analysis used DataFrame®, a proprietary database of Medicare Part D plan features to assess plan formularies. 2016 plan data were released in October 2015. [↑](#footnote-ref-2)
3. Avalere Health. “Medicare Has the Potential to Avoid Preventable Illnesses by Encouraging Broader Coverage for Adult Vaccines.” February 18, 2016. <http://avalere.com/expertise/managed-care/insights/medicare-has-the-potential-to-avoid-preventable-illnesses-by-encouraging-br> [↑](#footnote-ref-3)
4. Data is not weighted by plan enrollment. [↑](#footnote-ref-4)