**National Association of Specialty Pharmacy**

**Summary of CMS Final 2016 Call Letter Pertaining to Medicare PDPs**

**April 8, 2015**

On April 6, 2015 the Centers for Medicare & Medicaid Services (“CMS”) issued the final payment rates and policy changes to Medicare Advantage and Prescription Drug Plans for 2016. On average, the expected revenue change is an increase of 3.25 percent. CMS released the proposed Advance Notice and Draft Call letter on Friday February 20 2015 and accepted comments through Friday, March 6. CMS states in its press release that Medicare Advantage (MA) enrollment has increased 42 percent since the ACA was passed with more than 16 million beneficiaries enrolled, which represents approximately 30 percent of the overall Medicare population. CMS further states that average premiums for MA plans are lower today than they were in 2010, dropping 6 percent between 2010 and 2015. Below please find a brief summary of the agency’s proposals that are relevant to specialty pharmacies.

CMS finalized the new clinical updates to its risk adjustment model to better predict plan liability for prescription drugs. CMS added two new drug category conditions and deleted four drug category conditions when calculating prescription drug risk. Specifically, the agency added chronic viral hepatitis C and secondary cancers of the bone, lung, brain and other specified sites as new drug condition risk categories and deleted the following four drug risk categories: gram negative/staphylococcus pneumonia and other lung infections, chronic kidney disease stage 3, chronic kidney disease stage 1, 2 or unspecified and nephritis.[[1]](#footnote-1) The agency states that these changes will help improve the predictive power of the drug condition categories and will reflect the impact on Part D that certain drugs are having.

CMS finalized the 2016 standard benefit structure as follows and as compared to 2015:[[2]](#footnote-2)

* + *Standard Benefit Deductible*: $320 to $360
  + *Initial Coverage Limit:* $2,960 to $3,310
  + *Out-of-Pocket Threshold*: $4,700 to $4,850
  + *Estimated Total Covered Part D Spending for Applicable Beneficiaries*: $7,061.76 to $7,515.22
  + *Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit:*
  + Generic/Preferred Multi-Source Drug $2.65 to $2.95
  + Other $6.60 to $7.40

The CY 2016 formulary submission window opens on May 8, 2015 and closes on June 1, 2015 and CMS anticipates releasing the 2016 formulary reference file in May. CMS finalized its proposed change to the formulary process for changes related to the notification requirements to beneficiaries that are subject to non-maintenance changes. There are two kinds of formulary changes; maintenance (e.g., generic substitution) and non-maintenance substitutions (e.g., therapeutic substitution), which must be submitted to and approved by CMS. Sponsors are currently prohibited from sending notice for non-maintenance changes until CMS has explicitly approved the change.

The 2016 Call Letter finalizes two important policies related to formulary changes. First, the July 31 deadline for the submission of both maintenance and non-maintenance changes, which went into effect for CY 2015 will also be the policy for 2016. Second, with respect to non-maintenance changes, CMS eliminated the current prohibition on sponsors of providing advanced notice to required parties until CMS explicitly approves the change.

CMS is revising the Part D denial notice to include a new section of the standard denial notice that plans will populate 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. Second, Plans will be required to, wherever possible, include extracted language from the relevant sections of the CMS approved plan formulary in this new section of the denial notice. The detailed clinical information that will be required in this new section will primarily be for the benefit of the physician or other prescriber (in contrast to the enrollee-friendly denial rationale that will continue to be provided in the existing free-text field of the denial notice). Thirdly, CMS is exploring the development of an appeals tracking system to receive regular data feeds for all coverage requests received and processed by plans in order to obtain a full data stream of information from beginning to end.

The 2016 Final Call Letter includes updates to policies related to Medication Therapy Management (MTM), Preferred Cost Sharing Pharmacies (PCSPs), Specialty Tier Threshold, and Maximum Allowable Cost (MAC) Pricing. Regarding MTM, targeted beneficiaries for a Part D Plan’s MTM program are enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual Part D drug costs that meet or exceed a certain threshold. The 2015 MTM program annual cost threshold is $3,138; whereas, the 2016 MTM program annual cost threshold will be $3,507.

As it relates to PCSPs, CMS finalizes three new policies. Currently, CMS evaluates Part D sponsor retail networks against TRICARE standards[[3]](#footnote-3) in which no distinction is made between standard cost sharing and preferred cost sharing pharmacies. In the spring of 2014, CMS initiated a study, to calculate plan-level beneficiary access to PCSPs. The study found that overall, 46% of plans provide a level of access to PCSPs in urban areas equivalent to the access standards stated above Compared to TRICARE) or all (i.e., preferred and non-preferred) retail pharmacies; 87% have PCSP networks that meet the suburban retail convenient access standard; and 95% have PCSP networks that meet the rural retail convenient access standard. Because of this, CMS is concerned that beneficiaries residing in areas of low access to PCSPs may be unable to obtain the lower cost sharing as advertised in plan materials.

In response, CMS is taking the following approach. First, CMS will publish information on PCSP access levels for each plan offering a preferred cost sharing benefit structure. Second, CMS will require plans that are outliers with respect to preferred cost sharing pharmacy networks to affirmatively disclose their outlier status in 2016 marketing materials. Third, prior to approving 2016 bids CMS will work with plans that have been identified as extreme outliers to address concerns about beneficiary access and marketing representations of the outlier plan. This is a change from the agency’s proposal, which was to work with plans whose PCSP networks are outliers (i.e., the bottom 10th percentile compared to all Part D plans in given geographic type) to either increase access to PCSPs in those areas or prevent plans from marketing themselves as offering preferred cost sharing in areas where the benefit is not meaningfully available.

For the tenth consecutive year, the minimum specialty tier eligibility threshold remains $600. Part D sponsors offering prescription drug benefit plans with a Specialty Tier are limited to the defined standard cost-sharing of 25%, if the plan requires a deductible, and to 33% cost-sharing if no deductible is required, or some percentage in-between dependent on a decreased deductible. Effective January 1, 2016 new regulations will be in effect governing the timeliness and format of drug pricing between the Plan sponsor and the pharmacy. These new regulations were finalized early in 2014 and CMS is using the 2106 Call Letter to caution Part D sponsors that updates of MAC prices must be disclosed to network pharmacies in a manner that is usable by pharmacies in order for them to validate prices and assure appropriate access.

Overall, CMS made only a few substantive relevant changes from its proposals that only impact payer network design related to pharmacies. CMS does not specifically address [NASP’s comments](http://media.wix.com/ugd/633570_c857a501884a42369367b0f4b227008b.pdf) related to transparency of the availability of a specialty drug or the timeframe in which the payer must notify the beneficiary of a change in specialty pharmacy. NASP will continue to advocate for these changes in the years to come.

1. <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors.html?DLSort=0&DLPage=1&DLSortDir=descending> [↑](#footnote-ref-1)
2. These costs do not reflect the fifty percent discount from manufacturers for therapies accessed in the “donut hole” nor the five discount that the government is providing on that same transaction. [↑](#footnote-ref-2)
3. The minimum standard for pharmacy [preferred or non-preferred] network access, based on the TRICARE standard, is as follows – urban areas: at least 90 percent of beneficiaries reside within 2 miles of a network retail pharmacy; suburban areas: at least 90 percent of beneficiaries reside within 5 miles of a network retail pharmacy; rural areas: at least 70 of beneficiaries reside within 15 miles of a network retail pharmacy. [↑](#footnote-ref-3)