March 4, 2016

Mr. Sean Cavanaugh
Deputy Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

**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**

**BY ELECTRONIC SUBMISSION**

Dear Mr. Cavanaugh:

The National Community Pharmacists Association (NCPA) 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," issued by the Centers for Medicare & Medicaid Services (CMS) on February 19, 2016.

NCPA represents the interests of America's community pharmacists, including the owners of more than 22,000 independent community pharmacies. Together they represent an $81.4 billion health care marketplace and employ more than 314,000 individuals on a full or part-time basis.

Our comments will primarily focus on the following issues raised in the proposed rule:

- Incomplete and Inaccurate Bid Submissions
- Enhancements to the 2017 Star Ratings and Beyond
- Part D Reporting Requirements for MTM
- Access to Preferred Cost Sharing Pharmacies
- Part D Benefit Parameters for Non-Defined Standard Plans
    - Tier Labeling and Composition
    - Specialty Tiers
- Improving Drug Utilization Review Controls in Medicare Part D and CMS' Expectation for Formulary-Level Cumulative Opioid POS Edits in CY 2017
- Establishing Mail Order Protocols for Urgent Need Fills to Prevent Gaps in Therapy


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**Incomplete and Inaccurate Bid Submissions**

NCPA supports CMS' continued close scrutiny of bid submissions, and strongly encourages CMS to more regularly and thoroughly review plan sponsors' bids for compliance with minimum provider access standards, formulary adequacy, and benefit parameters. Ensuring that plan sponsors meet these minimum standards is critical to ensuring that Medicare beneficiaries have access to appropriate and adequate coverage.

NCPA would like to share some recommendations for improving the Part D program aimed not only at the more cost-effective delivery of the benefit but also at better pricing and cost transparency for pharmacies under network agreements with Part D plan sponsors/pharmacy benefit managers ("PBMs"). Such recommendations will also serve to ensure that plan sponsors are incentivized to provide accurate annual bids to the CMS that will also result in savings to the Medicare Part D program overall.

*Medicare Part D Plan Sponsors Should Incur a Financial Penalty or Other Sanction for an Inaccurate Bid*

As described by the Department of Health and Human Services Office of Inspector General in its report entitled "Concerns with Rebates in the Medicare Part D Program," OEI-02-08-00050 (Mar. 2011), it is a common practice for Medicare Part D plan sponsors to underestimate expected rebates related to the formulary placement of manufacturer products in their annual plan bids to CMS. The same is true of so-called DIR fees imposed by Medicare Part D plan sponsors and their PBMs on pharmacies. Medicare Part D plan sponsors underestimate recoupment of such DIR fees from pharmacies at year end or other intervals in their annual bids resulting in gross prescription drug costs appearing higher in such sponsors' annual bids. The amount of rebates and DIR fees received and subsequently reported to CMS in the annual DIR report is much higher than those estimated in the sponsor's annual plan bid. The result is higher premiums for beneficiaries and CMS alike. While beneficiaries never recoup any premium overpayments at the end of a plan year, CMS does recoup some of its premium overpayments to a Medicare Part D plan sponsor that underestimates rebates and DIR fees in its annual bid during the annual reconciliation but only after floating the Medicare Part D plan sponsor an interest-free loan for the year in the form of artificially inflated premium payments.

To curb this pervasive practice, NCPA recommends that CMS consider financial penalties on Medicare Part D plan sponsors that owe an amount above a certain threshold as a result of the annual reconciliation. Such a penalty would reduce or eliminate the incentive for Medicare Part D plan sponsors to manipulate their annual plan bids by underestimating rebates and ignoring or underestimating the impact of DIR fees and offset any interest-free loan that CMS has provided to such plan sponsors in the form of

higher premiums paid by CMS to such Medicare Part D plan sponsors during the plan year.

**Enhancements to the 2017 Star Ratings and Beyond**

NCPA fully supports focusing on the development and endorsement of outcomes-based MTM measures as potential companion measures to the CMR measure. NCPA also supports the efforts of PQA as PQA continues to work with CMS to consider socioeconomic status risk adjustment of the PQA measures used in the Star Ratings program, including the three Proportion of Days Covered (PDC) measures. Related to forecasting to 2018 and beyond, NCPA supports CMS' consideration of measures related to the use of opioids from multiple providers or at high dosage in persons without cancer.

**Part D Reporting Requirements for MTM**

NCPA would like to reference comments submitted by the Pharmacy HIT Collaborative related to Part D Reporting Requirements for MTM. The Collaborative has been working with several pharmacy organizations and other groups regarding the use of a structured coding system – SNOMED CT – for medication therapy management (MTM) services clinical documentation by pharmacists.

NCPA strongly supports the Collaborative viewpoint that the consistent use of structured universal codes is critical to the expansion of documentation of MTM services and support the use and implementation of SNOMED CT codes for these services. The Collaborative has provided a way for prescription drug plans to request codes to map clinical terms to MTM SNOMED CT codes identified by the Collaborative. These MTM codes will be published on the National Library of Medicines Value Set Authority Center (VSAC). The Collaborative encourages CMS to incorporate the use of SNOMED CT into the Part D reporting requirements for MTM.

SNOMED CT is a strong universal coding system that can be tailored to meet medical specialties or subspecialties as they are needed. One specialty recently added to SNOMED CT is a medication management category that includes MTM. SNOMED CT documentation for MTM services will allow the pharmacist to document the clinical care that is provided through encounter-based coding and intervention-based coding. Encounter-based coding elements for MTM services include reasons or indications for the MTM visits and a description of the services that were provided (e.g., referral to MTM service, complications with medication therapy, comprehensive medication therapy review, targeted medication therapy review, medication-related action plan, pharmacist consultation with health care provider, patient education). Intervention-based coding allows the pharmacist to document drug therapy problems identified

during the medication regiment assessment, as well as provide the necessary SNOMED CT codes to document the patient's care plan or medication action plan.

Overall, SNOMED CT has the potential to create benefit for the patient and the greater health care environment, and again, the reason we encourage CMS to incorporate the use of MTM SNOMED CT codes into the Part D Reporting Requirements for MTM.

**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.

While recent CMS data shows an improvement in the number of Medicare Part D beneficiaries who have access to preferred cost-sharing pharmacies, NCPA remains concerned that the data still identifies many plans that are 'access outliers' which impact a significant number of beneficiaries. The total number of outliers could be higher because CMS excluded from this analysis plans granted waivers to the retail pharmacy convenient access standard requirement. So while progress has been made to improve access, NCPA encourages CMS to continue its work to achieve the goal of improving access to beneficiaries. Specifically, NCPA 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. We encourage CMS to provide greater oversight of marketing materials since the PCSP-outlier language can be difficult to find. In addition, we recommend that CMS include information regarding PCSP access in the Plan Finder so that beneficiaries can make a more informed choice when shopping for drug plans. Moving forward, NCPA would recommend that those plans that to date have been identified as "outliers" not be permitted to advertise that they offer "preferred cost sharing" in light of the fact that lack of meaningful access renders any potential benefit or savings meaningless.

*Medicare Part D Plan Sponsors Using a Preferred Network Should Incur a Financial Penalty or Other Sanction in the Event Drugs are More Expensive at Preferred Pharmacies than Non-Preferred Pharmacies After Considering DIR*

CMS has previously expressed concerns that Medicare Part D plan sponsor treatment of DIR fees and other pharmacy price concessions as DIR may result in the price for certain brand and generic drugs appearing lower at Medicare Part D plan preferred pharmacies when at the end of the year, considering all the DIR fees and price concessions in the annual DIR report, the cost to beneficiaries and the Medicare Part D program as a whole is actually higher for certain drugs at preferred pharmacies than at non-preferred pharmacies.

DIR fees are fees imposed by plan sponsors and their PBMs on pharmacies participating in their networks under various titles and with differing terms. Medicare Part D plan sponsors tend to ignore or underestimate the impact of the recoupment of DIR fees in their annual plan bids to CMS, only recognizing such fees in the DIR report filed with CMS after the end of the plan year. In addition to resulting in gross prescription drug costs being underestimated in sponsor bids, recognizing DIR fees solely in the DIR report at year-end results in the cost of certain drugs appearing lower on the Medicare Part D plan finder and in Prescription Drug Event ("PDE") records than they actually are after considering DIR fees.

As such, in order to incentivize Medicare Part D plan sponsors to cease this practice and present an accurate depiction of the true net cost of dispensing a drug to a Medicare Part D beneficiary at a particular pharmacy throughout the plan year, NCPA recommends that CMS consider a financial penalty or alternate sanction on Medicare Part D plan sponsors utilizing preferred networks when the true net cost of dispensing drugs from the preferred pharmacy locations exceeds the true net cost of dispensing drugs from the non-preferred pharmacy locations considering the PDE records and all DIR.

**Part D Benefit Parameters for Non-Defined Standard Plans**

*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, the healthcare consulting firm Avalere Health's data found that, on average, 23 percent of covered generic drugs are placed on standalone prescription drug plan (PDP) non-preferred brand tiers in 2016. 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.

NCPA remains concerned about increasing beneficiary costs for generic drugs. In particular, we are concerned that, should a large number of generic drugs shift to coverage on a non-preferred drug tier, beneficiaries could face significant cost sharing increases. As plans increasingly employ coinsurance amounts in excess of 40 percent of the negotiated price of the drug on non-preferred tiers, it is essential that CMS

rigorously review their composition to ensure appropriate access and prevent discrimination.

NCPA agrees with CMS that plans should utilize reasonable co-pays, and CMS' view that "consumers often prefer copayments to coinsurance because the former are more transparent and make it easier for consumers to predict their out-of-pocket costs." The use of coinsurance defeats the purpose of providing patients with greater clarity in a plan's design. The inability to access drug information prior to choosing a plan puts individuals who rely on prescription drugs at a significant disadvantage. Coinsurance also results in higher patient costs, especially for those enrollees who do not qualify for cost-sharing reductions, since insurers are increasingly placing high-cost drugs on 'specialty' tiers.

NCPA opposes the use of coinsurance for specialty drug tiers. 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. We urge CMS to implement an outlier test to assess whether beneficiaries receive a benefit for all covered drugs placed on non-specialty tiers.

Specialty Tiers

The Draft Call letter proposes to amend the definition of "specialty" drugs by amending the cost threshold from $600 per month to $670 per month for 2017. NCPA is generally supportive of this proposed change. In addition, NCPA would like to take this opportunity to highlight our support for the current regulatory guidance that CMS has provided to Part D plans that provides that "Part D plans may not restrict access to certain Part D drugs to "specialty" pharmacies within their Part D network in such a manner that contravenes the convenient access protections of Section 1860D-4(b)(1)(C) of the Social Security Act and 42 CFR 423.120(a)."

The Agency's own FAQ:
https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/QASpecialtyAccess_051706.pdf)
provides that in recognition of the fact that restricted access to specialty medications can be discriminatory in nature, Part D plans may not restrict access to Part D drugs by limiting distribution through a subset of network of pharmacies, except when necessary to meet FDA limited distribution requirements or to ensure the handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy. Therefore, Part D plans may not restrict access based solely on the placement of a Part D drug in a "specialty/high cost" tier because this tier placement alone is not indicative of any special requirements associated with such drug."

The CMS guidance allows Part D plans to specify, on a drug by drug basis, reasonable requirements for network pharmacies to ensure appropriate handling and dispensing of a particular Part D drug that requires special attention. These drug by drug requirements should only apply to special handling and dispensing that may be required by a "specialty" drug and not to reimbursement or other standard contracting terms and conditions. Requiring pharmacies to accept different reimbursement rates for certain "specialty" drugs is inconsistent with standard industry practice, could result in plans setting reimbursement rates below the market rates set in their standard contracts, and could be used to subvert beneficiary access to these medications.

**Improving Drug Utilization Review Controls in Medicare Part D and CMS' Expectation for Formulary-Level Cumulative Opioid POS Edits in CY 2017**

NCPA has been generally supportive of CMS expectations of plan sponsors related to improved drug utilization controls to prevent overutilization of medications in Part D. NCPA appreciates that CMS has required that plans take a step-wise approach to prevent overutilization. We are very pleased to see a reduction in overutilization of opioids in the Part D program, and would like to take this opportunity to comment on CMS' expectations that Part D sponsors implement formulary-level cumulative MED POS edits effective January 1, 2017.

NCPA appreciates that related to both soft and hard edits, CMS is recommending that sponsors minimize false positives by accounting for known exceptions. NCPA has previously recommended that patients residing in skilled nursing facilities are taken into account for purposes of exceptions. With many of our members providing pharmacy services to skilled nursing facilities, we have been concerned that formulary-level-POS edits may be especially prevalent in long-term care settings. We would ask that the patient residence code is taken into account when sponsors' Pharmacy and Therapeutics (P&T) committees develop the specifications for the soft and hard cumulative MED POS edits. We would also like to encourage CMS to continue to collaborate with the Pharmacy Quality Alliance related to measures that include criteria to monitor opioid overutilization.

Related to soft and hard POS edits, we remain concerned that pharmacists may end up processing a valid prescription, receive payment upfront and then be subject to retroactive recoupment. The community pharmacy should not be put in this position, as the pharmacist is not the party responsible for determining medical necessity or whether clinical upper thresholds should be waived in a particular situation. Rather, the prescriber and the payer should ultimately be responsible for those decisions. It is important that pharmacists are not held financially responsible for situations which may be beyond their control.

Also regarding soft and hard POS edits, we commend CMS for proposing parameters related to a certain daily cumulative MED threshold. We urge CMS to ensure that plans

are not deviating from the proposals to any great extent, as we have concerns that different plans will impose edits based on varying criteria so it may be more difficult for community pharmacists to triage these patients and explain the situation.

In summary, we would like to commend CMS on its step-wise approach to addressing potential overutilization, especially as it relates to the use of opioids. NCPA supports the current drug utilization review controls in the Medicare Part D program, rather than taking steps to move to a more restricted access program such as a prescriber and/or pharmacy "lock-in" program. Pharmacists stand ready to work with CMS and plan sponsors to make sure current and proposed controls are implemented correctly.

**Establishing Mail Order Protocols for Urgent Need Fills to Prevent Gaps in Therapy**

In the Call Letter, CMS states that it has "received beneficiary complaints about mail order pharmacies indicating that they will rush ship an urgently needed order, but the order does not arrive when promised or at all, potentially resulting in gaps in therapy." NCPA shares these concerns and urges CMS to explicitly require Part D sponsors to overnight medications or have the option to visit a retail pharmacy in response to urgent medication needs. NCPA also agrees with CMS that "beneficiaries should be informed of their options when requesting a rush order, with clear steps detailed in all applicable beneficiary materials."

Though not specifically addressed in the Call Letter, NCPA would like to highlight the difficulties that accredited diabetes self-management trained (DSMT) pharmacies are having getting enrolled with local Medicare Administrative Contractors (MACs) to be paid to provide these services. The American Association of Diabetes Educators (AADE) currently has 149 pharmacies accredited nationwide, but over the past three years more than 60 locations have had to give up their accreditation due to an inability to service patients, with pharmacies citing the lack of reimbursement due to complicated enrollment and billing processes. There could be a much healthier supply of accredited pharmacies; however a large number of local MACs are still unable to efficiently process 855B enrollment applications from accredited DSMT pharmacies. This effectively discourages already accredited DSMT providers from continuing the process and the problem lies in how pharmacies are enrolled in Medicare Part B. While pharmacy providers are accredited and trained to provide DSMT, the barriers to entry are daunting and often become a deterrent, which other providers are likely to face as well if additional entities are included as eligible providers.

Moreover, plan sponsors claim that they offer such training, yet significantly limit the eligible providers in their network and are often excluding community pharmacies as participating providers. As an example, there is a community pharmacy that is an accredited provider in Sparta, TN that was unable to service the beneficiary because they were enrolled in a managed care plan. The patient had to travel 100 miles round-trip to Nashville's Vanderbilt Hospital to get the training that she needed. Greatly

limiting provider networks for this population will only cause greater harm to the beneficiaries who could most benefit from such services. NCPA encourages CMS to provide clarity to MACs and plan sponsors that pharmacists can serve as DSMT instructors without being certified diabetes educators to provide this valuable service to beneficiaries.

**Conclusion**

NCPA greatly appreciates the opportunity to share with you our concerns and suggestions on the Advance Notice and Draft Call Letter. We would welcome the opportunity to discuss any of these issues with you at your convenience.

Sincerely,

Susan Pilch
Vice President, Policy and Regulatory Affairs