By electronic submission

March 1, 2019

The Honorable Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard C1-13-07
Baltimore, MD 21244

Re: *Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter*

Dear Administrator Verma,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to comment on CMS' Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter (the "Draft Call Letter"). NCPA represents America's community pharmacists, including 22,000 independent community pharmacies. Together they represent a $76 billion healthcare marketplace, employ 250,000 individuals, and provide pharmacy services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

Our comments will focus on the following issues addressed in the Draft Call Letter:

- Enhancements to the 2020 Star Ratings and Future Measurement Concepts
- Incomplete and Inaccurate Bid Submissions
- Improving Access to Opioid-Reversal Agents
- Access to Medication-Assisted Treatment
- Improving Access to Part D Vaccines
- Improving Drug Utilization Review Controls in Medicare Part D
- Part D Mail Order Auto-Ship Modifications

Enhancements to the 2020 Star Ratings and Future Measurement Concepts

<u>Forecasting to 2021 and Beyond</u>

Currently, in relation to the measure of pharmacy quality, there is wide variance and a complete lack of standardization across sponsors and PBMs in the quality measures utilized, terminology, timing, attribution methods, number of patients required to capture a metric, and calculation

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methods. In the environment NCPA's members operate in today, Part D plans and PBMs create their own "homegrown" measures with unrealistic thresholds and unattainable cut points. In contrast, plan sponsors and PBMs have a clear and defined understanding of how they are being measured, pharmacies are afforded no such opportunity. The "quality based" measures often used were developed for use in population health measurement at a health plan level, not developed for use in pharmacies with much smaller numbers of patients and are therefore not reflective of an individual pharmacy's overall quality.

When Part D plans and PBMs do use endorsed measures to evaluate pharmacies, such as those from the Pharmacy Quality Alliance (PQA) discussed below, they do not adhere to the measure specifications. Plans and PBMs will oftentimes alter the list of drugs used to capture a metric during the evaluation period. Moreover, our members sometimes have no insight into their individual pharmacy's quality standing in any given PBM network. Therefore, we urge CMS to move forward immediately and develop a standard set of metrics in conjunction with groups like PQA from which plans and pharmacies base contractual agreements.[1] This will ensure pharmacies are actually paid for the value they provide to plans and patients. Such metrics should be directly related to patient care.

NCPA continues to support and encourage CMS to recognize PQA's work on pharmacy-level metrics. For example, no one system or methodology exists to holistically evaluate the quality of a community pharmacy or to compare pharmacies within a network. Although EQuIPP currently is used to assess pharmacy performance on quality measures, the clear majority of which are for health plan level comparison, community pharmacies desire measures to demonstrate their value, which use data from all transactions and across all payers (including those that are not currently contracted with PQS for use in EQuIPP). In the context of PQA's current measure development efforts in this area, pharmacy-level measures are those that use data captured by the pharmacy. Such measures would be specified at the pharmacy unit of analysis and tested for validity and reliability for their intended use. NCPA fully supports these efforts and encourages CMS to closely track this work, as these efforts can lead to more consistent measurement of pharmacy quality in the Part D program, thus positively impacting beneficiary outcomes.

Finally, NCPA continues to advocate that risk adjustment needs to occur at the pharmacy level, in addition to the plan level, and pharmacies need to know which patients were included or excluded from a given measure. Not knowing which patients were included or excluded from any given measure being applied by a plan/PBM on a pharmacy today is a major barrier. If the pharmacy were to be given access to exclusions they would be better equipped to handle situations that are causing lower quality scores.

[1] NCPA made this suggestion in our recent comments to CMS' *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of Pocket Expenses,* CMS 4180-P.

Incomplete and Inaccurate Bid Submissions

NCPA supports CMS' reminder to plan sponsors to submit complete and accurate bids during the bid submission process. NCPA reminds CMS that pursuant to longstanding agency policy[2] reiterated as recently as CMS' proposed rule titled, *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses,* CMS-4180,[3] so-called pharmacy administrative service fees that are deducted by plans sponsors and their PBMs from reimbursement due to pharmacies participating in their Part D networks represent valid administrative costs and should be accounted for as such in their Part D bids.[4] In the aforementioned proposed rule, CMS correctly highlighted that fees charged to pharmacies such as "network access fees," "administrative fees," "technical fees," or "service fees" only serve the ability of our members to participate in the Part D plan's pharmacy network and bring no additional value. These fees must be accounted for as administrative costs in the bid. Otherwise, a plan sponsor could misrepresent the costs that are necessary to provide a benefit resulting in an artificially low bid and subsequent premiums. Therefore, NCPA urges CMS to ensure that all bid submissions include these administrative costs.

NCPA further suggests that CMS enumerate the following fees that our members say are included in their current contracts, in addition to the fees cited in the aforementioned proposed rule, that represent valid administrative costs that must be included in a plan's bid: claim transaction fees, network enrollment fees, customer service fees, network administration fees, payment processing fees, and remittance reporting fees.

Improving Access to Opioid-Reversal Agents

NCPA shares CMS' top priority to address prescription opioid overdoses by ensuring appropriate access to potentially lifesaving interventions, including naloxone. A common problem our community pharmacists have seen with naloxone access, however, is that a particular plan does not cover naloxone. Thus, NCPA supports CMS' suggestion that Part D sponsors at least include naloxone product on a plan's generic tier or if applicable, a Select Care Tier. NCPA also supports CMS' stance that benefit designs that inappropriately restrict access to naloxone (when use of the drug is clinically appropriate) will not be approved.

Access to Medication-Assisted Treatment

NCPA supports plan benefit designs that ensure access to Medication-Assisted Treatment (MAT), including CMS' expectation that MAT product be included in preferred formulary tiers. Further, NCPA continues to support expanding practitioner eligibility for DATA waivers, including pharmacists. Advancement of the pharmacist's role in MAT for opioid use disorders can help improve access and outcomes, while reducing the risk of relapse.

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[2] 79 Fed. Reg. 29,877 (May 23, 2014).
[3] 83 Fed. Reg. 62,152 (Nov. 30, 2018).
[4] 83 Fed. Reg. at 62,179.

Improving Access to Part D Vaccines

NCPA supports CMS in encouraging Part D sponsors to either offer a $0 vaccine tier or place vaccines on a tier with lower cost-sharing. Immunization is one of the most cost effective preventative healthcare techniques and has led to drastic reductions in the incidence of several diseases associated with morbidity and mortality. However, as CMS states, vaccination rates are still not at optimal levels and there are many individuals that are still not receiving them in Part D. In addition to having plans that offer vaccines at no or low costs, pharmacists can help to increase vaccination rates for a variety of reasons, including convenient locations and service hours and patients do not have to wait to make an appointment as they do with a physician. For this reason, NCPA continues to support robust access to vaccinations such as those for herpes zoster and tetanus-diphtheria acellular pertussis at community pharmacies.

Improving Drug Utilization Review Controls in Medicare Part D

For future Medicare Part D Opioid Overutilization Policies, NCPA continues to support the usage of PQA's revised opioid overuse measures, which aligns with CDC Guidelines for Prescribing Opioids from Chronic Pain.

Part D Mail Order Auto-Ship Modifications

<u>NCPA has long advocated for the use of mail-order prior patient consent</u>

NCPA has advocated over the past few years for the importance of mail-order patient consent for both new and refilled prescriptions prior to when the prescription is mailed to the patient. For example, prior to changes that CMS announced in the 2014 Call Letter, NCPA members recounted first-hand experience of the vast amounts of waste they saw generated through mail order auto-ship programs when patient's drop-off their unused or expired mail order medications at their local community pharmacy. The mail-order abuses were so rampant that NCPA's own "Dispose My Meds" program reported that community pharmacists collected over 100,000 pounds in unused or expired non-controlled medications. Many pharmacies utilizing the program noted the returns included thousands of dollars in returned medication from mail order pharmacies that continued to ship medications despite patient protests to stop.[5]

Unfortunately, in the 2016 Call Letter, NCPA was disappointed CMS' changed its policy and allowed Part D sponsors interested in offering automatic deliveries of new prescriptions to no longer need to request an exemption to the auto-ship policy by emailing CMS. At that time, NCPA questioned how CMS would monitor and enforce the exception for new prescription delivery conditions when they will be unaware how plans are implementing these policies.

More recently, NCPA conducted a survey on issues with mail order prescriptions, which demonstrates that changes in CMS' mail order policies in 2014 positively impacted the flow of

[5] NCPA, *Waste Not, Want Not*, *available at* https://www.ncpanet.org/pdf/leg/sep11/mail_order_waste.pdf.

patients coming into pharmacies with unwanted mail order prescriptions, while CMS' 2016 policy resulted in a negative change. The survey showed that about 39 percent of surveyed pharmacists said that following the 2014 changes in Part D plans, pharmacists saw a decline in patients coming into the pharmacy with unused mail order medications. In contrast, about 53.9 percent of surveyed pharmacists reported about the same or more patients came into the pharmacy with unused mail order medications, potentially signaling more restraints on mail order pharmacy could prevent unwanted mail order medications from being mailed to patients. Another 7.1 percent reported they did not recognize a change in patients coming into the pharmacy with unused mail order mediations.[6]

In comparison, following CMS' relaxation of patient consent requirements for 2016 Part D plans, the recent survey showed that about 70.6 percent of surveyed pharmacists reported that patients came into the pharmacy with the same or more of unused mail order medications. NCPA suggests that the increase of patients coming into the pharmacy with the same or more amount of unused mail order medications following CMS' 2016 change demonstrates that relaxing patient consent for mail order is not solving the problem. Based on these survey findings, NCPA continues to advocate for the use of patient consent for both new and refilled prescriptions prior to when the prescription is sent to the patient.

<u>NCPA urges proper guardrails are necessary for the proposed opt-in voluntary auto-ship program</u>

NCPA contends that guardrails are necessary for implementation of CMS' proposal to permit Part D sponsors to offer an opt-in voluntary auto-ship program for refills of established therapies. If these guardrails are not in place, it is likely waste and abuse will continue in the Part D mail order programs.[7] NCPA offers the following comments to support the creation of such guardrails.

First, NCPA appreciates CMS' reiteration that plan sponsors cannot require Part D beneficiaries to use mail order to auto-ship. NCPA stresses that this voluntary auto-ship program must remain exactly as it is described: optional for the beneficiary. The beneficiary must give prior consent before being enrolled in any mail order program and as outlined in the proposal, there must be adequate avenues for a beneficiary to opt-out of the program should the beneficiary choose to do so.

Further, NCPA appreciates the requirement under this proposal that plans must notify beneficiaries of the shipments of the prescription drugs twice before the prescription drugs are sent. NCPA requests that CMS require plan sponsors to keep record of such shipment notices as well as information on when the notices resulted in a missed call with no message left, bounce back email, or return direct mailings. NCPA requests that this information be collected should CMS choose to initiate an audit in the future on compliance with the requirements for this opt-in voluntary auto-ship program.

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[6] NCPA, *Report for 2018 Mail Order Survey* (Feb. 2018). A copy of the survey is attached as "Attachment A" to our 2019 Draft Call Letter comments.

[7] NCPA remains concerned that mail-order programs are not in the best interest of many patient given the emphasis on process-based metrics in these programs as compared to outcomes-based metrics. NCPA incorporates by reference our concerns outlined in our comments to the 2019 Draft Call Letter.

Additionally, NCPA supports that once a beneficiary is enrolled in an opt-in voluntary auto-ship program, programs should not default to refill all drugs automatically and that patients should be given the opportunity to select which prescription drugs should be refilled and shipped. NCPA appreciates CMS' reiteration that permitted auto-shipments cease once information becomes available that a beneficiary has entered a skilled nursing facilities or hospice.

Finally, NCPA requests that CMS maintain a portal or email whereby patients can create complaints against plan sponsors that do not comply with aforementioned requirements outlined in the Draft Call Letter.

Conclusion

We appreciate the opportunity to share with you our comments and suggestions on *Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter*. Should you have any questions, please contact us.

Sincerely,

Ronna B. Hauser, PharmD
Vice President, Pharmacy Policy and Regulatory Affairs