

By Electronic Submission via www.regulations.gov

March 5, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Re: Advanced Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter

Dear Administrator Verma:

The National Community Pharmacists Association (“NCPA”) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services’ (“CMS”) Advanced Notice of Methodological Changes for Calendar Year (“CY”) 2019 for Medicare Advantage (“MA”) Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter (the “Call Letter”) issued on February 1, 2018.

NCPA represents the interests of America’s community pharmacists, including the owners of more than 22,000 independent community pharmacies. Together they represent an \$80 billion health care marketplace and employ more than 250,000 individuals on a full and part-time basis.

Our comments will primarily focus on the following issues raised in the Call Letter:

- Enhancements to the 2019 Star Ratings and Future Measurement Concepts;
- Incomplete and Inaccurate Bid Submissions and Plan Finder Civil Money Penalty (CMP) Icon or Other Type of Notice;
- Improving Drug Utilization Review Controls in Medicare Part D;
- Part D Mail-Order Refill Consent Policy-Solicitation for Comments.

Enhancements to the 2019 Star Ratings and Future Measurement Concepts

NCPA supports CMS' focus on the new measures in the Call Letter, as well as the proposed changes to the star rating measures. However, regarding potential new measures for 2020 and beyond, we are concerned with inclusion of opioid overuse Part C measures on the display page, given the similar Part D measures that constitute data for Patient Safety reports back to plans and which may also be reported on the display page. PQA's opioid measures are NQF endorsed and have already been adopted into national programs.

NCPA is concerned that the addition of NCQA's measure, Use of Opioids at High Doses and Use of Opioids from Multiple Providers, which is not NQF endorsed, will add to measurement burden without any added benefit to improving quality. Additionally, NCPA has concerns that NCQA's measure will continue to cause confusion in the marketplace due to its similarity to PQA's measure.

Regarding NCQA's consideration of testing a measure concept that addresses the concurrent prescription of opioids and CNS depressants, NCPA also has concerns. Given that NCQA's measure concept would be partially duplicative of PQA's Concurrent Use of Opioids and Benzodiazepines measure, NCPA has concerns that the NCQA measure concept could cause undue measurement burden and confusion in the marketplace.

Related to CMS' proposal to begin reporting the Poly-ACH and Poly-CNS measures in the Patient Safety reports for the 2018 measurement year, NCPA appreciates this proposal and encourages adding these measures to the display page for 2021 and 2022. We also encourage CMS to consider proposing the Poly-ACH and Poly-CNS measures through rulemaking for the 2023 Star Ratings.

NCPA also appreciates and supports CMS' proposals for use of PQA's Concurrent Use of Opioids and Benzodiazepines (COB) measure in the Patient Safety reports for the 2018 measurement year, subsequent addition to the display page for 2021, and consideration for the 2023 Star Ratings.

Lastly, regarding Measurement and Methodological Enhancements, NCPA would like to make sure CMS is aware of ongoing efforts by the Pharmacy Quality Alliance to develop pharmacy level measures via the newly formed Pharmacy Level Measures Task Force. Community pharmacies today have no consistent or predictable way in which they are measured regarding quality, and unfortunately, in the Part D program, any quality is rewarded in the form of lower "DIR fees." Currently, 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 (including cash) 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, including cash transactions (in addition to third party payer transactions). 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.

Incomplete and Inaccurate Bid Submissions and Plan Finder Civil Money Penalty ("CMP") Icon or Other Type of Notice

In recent years, CMS has taken steps to combat the common practice for Medicare Part D plan sponsors to underestimate the expected rebates related to the formulary placement of manufacturer products in their annual plan bids to CMS. NCPA would like to highlight that the same is true for retroactive pharmacy direct and indirect remuneration fees ("DIR fees") imposed by Medicare Part D plan sponsors and their PBMs on pharmacies. In fact, NCPA has recently detailed this practice in its comments to CMS' current Proposed Part D Rule.¹

By way of background, Medicare Part D plan sponsors underestimate recoupment of DIR fees from pharmacies at year end or other intervals in their annual bids. The number 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 bids. 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 underestimate rebates and DIR fees in its annual bid during the annual reconciliation. However, this only occurs after floating the Medicare Part D plan sponsor an interest-free loan from the year in the form of artificially inflated premium payments.

To this end, NCPA supports the Civil Money Penalties ("CMP") that CMS has implemented to encourage plan sponsors to submit complete and accurate bids. NCPA would further encourage CMS to consider financial penalties on Medicare Part D plan sponsors that owe an amount above a certain threshold because 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 pharmacy DIR fees. Further, this policy would offset any interest-free loan that CMS has provided to such plan sponsors in the form of higher premiums paid by CMS to plan sponsors during the plan year.

¹ NCPA Comments to CMS Proposes Policy Changes and Updates for Medicare Advantage and the Prescription Drug Benefit Program for Contract Year 2019 (CMS-4182-P), Jan. 16, 2018, available at <http://www.ncpa.co/pdf/2019-proposed-part-d-rule-comments.pdf>.

CMS has further noted that, “[o]rganizations and sponsors should engage in sufficient due diligence to make certain their bids are accurate before submission.” To promote due diligence in bids, NCPA encourages CMS to consider requiring all plans to submit along with bid documents a company plan or policy that would be employed in the event of becoming aware of incorrect or erroneous Plan Finder information. Such plan or policy should also indicate the approximate response time within which the entity estimates the information being corrected.

Finally, NCPA appreciates CMS’ intention to display an icon or other type of notice on Plan Finder for sponsoring organizations that have received a CMP starting with the 2019 Annual Election Period. We support CMS in its efforts to continue to provide information to enable beneficiaries to make an informed enrollment decision.

Improving Drug Utilization Review Controls in Medicare Part D

NCPA is supportive of CMS expectations of plan sponsors related to improved drug utilization controls to prevent overutilization of medications in Part D. While NCPA recognizes enhanced controls are a necessary tool to prevent overutilization, NCPA suggests that CMS continue to consider exceptions to provide appropriate access to vulnerable populations struggling with pain management.

NCPA generally supports hard formulary-level cumulative opioid safety edits at POS at a dosage level of 90 MME per day. We also generally support implementing a days supply limit for initial fills of prescription opioids for the treatment of acute pain with or without a daily dose maximum.

Regarding hard POS edits, we commend CMS for setting parameters related to a certain daily cumulative MME threshold. We were previously concerned in past Call Letters that without consistent thresholds, plans would impose edits based on varying criteria, making it more difficult for community pharmacists to triage these patients and explain the situation.

Related to 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 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 and NCPA requests that CMS make this clear in the final Call Letter.

We are also concerned about vulnerable populations with the hard POS edits. For example, NCPA has previously recommended that patients residing in skilled nursing facilities are considered for purposes of exceptions. With many of our members providing pharmacy services to skilled nursing facilities, we have been concerned that POS edits may be especially prevalent in long-term care settings. We would ask that the patient residence code is considered when developing the specifications for POS edits.

Although we appreciate CMS' consideration to allow beneficiaries to receive a 7 days supply of the prescription that triggered the hard edits as written, we are concerned with the administrative burden this process would place on the pharmacist. NCPA is concerned about situations such as those outlined in the proposal, whereby a patient may present with more than one opioid prescription. The pharmacist would then be responsible for which prescription should qualify for the 7 days supply.

NCPA is concerned with potential retroactive recoupment as we previously mentioned, as well as burdensome recordkeeping requirements associated with this proposal. NCPA would rather work with CMS and all stakeholders on a consensus based set of exceptions to the hard edit. It will also be overly burdensome for independent community pharmacies to have to be familiar with each different plan formulary and subsequent related edits. It puts the pharmacist in the untenable position of being the sole gatekeeper to a medication that may be sorely needed, without having the complete picture of the patient's overall healthcare.

Related to a hard safety edit for initial opioid prescription fills that exceed 7 days for the treatment of acute pain, NCPA again asks for a consensus based set of exceptions to this edit. NCPA could generally support a 7 days limit but would not support fewer days. It is our members experience that many of the limits in place already via state law or imposed by PBM's are for 7 days. Again, we stress the need for exceptions for beneficiaries residing in skilled nursing facilities or other settings in which pharmacy care is provided under a single contract with a pharmacy. In these situations, limiting to a 7 or fewer day supply has proved to be a problem in states who have required this and not excepted nursing home patients. Limiting the number of days for LTC patients on opioids can cause issues with patients receiving their medications on time especially if the pharmacy must wait for an actual prescription from the physician/prescriber. So many of LTC prescriptions are still not electronically transmitted.

In sum, pharmacists stand ready to work with CMS and plan sponsors to make sure controls are implemented correctly.

Part D Mail-Order Refill Consent Policy-Solicitation for Comments

NCPA is concerned that CMS is considering changing its current policy on mail-order refill consent, further diluting the important guardrails that CMS has implemented to promote patient safety and discourage fraud, waste, and abuse in the Part D program. To this end, NCPA encourages CMS to maintain, reinforce, and strengthen its policy on mail-order consent.

CMS' Past Changes to Patient Consent

NCPA has frequently advocated over the past few years the importance of mail-order patient consent in both new and refilled prescriptions. 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 that they saw generated through mail order auto-ship programs when patient's drop-off their unused or expired mail order medications in 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.²

In the 2014 Call Letter, CMS sought to prevent the immense waste generated through mail order by requiring plan sponsors to obtain patient consent prior to initiating new prescriptions and prior to each refill for a prescription. While plan sponsors could ask for a waiver from such requirements, waivers were required to be emailed to CMS. Specifically, CMS noted:

CMS has received complaints indicating that some mail-service pharmacies automatically deliver new prescriptions that were phoned in or e-prescribed from the physician's office without confirming that the patient wants the prescription filled and delivered.

As a result of the automatic delivery practices described above, CMS has received complaints that beneficiaries have had medications delivered that had been previously discontinued or were otherwise unwanted and unnecessary at the time of delivery. Once the prescription is delivered, pharmacies are unable to return the medication to stock and generally do not reverse the claim if the patient does not want the prescription. Consequently, automatic delivery practices are potentially generating significant waste and unnecessary additional costs for beneficiaries and the Part D program overall.

. . . .

Therefore, to help control fraud, waste, and abuse as required by 42 CFR §423.504, and ensure that Medicare beneficiaries only receive new prescriptions and refills that are requested, for coverage year 2014, Part D sponsors should require their network retail and mail pharmacies to obtain patient consent to deliver a prescription, new or refill, prior to each delivery. We believe unintended waste and costs could be avoided if pharmacies confirmed with the patient that a refill, or new prescription received directly from the physician, should be delivered.³

² NCPA, *Waste Not, Want Not*, available at https://www.ncpanet.org/pdf/leg/sep11/mail_order_waste.pdf.

³ CMS, *Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, p. 144, available at <https://www.cms.gov/Medicare/HealthPlans/MedicareAdvgtgSpecRateStats/Downloads/Announcement2014.pdf>.

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

Even CMS publicly acknowledged the myriad of problems associated with mail order pharmacy by posting on its website specific complaints filed from January 1, 2013 to September 16, 2016 in the CMS Complaint Tracking Module (“CTM”) as well as specific grievances from a major Part D sponsor and PBM.⁴

Since the 2016 Call Letter changes, NCPA has continued to receive calls from members whose patients are continually duped into mail order by Part D plan sponsors/PBMs for new prescriptions. More so, patients still come into pharmacies with mail order prescriptions that were sent to the patient for a new or refilled prescription. Thus, NCPA does not support CMS’ recent proposal to replace affirmative prior consent for refills with a refill shipping reminder, prior to shipping. NCPA argues that replacing such consent will only increase the shipment of unwanted mail order prescriptions, even if mail order programs provide “sufficient” time for beneficiaries to cancel an order. “Sufficient” is an ambiguous term and NCPA highlights that mail order programs need more guardrails than CMS’ is currently proposing.

Further, NCPA recommends that CMS’ proposal to eliminate affirmative prior consent for refills but expect plans to implement a full refund policy for any refills auto shipped will also not eliminate the problem of programs sending unwanted prescriptions to patients. Refunds, while making the patient whole, will not stop mail order programs from shipping the medications because plan ratings are based off the amount of prescriptions sent (the problems with process-oriented measures verses outcomes-oriented measures is described in detail in the next section). Thus, NCPA advocates for policies that completely stop the shipment of unwanted mail order prescriptions.

NCPA recently 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 patients coming into pharmacies with unwanted mail order prescriptions, while CMS’ 2016 policy resulted in a negative change.⁵ The survey is attached to these comments as Attachment A.

⁴ CMS, Sample of Beneficiary Complaints, *available at* <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/sampleofbeneficiarycomplaintsmailorder.pdf>.

⁵ NCPA, Report for 2018 Mail Order Survey, Feb. 2018.

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 medications.

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.

Thus, as CMS now considers diluting patient consent for refills too, NCPA urges that relaxing policies on patient consent leads to serious concerns about patient safety and potential fraud and abuse when medication refills are never requested by the patient but are shipped out anyway and paid claims are not reversed. For these reasons, NCPA advocates that at the crux of the proper use of medications needs to be a shared decision among the prescriber, pharmacist, and most importantly, the patient. CMS should continue to require patient consent for refill mail order prescriptions and require consent for new prescriptions.

Mail Order Incentives to Ship Without Patient Consent

NCPA highlights that the misalignment of payment incentives and profit motives of pharmacy benefit managers only serve to encourage greater utilization of mail order and the practice of automatic shipment of refills. An example is within the current structure of the Medicare star ratings for plans. The incentive for plans to improve their quality ratings is the ability to market their plans on a broader basis. One such component is related to medication adherence, which NCPA has contended is based solely on prescription claims data with no tie or correlation to outcomes.

Simply shipping the product every 30 or 90 days without proper clinical assessment of the patient for therapeutic appropriateness is not true adherence and in fact, can generate more waste. If these ratings are calculated on how many fills a patient receives without factoring true clinical improvement, plan sponsors are motivated to ensure that patients are always receiving their refills. A consequence of this is seniors can find themselves advancing through the Part D benefit phases prematurely if they truly did not need those extra refills but were billed anyway.

Furthermore, when medications are being automatically filled without prior consent from the patient, this presents the possibility of overbilling to payers, including government programs such as Medicare. NCPA urges CMS to establish clear policies and parameters surrounding auto-ship refill programs, including revisiting CMS' prior policy of requiring that retail and mail pharmacies obtain patient consent prior to the delivery of each refill or new prescription. Even with this policy, however, NCPA is concerned that mail order facilities may try to fulfill this requirement by creating a blanket consent agreement for patients to sign that further authorizes future refills to circumvent the patient affirmation needed each time. Given the opportunities for increasing their star ratings, plans could be moving patients without their consent over to mail-order (often the PBM's own facility), to place them on an auto-ship refill program.

Again, NCPA maintains that proper medication management needs to be a shared activity among the care triad of patient, prescriber and pharmacist. Not all patients are candidates for enrollment in an auto-ship refill program, nor are all medications appropriate to be on an automatic shipment schedule. For example, medication synchronization programs that are based in pharmacies, not mail-order programs, simplify the refill process by enabling patients to pick up all their medications on a single visit. A recent 2018 Health Affairs study found that medication synchronization programs are especially useful for improving medication adherence in patients with complex chronic diseases.⁶ Thus, the determination to place a patient on any such program should be made by a clinician, not a plan sponsor with motives other than improved patient outcomes. Given the incentives for plans who ensure patients are refilling their medications on a regular basis, we believe such methods employed by plans that are quantity and not quality driven should be closely examined.

NCPA encourages CMS to place greater scrutiny of adherence measures based on proportion of days covered, especially in relation to mail order benefits and the automatic shipment of refills. One such recommendation is to explore the possibility of re-configuring the calculations for star ratings to account for the fact that patients are enrolled in an auto-ship refill program, and possibly assigning a different weight for scoring. Because once a prescription has left a mail order facility it cannot be reversed, unlike in the community setting where even if a prescription is automatically refilled it can always be reversed and returned to stock if the patient doesn't pick it up.

⁶ Health Affairs, *Medication Synchronization Programs Improve Adherence To Cardiovascular Medications And Health Care Use*, Jan.2018, available at <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.0881>.

Conclusion

NCPA greatly appreciates the opportunity to share with you our comments and suggestions. If you have any questions, please contact Kala Shankle, Director of Policy and Regulatory Affairs, 703-600-1178, kala.shankle@ncpanet.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Ronna B. Hauser". The signature is fluid and cursive, with a long horizontal stroke at the end.

Ronna B. Hauser, Pharm.D.
VP Pharmacy Affairs
National Community Pharmacists Association