March 27, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: Medicare Part D Reporting Requirements of Pharmacy Performance Measures

Dear Administrator Brooks-LaSure:

With this letter, the National Community Pharmacists Association (NCPA) is following up on a similar letter NCPA sent to CMS in May 2021 to provide feedback on CMS' Medicare Part D reporting requirements. **NCPA requests that CMS expediently propose, through the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) process, the data elements that are used by Part D plans to assess pharmacy performance.**

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $78.5 billion healthcare marketplace, employ 240,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

Background

NCPA has repeatedly weighed in with CMS regarding our concerns with direct and indirect remuneration (DIR) and pharmacy price concessions in the Medicare Part D program and the need for the development of standard pharmacy quality measures. The way in which pharmacy quality is currently measured in the Part D program is unfortunately tied to PBM recoupments from the pharmacy post point-of-sale versus a standardized quality payment program. Community pharmacists should be rewarded for efforts to drive performance and not solely penalized, especially when plan sponsors are receiving bonus payments.

Community pharmacy providers have experienced a skyrocketing increase in the amount of post point-of-sale price concessions (often referred to as direct and indirect remuneration fees) extracted from their businesses by Part D plan sponsors and PBMs. The increase in these retroactive fees continues to have a detrimental effect on Part D beneficiaries, the Medicare program, pharmacies, and taxpayers, and the trend is not slowing.

These fees blur the line between the cost of a prescription drug, payment for pharmacy services, quality measures, and pharmacy price concessions. Many of these retroactive fees are marketed by Medicare Part D plan sponsors/PBMs as "quality based." However, these retroactive fees are based on payment methodologies consisting of a withhold of a certain amount with the opportunity for the pharmacy to have the penalties decreased (or "earned back") based on achieving certain arbitrary quality measures implemented by the plan/PBM. Oftentimes the retroactive fees are based on the ingredient cost of drugs dispensed, far from "quality."

For example, one of our members, an independent pharmacy owner, in 2022 paid $430,157.70 in DIR fees, versus $215,125.49 in 2020, an increase of approximately $215,000 in 2 years. His year-to-date 2023 DIR fees (with 7 days left in the quarter, at the time of this writing) are $88,798, versus $66,271 for DIR fees in the first quarter of 2022. It is difficult for this pharmacy owner to determine exactly how much of this amount was "earned back" in the name of quality, but his best approximation is 6% of the total amount paid in DIR fees was returned in 2022 ($27,927) versus 7% in 2020 ($15,670.24). These "earn back" amounts are minimal for the pharmacist, based on time/staff commitment to quality. This pharmacist has also spoken with his pharmacy consultant about his DIR fees, and the consultant said our member's pharmacy is high performing and could not improve/decrease its DIR fees to be penalized any less.

Plan sponsors are receiving significant bonus payments for their performance, yet bonus payments are not being passed down to providers to drive performance. Pharmacists are driving performance through their services and relationships directly with patients yet are being penalized for their efforts that contribute to a plan's quality rating.

NCPA Applauds CMS for Requiring Part D plans/PBMs to Disclose Pharmacy Performance Measures

On January 15, 2021, CMS finalized a rule requiring Part D plans to disclose pharmacy performance measures and how they are applied to pharmacies to CMS. CMS will be able to make those measures publicly available to increase transparency in the Part D space and use the information to begin development of standardized pharmacy performance measures. The requirement became effective on January 1, 2022.

In CMS' Medicare Part D final rule issued in May 2022, CMS encouraged the industry to continue to work together on developing a set of pharmacy performance measures through a consensus process and Part D sponsors to adopt such measures to ensure standardization, transparency and fairness. CMS also stated that the authority to establish a reporting requirement is effective January 2022; however, CMS stated that the actual data elements must be proposed through the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) process in a future package. The Paperwork Reduction Act (PRA) requires federal agencies (1) to seek public comment on proposed information collections and (2) to obtain approval from the Office of Management and Budget (OMB) before collecting information from the public. **NCPA requests an update on this future package, as we request that plans start reporting this information immediately.**

NCPA recognizes these are important first steps in the process of standard pharmacy performance metrics being applied across the industry. NCPA appreciates CMS hearing the issues raised by past comments in the Part D space and for willingly taking the first steps in situational awareness around the discrepancies in the application of performance measures by plans/PBMs to pharmacies within the various PBM networks.

NPCA urges CMS to use a wide scope under their authority to collect information related to how pharmacy "performance" is measured, regardless of whether a plan or PBM utilizes the term "pharmacy performance measures" in contractual language.

NCPA Recommends for Each Pharmacy Performance Metric Being Used by a Plan/PBM to Measure a Pharmacy, CMS Shall Collect:

- The measure developer or entity responsible for development of the measure;
- How the measure was validated and tested;
- How often the measure is updated;
- If the plan/PBM is using the measure in accordance with published measure specifications which have been validated and tested;
- If the plan/PBM is using the measure according to licensing agreements with measure stewards;
- Adjustments or modifications to measure steward specifications;
- Source of data used to calculate the measure;
- The minimum number of patients required in the denominator to reliably calculate the measure;
- The platform, e.g., EQuIPP, and measurement period used in calculating the measure;
- Thresholds for incentives or other cut points related to pharmacy performance;
- Level of attribution, e.g., individual pharmacy vs. Pharmacy Services Administration Organization (PSAO), and attribution criteria;
- Risk adjustment or stratification included in the measure to account for clinical or socioeconomic variables;
- Whether the measure is being used to calculate reimbursement, either through recoupment, credit to a deduction in payment or bonus payments, or a combination thereof;
- Claim ID for payor, prescription number, pharmacy NCPCP number, transaction number, or Generic Product Identifier, and fill date to identify the claim(s) being used to determine the measure; and
- Where the measure should apply i.e., community pharmacy-based claims, specialty pharmacy-based claims, LTC pharmacy-based claims and if the quality measures are different based on where the patient lives.

It is imperative that such level of detail outlined above be provided to CMS via Medicare Part D reporting requirements. This is because the measures often being applied by plans/PBMs to pharmacies were developed for use in population health measurement at a health plan level, not developed for use in pharmacies with smaller numbers of patients.

There is wide variance and lack of standardization among PBMs and plans with respect to terminology, metrics, timing, and calculation methods. PBMs and plans regularly deviate from the measure specifications when using endorsed measures to determine pharmacy level quality.

PBMs and plans will oftentimes alter the list of drugs used to capture a metric during the evaluation period. There is a lack of transparency as to how PBMs and health plans are implementing their own and/or altering endorsed measure specifications. Moreover, the frequency of changes makes it challenging for pharmacies to consistently track their performance. There is a lack of consistency in attribution methods or number of patients required to capture a metric. PBMs and plans may use a measure to determine the entire pharmacy's quality based on as few as one patient.

Pharmacies experience systematic payment reductions based on ambiguous contract terms and no consistency exists among measurement time periods. While CMS and plans should be connecting the patients most in need with medication management with the highest performing pharmacies, there is a disincentive to care for these patients in the current environment of penalties (i.e., lower quality scores equal increased retroactive pharmacy price concessions) and pharmacy performance "goals" are oftentimes unattainable due to unrealistic thresholds and cut points.

Looking to the Future

Community pharmacists oftentimes have no insight into their individual pharmacy's quality standing in any given PBM network. A pharmacy may not be given access to a dashboard or data/metrics showing where it stands in relation to other pharmacies in the PBM "quality" network. **For these reasons, NCPA strongly urges CMS to require the greatest level of detail when requiring plans/PBMs to report pharmacy performance measures.**

It is important for community pharmacy that plans and PBMs make all aspects of these measures fully transparent, and CMS ensures plans/PBMs are held accountable for the measures being used. As CMS begins to collect data from the plans/PBMs, NCPA recommends CMS identify potential misuses and unfair applications of pharmacy performance measures, particularly focused on independent pharmacies arbitrarily grouped together within a particular network.

NCPA also suggests CMS make all the information on pharmacy performance measures collected publicly available as soon as possible so pharmacies can make decisions on their Part D contracts, increase transparency, and benefit patients. It is important that participating pharmacies are aware of the measures for which they are being held accountable.

Furthermore, NCPA requests CMS develop a system where pharmacies can validate the data submitted by the plans/PBMs. CMS accords plans and PBMs to reconcile, validate, dispute, and review submitted data. Since pharmacies are being judged on similar criteria, they should have the same opportunity to audit the submitted data to correct for mistakes and inaccuracies.

Finally, NCPA supports the natural outgrowth of a Star Ratings system for pharmacies to better provide information to patients when choosing a potential Part D plan and pharmacy partner. NCPA has participated in PQA's creation of pharmacy level measures. Measures are being created that look at a given pharmacy's entire patient population and pharmacy system data, not just patients siloed by plan/PBM or solely using plan/PBM claims data.

In doing so, NCPA requests CMS require the use of pharmacy level measures and develop a verification process to ensure the data being used to measure pharmacy performance is correct and statistically meaningful. However, given the unique needs and the possibility of statistically skewed patient populations, NCPA recommends CMS consider separating long term care and specialty pharmacies from community pharmacies when designing such a Star Ratings system.

Conclusion

Under the Part D program, plans/PBMs have clear and consistent quality measurement rules that are not suitable for pharmacies. Community pharmacies have no such rules. As pharmacies serve patients from multiple health plans and PBMs, there is an inconsistent and untenable application of the definition of "quality" applied to pharmacies among the various payors. This lack of consistency has led to the extraction of billions of dollars in pharmacy DIR fees, and we appreciate CMS taking this first important step to address the problems our members are facing in serving Part D patients.

NCPA greatly appreciates the opportunity to share our views on the data collection for Medicare Part D Reporting Requirements. NCPA looks forward to continuing to work with CMS and other interested stakeholders to develop universal pharmacy performance measures as well as responsible and practicable ratings for pharmacy. Should you have any questions or concerns, please feel free to contact me at ronna.hauser@ncpa.org or (703) 838-2691.

Sincerely,

Ronna B. Hauser

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Senior Vice President, Policy & Pharmacy Affairs

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