

January 16, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P)

Dear Administrator Verma:

On behalf of McKesson Corporation (“McKesson”), I am pleased to submit comments and recommendations on the proposed rule, “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P).”

About McKesson and Health Mart

For over 180 years, McKesson has led the industry in the delivery of medicines and healthcare products. We deliver vital medicines, medical supplies, care management services and health information technology (IT) solutions that touch the lives of over 100 million patients in healthcare settings that include more than 25,000 retail pharmacies, 5,000 hospitals, 200,000 physician offices, nearly 12,000 long-term care facilities and 2,400 home care agencies.

Health Mart, an affiliate of McKesson, is America’s fastest-growing independent pharmacy franchise with more than 4,800 locally owned community pharmacies across all 50 states. Health Mart pharmacists provide personalized care and take the time to help patients understand their prescription-drug coverage, how to safely manage multiple medications, and how to take advantage of lower-cost medication options.

General Comments

McKesson appreciates CMS’ commitment to improving the Medicare program. McKesson applauds CMS for soliciting ideas for regulatory, sub-regulatory, policy, practice and procedural changes to better accomplish transparency, flexibility, program simplification and innovation in Medicare Advantage and Part D via the Agency’s request for information (RFI) in April 2017. In our response to that RFI, we highlighted the significant, detrimental impact that direct and indirect remuneration (DIR) fees can have on all retail pharmacies, particularly independent community pharmacies which often serve patients in underserved rural or urban areas. Among our recommendations, we asked CMS to “finalize [rulemaking] that would essentially state that pharmacy price concessions can be determined at the point of sale, or at least ‘reasonably estimated’ at the point of sale.” McKesson appreciates CMS’ consideration of this request, which has also been made by the National Community Pharmacists Association (NCPA) and other stakeholders, including countless independent community pharmacists. We are grateful for the opportunity to provide further feedback on this important issue, as CMS actively considers implementing a policy that

would require pharmacy benefit managers (PBMs) and Part D plan sponsors to include pharmacy price concessions received for a covered Part D drug in the drug's negotiated price at the point of sale. We look forward to working with the Agency on this and other policy changes towards the goals of improving patient care and access, reducing beneficiary costs, and better aligning incentives for PBMs and Part D sponsors with the interests of beneficiaries and taxpayers. Our comments are organized into the following sections:

- 1) RFI Regarding Pharmacy Price Concessions to Drug Prices at the Point of Sale
- 2) Implementation of the Comprehensive Addiction and Recovery Act (CARA)
- 3) National Council for Prescription Drug Program (NCPDP) Script
- 4) Definition of "Retail Pharmacy" and "Mail Order Pharmacy"
- 5) Any Willing Pharmacy Requirements

1) RFI Regarding Pharmacy Price Concessions to Drug Prices at the Point of Sale

McKesson applauds CMS' drive towards value, and we encourage the Agency to continue to partner with pharmacies as an integral part of achieving value-based healthcare that is driven by quality and performance. McKesson supports regulatory and legislative changes that would limit the practices that are adversely affecting pharmacies, patients, and the federal government.

McKesson strongly supports requiring PBMs and plan sponsors to include all pharmacy price concessions received for a covered Part D drug in the drug's negotiated price at the point of sale. CMS' proposal to reflect pharmacy price concessions in negotiated price would directly translate to lower patient out-of-pocket costs since patient cost sharing is often based on negotiated price. Similarly, government costs in Part D are based on negotiated price, so pharmacy price concessions that reduce negotiated price would lower government spending. We support revising the definition of negotiated price to reflect the lowest possible pharmacy reimbursement, as put forth in the RFI. Under the requirements in place today, the reasonably determined exception is so broad that virtually all pharmacy payment adjustments fall under that exception. Moving to a lowest possible reimbursement approach would make it more difficult for PBMs and plan sponsors to circumvent and exclude fees from the negotiated price.

McKesson appreciates CMS' intent and believes the current proposal would greatly reduce the incentive for PBMs and plan sponsors to apply retrospective penalties based on "performance" measures, which are often ill-defined. This approach would provide much needed transparency, clarity, and predictability for community pharmacists who are struggling to remain financially viable. However, we note that the RFI does not explicitly prohibit plan sponsors, PBMs, and other entities from doing so, which may still lead to variations across plans. Therefore, McKesson requests that CMS clarify that retroactive penalties based on performance are distinctly prohibited.

McKesson supports CMS' proposal; however, we would like to share some concerns, as well as recommendations to address those concerns. First, we are concerned that if finalized, the proposal may discourage PBMs and plan sponsors from rewarding high-performing pharmacies. Therefore, we strongly recommend that CMS preserve and enhance the extent to which plans employ performance-based programs with pharmacies that allow bonus payments for high performance, based on activities that pharmacies are reasonably able to influence. CMS could accomplish this goal by creating an incentive payment program that eliminates retroactive performance penalties and allows bonus payments for high performance based on factors that a pharmacy can reasonably influence. Tying performance to factors that a pharmacy can actually influence would eliminate situations such as when a pharmacy that dispenses exclusively oncology drugs winds up having DIR fees assessed based on Medicare Advantage Star Ratings measures focused on diabetes or hypertension.

Second, the proposal, if finalized, could reduce the net reimbursement at the point of sale, making it difficult for pharmacies to have sufficient cash flow to remain viable and continue to care for patients.

This concern could be mitigated by directing PBMs and plan sponsors to use performance data from the last available month (or quarter) prior to the month the drug was dispensed. As CMS moves forward on this proposal, we urge the Agency to ensure that the reimbursement that is adjudicated is comparable, to the extent possible, to the actual rate negotiated in plan agreements, net of all performance payments and fees (assuming the plan meets its “fast-pay” requirements).

McKesson offers the following additional recommendations to bring meaningful reforms to the DIR program:

- *Protections for pharmacies who have inadequate access to an appeals process for unjustly applied DIR fees:* Pharmacies may not have guidance in place that specifies reimbursement processes and timeframes for maximum allowable cost (MAC) appeals and payment adjustments, which generally includes “retroactive payments.”¹ These laws can clarify and set baseline protections for the appeals process between pharmacies and PBMs; however, there is no regulation at the federal level and PBM Watch reports that less than half of the states have MAC laws.² Given that less than half the states have such protections under the law and that not all include DIR fees in the scope of pharmacy appeals protections, we recommend that CMS use its existing authority, in consultation with Congress, to institute appeals protections at the federal level to ensure all pharmacies are given the opportunity to appeal payment adjustments.
- *Requirement for plan sponsors to provide a unique Bank Identification Number (BIN)/Processor Control Number (PCN)/Group for each plan:* Today, CMS requires a unique BIN/PCN combination for the Medicare Part D business, but a group number is not required as part of the combination. If CMS were to allow DIR to continue, the current system of requirements makes it extremely challenging for pharmacies to plan for appropriate accruals. Today, when retroactive DIR is collected months after a claim is filled, pharmacies must accrue, or set aside, funds, so they have the funds available when the DIR amounts are collected by plans sponsors. Without a requirement for a unique BIN/PCN/Group number for each specific plan, it is virtually impossible for pharmacies to calculate funds (for plans with DIR) when multiple plans with different DIRs have the same processing information. For example, if a plan sponsor has two plan designs that use two different networks with two different DIR arrangements, it is impossible for pharmacies to calculate appropriate accrual amounts if the processing information (BIN/PCN/Group) is the same for both plan designs. As long as DIR continues, we recommend that CMS consider requiring plan sponsors to provide a unique BIN/PCN/Group combination for each plan, which will help pharmacies achieve greater operational predictability and continue to provide quality care for patients. We would be happy to provide CMS with further details and context on this recommendation.

2) Implementation of the Comprehensive Addiction and Recovery Act (CARA)

McKesson appreciates CMS’ efforts to implement statutory provisions of CARA, as well as the Agency’s ongoing commitment to combat our country’s opioid epidemic. McKesson supports CMS’ efforts to reduce abuse and diversion of prescription opioids.

“Lock In” for “At-Risk Beneficiaries”

As CMS contemplates a drug management program for “at-risk beneficiaries,” we encourage the Agency to ensure that any such framework protects patients with legitimate need for prescription pain medicines, such as patients with cancer or terminal illnesses, from being restricted in their access to the medicines they need. We also urge CMS to ensure that patient preference is a top priority during prescriber and pharmacy lock-in selection, particularly for patients in rural areas that rely on independent community pharmacies for their medications.

Real-Time Solution Needed to Address Abuse and Diversion

We commend CMS for proposing strategies to address the opioid epidemic; however, the Agency's approach does not identify potentially at-risk patients on a real-time basis, does not ensure effective communication of a patient's at-risk status to dispensers, and may take more than six months to implement any access restrictions for truly "at-risk" beneficiaries. For these reasons, we believe CMS' approach, as proposed, falls short of adequately curbing the impact of our nation's greatest public health crisis. We offer the following recommendations:

McKesson encourages CMS to harness the untapped potential of pharmacists to address the opioid epidemic by leveraging their relationship with patients. Pharmacists are uniquely positioned to have a comprehensive view of a patient's health status. They see the prescriptions and diagnoses of multiple physicians. This vantage point allows pharmacists to detect potential problems of drug interactions with opioids, potential misuse and/or signs of potential abuse. Additionally, pharmacists provide counseling and education to patients, and are viewed as a trusted resource for information.

Given our country's impending physician shortage crisis and the availability of highly skilled, medically-trained pharmacists that are ready and able to help now, we must make it a priority to utilize the full breadth of all of our clinical capabilities. McKesson encourages CMS to consider policies that make it easier for pharmacists to provide and be reimbursed for medication assisted treatment (MAT) and other clinical services to individuals suffering from opioid addiction. We also recommend that CMS consider testing pharmacist-led opioid care management models that harness the expertise of pharmacists to identify at-risk patients, provide appropriate clinical interventions, patient and caregiver education, and coordination of care with prescribers.

McKesson is committed to real-world solutions to address the opioid epidemic. In March 2017, McKesson released a White Paper, outlining our recommendations to combat opioid abuse. This White Paper was crafted by McKesson's Task Force on Prescription Drug Abuse and Diversion. We have attached the paper for your review.

McKesson has partnered with the National Council for Prescription Drug Programs (NCPDP), a non-profit organization that sets standards for pharmacy claims to advocate for a national patient safety system. The patient safety system would be a nationwide clinical alert system that uses data analytics to identify patients at-risk for opioid overuse, abuse, addiction or misuse. The patient safety system could be the critical infrastructure or backbone of an effective opioid care management program.

Here's how the model could work:

- The patient safety system would provide the pharmacist or the dispenser with patient prescribing history, including attempted fills, and could eventually employ a clinical algorithm to identify prescription patterns that may indicate abuse/misuse (i.e. doctor shopping, pharmacy shopping etc.) or drug interactions.
- The pharmacy would receive real-time clinical alerts from the patient safety system during claim processing, flagging for the pharmacist that they should gather additional patient information before dispensing (such follow-up could include checking the state prescription drug monitoring program, contacting the prescribing clinician, etc.).
- The pharmacist engages the patient at the point of care. Depending on the nature of the alert and patient status, the pharmacist may use shared-decision making tools to educate the patient on non-opioid treatment alternatives, risks of addiction, non-drug pain management techniques and appropriate disposal of unused medication.

- As part of ongoing patient education and effective medication therapy management (MTM), the pharmacist could follow up with the patient at an appropriate interval (e.g., 3 to 7 days post dispensing of opioids) to assess the patient's pain status and further determine need for clinical intervention or physician referral.

A national patient safety system would be an important complement to the Prescription Drug Monitoring Programs (PDMPs) in use by states to track controlled substance prescriptions dispensed by pharmacists. While PDMPs allow physicians and pharmacists to look up a patient's controlled substance prescription history, the full potential of PDMP's is not being realized; usage rates are low, data are not real-time and the pharmacist must break from his/her workflow to check the separate state database.

The national patient safety system would supplement the PDMP data by using existing claims data, proactively identify at-risk patients and provide real-time alerts thus allowing pharmacists to exercise their clinical judgment in checking PDMPs. By providing proactive clinical alerts, in real-time, in workflow, and across state lines, the patient safety system would be an important additional tool in conjunction with the state PDMP.

To advance the development of the patient safety system, McKesson is helping to lead a coalition of technology companies, provider organizations, payers and the pharmacy community. We are committed to providing data-driven solutions that provide the clinical data necessary to inform pharmacist clinical decision making at the point of care. We would welcome an opportunity to discuss the role of the patient safety system in pharmacist-led opioid care management models in greater detail.

3) NCPDP Script

McKesson supports CMS' proposal to adopt NCPDP SCRIPT Standard Version 2017071; however, we request that CMS include the adoption of electronic prior authorization (ePA) transactions in the final rule. ePA streamlines the prior authorization process by automating many of the communications amongst providers, payers, and pharmacists. Most importantly, it helps patients obtain their prescribed therapies without delay. In instances when a payer determines an alternative is more appropriate, ePA allows the patient to appeal or gain approval and access to the alternative therapy in a much quicker manner. Broad adoption of ePA in the Medicare program can create efficiencies for Medicare and providers, improve beneficiary access to and adherence to prescribed medicines, and ultimately, improve health outcomes while reducing overall costs.

In addition, McKesson requests that CMS include a voluntary use date to be the effective date of the final rule and that the sunset date for SCRIPT Version 10.6 be 24 months after the effective date of the final rule. We believe the implementation of such a transition period, which has been helpful in the past, will decrease unnecessary delays and interruptions in the delivery of healthcare.

Finally, though CMS has not proposed to mandate e-prescribing (eRx) within Medicare Parts C and D, we recommend that the Agency prioritize eRx, particularly for controlled substances, in future rulemaking. Traditional handwritten prescriptions can be forged, altered, or diverted and can enable illegal access to opioids. E-prescribing allows prescriptions to be transmitted to pharmacies securely without risk of alteration or diversion, and prescribers can be authenticated before dispensing of controlled substances and prescriptions. The American Journal of Pharmacy Benefits has recommended e-prescribing to help address the misuse and diversion of opioids. We believe a nationwide e-prescribing requirement for opioids could be a promising solution for reducing forged prescriptions.

4) Definition of “Retail Pharmacy” and “Mail Order Pharmacy”

McKesson appreciates CMS’ efforts to clarify the definitions of “retail pharmacy” and “mail order pharmacy” to avoid confusion in the marketplace. We strongly support CMS’ proposed definitions and recommend that CMS finalize both definitions with the addition of the word “primarily” to avoid further confusion, unintended consequences, or reduced patient access. Our proposed revised definitions, therefore, would be:

- “Retail pharmacy” is “any licensed pharmacy that **primarily** dispenses prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy.”
- “Mail-order pharmacy” is “a licensed pharmacy that **primarily** dispenses and delivers extended days’ supplies of covered Part D drugs via common carrier at mail-order cost sharing.”

5) Any Willing Pharmacy Requirements

McKesson believes that patients should have access to discounted copays at any pharmacy that is willing to accept the plan’s terms and conditions. McKesson strongly supports CMS’ efforts to clarify that plan sponsors must permit the participation of “any pharmacy” that meets the standard terms and conditions. We agree that while plans may continue to tailor its respective terms and conditions to various pharmacy types, they should not “exclude pharmacies with unique or innovative business or care delivery models” based on not fitting into a certain pharmacy classification. We encourage CMS to continue to encourage price competition, lower costs in Part D, and promote patient access by both preserving current requirements and expanding pharmacy choice for patients.

Conclusion

McKesson appreciates the opportunity to comment on this proposed rule and RFI. We hope our comments and recommendations contribute to meaningful improvements to the Medicare program. We look forward to continuing our partnership with CMS and working with the Administration to promote a robust, patient-centered healthcare ecosystem that works for patients. If you have questions or need further information, please contact Matt Shiraki, Director of Public Policy, at (415) 866-8654 or Matt.Shiraki@McKesson.com.

Sincerely,



Pete Slone

¹ GW Law Faculty Publications & Other Works. Health Care Competition Law in the Shadow of State Action: Minimizing MACs. August 25, 2017. ([link](#))

² PBM Watch. Current State Maximum Allowable Cost Legislation. ([link](#))