



Optimizing Health by Advancing the Quality of Medication Use

December 31, 2019

Joanne M. Chiedi
Acting Inspector General
Department of Health and Human Services
Wilbur J. Cohen Building, Room 5521
330 Independence Avenue, SW
Washington, DC 20201

Attention: OIG-0936-AA10-P

Dear Inspector General Chiedi:

On behalf of the Pharmacy Quality Alliance (PQA), we are pleased to submit comment on the proposed rule regarding "Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements" (OIG-0936-AA10-P).

PQA is a national quality organization dedicated to improving medication safety, adherence and appropriate use. A measure developer, researcher, educator and convener, PQA's quality initiatives support better medication use and high-quality care. A non-profit organization with more than 250 diverse members across healthcare, PQA was established in 2006 as a public-private partnership with the Centers for Medicare and Medicaid Services shortly after the implementation of the Medicare Part D Prescription Drug Benefit. PQA members include community and specialty pharmacy organizations, pharmacists and other healthcare providers, pharmacies, health plans, pharmacy benefit managers, life sciences, technology vendors, government agencies, health information technology partners, academia and researchers.

PQA's comment focuses on the proposed rule's section on "VBE participant." A section of the proposed rule says:

"We are considering for the final rule, and seek comments on, whether we should exclude other entities from the definition of "VBE participant." For example, we are considering excluding pharmacies (including compounding pharmacies) from the definition of "VBE participant." We acknowledge that some pharmacies (and pharmacists) have the potential to contribute to the type of beneficial value-based arrangements this rulemaking is designed to foster (*e.g.*, through medication adherence programs or educational services for patients with diabetes). However, pharmacies, like the entities we propose to exclude from the definition of "VBE participant," primarily provide items, and we are concerned that their participation in value-based arrangements

may not further the care coordination purposes of this rulemaking. We seek comments on beneficial arrangements pharmacies may want to undertake under the new value-based framework and any safeguards we could implement in the final rule if we were to allow such entities to participate in value-based arrangements eligible for safe harbor protection.”

We encourage OIG to not exclude pharmacies or pharmacists from the definition of “VBE participant.” Pharmacies and pharmacists can provide valuable care coordination across multiple prescribers and multiple care settings that can prevent or mitigate adverse drug events. These services include, for example, medication reviews, medication synchronization, medication reconciliation, medication therapy management, medication adherence, patient education and support for transitions of care. These services are particularly important for complex and underserved patients. Including pharmacies and pharmacists in the definition of VBE participant will encourage innovation in healthcare delivery that further integrates these providers in team-based care for the purpose of improving care efficiency and patient outcomes.

Notably, in response to interest from community and specialty pharmacy providers, CMS and Congress, PQA is developing pharmacy performance measures that would be appropriate for use in accountability and value-based programs.¹ These measures will evaluate the quality of pharmacies and assess pharmacist-provided care and pharmacy-based services, including care coordination. In addition, PQA’s 2019 Strategies to Expand Value-Based Pharmacist-Provided Care Action Guide² and our forum on Caring for the Whole Patient: Leveraging Pharmacists to Address Social Determinants of Health³ further documented current examples and future opportunities for pharmacists to play expanded roles in team-based, coordinated and value-based care.

PQA appreciates OIG’s thoughtful consideration of our comments submitted in response to the proposed rule. If you have questions, please do not hesitate to contact us.

Respectfully,



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¹ “PQA Pharmacy Performance Measures in Development.” Pharmacy Quality Alliance. pqaalliance.org/pharmacy-measures (Accessed Dec. 31, 2019)

² “Strategies to Expand Value-Based Pharmacist-Provided Care Action Guide.” Pharmacy Quality Alliance. pqaalliance.org/pharmacist-provided-care (Accessed Dec. 31, 2019)

³ “Caring for the Whole Patient: Leveraging Pharmacists to Address Social Determinants of Health.” Pharmacy Quality Alliance. pqaalliance.org/pqa-caring-for-the-whole-patient (Accessed Dec. 31, 2019)