



December 31, 2019

Joanne M. Chiedi
Acting Inspector General
Department of Health and Human Services
Attention: OIG-0936-AA10-P
Room 5521
Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Dear Acting Inspector General Chiedi:

NHIA thanks the Office of Inspector General (OIG) and the Department of Health and Human Services (HHS) for the opportunity to comment on the Notice of Proposed Rulemaking concerning federal anti-physician self-referral (Stark Law) and anti-kickback statute (AKS). We applaud the agency's efforts to promote the continued shift to value-based payment models while protecting the Medicare program from potential fraud and abuse.

The National Home Infusion Association (NHIA) appreciates the opportunity to submit comments on the proposed rule entitled "Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," (hereinafter "Proposed Rule") published in the *Federal Register* on October 17, 2019.¹ NHIA is a trade association that represents companies that provide infusion therapy to patients in their homes, as well as companies that manufacture and supply infusion and specialty pharmacy products. As the leading voice for the home and specialty infusion industry, we write to share our feedback regarding modifications to anti-kickback statute safe harbors. Our specific comments are below.

Definition of "VBE Participant"

In the Proposed Rule, the Office of Inspector General (OIG) proposes a safe harbor for value-based arrangements. The OIG would exclude from the definition of value-based enterprise (VBE) participants" pharmaceutical manufacturers; manufacturers, distributors or suppliers of durable medical equipment, orthotics or supplies (DMEPOS); and laboratories. The OIG states that for the final rule it also is considering whether to exclude other entities from the definition of VBE participant and seeks comment on this issue. The OIG acknowledges that it is considering excluding pharmacies, including compounding pharmacies, from the definition of VBE participant. While the OIG concedes that some pharmacies could potentially contribute to the type of beneficial value-based

¹ 84 Fed. Reg. 55694

² Levine DM, Ouchi K, Blanchfield B, et al. Hospital-Level Care at Home for Acutely Ill Adults: A Randomized Controlled Trial. *Ann Intern Med.* 2019; [Epub ahead of print 17 December 2019]. doi: <https://doi.org/10.7326/M19-0600>

arrangements the Proposed Rule is intended to encourage, the OIG expresses concern that pharmacies “primarily provide items” and that their participation in value-based arrangements may not further the care coordination purposes of its rulemaking. The OIG also notes that it is considering excluding some types of pharmacies, such as compounding pharmacies, while allowing others, such as retail and community pharmacies, to participate in value-based arrangements that would be eligible for safe harbor protection.

NHIA disagrees with the exclusion of DMEPOS suppliers in that it could inadvertently prevent home infusion providers from entering into value-based arrangements where they offer significant potential to advance the optimum patient care that results from these arrangements. Considering Congress’ recent action to expand home infusion therapy coverage for beneficiaries, we strongly urge the Agencies to reconsider the DME exclusion for home infusion services.

NHIA disagrees with broadly excluding pharmacies from the definition of VBE participant. Home infusion and specialty pharmacies provide the types of care coordination and direct patient care services that the OIG seeks to promote. Pharmacies that provide services including medication reconciliation; monitoring or remote monitoring for adherence, efficacy and side effects; and education should not be excluded from the definition of VBE participant. These services are associated with value-based outcomes – reduced hospital readmissions, reduced hospital lengths of stay and high patient satisfaction – and should be encouraged.

Home infusion is an essential element in successful hospital-to-home models that allow patients to receive care at home, avoiding hospitalization or extended stays in a skilled nursing facility. Such programs have generated documented cost savings and improved outcomes and should be encouraged.²

Recommendation:

NHIA requests that the OIG expressly include home infusion pharmacies as eligible VBE participants. At a minimum, the OIG should not broadly exclude DMEPOS and pharmacies from participation in protected value-based arrangements.

Home infusion services can play a pivotal role in coordinating patient care across the continuum and optimizing site of care by treating patients in non-acute settings. For this reason, we request that these providers not be inadvertently excluded from participating in the value-based arrangements meant to advance these same principles.

NHIA thanks you for the opportunity to provide comments on this important issue and we welcome the opportunity to discuss with you the direct patient care services that home infusion pharmacies provide. work with you on alternative approaches to implementation of the home infusion therapy services benefit. If you have questions or need additional information, please contact me at connie.sullivan@nhia.org.

Sincerely,

Connie Sullivan, B.S. Pharm
President and Chief Executive Officer