



January 17, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Verma:

The National Home Infusion Association (NHIA) appreciates the opportunity to submit feedback in response to the Centers for Medicare & Medicaid Services' (CMS) solicitation regarding health professional scope of practice. CMS is seeking comments on eliminating Medicare supervision regulations that have more stringent requirements than existing state scope of practice laws or other Medicare requirements that limit health professionals from practicing to the full extent of their licenses. 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 on this important issue.

NHIA applauds CMS for considering giving pharmacists provider status under the Medicare program and encourages the administration to expeditiously move forward with making this change so that pharmacists can more fully participate in expanding access to essential healthcare services. Pharmacists today are not limited to roles that focus on the dispensing and delivery of medications as they work in a wide variety of settings alongside physicians, nurses, social workers, dietitians, and other healthcare practitioners performing direct patient care, developing pharmaceutical care plans, and preventing medication misutilization. For decades, the home infusion industry has demonstrated how pharmacists bring value to the Medicare DMEPOS program by facilitating access to high quality home infusion services and by working as an integral member of the post-acute healthcare team. Home infusion services are centered around the pharmacist, who plays the leading role in care coordination for the patient. Typically, the first step in enrolling a patient in home infusion is for the pharmacist to work closely with the referring physician and discharge planner to develop a transition plan, facilitate nursing services, and initiate patient and caregiver education. Beyond that, the pharmacist maintains responsibility for case management, customizing the medication plan, sterile drug preparation (including clean room operations), clinical assessments and monitoring, coordination with the patient's other health care providers, provision of equipment and supplies, and 24/7 patient support.

We believe Congress understood the importance and value of home infusion pharmacists in providing home infusion services when they passed the *21st Century Cures Act* and *Bipartisan Budget Act of 2018* (BBA) that established a payment system for home infusion pharmacist professional services, essentially creating provider status for home infusion pharmacists. Unfortunately, CMS's interpretation of these laws has reverted to old ways of thinking that assume professional services are only provided by physicians and nurses and must occur face to face. By limiting home infusion professional service payments to days



when the nurse visits the home, the essential pharmacist services that ultimately make home infusion possible remain under-funded and unrecognized by CMS.

Additionally, CMS claims in the final rule with comment period entitled “*Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements,*” published in the Federal Register on November 8, 2019¹, that the home infusion plan of care must be established and reviewed by the physician in consultation with the durable medical equipment (DME) supplier responsible for furnishing the home infusion drugs. Requiring the physician to coordinate services between the home infusion therapy (HIT) and DME suppliers will create an unnecessary administrative burden for physicians as well as HIT providers, and will further reduce access to HIT services for Medicare Part B beneficiaries. This is a perfect example of how CMS has limited the role of the pharmacist for Medicare beneficiaries as compared to how pharmacists operate in the commercial sector. Commercial payers recognize the case management and care coordination services for home infusion patients fall primarily to the pharmacist, and therefore the pharmacy is paid a fee by commercial plans for each day the medication is infused. Commercial payers understand the value of pharmacists in home infusion and do not limit payment to days when a nurse visits the patient’s home, nor do they place such burdens on physicians to coordinate care among different providers within the DME program.

As you continue your work to modernize and enhance regulations that allow pharmacists to practice at the top of their license, NHIA asks you to start by stemming the damage that has been done to home infusion pharmacists by restoring the original intent of the *21st Century Cures Act*. Specifically, NHIA asks you to engage in additional rulemaking to ensure that Medicare reimburses for the whole array of pharmacist professional services that are necessary for the safe and effective delivery of home infusion therapy by:

- Clarifying the definition of infusion drug administration calendar day to ensure that home infusion providers are reimbursed for each day the patient receives an infusion medication.
- Expanding upon the definition of professional services to capture pharmacist-related services and other services that are performed remotely, which will result in better coordinating care for patients who are eligible for both home infusion and home health.
- Providing that a plan of care can be signed by an “applicable provider,” not just a physician.

NHIA thanks you for the opportunity to provide comments on the scope of practice issue. If you have questions or need additional information, please contact me at connie.sullivan@nhia.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Connie Sullivan".

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