

August 30, 2023

Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Request for Comment: Increasing Patient Access to At-Home Use Medical Technologies

Dear Dr. Califf:

The National Home Infusion Association (NHIA) appreciates the opportunity to submit comments in response to the Request for Comment: *Increasing Patient Access to At-Home Use Medical Technologies*, issued by the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) on June 28, 2023.¹ 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 alternate infusion community, we write to share our feedback regarding patient access to medical technologies at home.

NHIA applauds the FDA for recognizing the importance of facilitating access to care in the home and for issuing this Request for Comment to promote expanded access to home use technologies. For more than 40 years, home infusion therapy (HIT) pharmacists and nurses have collaborated to provide and administer intravenous (IV) and subcutaneous infused medications to patients in their homes safely and effectively. Home infusion therapy keeps high-risk patients with serious infections, heart failure, immune diseases, cancer, and other conditions out of institutional settings and allows them to receive treatment at home. This proven model of care is overwhelmingly preferred by patients, while also being cost-effective relative to institutional care. In fact, research shows that up to 95 percent of patients prefer receiving their infusions at home² and nearly 98 percent of patients recently indicated that they are highly satisfied with their home infusion services.³ In addition, a report last year by McKinsey, which examined potential

¹ <https://www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/cdrh-seeks-public-comment-increasing-patient-access-home-use-medical-technologies>

² Polinski, J. M., Kowal, M. K., Gagnon, M., Brennan, T. A., & Shrank, W. H. (2017). *Home infusion: Safe, clinically effective, patient preferred, and cost saving*. *Healthcare*, 5(1-2), 68-80. doi:10.1016/j.hjdsi.2016.04.004

³ Haines, D., PhD. et. al. (2019). 2019 Industry Benchmarks for Home Infusion Patient Satisfaction. Accessed February 9, 2021: <https://www.nhia.org/wp-content/uploads/2020/08/2019.patient.sat-benchmarks.8.13.20-onlinefinal.pdf>

shifts in healthcare to the home by 2025, stated that receiving care at home “could improve the quality of care and the patient experience by providing patients with care in the comfort of their homes and by potentially reducing preventable adverse health events.”⁴ HIT services allow patients needing certain medications to resume or maintain normal activities while receiving treatment, improve health equity by increasing access to services for patients living in rural areas, and reduce the risk of hospital-acquired infections.

Below are NHIA’s answers to questions outlined by CDRH.

- How can the FDA support the development of medical technologies, including digital health technologies and diagnostics, for use in non-clinical care settings, such as at home?

NHIA Response:

Related to the use of infusion pumps, NHIA recommends that the FDA encourage development of technologies that enable clinicians to remotely view, program, and download data from devices used in the home to improve patient care and minimize treatment disruptions and/or the need to replace equipment for reprogramming, investigating alarms, or performance issues. In addition, NHIA recommends that the FDA hold listening sessions with clinicians and consumers who utilize devices in the home setting to better understand how the home site of care impacts the desired capabilities of the equipment and devices used at home.

NHIA also encourages FDA to consider an accelerated approval pathway for catheter lock combination solutions (i.e., antimicrobial, anticoagulant) for the prevention of catheter-related bloodstream infections in high-risk populations requiring long-term central venous access (e.g., pediatrics and long-term parenteral nutrition patients). Central line catheter infections can be life-threatening and are a persistent challenge in the home infusion patient population. There are currently no FDA-approved combination products available in the U.S. for practitioners to utilize to minimize the occurrence of these infections, leaving practitioners to rely on compounded products at costs that are out of reach for most patients. Catheter infections are also a financial burden to the healthcare system with an annual occurrence of approximately 250,000 cases, costing \$48,000 per occurrence.

Finally, NHIA supports the emergence of telehealth technology with real-time data and image transmission to keep patients in the home, reduce hospitalizations and emergency department

⁴ Bestsenny, O., Chmielewski, A.K., and Shah, A (2022). *From facility to home: How healthcare could shift by 2025*. Accessed January 21, 2023: <https://www.mckinsey.com/industries/healthcare/our-insights/from-facility-to-home-how-healthcare-could-shift-by-2025>

visits; and to promote efficient use of nursing resources. For example, musculoskeletal ultrasound (MSKUS), as a tool applied during telehealth, is an evolving technology used for the assessment and treatment of persons with hemophilia and bleeding disorders, with applications in both clinical and home settings. Patient home use of MSKUS, with real-time transmission of images, can inform clinicians if additional home infusion treatment is required while preventing unnecessary infusion of medication, and aims to intervene at home as opposed to the emergency department, clinical or hospital setting. In addition, other technology such as wearables to capture biometric data, such as weight and cardiovascular status, can also inform home treatment decisions, and ensure proper use of costly infusion medications.

- What factors should be considered to effectively institute patient care that includes home-based care?

NHIA Response:

NHIA recommends that the FDA focus on the needs of patients in this evaluation. Devices used at home – including infusion pumps, other devices, and applications – must be designed for use by the patient, rather than the clinician. With the increasingly severe shortage of nurses, technology could improve efficiency by enabling nurses to provide remote support for patients performing infusions independently.

- What are the ways that digital health technologies can (a) foster the conduct of clinical trials remotely and (b) support local or home-based healthcare models?

NHIA Response:

The FDA recently acknowledged the use of decentralized trials (DCT) and in-home research activities, expanding its guidance to allow more flexibility in using routine providers in home-based device clinical trials. The use of digital technologies in decentralized device clinical trials will increase diversity and inclusion by removing common barriers to clinical trial participation (e.g., transportation, geographical location, physical abilities). Additionally, home-based health technologies may allow for a more robust data set in clinical trials by capturing patient-driven follow-up data and can be used to allow patients to arrange for unscheduled, remote health visits to quickly troubleshoot issues as needed throughout a clinical trial.

Additionally, NHIA requests that the FDA ensure clinical trials consider alternative settings when developing novel medication therapies and devices. Currently, most products are developed with the assumption that that treatment will take place in a facility-based setting. For example, drug manufacturers do not often consider medication stability at room temperature, a

factor that can determine feasibility of home use and minimize aseptic preparation steps that occur outside of the pharmacy compounding facility. The FDA also should, when possible, encourage ranges for infusion times, instead of specific rates and infusion times that reflect what was done in a clinical trial performed in a facility. Having a range for infusion time offers flexibility to adapt the infusion to the method of administration and patient response to therapy. For example, dosing schedules for infusions of monoclonal antibodies used to treat COVID-19 allowed for infusion times ranging from 15 to 60 minutes.

- What processes and medical procedures, including diagnostics, do you believe would be ideal for transitioning from a hospital and/or healthcare setting to non-clinical care setting, for example, home use or school/work use?

NHIA Response:

A report last year by McKinsey, which examined potential shifts in healthcare to the home by 2025, stated that receiving care at home “could improve the quality of care and the patient experience by providing patients with care in the comfort of their homes and by potentially reducing preventable adverse health events.”⁵ The report specifically identified intravenous antibiotic infusions as a specific area of opportunity. Unfortunately, there is simply no Medicare home infusion therapy benefit for administration of intravenous antibiotics outside of hospital and other facility-based settings to Medicare beneficiaries. In fact, home infusion coverage for Medicare beneficiaries is limited to a small number of drugs that utilize infusion pumps. There are a wide range of already approved disposable (non-durable) devices that can be used to facilitate home infusions that are simpler for patients to learn and use, but are under-utilized for Medicare beneficiaries.

NHIA also recommends that FDA not be prescriptive in drug labeling regarding methods of administration for medications, as doing so often restricts options for pharmacists and nurses designing a patient-specific treatment plan for drugs infused in the home. Limiting coverage to one method of administration (i.e., requiring a mechanical pump) is often an unnecessary restriction and may lead to limitations in site of care. FDA should facilitate access to patients with transportation challenges or who lack access to infusion centers in rural areas by allowing clinicians to determine the best method of administration and site of care for a particular patient and therapy. Additionally, the home is a healthcare setting when the proper protocols and/or personnel are available. Language in approved drug labeling should be considerate of how it may unintentionally limit site of care options for patients, including requiring administration by a

⁵ Bestsenny, O., Chmielewski, A.K., and Shah, A (2022). *From facility to home: How healthcare could shift by 2025*. Accessed January 21, 2023: <https://www.mckinsey.com/industries/healthcare/our-insights/from-facility-to-home-how-healthcare-could-shift-by-2025>

healthcare provider when there may be insufficient data to support restrictions for patient self-administration. Patient capabilities and needs are highly variable and FDA should rely on clinicians to determine whether potential risks can be overcome with experience, training, and other mitigation strategies.

- What potential methods and strategies for evidence generation and data analysis could facilitate the regulatory review of medical technologies intended to be used in non-clinical settings, for example home use or school/work use?

NHIA Response:

NHIA believes that data collection to evaluate quality should consider the setting of use. For example, NHIA has developed standardized definitions for collecting data for pump-related events that occur in the home setting. Additionally, patient reported outcomes are key to documenting and analyzing the patient/caregiver experience with medical technologies in non-clinical settings and warrant specific consideration in the regulatory review process.

NHIA appreciates the opportunity to provide comments on these important issues and we appreciate FDA's attention to increasing access to care in the home. For questions or additional information, please contact me at connie.sullivan@nhia.org.

Sincerely,



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