National Home Infusion Association
1600 Duke St. Suite 410
Alexandria, VA 22314

February 9, 2021

The Honorable Norris Cochran
Acting Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Liz Richter
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Acting Secretary Cochran and Acting Administrator Richter:

The National Home Infusion Association (NHIA) applauds President Biden's and the new administration's focus on health care and combatting the coronavirus (COVID-19) pandemic, and we look forward to working closely with you on these issues. As hospitals, nursing homes, and other institutional health care facilities have been pushed to the brink by the COVID-19 pandemic, home health care services, including home infusion stand out as high-value and underutilized resources that can add capacity to the health care system while keeping vulnerable patients away from the threat of infectious disease. We appreciate your efforts to provide waivers that make rendering critical health care services in the home more practicable. To accelerate our nation's recovery from COVID-19 and build on the lessons we've learned over the last year, we urge you to continue to prioritize home-based care, including home infusion.

Given recommendations from the Centers for Disease Control and Prevention (CDC) that patients with underlying health conditions avoid settings where they are likely to be exposed to COVID-19, ensuring access to home-based care is more important than ever. Home infusion therapy allows patients with serious infections, heart failure, immune diseases, cancer, and other conditions to receive treatment at home, while allowing hospitals and other providers to focus their resources on treating COVID-19 patients. Moreover, provided our extensive experience delivering care to patients in the comfort and safety of their own homes, we are offering several specific policy recommendations that would increase patient access to vaccines and monoclonal antibody treatments, as well as other treatments for patients who need infused medications but don't otherwise need to be hospitalized.

Home infusion pharmacies have been safely and effectively coordinating the administration of a wide range of IV medications to patients in their homes for over 40 years. This proven model of care is overwhelmingly preferred by patients while also being cost-effective compared to institutional care. In fact, research shows that up to 95 percent of patients prefer receiving their

infusions at home,[1] and nearly 98 percent of patients recently indicated they are highly satisfied with their home infusion services.[2]

Additionally, NHIA has been actively involved in facilitating the provision of monoclonal antibodies for COVID-19 infection as part of the Special Projects for Equitable and Efficient Distribution (SPEED) program, conducted in partnership with the Department of Health and Human Services (HHS) and the Office of the Assistant Secretary for Preparedness and Response (ASPR). As part of this effort, over 170 individual pharmacies are enrolled to provide monoclonal antibodies to high-risk individuals in long-term care facilities and correctional facilities, as well as those receiving care from federally qualified health care and dialysis centers.

Home infusion therapy providers across the country stand ready to advance the administration's COVID-19 response by ensuring patients receive prompt access to the medications they need. To support this commitment, we urge you to consider four recommendations that will accelerate the country's response to COVID-19 and improve access to care in the home setting for all Medicare beneficiaries:

1. Engage home infusion and home care providers to vaccinate homebound and vulnerable populations;
2. Promote home infusion for COVID-19 treatments;
3. Provide all Medicare beneficiaries with home infusion access; and
4. Waive in-person requirements for home infusion services during the Public Health Emergency (PHE).

RECOMMENDATION #1: ENGAGE HOME INFUSION AND HOME CARE PROVIDERS TO VACCINATE HOMEBOUND AND VULNERABLE POPULATIONS

As the administration works toward reaching its goal of vaccinating more Americans over the coming months, we encourage you to consider making COVID-19 vaccines available to home infusion pharmacies for certain high-risk patients. Home infusion pharmacies and home health nursing providers partner on a routine basis to deliver infused medications to homebound and vulnerable populations. These providers can play an essential role in expediting access to COVID-19 vaccines for rural and vulnerable patients, especially those with medical conditions that make it difficult to obtain care outside of the home setting, or those who have compromised immune systems placing them at a higher risk of serious disease if they contract COVID-19.

A home-based vaccination program requires home health and home infusion providers to invest substantial time and resources to procure, prepare, deliver, and coordinate the administration of vaccines. Unfortunately, the current reimbursement structure for administration of vaccines does not account for situations where access requires collaboration among separate entities, and situations where vaccines must be brought to individual patients. To ensure that home-based

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[1] 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

[2] 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-online-final.pdf

administration of COVID-19 vaccines is financially viable for providers, it is important that the Centers for Medicare and Medicaid Services (CMS) address the existing reimbursement gaps for pharmacies that prepare doses of vaccines for administration by home health nursing providers, or other entities that do not have the ability to store, prepare, and/or dispense vaccines.

Detailed Recommendations:

- Allow for the home-based administration of COVID-19 vaccines for patients who are homebound or have underlying health conditions that put them at high-risk if they contract COVID-19.
- Allocate COVID-19 vaccine doses to home infusion pharmacies either directly through a pilot program similar to SPEED, or through the states.
- Allow both the home infusion pharmacy and home health nursing provider to bill for their respective components of service associated with the provision and administration of COVID-19 vaccines in the home.

RECOMMENDATION #2: PROMOTE HOME INFUSION FOR COVID-19 MONOCLONAL ANTIBODY TREATMENTS

The ongoing pandemic continues to place immense strain on hospital systems and their medical personnel. While progress has been made in providing vaccines to frontline health care personnel and to seniors residing in long-term care facilities, it will take many more months to vaccinate high-risk individuals living independently in the broader community. Monoclonal antibodies (mABs) for COVID-19 present an opportunity to reduce the burden on hospitals until vaccines are more widely available.

NHIA has been successful in deploying home infusion providers to administer monoclonal antibodies to individuals residing in long-term care facilities, but the current reimbursement for mABs is based upon facility-based infusions and does not support home access. NHIA recommends the administration direct CMS to consider reimbursement for monoclonal antibodies within the context of the site of care. While home administration for these one-time infusions comes at a higher cost,[3] NHIA believes the benefits are justified by ensuring equitable access to patients living in rural areas, as well as for those for whom transportation is unavailable or difficult. Additionally, by leveraging the expertise and capacity of home infusion providers, patients would gain access to these important therapies in a manner that reduces the risk of exposure to the general public and medical personnel.

As the Duke Margolis Center for Health Policy suggested in a recent paper, "current Medicare reimbursement may not reflect all efforts associated with safe and effective infusion delivery, such as hiring staff, and transportation costs for staff and medication, especially since economies

[3] Sullivan, C., BS Pharm. (2021). *A Home Infusion Program for Administration of Bamlanivimab in Long-term Care Settings: Early Findings from the NHIA SPEED Program*. National Home Infusion Association. Accessed February 9, 2021: https://www.nhia.org/wp-content/uploads/2020/03/NHIA-SPEED-SUMMARY_FINAL_020921.pdf

of scale may be limited."[4] The paper goes on to explain that the home infusion model "is primarily used for other monoclonal antibodies by commercial and Medicare Advantage insurance plans, because of greater payment flexibility compared to traditional Medicare."[5]

Detailed Recommendations:

- Increase reimbursement for home-based administration of mABs to account for the additional costs associated with delivering these medications in the home setting.

RECOMMENDATION #3: PROVIDE ALL MEDICARE BENEFICIARIES WITH HOME INFUSION ACCESS

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. However, Medicare fee-for-service is currently the only major payer of health care services that does not offer a comprehensive home infusion benefit — leaving traditional Medicare beneficiaries with limited options for receiving infused medications.

Currently, Medicare only offers home-based drug administration services for a limited subset of drugs (i.e., about 30 medications that are covered under the Durable Medical Equipment benefit because they require an external infusion pump to administer). The majority of home infused drugs (e.g. IV antibiotics, monoclonal antibodies, hydration with electrolytes) do not require the use of a mechanical pump and are readily accessible to patients with commercial insurance. While infusion drugs administered at home using non-mechanical devices are billed to Medicare Part D, there is no coverage for the supplies and professional services. As a result, millions of seniors with underlying health care conditions don't have coverage for home-based care and are forced to either pay out-of-pocket, risk exposure to COVID-19 by receiving treatment in more expensive facility-based settings, or skip needed medical treatments.

The most significant shortcoming of Medicare's coverage for home infusion services is the requirement that medications be delivered using an infusion pump. Traditionally in commercial plan coverage, the use of an infusion pump at home is driven by factors concerning how the drug is administered, such as the length of the infusion and volume of the medication being administered. However, using an infusion pump in the home setting can introduce unnecessary complexity for the patient creating additional opportunities for error. In practice, by basing coverage on whether a pump is used to administer the drug, CMS is effectively incentivizing providers to use the less optimal method of pump administration when clinical conditions don't warrant its use.

In order to fix this disparity in coverage between patients with commercial plans and Medicare, NHIA recommends that CMS add coverage for the related services and disposable supplies under Medicare Part B for drugs billed to Medicare Part D when they are used in the home setting. Under this model, home infusion providers would receive a bundled supplies and

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[4] McClellan, M., MD, PhD., et. al. (2020). *COVID-19 Monoclonal Antibodies Paying for Administration and Better Evidence*. Duke Margolis Center for Health Policy. Accessed February 5, 2021: https://healthpolicy.duke.edu/publications/covid-19-monoclonal-antibodies-paying-administration-and-better-evidence

[5] *Ibid.*

services payment for each day a patient administers the drug, which would be designed to cover the costs associated with care coordination, patient assessments, plan of care development, clean room certification and maintenance, and other services provided by the pharmacy. The recommended change could be easily implemented by CMS in a demonstration project for infusion medications currently covered under the Part D benefit. This model has been overwhelmingly effective in commercial plan coverage at lowering costs by shortening hospital stays and avoiding long-term care admissions.

Detailed Recommendations:

- Leverage existing authority under CMS's Innovation Center to establish a demonstration program that provides Medicare beneficiaries with coverage for home infusion services during the current Public Health Emergency.
    - Allow home infusion providers to bill Medicare Part B for home infusion therapy services and disposable supplies, while billing Part D prescription drug plans (PDPs) for infused medications.
    - Provide direct reimbursement to the home infusion provider, which should be billable every day the medication is infused.
    - Consider mechanisms to reduce out-of-pocket costs for drugs covered by Part D, particularly for high-dollar specialty infusion products.
- Do not finalize the provision contained in the November 4, 2020 proposed rule titled "Medicare Program; DMEPOS Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS)" that proposes expanding home infusion access by requiring the use of an ambulatory infusion pump.

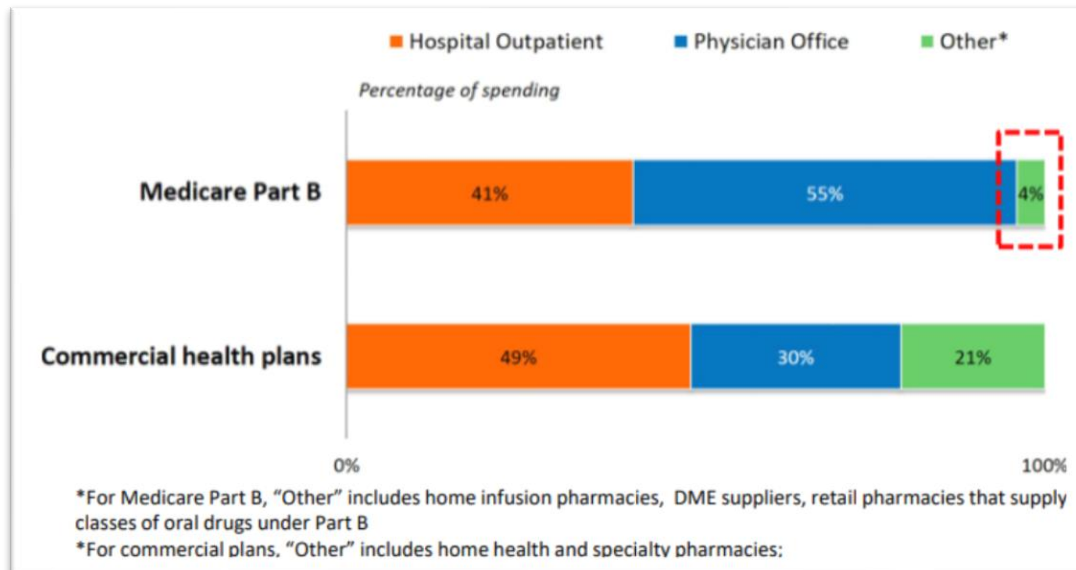
RECOMMENDATION #4: WAIVE IN-PERSON REQUIREMENTS FOR HOME INFUSION SERVICES DURING THE PHE

Home infusion services are centered around the pharmacy, which 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, aseptic 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.

Unlike in commercial plan coverage, where home infusion is generally paid for every day that a drug is infused (in order to account for services rendered remotely by pharmacists), CMS' implementation of the home infusion therapy benefit only acknowledges face-to-face visits from a nurse. As Congress has pointed out in letters to the agency, "this physical presence requirement contradicts [the] intent in drafting and enacting this legislation and makes the reimbursement

required by the bill inadequate."[6][7] And as a result, provider participation in Medicare's DMEPOS home infusion benefit has waned and beneficiaries have seen reduced access to home infusion over the last several years.

The chart below represents the medical benefit spending by site of care and payor:



Source: Drug Channels Institute, via data from MedPAC and Magellan (April 2020)

Given the desire for patients with underlying health conditions to avoid exposure to COVID-19, we urge the agency to consider enacting an interim final rule with comment (IFC) to eliminate the in-person requirement for billing home infusion professional services during the PHE. Similar to the commercial sector model for home infusion reimbursement, this would incentivize the provision of home infusion during the pandemic by covering the extensive, wrap-around pharmacy services which occur behind the scenes. Notably, private payers have found that utilizing home infusion serves a cost-effective alternative to hospital and skilled facility stays, and several leading hospital systems have submitted requests for this flexibility during the PHE.[8]

Detailed Recommendations:

- Enact an IFC to modify the definition of infusion drug administration day (as defined in 1834(u)(7)(E)(i)) and unit of single payment (as defined in 1834(u)(1)(A)(ii)) to allow payment for the date on which a home infusion drug is administered to the individual, regardless of whether a qualified home infusion therapy supplier was physically present in the home of such individual on such date, for the duration of the PHE.

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[6] Letter to CMS Administrator Seema Verma, October 8, 2018, U.S. Senators Johnny Isakson, Mark Warner, et. al. Accessed February 2, 2021: https://www.nhia.org/wp-content/uploads/2020/09/USS_Seema_Verma_Ltr.pdf.

[7] Letter to CMS Administrator Seema Verma, September 26, 2018, U.S. Representatives Kenny Marchant, Fred Upton, Elliot Engel, Terri Sewell, et. al. Accessed February 2, 2021: https://www.nhia.org/wp-content/uploads/2020/09/CMS_Proposed-Rule_House_Letter_to_CMS.pdf.

[8] Letter to CMS Administrator Seema Verma, April 17, 2020, Partners Healthcare, Johns Hopkins Health System, et. al. Accessed February 5, 2021: https://www.nhia.org/wp-content/uploads/2020/04/Home-Infusion-Waiver-Request-4-17-20.pdf

CONCLUSION

Despite alignment from across the spectrum of health care stakeholders — including health systems, drug manufacturers, epidmiologists, pharmacists, nurses, and more — the federal government has failed to take full advantage of capacity and efficiencies that home infusion can provide. In many cases home infusion is less expensive than treating patients in facilities. In other instances, where higher reimbursement may be needed, it is the safest and most equitable venue to treat certain patients. Commercial payers embrace home infusion for being cost effective; while patients laud the convenience, higher quality of life, and improved feelings of control over their care decisions.

We appreciate your consideration and look forward to working with the new administration to advance these policies.

Sincerely,

Connie Sullivan, B.S. Pharm
President and CEO

CC: Jeffrey Zients, White House COVID-19 Coordinator
Dr. David Kessler, Chief Science Officer, COVID Response Team