UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL HOME INFUSION ASSOCIATION, 1600 Duke Street, Suite 410 Alexandria, VA 22314, Plaintiff, v. ALEX M. AZAR II, *in his official capacity as Secretary of Health & Human Services*, U.S. Department of Health & Human Services, 200 Independence Avenue, S.W. Washington, D.C. 20201 Defendant.	)	Case No. 1:19-cv-393

COMPLAINT

1. Tens of thousands of patients, including Medicare beneficiaries, require infused drugs or biologics as part of their medical care. Home infusion therapy is a medical service that allows these patients to be treated at home, rather than in a more costly and inconvenient setting such as a hospital or a skilled nursing facility. Treatment at home significantly improves these patients' health outcomes for a variety of reasons, including the avoidance of hospital-acquired infections. In recognition of the importance of home infusion therapy, Congress created a temporary transitional payment for professional services associated with home infusion therapy and directed the Medicare program to reimburse the suppliers of these services for each day that the drug or biologic is administered to the patient at home. Bipartisan Budget Act of 2018 ("BBA18"), Pub. L. No. 115-123, § 50401, 132 Stat. 64, 214 (2018). In contravention of the statute, the Medicare program has issued a final rule that provides for payment for home infusion therapy services only for those days on which a nurse is physically present at the patient's home.

See 83 Fed. Reg. 56,406 (Nov. 13, 2018) (the "Final Rule"). The Final Rule cannot be reconciled with the plain language of the statute. The Final Rule, moreover, irrationally denies reimbursement for many home infusion therapy services. For many home infusion drugs, a nurse is rarely, or never, present in the home for the administration of that drug. For example, patients with immune deficiency require life-saving subcutaneous immune globulin (or SCIG) to bolster their immune system and protect against infection. These patients require regular infusions throughout their lives, and they are able to independently administer SCIG—which can simply be infused under the skin and does not need to be fed directly into the veins—without the assistance of a nurse. These patients do, however, rely on a home infusion professional for infusion drug preparation and dispensing, clinical care planning and implementation, care coordination, and other professional services. In these circumstances, the home infusion supplier would *never* be paid for its professional services by the Medicare program, despite the many costs that it would incur to furnish the drug to a patient at home.

2. In order to preserve the availability of treatments like SCIG for Medicare patients who are treated at home, Plaintiff National Home Infusion Association ("NHIA"), on behalf of itself and its members, brings this complaint against Defendant Alex M. Azar II, in his official capacity as Secretary of Health and Heath Human Services ("Secretary"). Plaintiff challenges the Secretary's disregard of Congress's statutory directives in the Final Rule and seeks declaratory and injunctive relief that will (1) set aside the provisions in the Final Rule that unlawfully limited the availability of reimbursement for home infusion therapy professional services and (2) instruct the Secretary to comply with the statutory requirements in setting reimbursement for these services. The Court's immediate intervention is needed to prevent imminent irreparable harm to NHIA, its members, and the Medicare beneficiaries they serve.

INTRODUCTION

3. Across the United States today, tens of thousands of patients, including Medicare beneficiaries, require an infused drug or biologic as part of their medical care. For decades, these patients needed to be treated in a hospital, nursing home, or physician's office depending on their illness. Over the past thirty years, however, these patients had an equally safe and far more convenient option for their care—home infusion. As its name suggests, home infusion allows patients to be treated at home, rather than in a more costly care setting. Not only are billions of dollars of care costs avoided, but health outcomes are substantially improved. Studies have shown that home infusion leads to significant improvements in care, and that patients receiving home infusion experience fewer complications in their care, avoid hospital-acquired infections, and enjoy a higher quality of life.

4. Patients and their insurers quickly recognized that home infusion offers a higher quality of care and improved health outcomes at lower costs. Over the past thirty years, commercial insurers, Medicare Advantage plans,[1] the military healthcare system (known as TRICARE), and the Veterans Administration have all embraced home infusion and covered the full spectrum of home infusion services. For legacy reasons, however, the Medicare fee-for-service program, known as "Medicare Part B," has never included a comprehensive home infusion benefit. Thus, while Medicare covered selected items used in the home infusion process, such as the drugs that were infused (which were already covered under Medicare Part B when infused in a physician's office or other outpatient setting)[2] and the supplies, pumps, and other durable medical

[1] Under Medicare Part C, a beneficiary may choose to enroll in a Medicare Advantage plan that is sold by a private insurer, in lieu of the coverage that would otherwise be available to the beneficiary under Medicare Parts A and B. 42 U.S.C. §§ 1395w-21 to 1395w-28.

[2] Some home infusion drugs are not covered under Medicare Part B, but are instead covered under the Medicare Prescription Drug Benefit, known as Part D. As described below, Congress has still not created a home infusion

equipment needed for infusion (which were already covered under Part B), Medicare never covered or reimbursed for the professional services, including the pharmacy services, needed to provide home infusion to Medicare beneficiaries.

5. Congress was aware that the absence of coverage and appropriate payment for home infusion professional services was a missing part of the Medicare program. For example, when Congress revised the methodology to reduce payment for most Part B drugs in 2003, it exempted home infusion drugs and kept payment for those drugs at an artificially high benchmark to subsidize the absence of a home infusion professional services Medicare benefit. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 303(b), 117 Stat. 2066, 2238 (2003). In 2016, however, Congress chose to rectify the imprecise subsidy and align home infusion drug payments with the general Part B drug payment methodology. 21st Century CURES Act, Pub. L. No. 114-255, § 5004, 130 Stat. 1033, 1190 (2016). Because Congress understood that it was eliminating the subsidy that had been informally covering the professional services costs incurred by home infusion pharmacy providers, Congress also adopted a home infusion professional services benefit for the first time. *Id.* § 5012, 130 Stat. at 1198.

6. At the time that it enacted the CURES Act, Congress inadvertently left a detrimental gap in payment for home infusion services. Congress reduced the drug reimbursement as of January 1, 2017, thereby eliminating the subsidy that had covered home infusion professional services. However, the Centers for Medicare and Medicaid Services ("CMS"), which operates the Medicare program, advised Congress that it needed four years to implement the new home infusion professional services benefit. To appease CMS's request for more time, Congress postponed the

benefit for the professional services required for infusion of these drugs, which include certain antibiotics, and the Part D drugs are not at issue in this litigation.

effective date of the new benefit until January 1, 2021, inadvertently leaving a four-year gap between the drug reimbursement reduction and the new home infusion benefit.

7. The four-year gap threatened the ability of Medicare beneficiaries to continue receiving home infusion care. To close this gap, in February 2018, Congress enacted a transitional provision in Section 50401 of BBA18 that provides Medicare beneficiaries with an interim benefit between January 1, 2019 and the time that Medicare is able to implement the full program. BBA18, § 50401, 132 Stat. at 214 (codified at 42 U.S.C. § 1395m(u)(7)). The transition legislation was purposefully detailed to address each of the questions CMS claimed it needed four years to evaluate—who would qualify as a home infusion provider of professional services, which drugs were covered, what rate should be paid for the professional services, and when the rate should be paid. (The provider eligibility criteria, the list of drugs, and the payment rate are not in dispute.) The legislation instructed CMS to pay specific reimbursement rates for each of three categories of home infusion—$138.75, $216.59, and $236.06—and assigned each of the eligible Part B home infusion drugs to one of the three categories. Congress was also explicit that the specified "professional service" payment was to be made for each "infusion drug administration calendar day"—each day that a home infusion drug was infused into a beneficiary. 42 U.S.C. § 1395m(u)(7)(B)(iv), (u)(7)(E).

8. The Secretary, however, who months earlier had advised Congress that he needed four years to calculate the correct payment rates, suddenly claimed that the rates set by Congress were too generous. Thus, through the rulemaking being challenged here, the Secretary "interpreted" the unambiguous law to permit reimbursement only when a "skilled professional" such as a nurse was physically present in the home, irrespective of the days when the professional services were used by the beneficiary when infusing the drug in their home, as Congress had

directed. As a result, for some home infusion drugs, the Secretary will pay for home infusion professional services only for the one day a week that a nurse is typically present in the patient's home, rather than for every day that the drug is infused. Other home infusion drugs, such as SCIG, do not require any home nursing visits; under the Secretary's theory, he will make no payment whatsoever for the professional services which are provided remotely by pharmacists to furnish these drugs.

9. The Secretary's interpretation is in direct contradiction of the plain meaning of the statute, as well as Congress' explicit intent. The Secretary is aware that his rule will result in severe underpayment of the professional services required to provide home infusion to Medicare beneficiaries. Congress required the transition rate be in effect on January 1, 2019, and the transition is intended to bridge the two-year gap until CMS implements the permanent home infusion benefit. In the interim, Medicare beneficiaries currently on home infusion therapy will lose access to care, and others will be forced to remain in hospitals or nursing homes for their infusion treatment—ironically costing the Medicare program hundreds of millions more and putting these beneficiaries at risk of infection and other negative health outcomes.

10. This Court should, on an expedited basis, review the Secretary's illegal actions and issue an order reversing the Secretary's decision and requiring the Medicare program to provide the professional services payment for each "infusion drug administration calendar day"—each day that a home infusion drug is administered to a Medicare beneficiary.

PARTIES

11. NHIA is a not-for-profit association with its principal place of business in Alexandria, Virginia. NHIA represents the nation's leading home infusion therapy companies that specialize in the intensive professional pharmacy services, clinical care planning and

implementation, and care coordination to provide infusion therapy to a patient at home. NHIA's members perform home infusion therapy services for tens of thousands of patients that are reimbursed under the Medicare program.

12. Defendant Alex M. Azar II is the Secretary of the United States Department of Health and Human Services, which administers the Medicare program established under title XVIII of the Social Security Act. Defendant Azar is sued in his official capacity only. CMS is the federal agency to which the Secretary has delegated administrative authority over the Medicare and Medicaid programs, including issues relating to the transitional payment for home infusion therapy services. References to the Secretary herein are meant to refer to him, his subordinate agencies and officials, and to his official predecessors or successors as the context requires. The Secretary oversees regulation of the home infusion therapy services under the Medicare program, including those actions complained of herein.

JURISDICTION AND VENUE

13. This Court has subject-matter jurisdiction pursuant to 42 U.S.C. § 405(g). Due to the Secretary's Final Rule, the Secretary has failed to reimburse NHIA's members the Congressionally-designated home infusion professional services fee for each "infusion drug administration calendar day." NHIA's members, including BioScrip, Inc., Intramed Plus, and Paragon Healthcare, Inc. have presented claims to the Secretary in the form of a concrete request for additional Medicare reimbursement that challenges the Secretary's authority to refuse professional services reimbursement for each infusion drug administration day when home infusion is provided to a beneficiary but a nurse or other "skilled professional" is not in the home.

14. In the alternative, this Court has subject matter jurisdiction under 28 U.S.C. § 1331 to review the Secretary's Final Rule because NHIA's causes of action arise under the laws of the United States, including under BBA18 and the APA, 5 U.S.C. § 702.

15. Venue is proper under 28 U.S.C. § 1391(b), because the Defendant resides in and performs his official duties in the District of Columbia and a substantial part of the events giving rise to this action occurred in this judicial district.

16. NHIA has standing to bring this lawsuit. NHIA actively participated in the rulemaking proceedings and has a substantial interest in ensuring that the Secretary's regulations comply with statutory mandates and that regulatory burdens are imposed in an even-handed manner, as Congress intended. In addition, at least one of NHIA's members has been injured by the Secretary's Final Rule and has standing to sue in its own right, the interests NHIA seeks to protect are germane with its purpose, and NHIA's members are not required to participate in this lawsuit in order to obtain relief against the Secretary.

17. An actual controversy exists between the parties under 28 U.S.C. § 2201, and this Court has authority to grant the requested declaratory and injunctive relief under 28 U.S.C. §§ 2201 & 2202 and 5 U.S.C. §§ 705 & 706.

STATEMENT OF FACTS

I. Home Infusion Therapy Leads to Better Health Outcomes, at Lower Costs, than Does the Same Therapy Offered in an Institutional Setting

18. Home infusion therapy is a treatment option for patients, including Medicare beneficiaries, who suffer from a wide range of acute and chronic conditions, ranging from infections to more complex conditions such as late-stage heart failure, cancer, and immune deficiencies. Home infusion can include the delivery of sterile medications, intravenous administration, subcutaneous administration, intramuscular injections, and epidural infusion (e.g.,

into the membranes surrounding the spinal cord). Infusion generally refers to the administration of sterile medications and drugs directly into a vein through a needle or catheter.

19. Infusion therapy is used to treat patients whose condition is so severe that periodic oral medications are not available or are not effective. Diseases that may require infusion therapy include, among many others, cancer and cancer-related pain, gastrointestinal diseases or disorders, pulmonary hypertension, congestive heart failure, hemophilia, immune deficiencies, rheumatoid arthritis, and infections that are unresponsive to oral antibiotics. Chemotherapy medications commonly use infusion therapy as the delivery mechanism.

20. With the advantages of modern-day technology, infusion therapy that historically had to be provided in a hospital can now be safely administered in the home. Home infusion therapy has evolved into a comprehensive medical therapy that is a far less costly alternative to inpatient treatment in a hospital. For chronic conditions that require ongoing sessions of infusion therapy, home infusion therapy is more convenient and supports an improved quality of life for patients.

21. The Secretary has recognized the many advantages that home infusion therapy offers for patients, including Medicare beneficiaries. "Home infusion therapy affords a patient independence and better quality of life, because it is provided in the comfort of the patient's home at a time that best fits his or her needs." 83 Fed. Reg. 56,406, 56,414 (Nov. 13, 2018). "This is significant, because generally patients can return to their daily activities after they receive their infusion treatments, and, in many cases, they can continue their activities while receiving their treatments." *Id.* "In addition, home infusion therapy can provide improved safety and better outcomes. … [P]atients receiving treatment outside of the hospital setting may be at lower risk of hospital-acquired infections, which can be more difficult to treat because of multidrug resistance

than those that are community-acquired. This is particularly important for vulnerable patients such as those who are immunocompromised, as hospital-acquired infections are increasingly caused by antibiotic-resistant pathogens." *Id.*

22. Home infusion therapy achieves these better health outcomes at lower cost. When Congress deliberated over the enactment of the transitional benefit in BBA18, the Congressional Budget Office ("CBO") studied the effects that such a benefit would have on the Medicare program. CBO estimated that, under the transitional reimbursement legislation, Medicare would pay for approximately 25 million home infusion days in each of 2018 and 2019. Congressional Budget Office, *Cost Estimate: H.R. 3178, Medicare Part B Improvement Act of 2017* at 3 (July 24, 2017), *available at* www.cbo.gov/publication/52969. In many cases, however, those additional payments would substitute for more costly payments for inpatient or skilled nursing care. For example, a patient receiving inotropes (a type of drug that affects the contraction of the heart) would move from a daily cost of care of $386 (even before accounting for Medicare rehabilitation payments, which are also often incurred with these patients) to a daily cost of care of $138.75. CBO projected that the enactment of the transitional benefit would save the Medicare Trust Fund $910 million dollars during the two-year transition period alone. Congressional Budget Office, *Estimated Direct Spending and Revenue Effects of Division E of Senate Amendment 1930, the Bipartisan Budget Act of 2018* at 2 (Feb. 8, 2018), *available at* www.cbo.gov/publication/53557.[3]

23. Given that home infusion therapy offers better care outcomes at lower costs, it is unsurprising that other insurance programs provide for payments for professional services

[3] At the time that CBO prepared its 2017 analysis of the home infusion transitional benefit legislation, it had projected that the benefit would lead to a slight increase in federal spending. The final legislation enacted in 2018 reduced the amount of the benefit from a payment equivalent to five hours of time in a physician's office (as contemplated in the bill that the Senate passed in 2017) to one equivalent to four hours of such time, resulting in CBO's projection that the benefit would lead to more than $900 million in budgetary savings.

associated with this form of treatment. An overwhelming majority of commercial insurers, Medicare Advantage plans, TRICARE, and the Veterans Administration cover and separately pay for all home infusion professional services associated with home infusion.

II. Home Infusion Therapy Requires a Wide Array of Professional Services in Order to Be Furnished to Home Patients Safely and Effectively

24. Home infusion therapy requires a distinct set of professional services that are different from any other class of treatment covered or reimbursed by the Medicare program. Although there is an array of professional services that home infusion suppliers provide, there are four core "professional services" required to provide home infusion therapy: (1) infusion drug preparation and dispensing, (2) clinical care planning and implementation, (3) care coordination, and (4) nursing services.

25. *Infusion Drug Preparation and Dispensing*. The core of home infusion occurs in a specialized home infusion pharmacy, which must be uniquely equipped and maintained to prepare and dispense the sterile parenteral medications. The maintenance and operation of an infusion pharmacy requires expertise beyond the scope of traditional pharmacy or nursing practice. Each infusion patient receives a sterile medication that is customized to meet their individual needs and circumstances. In order to design the patient therapy, a pharmacist must review the patient's past medical history, history of present illness, complete medication list, laboratory reports, home environment, ambulatory status or other physical limitations, vascular access, infusion medication order, and other dosing considerations. The patient's medication profile must be created, and drug utilization review must occur before the first infusion is provided. Home infusion pharmacies prepare patient-specific products that are not commercially available in a finished form, because doses are based upon patient-specific criteria, such as weight and fluid status, vascular access, tolerance, and kidney function.

26. Following dose preparation, the home infusion supplier must deliver or otherwise ship the medications to the patient's home. The composition of infused drugs almost always requires cold chain storage, which utilizes significant resources and requires specialized knowledge beyond what is required for a standard delivery of a drug. And before shipping, the home infusion pharmacy must communicate with the patient to conduct a disease-based patient assessment to identify and address side effects, measure effectiveness, and ensure adherence with the regimen. Often, at this point, the patient has questions and may speak to a pharmacist, nurse, or dietitian to discuss diet, activity, or other concerns associated with the drug.

27. *Critical Care Planning and Implementation*. Clinical care planning and care implementation services must take place before, during, and after the infusion process. These services include the development and implementation of care plans by a multidisciplinary team, which includes pharmacist, nurse, and dietitian professionals where appropriate. These teams, in coordination with the treating physician, will need to create the care plan at the start of the infusion treatment and modify it—sometimes everyday—based upon the changed circumstances of the patient. Importantly, home infusion pharmacists are key to the clinical care planning and implementation process, and professional services are often provided outside the patient's home on each day of drug administration.

28. *Care Coordination*. Prior to accepting a patient, the pharmacy intake department performs many functions, including, among others, assessing whether a patient is eligible for home infusion services and coordination with the provider to ensure a smooth and orderly discharge to home. Once a patient is admitted to home infusion, all aspects of the home infusion plan of care must be communicated and coordinated to avoid medication errors, missed or delayed doses, or unplanned hospitalizations. The pharmacy care team provides comprehensive case management

of the infusion therapy and ensures that all members are informed of changes to the plan of care, changes in patient clinical status, adverse events, changes in supply needs, or schedule changes. Communication for the purposes of coordinating care takes place continuously during treatment. Clinicians are available around the clock for patient problem solving, trouble shooting, answering questions, unplanned nursing visits (as needed), and other professional duties from pharmacy staff that do not require an in-person visit to the patient's home.

29. *Nursing Services*. While in-home patient visit services are frequently provided by a skilled nurse, skilled nursing services do not represent the totality of nursing services, much less professional services, provided for home infusion. Home infusion nursing services are fundamentally different than home health nursing services, skilled nursing facility nursing services, or other nursing services that the Secretary previously has covered under other Medicare program benefits. The infusion nurse has specialized training and unique knowledge of, and experience in, vascular access devices (catheters) and maintenance, safe administration of sterile medications, preventing catheter infection and occlusion, patient education regarding the access device and infusion therapy, and maintaining a safe infusion environment in the home. Because the infusion service is delivered based upon the required dosing schedule, the infusion nurse strives to balance the patient's schedule with the specifications of the drug.

III. Different Home Infusion Therapies Require Differing Degrees of In-Home Nursing Services, and Some Require None at All

30. Although all home infusion therapies require the full array of professional services described above in order that the drug may be furnished to a home patient safely and effectively, not all home infusion drugs require a nurse or other "skilled professional" to be present in the home for the drug to be administered. Indeed, certain drugs that Congress designated for the transitional benefit (under Payment Category 1, *see* 42 U.S.C. § 1395m(u)(7)(C)), such as milrinone (a drug

used to prevent heart failure), are typically infused each day (on a continuous, 24-hour-a-day basis) but have a professional present only once a week (after the first week during which patient training occurs).

31. For other drugs (under Payment Category 2), a nurse or other skilled professional may *never* be present; thus, under the Secretary's reading of the statute, these therapies would never qualify for professional services reimbursement even though professional services are necessary to allow home infusion to occur. For example, most patients who are treated with SCIG (a therapy to treat immunodeficiency) will not require a nurse in the home after the initial training is complete and the patient properly trained. Similarly, many patients receiving deferoxamine (a treatment for patients with anemia) and epoprostenol (a treatment for patients with pulmonary hypertension) often become sufficiently adept at home infusion that they do not need any skilled professional in the home other than an initial instructional visit. While these patients would still need all the "professional services" required to be able to infuse at home, under the Secretary's Final Rule, home infusion providers will receive zero reimbursement for their services.

32. In contrast, "Category III" drugs, such as chemotherapy drugs for cancer treatment, may have a nurse or other professional in the home every time a drug is infused into the patient. Despite these differing schedules for nursing services, the same array of pharmacist professional services is needed to prepare the drug, review patient health records, and monitor the patient's laboratory test results to permit every infusion to occur, regardless of whether the drug falls into Category I, II, or III.

IV. Congress Instructed the Medicare Program to Pay for the Full Range of Professional Services that Are Needed to Furnish Home Infusion Therapy to Medicate Beneficiaries

33. The Medicare program provides federally funded health insurance for certain elderly and disabled persons under title XVIII of the Social Security Act. 42 U.S.C. § 1395. Part

A of the Medicare program covers payment for inpatient hospital services and post-hospital extended care in an institutional setting. 42 U.S.C. § 1395d(a)(1)-(2). Part B covers payment for "medical and other health services." 42 U.S.C. § 1395k(a)(1); *id.* § 1395x(s).

34. As explained above, historically Medicare never provided coverage for home infusion therapy professional services. While every other payer and insurer, including governmental health programs, paid for home infusion services, Congress did not do so for the Medicare program until 2016. Instead, Medicare paid for only the cost of the drugs used for infusion and the "durable medical equipment" used during infusion. There was no Medicare payment for the four categories of professional services described above, including the nursing services, that were necessary for home infusion.

35. Home infusion pharmacies were able to continue to serve Medicare beneficiaries because Congress set an unusually generous reimbursement for the drugs providers dispensed when serving Medicare beneficiaries. That changed in December 2016, when Congress, in legislation known as the 21st Century CURES Act, reduced the generous drug reimbursement, effectively eliminating the ability of home infusion providers to serve Medicare beneficiaries. To address that problem, Congress also created a new home infusion benefit by adding "home infusion therapy" as one of the "medical and other health services" that are payable under Medicare Part B. 21st Century CURES Act ("CURES Act"), Pub. L. No. 114-255, § 5012, 130 Stat. 1033, 1198 (2016). As amended by the CURES Act, Sections 1861(s)(2)(GG) & (iii) of the Social Security Act for the first time defined home infusion therapy as "medical and other health services" provided by Part B and specified the conditions that suppliers had to meet in order to participate in the Medicare program, and which are considered necessary to ensure the health and safety of patients. 42 U.S.C. § 1395x(s)(2)(GG), 1395x(iii). The professional services payment created by

Congress was explicitly *in addition to* the separate payment for DME and the separate payment for drugs and was in recognition that the DME payment rates set for the general population were inadequate for home infusion services.

36. However, Section 5012 of the CURES Act does not take effect until January 1, 2021. Congress provided for this four-year delay after CMS represented to Congress that it needed those four years before it would be able to develop an informed view as to the appropriate amount of payment for home infusion therapy services.

37. From the moment it enacted the CURES legislation, Congress understood that it was placing Medicare beneficiaries who were receiving home infusion therapy at risk, and that it had effectively eliminated payment for needed home infusion treatments. For that reason, in February 2018, Congress enacted a temporary transitional payment benefit for home infusion therapy in Section 50401 of BBA18, which requires a temporary, transitional payment be made to eligible home infusion suppliers for home infusion therapy services furnished on or after January 1, 2019, until the implementation of the full home infusion therapy benefit on January 1, 2021, as required by Section 5012 of the CURES Act. In response to CMS's statements that the agency did not know who could qualify as a home infusion provider, which drugs to cover under the Part B home infusion benefit, and what to pay for them, Congress instructed CMS to qualify certain entities for the transitional benefit, to cover a designated list of drugs, and to pay one of three specified rates depending on the drug. The rates (in 2019 terms) were $138.75, $216.59, and $236.06—with the highest payment for chemotherapy, the second highest for subcutaneous immunotherapy, and the lowest payment for, essentially, the remaining infusion drugs.

38. Notably, Congress directed that reimbursements for all categories of home infusion under this transition payment benefit were for each "infusion drug administration calendar day"—

i.e., each day an infusion drug was administered to a beneficiary. Section 50401 of BBA18 defines "infusion drug administration day" as the following:

> For purposes of this subsection, with respect to the furnishing of transitional home infusion drugs or home infusion drugs to an individual by an eligible home infusion supplier or a qualified home infusion therapy supplier, a reference to payment to such supplier for an infusion drug administration calendar day in the individual's home shall refer to payment only for the date on which professional services (as described in section 1395x(iii)(2)(A) of this title) were furnished to administer such drugs to such individual. For purposes of the previous sentence, an infusion drug administration calendar day shall include all such drugs administered to such individual on such day.

42 U.S.C. § 1395m(u)(7)(E)(i).

39. The definition of "infusion drug administration day" ties payment for home infusion therapy to days on which "professional services" were furnished to administer infusion drugs to patients. Further, this definition refers to "professional services" as described in section 1395x(iii)(2)(A), which simply states: "[p]rofessional services, including nursing services, furnished in accordance with the plan." 42 U.S.C. § 1395x(iii)(2)(A).

40. In order to provide home infusion therapy, home infusion therapy suppliers must provide and coordinate a myriad of professional services, several of which are mentioned in paragraphs 24 to 29 above. The plain language of Section 50401 of BBA18 does not limit reimbursable professional services to those that are performed at the same location that the drug is administered. Instead, the statute directs that the day for which payment would be made for the range of professional services involved in providing home infusion is the day that a drug is actually administered to a beneficiary—an "infusion drug administration calendar day." In turn, Congress designated specific reimbursement rates for each of the three payment categories of home infusion to be paid "for *each* infusion drug administration calendar day in the [patient's] home." 42 U.S.C. § 1395m(u)(7)(B) (emphasis added).

V. The Secretary's Final Rule Rewrites the Statute to Limit the Home Infusion Benefit to Pay Only for Services Performed by a Skilled Professional in the Home

41. *The Proposed Rule*. The Secretary issued a notice of proposed rulemaking to address the transitional home infusion benefit. Despite the clarity of the congressional directive, the Secretary proposed to permit reimbursement only when a "skilled professional" was in the patient's home, irrespective of the days when other "professional services" were delivered to the Medicare beneficiary when the drug was infused. *See* 83 Fed. Reg. 32,340 (July 12, 2018) (the "Proposed Rule").

42. Rather than applying Congress's language, the Secretary proposed to find somewhere in the statutory phrase "infusion drug administration calendar day" a rule that payment may be made "only for the day on which the *nurse is in the patient's home* when an infusion drug is being administered." *Id*. at 32,464 (emphasis added). Inexplicably, the Secretary sought to narrow the express statutory language of "[p]rofessional services, including nursing services," 42 U.S.C. § 1395x(iii)(2)(A), to mean effectively that *only* nursing services qualify as reimbursable "professional services."

43. The Secretary compounded his error by offering the further, and equally baffling, observation that he believed "professional services, including nursing services, . . . to mean *skilled services* as set out at 42 C.F.R. § 409.32." 83 Fed. Reg. at 32,464 (emphasis added). As defined in 42 C.F.R. § 409.32, a "skilled service . . . must be so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel."

44. The Secretary's reliance on 42 C.F.R. § 409.32 for a definition of "skilled services" is not without irony. The referenced regulation is contained within the scheme for hospital insurance benefits that "describe[s] the benefits available *under Medicare Part A* and set[s] forth

the limitations on those benefits." 42 C.F.R. § 409.2 (emphasis added). 42 C.F.R. Subpart D, which outlines the requirements for coverage of post-hospital skilled nursing facility ("SNF") care, contains several criteria pertaining to SNFs as institutional providers under Medicare Part A. Of course, home infusion therapy exists precisely to avoid those costly and high-intensity levels of care, and home infusion therapy providers are not institutional providers under Part A. While CMS may have sought to use an existing regulatory definition rather than developing a new definition of professional services, because of the fundamental difference between skilled services provided in the SNF context and professional services by home infusion suppliers, using the existing regulatory definition is not supported by statute nor by the services that are actually furnished by home infusion suppliers. The Secretary's post-hoc justification that "skilled services" is part of the "professional services" fundamentally alters the statutory definition of "infusion drug administration day," as mandated by Congress in Section 50401 of BBA18. *See* 42 U.S.C. § 1395m(u)(7)(E)(i).

45. The Secretary added his own overlay to the statutory language by proposing to add a physical presence requirement—in other words, that reimbursement would only be made for the "day on which the nurse *is in the patient's home when an infusion drug is being administered*." 83 Fed. Reg. at 32,464 (emphasis added). The plain language of Section 50401 of BBA18 makes no reference to any physical presence-like requirement as part of the definition of "infusion drug administration day." The Secretary overlooked the full scope of professional services that are required for a patient to be infused in his or her home, the most obvious of which is the pharmacy compounding process that is required in order to prepare a sterile medication without introducing contamination. Quite obviously, initial therapy design, pharmacy care planning, coordination with

the physician, monitoring, and compounding are services that are necessarily performed outside the patient's home.

46. By limiting the definition of "infusion drug administration day" to require a nurse in the patient's home, the Secretary improperly limited the home infusion benefit to such a degree that most Medicare beneficiaries will no longer be able to receive home infusion. Under the Secretary's misinterpretation in the Proposed Rule, only the most severe cases of home infusion—cases that require nursing care every day—would receive more than a *de minimis* reimbursement under the home infusion benefit. This is in direct contradiction of the plain language of Section 50401 of BBA18 and contrary to Congress's intent when enacting a new home infusion benefit to encourage beneficiaries to receive infusion at home instead of costlier settings.

47. *Comments to the Proposed Rule*. During the comment period to the Proposed Rule, stakeholders submitted written comments, including NHIA and several of its members, stating that the Secretary's improper narrowing of the definition of "infusion drug administration day" was contrary to the statutory definition, neglected Congress's purpose in enacting BBA18, and ignored the realities of the full scope of professional services inherent when supplying home infusion therapy. In particular, commenters stated:

a. NHIA submitted a comment letter to the Proposed Rule urging the Secretary to "remove the physical presence requirement in the definition of a 'infusion drug administration calendar day' and provide a specific definition for professional services associated with home infusion."

b. Other commenters also advised CMS that it had inappropriately and incorrectly excluded major components of the items and services that Congress required it to cover and explicitly included in the law. These commenters noted that Congress

had explicitly recognized the central role that pharmacy services play in home infusion; indeed, the statute highlights pharmacy services in defining "eligible home infusion therapy supplier" and "qualified home infusion therapy supplier" in Section 5012 of the CURES Act and Section 50401 of BBA18. An "eligible home infusion therapy supplier," the entity that will receive the transition payment in 2019 and 2020, is "a supplier that is enrolled under [Medicare] as a *pharmacy* that provides external infusion pumps and external infusion pump supplies and that maintains *all pharmacy licensure requirements* in the State in which the applicable infusion drugs are administered." BBA18, § 50401, adding 42 U.S.C. § 1395m(u)(7)(F) (emphasis added). Similarly, in the CURES Act, Congress also included "a pharmacy" in the definition of a qualified home infusion therapy supplier that will be eligible for the payment that begins in 2021. *See* 42 U.S.C. § 1395x(iii)(3)(D). As these commenters noted, pharmacy services are explicitly within the scope of professional services for which the statute requires reimbursement.

c. Several members of Congress, including the sponsors of the Senate bill that eventually became Section 50401 of BBA18, also offered comments to express their strong disagreement with the Proposed Rule. Senators Johnny Isakson and Mark Warner wrote to CMS Administrator Seema Verma that Congress's "intent was that home infusion providers' professional services, such as drug preparation, clinical care planning, care coordination, nursing and other associated professional work should be a component of the home infusion benefit." Further criticizing the Proposed Rule, they took issue with requiring professional services to solely be

performed "in the individual's home" as "[t]his physical presence requirement contradicts [Congress's] intent in drafting and enacting [BBA18] and makes the reimbursement required by the bill inadequate."

d. Congressman Pete Sessions also commented on the proposal and asked the Secretary to "remain true to both the legislation and [Congress's] intent" by "withdraw[ing] the requirement that a nurse or other professional be physically present 'in the home' for reimbursement to occur, and instead . . . recognize that reimbursement be made for each day that a home infusion drug is infused."

48. *The Final Rule*. On November 23, 2018, the Secretary issued his Final Rule, adhering to his proposed definition of "infusion drug administration day," but offering only cursory responses to the serious objections that had been raised to the Proposed Rule. *See* 83 Fed. Reg. 56,406, 56,579 (Nov. 13, 2018). Instead of meaningfully grappling and addressing comments to the Proposed Rule, the Secretary simply ignored the comments, finalized the proposal, and stated that the "best course of action is to monitor the effects . . . of finalizing this definition." *Id*. at 56,583.

49. In the Final Rule, the Secretary rewrote the definition of "infusion drug administration day" so that it now "means the day on which home infusion therapy services are furnished *by skilled professionals in the individual's home on the day of infusion drug administration*." *Id*. at 56,631 (emphasis added); 42 C.F.R. § 486.505.

50. The Secretary's Final Rule imposes significant, additional requirements not found in the statute—that the professional services can *only* be performed by "skilled professionals" and that professional services *must* be performed in the "individual's home." The Secretary ignored the statutory directive to provide the mandated payments on each "drug administration calendar

day in the individual's home," 42 U.S.C. § 1395m(u)(7)(B)(iv), and gave no thought to the many professional services required to provide home infusion therapy. The Secretary's interpretation is in direct contradiction with the plain language of Section 50401 of BBA18 and wholly disregards Congress's explicit intent in creating the home infusion benefit.

51. In the Secretary's inadequate responses to industry stakeholders, he explains that "[o]ur interpretation of the phrase 'only for the date on which professional services . . . were furnished' is that mere infusion *without any professional services furnished* cannot trigger a home infusion therapy services payment for any day the drug is infused." *Id*. at 56,580 (emphasis added). The Secretary continues his misinterpretation of the statutory language by stating that he "believe[s] that the language in the statute clearly delineates a *subset of days* on which professional services are provided in the patient's home in order for payment to occur." *Id*. (emphasis added).

52. The Secretary's strained interpretation of the statutory language discounts the full scope of professional services that are required to provide home infusions. Without any support, the Secretary notes that the temporary transitional payment is a "unit of single payment, meaning all home infusion therapy services furnished, which include professional services, training and education, remote monitoring and monitoring, are built into the payment for the day the professional services are furnished in the home and the drug is being administered." *Id*. at 56,581. In that statement, the Secretary properly acknowledges that there is a myriad of required services in furnishing home infusion drugs; however, the Secretary inappropriately limits that "unit of single payment" to only a *subset* of the days where professional services are provided *in a beneficiary's home* when the drug is actually infused.

53. The plain language of Section 50401 of BBA18 does not require professional services to be performed in the home during the administration of the infusion drug, although that

can occur. Rather, the statute simply requires that payment be made for the day on which "professional services . . . were furnished to administer such drugs." *See* 42 U.S.C. § 1395m(u)(7)(E)(i). As explained in paragraphs 24 to 32 above, a myriad of professional services must be performed in order to allow a home patient to infuse his or her medication. Many of those services are, by necessity, performed outside of the patient's home. Those professional services are furnished to the beneficiary *every day* that a patient is infused. Congress, accordingly, understood that payment is properly made every day of infusion drug administration in a patient's home, because each day that that occurs the patient receives the home infusion therapy supplier's professional services. The Secretary disregarded the plain statutory text and Congress's manifest purpose in enacting the transitional benefit by limiting reimbursement only to those days that nursing services are performed in the patient's home. The Secretary's unreasonable interpretation misconstrues this fundamental aspect of the transitional payment of home infusion benefit.

54. Given the Secretary's radical departure from the statutory text, it is unsurprising that he projected that Medicare beneficiaries would make drastically lesser use of home infusion therapies than Congress had intended. As noted above, CBO had found that CMS would pay for approximately 25 million home infusion days in each year under the transitional reimbursement legislation. Contrary to Congress's expectations, however, the Secretary anticipated that his Final Rule would lead to only 305,595 reimbursable days of care in a given year. 83 Fed. Reg. at 32,507 (tbl. 66, col. 3, total for "estimated total visits of care"). Remarkably, the Secretary opined that he "[did] not anticipate an increase in beneficiaries receiving home infusion therapy services" under the Final Rule. *Id*. at 32,482.

55. *Extended Comment Period*. Although he finalized a definition of "infusion drug administration calendar day" that the industry and Congress vehemently opposed, the Secretary opened his Final Rule for an extended comment period. 83 Fed. Reg. at 56,583.

56. Industry stakeholders submitted additional comments reiterating their fundamental objections to the Final Rule. In particular, commenters stated:

a. Plaintiff NHIA encouraged the Secretary to revise his interpretation of "home infusion administration day" to capture a broader cross-section of the professional services provided for home infusion therapy. For example, infusion pharmacies remotely provide initial and ongoing pharmacist assessments, clinical care planning, drug preparation, care coordination, monitoring for adverse events and response to therapy, patient education, among others. Such remote pharmacy services are "fluid and occur at various frequencies depending on the patient acuity and frequency of administration." The Secretary includes remote monitoring as part of the professional services but adds a requirement that professional services must be provided in the individual's home—in other words, adding a physical presence requirement to the definition of "infusion drug administration day." Notably, there is nothing in the statutory language of Section 50404 of BBA18 that prevents payment when these professional services are furnished remotely.

b. Another set of industry commenters urged the Secretary to follow the practice of "virtually every payer in the United States" and to provide "that payment should be made for each day a drug is administered to a beneficiary, whether or not a skilled professional is in the home." These commenters noted that "beneficiaries will lose access to home infusion services" under the Final Rule, and that the "rule will

severely compromise the government's overall goals of moving high quality patient care to the most clinically appropriate and less expensive care settings."

VI. The Secretary's Final Rule Will Jeopardize the Availability of Needed Therapies for Medicare Beneficiaries

57. If the Secretary's Final Rule is not set aside, NHIA and Medicare beneficiaries are likely to suffer irreparable harm. Without relief, it will no longer be viable for suppliers to furnish many important and life-saving home infusion treatments. To name but one example, suppliers will be unable to furnish home inotropic infusions, such as milrinone, for home infusion for patients with heart failure. The change in the drug payment methodology in the 21st Century CURES Act cut payments for milrinone from $64,512 per beneficiary per year to $5,403 per beneficiary per year (in 2017 dollars). Lauren G. Gilstrap, M.D., M.P.H., *An Unintended Consequence of the 21st-Century Cures Act for Patients with Heart Failure*, 136 Circulation 123, 124 (July 11, 2017), *available at:* https://www.ahajournals.org/doi/pdf/10.1161/CIRCULATIONAHA.117.028747. The cost to the supplier to perform all of the services associated with furnishing this needed drug to home patients, however, is $43,800 per beneficiary per year. *Id.* "Drastically cutting milrinone funding without making allowance for these necessary but otherwise unreimbursed professional services risks a significant financial shock to the home infusion industry, the ramifications of which are unknown." *Id.* Absent reimbursement for professional services, home infusion suppliers in rural and other underserved areas "may not be able to continue supporting home inotropic infusions financially. This could result in some patients losing access to home infusion services temporarily or permanently." *Id.* "Without access to home therapy, many patients with advanced heart failure may face longer and more frequent hospital stays, expensive rehabilitation hospitals, or the loss of therapy." *Id.* at 125.

58. Congress enacted the transitional home infusion benefit to prevent the disruptions in care that Dr. Gilstrap and her colleagues described. Yet the Secretary's Final Rule would reinstate the gap in funding that, as Dr. Gilstrap explained, would make it impossible for many suppliers to furnish home infusion therapies like milrinone to Medicare beneficiaries. As milrinone therapy requires continuous infusion for a home patient, but only requires the presence of a nurse in the home one day a week, the Secretary's Final Rule will reimburse suppliers only for one-seventh of the cost they incur for the professional services needed to furnish milrinone for home patients. Absent appropriate reimbursement for milrinone services, NHIA's members will no longer be able to furnish home infusion therapies, and patients with heart failure will suffer irreparable harm. These patients will be forced to seek care as inpatients or at skilled nursing facilities, leading to worse health outcomes for these patients and greater costs for the Medicare program.

CLAIMS

COUNT 1
Agency Action Contrary to Law
(42 U.S.C. § 1395m(u)(7); 5 U.S.C. §§ 706(2)(A), 706(2)(C))

59. Paragraphs 1–58 are incorporated herein in their entirety.

60. The APA permits judicial review of agency actions, findings, and conclusions that are "not in accordance with law" or are "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. §§ 706(2)(A), 706(2)(C).

61. When "Congress has directly spoken to the precise question at issue," this Court must give effect to Congress's unambiguously stated intent. *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984). It is a "core administrative-law principle that an

agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Regulatory Gp. v. EPA*, 134 S. Ct. 2427, 2446 (2014).

62. Congress has directed the Secretary to "provide a home infusion therapy services temporary transitional payment" to eligible home infusion suppliers provided for the professional services needed to furnish home infusion drugs for Medicare beneficiaries, 42 U.S.C. § 1395m(u)(7)(A)(i), and has specified that this payment shall be "for each infusion drug administration calendar day," *id.* § 1395m(u)(7)(B)(iv). Congress further clarified that an infusion drug administration calendar day "shall refer to payment only for the date on which professional services (as described in [42 U.S.C. § 1395x(iii)(2)] were furnished to administer such drugs to such individual." *Id*. § 1395m(u)(7)(E)(i). The referenced section provides for payment for "professional services, including nursing services, furnished in accordance with the plan" established by the patient's physician for home infusion therapy services. 42 U.S.C. § 1395x(iii)(2). The statutory text is unambiguous; it requires reimbursement for all professional services that are needed to furnish home infusion therapy to a Medicare beneficiary on a particular day.

63. In contravention of the statute, the Secretary has defined an "infusion drug administration calendar day" for which reimbursement may be made as only "the day on which home infusion therapy services are furnished by skilled professionals in the individual's home on the day of infusion drug administration." 42 C.F.R. § 486.505. The Secretary's definition precludes payment for those days in which a patient is infused with a treatment without a nurse or other professional present in the patient's home. This definition conflicts with the statutory directive that all professional services that are needed to furnish home infusion therapy should be reimbursed. Moreover, the Secretary's definition unlawfully limits reimbursement for those days

in which a "skilled professional" is present in the patient's home; the statutory text contains no such limitations. By adopting his own definition in conflict with the statute, the Secretary has violated an unambiguous statutory directive and specific command of the statute.

64. The Secretary's Final Rule violates the unambiguous statutory directive of 42 U.S.C. § 1395m(u)(7), as enacted by BBA18. Accordingly, the Final Rule must be set aside.

COUNT 2
Unreasonable Construction of Statute
(42 U.S.C. § 1395m(u)(7); 5 U.S.C. §§ 706(2)(A), 706(2)(C))

65. Paragraphs 1–64 are incorporated herein in their entirety.

66. The Secretary is obligated to adopt a permissible construction of the statutory requirements. *Chevron*, 467 U.S. at 843. The Court may defer to an agency's interpretation only if it falls within "the bounds of reasonableness." *Goldstein v. SEC*, 451 F.3d 873, 881 (D.C. Cir. 2006).

67. The Secretary has unreasonably defined an "infusion drug administration calendar day" for which reimbursement may be made as only "the day on which home infusion therapy services are furnished by skilled professionals in the individual's home on the day of infusion drug administration." 42 C.F.R. § 486.505. Some home infusion therapies require the presence of a nurse in the patient's home every day that the patient is furnished with an infusion. Other such therapies require the presence of a nurse in the patient's home only once a week, even though the drug is administered every day. Still other such therapies rarely require the presence of a nurse in the patient's home once the patient is trained. Yet for all home infusion therapies, suppliers must perform a variety of professional services outside of the patient's home to prepare the drug, review patient health records, monitor the patient's laboratory test results, and to perform all of the services that are necessary for safe and effective home infusion treatment.

68. The Secretary's definition unreasonably limits reimbursement for home infusion therapy services for many home infusion drugs and eliminates payment entirely for others. The Secretary's reading of the statute falls outside "the bounds of reasonableness" and must be set aside.

69. Because any "unsupported agency action normally warrants vacatur," *Advocates for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1151 (D.C. Cir. 2005), and because the Secretary's Final Rule is manifestly contrary to BBA18's requirements and is otherwise unreasonable, it must be set aside.

COUNT 3
Violation of the Administrative Procedure Act
Arbitrary and Capricious Action Without Observance of Procedure Required by Law
(5 U.S.C. § 706(2)(A), 706(2)(D))

70. Paragraphs 1–69 are incorporated herein in their entirety.

71. The APA permits judicial review of agency actions, findings, and conclusions that are "arbitrary, capricious," or "an abuse of discretion." 5 U.S.C. § 706(2)(A). The APA also permits judicial review of agency actions, findings, and conclusions that are made "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

72. Agency action is arbitrary and capricious and an abuse of discretion when the agency "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 43 (1983). The agency must provide a "rational connection between the facts found and the choice made" so as to afford a reviewing court the opportunity to

evaluate the agency's decision-making process. *Id.*; *see also FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (noting "the requirement that an agency provide reasoned explanation for its action").

73. The Secretary arbitrarily and capriciously limited payment for home infusion therapy services only for days on which a skilled professional is present in the patient's home. The statutory text provides for reimbursement for professional services performed for each "infusion drug administration calendar day." Nothing in the statute requires professional services to be performed in the patient's home, and nothing in the statute limits reimbursement to "skilled" professional services. Instead of applying the statutory language, the Secretary adopted a different rule that drastically limits payment for home infusion therapies and that jeopardizes the availability of home infusion for many patients. He has yet to, and cannot, provide a rational explanation for this illogical departure from the language of the statute.

74. The Secretary's reasoning and explanation contradicts his final action. The Secretary acknowledged that "[h]ome infusion therapy affords a patient independence and better quality of life, because it is provided in the comfort of the patient's home at a time that best fits his or her needs," 83 Fed. Reg. at 56,414, and that this therapy "can provide improved safety and better outcomes," notably because patients receiving the therapy "may be at lower risk of hospital-acquired infections," *id.* Nonetheless, the Secretary acted to limit the availability of this important therapy for many Medicare beneficiaries. The Secretary did not provide a rational explanation for this choice.

75. The Secretary's notice and comment procedure was equally flawed, as he never gave serious consideration to any of the numerous objections he received to his total disregard of a statutory directive. When commenters, including NHIA, objected to the Proposed Rule's attempt

to deprive home infusion therapy suppliers of the reimbursement that Congress intended to provide, the Secretary did not meaningfully or adequately respond. The Secretary's decision to reimburse suppliers only for days that a skilled professional is in the patient's home implicates a "fundamental norm of administrative procedure"—the requirement that "an agency … treat like cases alike." *Westar Energy, Inc. v. FERC*, 473 F.3d 1239, 1241 (D.C. Cir. 2007). The Secretary has offered no reasoned or reasonable explanation for why Category I infused drugs should be treated differently from Category II or Category III drugs just because a nurse is required for one infusion and not the other.

76. Because the Secretary's Final Rule is not the product of reasoned decision-making and provides no reasonable basis for the regulatory definition of an "infusion drug administration calendar day," the Final Rule is arbitrary and capricious and must be vacated. *See* 5 U.S.C. § 706(2).

COUNT 4
Violation of the Administrative Procedure Act
Injunctive and Declaratory Relief
(5 U.S.C. § 706)

77. Paragraphs 1–76 are incorporated herein in their entirety.

78. The APA requires a court to "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, . . . or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

79. The APA also allows a reviewing court to "issue all necessary and appropriate process[es] to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." *Id.* § 705.

80. For the reasons discussed above, the Secretary's decision to adopt a regulatory definition of an "infusion drug administration calendar day" that differs from that required by Congress under BBA18 is arbitrary, capricious, and contrary to law.

81. This Court, therefore, should declare that the Secretary is enjoined from implementing the current regulatory definition of an "infusion drug administration calendar day," and that the Secretary is required to make payment for the full range of professional services that Congress intended to reimburse when it enacted the transitional home infusion therapy benefit while this litigation is pending and beyond.

82. Preliminary injunctive relief is warranted because NHIA, its members, and Medicare beneficiaries are likely to suffer irreparable harm, the balance of equities and the public interest favor injunctive relief, and NHIA is likely to succeed on the merits.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that this Court enter judgment in their favor:

A. Vacating any agency action found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, and remand any matters herein to the Secretary for further proceedings in accord with any legal instructions the Court may deem proper and just;

B. Requiring the Secretary to change his regulations to comply with the statutory requirements, including faithfully implementing the statutory definition of "infusion drug administration calendar day";

C. Entering a preliminary and permanent injunction that (1) directs the Secretary to withdraw or suspend his Final Rule until such time as it can be brought into compliance with the statute, and (2) directs the Secretary to make prompt payments of any amounts improperly withheld as a result of the Final Rule; and

D. Ordering such other and further relief as the Court deems just and proper, including the award of costs and disbursements of this action and reasonable attorneys' fees.

Respectfully submitted,

Dated: February 14, 2019

/s/ *Mark D. Polston*
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(admission pending)
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CIVIL COVER SHEET

JS-44 (Rev. 6/17 DC)

I. (a) PLAINTIFFS
NATIONAL HOME INFUSION ASSOCIATION
1600 Duke Street, Suite 410
Alexandria, VA 22314

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF 88888
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS
ALEX M. AZAR II, in his official capacity as
Secretary of Health & Human Services
United States Department of Health & Human Services

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)
Mark D. Polston, David Farber, Joel McElvain
KING & SPALDING LLP, 1700 Pennsylvania Avenue,
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ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION
(PLACE AN x IN ONE BOX ONLY)

- ○ 1 U.S. Government Plaintiff
- ○ 3 Federal Question (U.S. Government Not a Party)
- ◉ 2 U.S. Government Defendant
- ○ 4 Diversity (Indicate Citizenship of Parties in item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) **FOR DIVERSITY CASES ONLY!**

	PTF	DFT		PTF	DFT
Citizen of this State	○ 1	○ 1	Incorporated or Principal Place of Business in This State	○ 4	○ 4
Citizen of Another State	○ 2	○ 2	Incorporated and Principal Place of Business in Another State	○ 5	◉ 5
Citizen or Subject of a Foreign Country	○ 3	○ 3	Foreign Nation	○ 6	○ 6

IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

○ **A.** ***Antitrust***
- ☐ 410 Antitrust

○ **B.** ***Personal Injury/ Malpractice***
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Medical Malpractice
- ☐ 365 Product Liability
- ☐ 367 Health Care/Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Product Liability

○ **C.** ***Administrative Agency Review***
- ☒ 151 Medicare Act

Social Security
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

Other Statutes
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 890 Other Statutory Actions (If Administrative Agency is Involved)

○ **D.** ***Temporary Restraining Order/Preliminary Injunction***

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

○ **E.** ***General Civil (Other)*** **OR** ○ **F.** ***Pro Se General Civil***

Real Property
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent, Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

Personal Property
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

Bankruptcy
- ☐ 422 Appeal 27 USC 158
- ☐ 423 Withdrawal 28 USC 157

Prisoner Petitions
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Conditions
- ☐ 560 Civil Detainee – Conditions of Confinement

Property Rights
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent – Abbreviated New Drug Application
- ☐ 840 Trademark

Federal Tax Suits
- ☐ 870 Taxes (US plaintiff or defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

Other Statutes
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 430 Banks & Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions
- ☐ 470 Racketeer Influenced & Corrupt Organization
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Satellite TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions (if not administrative agency review or Privacy Act)

○ **G. *Habeas Corpus/ 2255***	○ **H. *Employment Discrimination***	○ **I. *FOIA/Privacy Act***	○ **J. *Student Loan***
☐ 530 Habeas Corpus – General ☐ 510 Motion/Vacate Sentence ☐ 463 Habeas Corpus – Alien Detainee	☐ 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation) *(If pro se, select this deck)*	☐ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	☐ 152 Recovery of Defaulted Student Loan (excluding veterans)
○ **K. *Labor/ERISA (non-employment)***	○ **L. *Other Civil Rights (non-employment)***	○ **M. *Contract***	○ **N. *Three-Judge Court***
☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 740 Labor Railway Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☐ 440 Other Civil Rights ☐ 445 Americans w/Disabilities – Employment ☐ 446 Americans w/Disabilities – Other ☐ 448 Education	☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	☐ 441 Civil Rights – Voting (if Voting Rights Act)

V. ORIGIN

◉ 1 Original Proceeding ○ 2 Removed from State Court ○ 3 Remanded from Appellate Court ○ 4 Reinstated or Reopened ○ 5 Transferred from another district (specify) ○ 6 Multi-district Litigation ○ 7 Appeal to District Judge from Mag. Judge ○ 8 Multi-district Litigation – Direct File

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)

42 U.S.C. 405(g),1395ff. Challenge to final rule that unlawfully limits Medicare Part B payment for home infusion therapy.

VII. REQUESTED IN COMPLAINT CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23 **DEMAND $** **JURY DEMAND:** Check YES only if demanded in complaint **YES** ☐ **NO** ☒

VIII. RELATED CASE(S) IF ANY (See instruction) **YES** ☐ **NO** ☒ If yes, please complete related case form

DATE: 02/14/2019 **SIGNATURE OF ATTORNEY OF RECORD** /s/ Mark D. Polston

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the cover sheet.

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.

III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.

IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of the case.

VI. CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.

VIII. RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

NATIONAL HOME INFUSION ASSOCIATION,
1600 Duke Street, Suite 410
Alexandria, VA 22314

Plaintiff(s)

v.

ALEX M. AZAR II,
in his official capacity as Secretary of
Health & Human Services,
U.S. Department of Health & Human Services

Defendant(s)

Civil Action No. 1:19-cv-393

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* ALEX M. AZAR II, in his official capacity as
Secretary of Health & Human Services
United States Department of Health & Human Services,
200 Independence Avenue, S.W.
Washington, D.C. 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Mark D. Polston
KING & SPALDING LLP
1700 Pennsylvania Avenue, N.W.
Washington, D.C. 20006

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

NATIONAL HOME INFUSION ASSOCIATION,
1600 Duke Street, Suite 410
Alexandria, VA 22314

Plaintiff(s)

v.

ALEX M. AZAR II,
in his official capacity as Secretary of
Health & Human Services,
U.S. Department of Health & Human Services

Defendant(s)

Civil Action No. 1:19-cv-393

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* United States Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Mark D. Polston
KING & SPALDING LLP
1700 Pennsylvania Avenue, N.W.
Washington, D.C. 20006

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

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❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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I declare under penalty of perjury that this information is true.

Date: _____

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Server's signature

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_____
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Additional information regarding attempted service, etc:

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UNITED STATES DISTRICT COURT

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NATIONAL HOME INFUSION ASSOCIATION,
1600 Duke Street, Suite 410
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Plaintiff(s)

v.

ALEX M. AZAR II,
in his official capacity as Secretary of
Health & Human Services,
U.S. Department of Health & Human Services

Defendant(s)

Civil Action No. 1:19-cv-393

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Jessie K. Liu
U.S. Attorney for the District of Columbia
United States Attorney's Office
555 4th Street, NW
Washington, DC 20530

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Mark D. Polston
KING & SPALDING LLP
1700 Pennsylvania Avenue, N.W.
Washington, D.C. 20006

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

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❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

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Date: _____

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Server's signature

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Printed name and title

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Server's address

Additional information regarding attempted service, etc: