UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL HOME INFUSION ASSOCIATION, Plaintiff, v. ALEX M. AZAR II, *in his official capacity as Secretary of Health & Human Services*, Defendant.	)	Case No. 19-cv-00393-RJL

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFF'S EXPEDITED MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Tens of thousands of patients, including Medicare beneficiaries, receive infusions of important, often life-saving, drugs or biologics in the safety and comfort of their homes. Not only is the home the lowest cost care setting, but it affords improved medical benefits. A broad array of professional services, such as the services of the pharmacist who prepares the medications for intravenous administration, is needed in order to furnish infusion therapy to the patient in his or her home. For decades, nearly all payers—including commercial insurers, Medicare Advantage, the Veterans Administration, and TRICARE—have recognized the value of home infusion, and have paid for the professional services that are needed to allow the patient to be treated at home. To bring the fee-for-service Medicare program in line with these other payers, Congress recently instructed the Medicare program to pay for professional services for each day that a Medicare beneficiary receives home infusion therapy. The Secretary, however, refuses to comply with Congress's unambiguous directive, and has instead issued a final rule that irrationally denies reimbursement for most of the services Congress intended to cover. If the Secretary's statutory violation is not corrected, Medicare beneficiaries will ultimately lose access to care or be forced to remain in hospitals or nursing homes for infusion treatment—costing the Medicare program hundreds of millions of dollars more and putting beneficiaries at risk of infection and other negative health outcomes.

Congress created a new Medicare benefit for home infusion therapy services in 2016. 21st Century CURES Act, Pub. L. No. 114-255, § 5004, 130 Stat. 1033, 1190 (2016). To allow the Secretary time to implement that benefit, Congress created a temporary transitional benefit that explicitly instructed the Secretary to make specific payments for a list of designated drugs to eligible home infusion therapy suppliers. Bipartisan Budget Act of 2018 ("BBA18"), Pub. L. No.

115-123, § 50401, 132 Stat. 64, 214 (2018). Leaving no room for agency discretion in the transitional legislation, Congress told the Secretary exactly which drugs to reimburse at what rates. Congress also directed the Secretary to make these payments for each day that the drug is administered to the patient at home. Congress designed this statute to "bridge the potential gap in care for beneficiaries" and enable home infusion therapy suppliers to continue to furnish these services "without going bankrupt." 163 Cong. Rec. H6236 (2017) (statement of Rep. Pat Tiberi).

The Secretary, who months earlier had advised Congress that he needed four years to calculate the correct payment rates for home infusion services, suddenly claimed that the rates set by Congress were too generous. The Secretary thus promulgated a final rule rewriting Congress's unambiguous directive to permit reimbursement for home infusion services only for those days when a "skilled professional"—in this case a nurse—is physically present in the home, irrespective of the days when other professional services are furnished to a patient through infusions, as Congress had intended. 83 Fed. Reg. 56,406, 56,579–583 (Nov. 13, 2018), adding 42 C.F.R. § 486.505 (the "Final Rule"). 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 drug is infused. For other home infusion drugs that do not require any in-home nursing visits, the Secretary's Final Rule will preclude any payment for the services that are provided remotely by pharmacists and other professionals to furnish these drugs.

The Secretary's rewrite violates the plain language of the statute and dramatically undermines Congress's explicit mandate that the Medicare program shall provide reimbursement for home infusion therapy services. There is nothing in the statute's language that ties payment to only those days in which a professional is physically present in a patient's home to provide "skilled

services." Rather, Congress directed the Secretary to make a bundled payment intended to cover the many professional services—performed inside and outside the home—that are furnished to the patient each "infusion drug administration calendar day." 42 U.S.C. §§ 1395m(u)(7)(B)(iv), (u)(7)(E). The Secretary's Final Rule should be vacated because it violates the unambiguously expressed intent of Congress.

The Final Rule should also be vacated because it is an unreasonable construction of the statute and arbitrarily pays for some home infusion drugs and not others. Despite acknowledging the importance of home infusion therapy services, the Secretary has severely limited the availability of this important therapy for many Medicare beneficiaries. For example, some life-saving home infusion services may safely be infused by the patients themselves, and as a result a nurse or other professional would almost *never* need to be in the patient's home; the Final Rule would deny payment *entirely* for the services needed to furnish these important therapies. The Secretary did not provide a rational explanation for this choice. Nor did the Secretary explain why infusion drugs should be treated differently simply because a nurse is required for some infusions and not the others.

If the Secretary's statutory violation is not corrected, the consequences will be severe. Home infusion suppliers will have no choice but to stop providing home infusion therapy services to Medicare beneficiaries, or face bankruptcy. Without access to home infusion therapy, Medicare beneficiaries will be forced to receive their infusions at physician's offices or hospitals—settings that are more expensive and inconvenient. Instead of providing a new Medicare benefit to increase the use of home infusion therapy, as Congress intended, the Secretary's statutory rewrite will lead to a *decrease* in home infusions, subverting Congress's express intent and harming patients. This

should not be allowed to occur. The Court should enforce the statute as written and strike down the Secretary's Final Rule.

STATEMENT OF FACTS

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

Infusion therapy generally refers to the administration of sterile medications and drugs directly into a vein through a needle or catheter, but it can also refer to drugs provided through other non-oral routes, such as intramuscular injections and epidural infusion (e.g., into the membranes surrounding the spinal cord). Ex. A to Noyes Decl. (Ex. 1), at 2. Doctors prescribe infusion for patients whose conditions are so severe that they cannot be treated effectively by oral medications. *Id.* Diseases that may require infusion therapy include, among many others, cancer and cancer-related pain, gastrointestinal diseases or disorders, congestive heart failure, hemophilia, immune deficiencies, rheumatoid arthritis, and infections that are unresponsive to oral antibiotics. *Id.* Chemotherapy medications commonly use infusion therapy as the delivery mechanism. *See id.*

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. *Id.* Home infusion therapy has evolved into a comprehensive medical therapy that is a far less costly alternative to inpatient treatment in a hospital. *Id.* For chronic conditions that require ongoing sessions of infusion therapy, home infusion therapy is also more convenient and supports an improved quality of life for patients. As the Secretary has recognized, "[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. "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.* What

is more, "patients 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.*

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) (Ex. 2), *available at*: www.cbo.gov/publication/52969 (hereinafter "CBO Cost Estimate"). In many cases, however, these 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 (2019 rate). Ex. B to Noyes Decl. (Ex. 1), at 19. CBO projected that the enactment of this transitional benefit would save the Medicare Trust Fund $910 million during the 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) (Ex. 3), *available at*: www.cbo.gov/publication/53557 (hereinafter "CBO Estimated Direct Spending").[1]

As noted above, Medicare is the last major payer in America to cover home infusion services. In fact, recognizing the treatment benefits and cost savings that home infusion offers, every other commercial and governmental payer has paid for home infusion for decades. Ex. A to Noyes Decl. (Ex. 1), at 4; Ex. B to Noyes Decl. (Ex. 1), at 17–18. The overwhelming majority of these insurers and governmental programs pay for home infusion services based upon each day that the patient is infused. Ex. C to Noyes Decl. (Ex. 1), at 2, 4–6; Ex. D to Noyes Decl. (Ex. 1), at 2–4. That is the model that Congress followed as well when it finally enacted the CURES benefit and the BBA18 Transitional Benefit. Yet, while Congress specifically instructed the Medicare program to "consider payment amounts established by Medicare Advantage plans under part C and in the private insurance market for home infusion therapy (including average per treatment day payment amounts by type of home infusion therapy)," 42 U.S.C. § 1395m(u)(2), the Secretary has ignored the payment methodologies used by those plans and has twisted the statutory text at issue in this case.

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

Because home infusion therapy operates as a "hospital without walls," it requires a set of professional services that are different from any other class of treatment covered or reimbursed by the Medicare program. As the Secretary acknowledged in his Final Rule, "there are a variety of

[1] 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 by 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.

providers and professional services involved in home infusion therapy" and those services are "significan[t] in ensuring that therapy is safe and effective in the home." 83 Fed. Reg. at 56,580. Most home infusion professional services fall into four core categories: (1) infusion drug preparation and dispensing, (2) clinical care planning and implementation, (3) care coordination, and (4) nursing services. Ex. B to Noyes Decl. (Ex. 1), at 4.

Infusion Drug Preparation and Dispensing. The majority of home infusion services are performed in a specialized home infusion pharmacy that prepares and dispenses sterile parenteral medications. Ex. B to Noyes Decl. (Ex. 1), at 5–7; *see also* Ex. A to Noyes Decl. (Ex. 1), at 3. These 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. Ex. B to Noyes Decl. (Ex. 1), at 5. As a result, each infusion patient receives a sterile medication that is customized to meet his or her individual needs. *Id.* To design that 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. *Id.* The pharmacist must also analyze on a patient-by-patient basis the drug stability, volume, and rate of administration of the proposed medication under the circumstances presented by each patient's home and daily living activities. *Id.* The pharmacist then prepares the infusion medications in a sterile environment, meeting stringent air particle count, air velocity and turnover rate, surface sterility, and aseptic drug/diluent manipulation standards. *Id.* at 6. To safely provide these services, the pharmacy must be uniquely equipped and maintained by professionals with expertise beyond the scope of traditional pharmacy or nursing practice. *Id.*

After dose preparation, the home infusion supplier must deliver or otherwise ship the medications to the patient's home. *Id.* at 7. Infusion drugs almost always need to be shipped with cold chain storage, which requires significant resources and specialized knowledge beyond the standard delivery of a drug. *Id.* Before each medication delivery, the pharmacy communicates with the patient to identify and address potential side-effects, measure effectiveness, and ensure adherence to the regime. *Id.* The patient will often have questions at this point and may speak to a pharmacist, nurse, or dietitian to discuss concerns with the treatment. *Id.*

Critical Care Planning and Implementation. Clinical care planning and care implementation services take place before, during, and after infusion. Ex. B to Noyes Decl. (Ex. 1), at 7–8. A multidisciplinary team, including a pharmacist, nurse, and dietitian (where appropriate), develop and implement care plans for the home infusion patient. *Id.* at 7. To do so, the team works with the treating physician to create a care plan at the beginning of the infusion treatment and then modifies it—sometimes every day—based on any changes with the patient. *Id.* Home infusion pharmacists and nurses play a key role in these treatment plans, and they often provide input to the team—from outside the patient's home—each day the drug is infused. *Id*. at 7–8. For instance, home infusion pharmacists review and interpret patient lab results and make improvements to the care plan and drug dosage based on those results. *Id.* at 8; *see also* Ex. A to Noyes Decl. (Ex. 1), at 3.

Care Coordination. Before accepting a patient for home infusion, the pharmacy intake department performs many services, including, assessing whether a patient is eligible for home infusion services and coordinating with the provider to ensure a smooth and orderly discharge to the patient's home. Ex. B to Noyes Decl. (Ex. 1), at 8. Once a patient is cleared for home infusion, the pharmacy care team communicates and coordinates all aspects of the home infusion plan of

care to avoid medication errors, missed or delayed doses, or unplanned hospitalizations. *Id.* This ensures that all members of the team are aware of any changes to the plan of care, changes in patient clinical status, adverse events, changes in supply needs, or schedule changes. *Id.* These remote services take place continuously during treatment. *Id.* 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. *Id.*

Nursing Services. Although skilled nurses frequently provide services during in-home patient visits, those skilled nursing services do not represent the totality of nursing services, much less professional services, provided for a patient to receive home infusion. Ex. B to Noyes Decl. (Ex. 1), at 8–9. Home infusion nursing services are fundamentally different from home health nursing services, skilled nursing facility nursing services, or other nursing services that the Secretary has previously covered under other Medicare program benefits. *Id.* at 9. Infusion nurses have specialized training and unique knowledge of, and experience in, vascular access devices (catheters) and maintenance; safe administration of sterile medications; prevention of catheter infection and occlusion; patient education regarding the access device and infusion therapy; and the maintenance of a safe infusion environment in the home. *Id.* Because drugs are infused based on the required dosing schedule, the infusion nurse aims to balance the patient's schedule with the specifications of the drug. *Id.*

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

Although all home infusion therapies require the full array of the professional services described above to ensure that the drug is infused safely and effectively, not all home infusion drugs require a nurse or other skilled professional to be present in the home during the actual

infusion. Ex. D to Noyes Decl. (Ex. 1), at 4. Indeed, several drugs that Congress designated for the transitional benefit (under Payment Category I, *see* 42 U.S.C. § 1395m(u)(7)(C)), such as milrinone (a drug used to prevent heart failure) are typically infused each day (continuously, 24/7) but only have a professional present once a week (after the first week, during which patient training occurs). Ex. D to Noyes Decl. (Ex. 1), at 4; *see also* CMS, Manual System, Pub. 100-04 Medicare Claims Processing Transmittal 4112 at Attachment A (Aug. 10, 2018) (providing payment categories for home infusion therapy services), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4112CP.pdf (hereinafter "CMS Transmittal 4112").[2] For other drugs, a nurse or other skilled professional may never be present. Ex. D to Noyes Decl. (Ex. 1), at 4. For example, most patients who are treated with subcutaneous immune globulin (or SCIG, a therapy to treat immunodeficiency; Payment Category II) will not require a nurse in the home after the initial training is complete and the patient properly trained. *Id.*; *see also* CMS Transmittal 4112 at Attachment A. Similarly, many patients receiving deferoxamine (a treatment for patients with anemia; Payment Category I) and epoprostenol (a treatment for patients with pulmonary hypertension; Payment Category I) often become sufficiently adept at home-infusion that they do not need any skilled professional in the home other than an initial instructional visit. Ex. D to Noyes Decl. (Ex. 1), at 4; *see also* CMS Transmittal 4112 at Attachment A. In contrast, "Category III" drugs, such as chemotherapy drugs for cancer treatment, may have a nurse

[2] NHIA's member comments submitted on December 30, 2018 (Ex. D to Noyes Decl. (Ex. 1)), included a technical misstatement regarding the payment categories of certain drugs. The correct payment categories are provided here and are listed in CMS Transmittal 4112 at Attachment A.

or other professional[3] in the home every time a drug is infused into the patient. Ex. D to Noyes Decl. (Ex. 1), at 4; *see also* CMS Transmittal 4112 at Attachment A.

Despite these different schedules for in-home nursing services, the same array of other professional services, including pharmacy 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 whether the drug falls into Category I, II or III. Ex. D to Noyes Decl. (Ex. 1), at 4. In sum, a broad array of professional services are required, beyond simply in-home nursing services, to furnish home infusion therapy, as even the Secretary has recognized.[4] *See, e.g.*, 83 Fed. Reg. at 56,559 ("The home infusion process typically requires coordination among multiple entities, including patients, physicians, hospital discharge planners, health plans, home infusion pharmacies, and, if applicable, home health agencies."); *id.* at 56,562 (noting requirement that home infusion therapy suppliers "ensure that professional services are available on a 7-day-a-week, 24-hour-a-day basis" because "the success of home infusion therapy is often dependent upon the professional services being available during all hours and days of the week that allows for the patient to safely and

[3] In practice, given state licensure laws, the only type of skilled professional who can be physically present for home infusions is a nurse. Home infusion therapy services are typically outside the scope of services performed by other professionals. *See* Ex. B to Noyes Decl. (Ex. 1), at 9 (discussing the range of in-home patient services provided by infusion nurses with "specialized training and unique knowledge").

[4] The Secretary also recognized the importance of these services in his taxonomy definition of a home infusion therapy pharmacy: "Pharmacy-based, decentralized patient care organization with expertise in USP <797> compliant sterile drug compounding that provides care to patients with acute or chronic conditions generally pertaining to parenteral administration of drugs, biologics and nutritional formulae administered through catheters and/or needles in home and alternate sites. Professional pharmacy services, care coordination, infusion nursing services, supplies and equipment are provided to optimize efficacy and compliance." *See Health Care Provider Taxonomy Code Set*, 3336H0001X, Home Infusion Therapy Pharmacy (Jan. 1, 2019), *available via Washington Publishing Company at*: http://www.wpc-edi.com/reference/codelists/healthcare/health-care-provider-taxonomy-code-set; *see also* Ex. A to Noyes Decl. (Ex. 1), at 10.

effectively manage all aspects of treatment"); *id.* at 56,580 (agreeing "that there are a variety of providers and professional services involved in home infusion therapy" and recognizing "their significance in ensuring that therapy is safe and effective in the home").

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

As noted above, patients and their insurers have recognized for decades that home infusion offers better care outcomes at lower costs. Commercial insurers, Medicare Advantage plans,[5] the military healthcare system (known as TRICARE) and the Veterans Administration have all embraced home infusion therapy and have covered home infusion services for decades. Ex. B to Noyes Decl. (Ex. 1), at 4; Ex. D to Noyes Decl. (Ex. 1), at 3. For legacy reasons, however, the Medicare fee-for-service program, known as "Medicare Part B," never included a home infusion benefit. As a result, 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)[6] and the pumps and other durable medical equipment needed for infusion (which were already covered under Part B), Medicare never covered or reimbursed for the professional services needed to provide home infusion to Medicare beneficiaries. Ex. A to Noyes Decl. (Ex. 1), at 4–5.

Congress knew that coverage for home infusion services was a missing part of the Medicare program over sixteen years ago. As a result, when Congress revised the methodology

[5] 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.

[6] 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. The Part D drugs are not at issue in this litigation.

to reduce payment for most Part B drugs in 2003, it exempted home infusion drugs and kept payment for the drugs themselves at an artificially high benchmark to subsidize the absence of a separate 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). Because of this work-around, home infusion pharmacies were able to continue serving Medicare beneficiaries.

That changed in December 2016, when Congress reduced the generous drug reimbursement, effectively eliminating the ability of home infusion suppliers to serve Medicare beneficiaries. *See* 21st Century CURES Act, Pub. L. No. 114-255, § 5004, 130 Stat. at 1190. To address that problem, Congress simultaneously created a new benefit for home infusion professional services by adding "home infusion therapy" as one of the "medical and other health services" that are payable under Medicare Part B. *Id*. § 5012, 130 Stat. at 1198. As amended by the CURES Act, Sections 1861(s)(2)(GG) and (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 payments for the drugs themselves, or for the durable medical equipment ("DME") used to deliver those drugs, in recognition of the fact that the DME payment rates set for the general population were inadequate for home infusion services. 42 U.S.C. § 1395m(u)(1)(A); *id.* § 1395x(iii)(2). Stated differently, although Medicare Part B had "covered" many of the aspects of home infusion, the "payment" was insufficient until Congress stepped in to correct it.

Congress originally intended for the new home infusion professional services benefit to begin at the same time the drug reimbursements were reduced (January 1, 2017). Ex. B to Noyes Decl. (Ex. 1), at 3, 15. But 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. *Id.* As a result, Congress authorized the new benefit effective January 1, 2021, but inadvertently kept the effective date of January 1, 2017, for the reduction in the Part B drug reimbursement. *Id.*; Ex. A to Noyes Decl. (Ex. 1), at 5. This created a four-year gap that threatened the ability of Medicare beneficiaries to receive home infusion care. Ex. B to Noyes Decl. (Ex. 1), at 15.

Recognizing that it had effectively eliminated payment for home infusion treatments and placed Medicare beneficiaries at risk, Congress enacted a transitional provision in Section 50401 of the BBA18 that provides Medicare beneficiaries with an interim benefit between January 1, 2019 and the time that Medicare is able to stand up the full program. Pub. L. No. 115-123, § 50401, 132 Stat. at 214 (codified at 42 U.S.C. § 1395m(u)(7)). In the transition legislation, Congress carefully included detailed instructions 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.[7] Specifically, Congress instructed the Secretary to qualify certain entities for the transitional benefit, to cover a designated list of eligible Part B home infusion 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 the remaining infusion drugs. Noyes

[7] The provider eligibility criteria, the list of drugs, and the payment rates are not in dispute.

Decl. ¶ 9 (Ex. 1); *see also Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Final Rule*, 83 Fed. Reg. 59,452 (Nov. 23, 2018).

Congress directed the Secretary to make these specified "professional service" payments for each "infusion drug administration calendar day"—*i.e.*, each day that a home infusion drug was infused into a beneficiary. 42 U.S.C. § 1395m(u)(7)(B)(iv), (u)(7)(E). Section 50401 of BBA18 clarifies that an "infusion drug administration calendar 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).

The plain language of Section 50401 of BBA18 does not limit reimbursement to nursing services that are performed in the patient's home. Instead, Congress's definition of "infusion drug administration calendar day" ties payment for home infusion therapy services to the days on which any "professional services" were furnished to administer infusion drugs to patients. By referring to the broad definition of "professional services" in 42 U.S.C. § 1395x(iii)(2)(A), which states "[p]rofessional services, including nursing services, furnished in accordance with the plan," Congress recognized that home infusion suppliers provide and coordinate a myriad of professional services, in home and outside the home, that are furnished to the patient when the drug is infused. Indeed, Congress always contemplated that the payment for these services would be made when the drugs (not the nursing services) were furnished in the home. For instance, in Section 1834(u)

of the CURES Act, Congress instructed the Secretary to make a "single payment" for the "items and services described in subparagraphs (A) and (B) . . . furnished by a qualified home infusion supplier . . . in coordination with the furnishing of home infusion drugs . . . ." 42 U.S.C. § 1395m(u).

E. 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

Five months after the BBA was passed by Congress, on July 12, 2018, the Secretary issued a proposed rule that redefined "infusion drug administration calendar day." 83 Fed. Reg. 32,340, 32,464 (July 12, 2018) ("Proposed Rule"). Instead of applying the clear statutory directive to make a payment for each day a drug is infused, the Secretary proposed a different definition that would require payment only for the days when a "skilled professional" was in the patient's home. *Id*. The Secretary then compounded his error by proposing to redefine "professional services, including nursing services, furnished in accordance with the plan" to mean "skilled services as set out at 42 C.F.R. § 409.32." *Id*. at 32,464–32,467 (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." Although the Secretary recognized that a variety of professional services must be performed at a pharmacy or at other locations outside the patient's home in order to furnish home infusion therapy to a patient, whether or not a nurse (let alone a "skilled" nurse) is physically present at the patient's home, the Secretary nonetheless proposed to pay "only 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).

In response, the Secretary received 1,345 comments—mostly heavily critical of his approach. As the National Home Infusion Association and other commenters pointed out, the

statute does not tie payment to "skilled services." Nor does it permit the Secretary to limit payment to only the days where a nurse is physically present in a patient's home. Those departures from the plain language of the statute drastically reduce the amount of reimbursement payments for professional services that Congress intended. Ex. B to Noyes Decl. (Ex. 1), at 19–20; Ex. A to Noyes Decl. (Ex. 1), at 22. The commenters warned that under the proposed rule "[p]roviders will no longer be able to care for beneficiaries" because the cost of care would vastly exceed the rule's minimal reimbursement for home infusion therapy services. Ex. B to Noyes Decl. (Ex. 1), at 19.

Concerned that the Secretary's proposed rule would "effectively gut the intent of the legislation," Ex. B to Noyes Decl. (Ex. 1) (Letter from Rep. Buddy Carter), multiple members of Congress wrote letters to CMS reiterating that the Secretary's "physical presence requirement contradicts our intent in drafting and enacting this legislation and makes the reimbursement required by the bill inadequate." Ex. B to Noyes Decl. (Ex. 1) (Letter from Sens. Warner & Isakson). The legislators urged the Secretary to "withdraw the requirement that a nurse or other professional be physically present 'in the home' for reimbursement to occur, and instead to recognize that reimbursement be made for each day that a home infusion drug is infused." *Id.*; *see also* Ex. B to Noyes Decl. (Ex. 1) (Letter from Rep. Pat Tiberi) ("We never intended to restrict Medicare reimbursement to only those days a nurse or other skilled professional was in the patient's home, but instead explicitly provided for reimbursement to be made on each day professional services were provided to the patient through infusion."). The members also noted that, although BBA18 was projected to significantly reduce federal costs by moving more Medicare beneficiaries to home infusion therapy, the Secretary's proposed rule "ironically, would cost the Medicare program significantly more money by shifting Medicare beneficiaries unable to access infusion in the home into far costlier inpatient settings and skilled nursing facilities." Ex. B

to Noyes Decl. (Ex. 1) (Letter from Chairman Pete Sessions). NHIA and its members referenced these concerns in the rulemaking process. Ex. A to Noyes Decl. (Ex. 1), at 22; Ex. B to Noyes Decl. (Ex. 1), at 17.

Despite these strong objections, the Secretary issued his Final Rule in November 2018 rewriting the definition of infusion drug administration calendar day "to mean payment is for the day on which home infusion therapy services are furnished by skilled professional[s] in the individual's home on the day of infusion drug administration." 83 Fed. Reg. at 56,583, 42 C.F.R. § 486.505. Although the Secretary "agree[d] that there are a variety of providers and professional services involved in home infusion therapy and recognize[d] their significance in ensuring that therapy is safe and effective in the home," he provided only cursory responses to the serious objections that had been raised to the proposed rule. 83 Fed. Reg. at 56,580. Instead, the Secretary finalized his proposal and stated that the "best course of action is to monitor the effects . . . of finalizing this definition," opening the Final Rule for an extended post-Rule comment period. *Id.* at 56,583.

In the extended comment period, commenters including NHIA and its members 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." Ex. D to Noyes Decl. (Ex. 1), at 1–2; *see also* Ex. C to Noyes Decl. (Ex. 1), at 5–6. They reiterated that the Final Rule would effectively deny adequate reimbursement for home infusion therapy services for all but the most severe drugs. Ex. D to Noyes Decl. (Ex. 1), at 4. Under the Secretary's Final Rule, the Secretary will pay for home infusion professional services for some home infusion drugs only for the one day a week that a nurse is present in the patient's home, rather than for every day that the drug is infused. *Id.* For

other home infusion drugs that do not require any home nursing visits, such as SCIG, the Secretary will make no payment at all for the professional services required to furnish these drugs. *Id.*; Ex. C to Noyes Decl. (Ex. 1), at 6–7. Because of these deficient reimbursement payments, commentators warned that "Medicare beneficiaries will lose access to home infusion services" under the Final Rule, Ex. C to Noyes Decl. (Ex. 1), at 2, 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," Ex. D to Noyes Decl. (Ex. 1), at 3.

F. NHIA Brings This Suit to Enforce the Statutory Mandate

The Secretary's Final Rule "represents a 78 percent rate cut for home infusion suppliers," far lower than the reimbursement payment Congress intended—a rate that is "simply unsustainable." Ex. C to Noyes Decl. (Ex. 1), at 7; *see also* Ex. D to Noyes Decl. (Ex. 1), at 5–6 (urging the Secretary "to consider that providers will not be able to treat Medicare beneficiaries for only 22% of the payment"). As a result, the Final Rule has caused and will continue to cause substantial harm to the home infusion suppliers and the Medicare beneficiaries that they serve.

For 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., et al., *An Unintended Consequence of the 21st-Century Cures Act for Patients with Heart Failure*, 136 Circulation 123, 124 (July 11, 2017) (Ex. 4), cited in Ex. B to Noyes Decl. (Ex. 1), at 4, 14–15, 20 and Ex. D to Noyes Decl. (Ex. 1), at 2. 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. The same is true for patients who receive the many other home infusion drugs that, like milrinone, do not require frequent in-home nursing services.

Ironically, if the Secretary's rule is allowed to stand, Medicare beneficiaries currently on home infusion therapy will lose access to care, and tens of thousands of others will be forced to remain in hospitals or nursing homes for their infusion treatment—costing the Medicare program millions more dollars and putting these beneficiaries at risk of infection and other negative health outcomes. *See* Ex. B to Noyes Decl. (Ex. 1), at 19–20; Ex. D to Noyes Decl. (Ex. 1), at 2–3, 6.

NHIA's members provide home infusion therapy services for tens of thousands of patients that are reimbursed under the Medicare program. Noyes Decl. ¶ 3 (Ex. 1). Because the Secretary's Final Rule is currently in effect, and is binding on his contractors, CMS 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 drug administration day when home

infusion is provided to a beneficiary but a nurse or other "skilled professional" is not in the home.[8] *Id.* ¶¶ 10–15; Ex. E to Noyes Decl. (Ex. 1).

On February 14, 2019, NHIA brought this action on behalf of its members. ECF Doc. No. 1, Compl. In this case, NHIA pleads claims under the Administrative Procedure Act (APA), 5 U.S.C. § 706, and the Social Security Act, 42 U.S.C. § 1395m-1, alleging that the Secretary's Final Rule violates the plain statutory language, relies on an unreasonable construction of the statute, and is arbitrary and capricious. *See* Doc. 1, Compl. ¶¶ 59–82. To remedy these violations, NHIA seeks permanent injunctive relief to (1) direct the Secretary to withdraw or suspend his Final Rule and (2) direct the Secretary to make payment for the full range of professional services that Congress intended to reimburse when it enacted the transitional home infusion therapy benefit. *Id.* ¶¶ 75–82.

STANDARD OF REVIEW

"[W]hen a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal," and "[t]he 'entire case' on review is a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). Under the APA, agency action must be set aside if it is "not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. §§ 706(2)(A), (C).

Agency action is invalid when it is contrary to the plain meaning of the governing statute. "[W]hen the statute's language is plain, the sole function of the courts—at least where the

[8] The submission of these claims satisfies the jurisdictional requirement that claims first be presented to the Secretary. Further exhaustion of these claims should be excused, given the futility of further administrative proceedings (the Secretary's adjudicators are bound by his rule) and the substantial harm that home infusion therapy suppliers and Medicare beneficiaries are suffering from the rule now. *See, e.g.*, *Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992) (excusing exhaustion requirement on futility grounds where "the Secretary g[ave] no reason to believe that the agency machinery might accede to plaintiffs' claims").

disposition required by the text is not absurd—is to enforce it according to its terms." *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000) (internal citations and quotation marks omitted); *see also Coal Emp't Project v. Dole*, 889 F.2d 1127, 1131 (D.C. Cir. 1989). It is an "essential function of the reviewing court . . . to guard against bureaucratic excesses by ensuring that administrative agencies remain within the bounds of their delegated authority." *Bensman v. Nat'l Park Serv.*, 806 F. Supp. 2d 31, 40 (D.D.C. 2011). When the agency's interpretation is "in conflict with the statute's plain language" and not "consistent with the statutory purpose," the agency's decision receives no deference. *Coal Emp't Project*, 889 F.2d at 1131; *see also Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984).

Agency action is also invalid if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). 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").

ARGUMENT

I. The Secretary's Final Rule Contravenes the Statute's Unambiguous Requirement that Reimbursement Be Made for Each Day a Patient Receives Home Infusion.

The Secretary's Final Rule is unlawful because it disregards the statute's unambiguous command to make specific payments for each day a drug is infused. Instead, the Secretary rewrites the statute to limit reimbursement payments to only the days on which a "skilled professional" is present in the patient's home. But no such limitation exists in the statute; Congress's instructions were clear and left no gaps for the Secretary to fill. The Final Rule thus violates the "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 Grp. v. EPA*, 573 U.S. 302, 328 (2014); *see also SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018) ("Where a statute's language carries a plain meaning, the duty of an administrative agency is to follow its commands as written, not to supplant those commands with others it may prefer."). Where, as here, "Congress has directly spoken to the precise question at issue," both the Secretary and this Court must give effect to Congress's stated intent. *Chevron*, 467 U.S. at 842–43.

In Section 50401 of BBA18, Congress directed the Secretary to "provide a home infusion therapy services temporary transitional payment" to home infusion suppliers for the professional services needed to furnish home infusion drugs for Medicare beneficiaries, 42 U.S.C. § 1395m(u)(7)(A)(i), and specified that the Secretary must make this bundled payment "for each infusion drug administration calendar day," *id.* § 1395m(u)(7)(B)(iv). Congress further clarified that an "infusion drug administration calendar day" means that the Secretary should reimburse for each "date on which professional services (as described in [42 U.S.C. § 1395x(iii)(2)(A)]) were *furnished to administer such drugs to such individual*." 42 U.S.C. § 1395m(u)(7)(E)(i) (emphasis added). By cross-referencing the CURES Act's broad definition of professional services, 42

U.S.C. § 1395x(iii)(2)(A), Congress made clear that these daily payments were to include "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)(A); *see also id.* § 1395x(iii)(1)(B).

There is no relevant ambiguity as to what the statute requires. *Chevron*, 467 U.S. at 843. Congress specifically directed the Secretary to make a set payment for each day that a home infusion drug is administered to a patient. There is nothing in the statute's language that limits payment to only those days in which "skilled services" are performed physically in the patient's home. Rather, the statute unambiguously requires that payment be made for days on which "professional services (as described in section 1395x(iii)(2)(A) of this title) were furnished to administer such drugs." 42 U.S.C. § 1395m(u)(7)(E)(i). The cross-referenced section refers to "[p]rofessional services, *including* nursing services, furnished in accordance with the plan" of treatment developed by a physician.[9] *Id.* § 1395x(iii)(2)(A) (emphasis added). The plain text of the statute, then, reveals that Congress did not intend for nursing services to be the only form of professional services that would be reimbursed under the transitional legislation. "[U]nder traditional rules of statutory construction, the term 'including' is not one of all-embracing definition, but connotes simply an illustrative application of the general principle." *Pub. Citizen, Inc. v. Lew*, 127 F. Supp. 2d 1, 23 (D.D.C. 2000) (internal quotation omitted).

The breadth of this language was purposeful. Congress recognized that a myriad of professional services must be performed to allow patients to infuse their medications at home.

[9] Congress explicitly referenced nursing services to ensure that both outpatient and homebound patients could receive in-home nursing services, in addition to the wide array of other professional services needed in order to furnish infusion therapy to the patient in his or her home. Ex. B to Noyes Decl. (Ex. 1), at 31.

Many of those services are, by necessity, performed outside the patient's home. Regardless of their physical location, however, *all* professional services are furnished to the beneficiary when he or she receives a home infusion. *See* Ex. A to Noyes Decl. (Ex. 1), at 7–8 ("[A] home infusion drug cannot be infused without some degree of sterile compounding that may happen prior to the day of administration. However, the preparation of that drug as a professional service is not furnished to that patient until the drug is administered. If the patient expired or moved to another site of care, then the professional services of preparing the drug would never be furnished to the beneficiary."). Accordingly, Congress instructed that payment be made for each "infusion drug administration calendar day," because patients receive the home infusion supplier's professional services every day they receive an infusion.

The statutory text and structure confirm that Congress directed the Secretary to make a payment for each day that a patient receives an infusion at home. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (statutory provisions must be interpreted as part of "a symmetrical and coherent regulatory scheme"); *Pharm. Research & Mfrs. of Am. v. Thompson*, 251 F.3d 219, 224 (D.C. Cir. 2001) (using the "traditional tools of statutory interpretation—text, structure, purpose, and legislative history" to "conclude that Congress has 'directly spoken to the precise question at issue'" (quoting *Bell A. Tel. Cos. v. F.C.C.*, 131 F.3d 1044, 1047 (D.C. Cir. 1997))). The transitional home infusion benefit that Congress enacted in BBA18 tracks the permanent benefit that Congress enacted in the CURES Act. And in the CURES Act, Congress directed the Secretary to "implement a payment system under which a single payment is made . . . to a qualified home infusion therapy supplier for items and services . . . furnished by a qualified home infusion therapy supplier . . . in coordination with the furnishing of home infusion drugs." 42 U.S.C. § 1395m(u)(1)(A)(i). In other words, Congress intended for the bundled professional

services payments to broadly cover all professional services furnished "in coordination" with the infusion of drugs. To ensure that the full scope of those services was reimbursed, Congress centered the timing of the payments on "the furnishing of home infusion drugs," not on the location or type of services.

Dispelling all doubt about its intentions, Congress then mandated that the varying levels of professional services should be reflected in the specific *amounts* of the bundled payments, not in the timing of those payments. Specifically, in the CURES Act, Congress directed the Secretary to "establish single payment amounts for types of infusion therapy, including to take into account variation in utilization of nursing services by therapy type." 42 U.S.C. § 1395m(u)(1)(A)(ii). Because CMS claimed it needed four years to establish the payment amounts, Congress enacted BBA18 to tell the Secretary exactly who would qualify as a home infusion provider of professional services, which drugs were covered, what rate should be paid for those services depending on the drug, and when those payments should be made. *See United States v. Home Concrete & Supply, LLC*, 566 U.S. 478, 487 (2012) (a statute is unambiguous when there is "no gap for the agency to fill" and thus "no room for agency discretion").

Specifically, Congress established a formula for payments for professional services needed to furnish three categories of home infusion drugs, and assigned treatments to one of those three categories in accordance with its judgment as to the level of professional services that would be needed to furnish those treatments. 42 U.S.C. § 1395m(u)(7)(C). For 2019, those single payment rates are $138.75, $216.59, and $236.06—with the highest payment for chemotherapy, the second highest for subcutaneous immunotherapy, and the lowest payment for the remaining infusion drugs. Noyes Decl. ¶ 9 (Ex. 1); *see also* 83 Fed. Reg. at 59,452. Because the variation in nursing services was already factored into the specific amounts of the payment rates, as Congress

contemplated from the very beginning, Congress instructed the Secretary to make these payments for each day the drug was infused, regardless of whether any "skilled services" were provided in the patient's home on the day of infusion. 42 U.S.C. § 1395m(u)(7)(B)(iv).

The legislative history further reinforces the statute's plain language and structure. *See Pharm. Research & Mfrs. of Am.*, 251 F.3d at 224; *Loving v. IRS*, 742 F.3d 1013, 1022 (D.C. Cir. 2014); *Ridgely v. Lew*, 55 F. Supp. 3d 89, 94 (D.D.C. 2014). When the four-year gap created by the CURES Act became clear, Congress understood that it would need to enact a transition benefit to cover and reimburse the "significant costs associated with services, home equipment, and facilities such as clean rooms needed to provide the drug." Ex. B to Noyes Decl. (Ex. 1), at 15 (quoting legislative colloquy). It did that by enacting BBA18 to provide the missing coverage and reimbursement payments. During the floor debate on the transitional legislation, one of the sponsors of the House Bill noted, "[t]his new temporary transitional payment will bridge the potential gap in care for beneficiaries, and home infusion providers will continue to administer these therapies without going bankrupt." 163 Cong. Rec. H6236 (statement of Rep. Pat Tiberi). As confirmed by multiple letters from Congress to CMS during the rulemaking, "Congress' intent was that home infusion providers' professional services, such as drug preparation, clinical care planning, care coordination, and nursing should be subject to reimbursement when they were provided to the Medicare beneficiary on the day the drug was infused, regardless of a professional's presence in the home." Ex. B to Noyes Decl. (Ex. 1) (Letter from Rep. Pat Tiberi).

The Secretary's Final Rule cannot be reconciled with Congress's clear statutory directive. The Secretary has not identified any absurdity or relevant ambiguity in the statute that might authorize him to deviate from its express terms. *See Rapanos v. United States*, 547 U.S. 715, 752 (2006) (plurality opinion). Nonetheless, rather than applying Congress's clear instructions and

making the designated payments for each day a drug is infused, the Secretary rewrote the definition of "infusion drug administration calendar day" in a way that denies payment altogether for professional services that Congress directed him to reimburse. The Secretary's Final Rule imposes a new requirement found nowhere in the statutory text: that payment is only for the days on which "skilled professional[s]" are "in the individual's home on the day of infusion drug administration." 83 Fed. Reg. at 56,583. The irony of the Secretary's choice of words should not be lost—"skilled" is typically used in the Social Security Act to refer to "Skilled Nursing Facilities" or a type of nursing home—precisely the environment that home infusion is trying to avoid. Additionally, although Congress directed the Secretary to make payments for professional services for each "infusion drug administration calendar day," the Secretary has made clear that he intends to only make payment for "a subset of days on which professional services are provided in the patient's home." *Id.* at 56,580. This temporal "in the … home" requirement is simply made up out of whole cloth.

As a result, the Secretary's Final Rule flouts the statutory directive. By limiting the definition of "infusion drug administration" to require a nurse or other skilled professional in the patient's home, the Secretary has effectively ensured that most Medicare beneficiaries will no longer be able to receive home infusion. 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. Ex. D to Noyes Decl. (Ex. 1), at 4; Ex. C to Noyes Decl. (Ex. 1), at 6–7. 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. Ex. D to Noyes Decl. (Ex. 1), at 4. Likewise, patients

treated with milrinone therapy will receive continuous infusions around the clock, but will only require the presence of a nurse in the home one day a week. *Id.* Although these drugs do not require frequent in-home visits for the infusions to take place, they still require extensive pharmacy services, clinical care planning, and care coordination. *Id.*; Ex. C to Noyes Decl. (Ex. 1), at 6–7. But under the Secretary's misinterpretation, home infusion therapy suppliers will rarely, if ever, receive payment for the professional services they furnished for the infusions of these drugs. Instead, only the most severe cares of home infusion—cases that require nursing care in the patient's home every day—will receive more than a *de minimis* reimbursement under the home infusion benefit.

That contravenes Congress's clear directions and expressed intent. Congress passed BBA18 to provide reimbursement payments for all eligible home infusion therapy services and unequivocally instructed the Secretary to make bundled payments for these services each day of infusion. Had Congress intended for these payments to be made only for the days where skilled services were provided in a patient's home, it could have simply said so. *See Knight v. CIR*, 552 U.S. 181, 188 (2008). Likewise, Congress could have incorporated the narrower definition of "skilled services" in 42 C.F.R. § 409.32, had that been what it wanted. But those were not the words Congress used. Instead, Congress expressed its intent that payment for "professional services" be made each "infusion drug administration calendar day." 42 U.S.C. § 1395m(u)(7)(B)(iv). The Secretary thus had no authority to rewrite "infusion drug administration calendar day" to mean the "day skilled services are rendered to a patient in the home." *See SAS Inst.*, 138 S. Ct. at 1358 ("Even under *Chevron*, we owe an agency's interpretation of the law no deference unless, after 'employing traditional tools of statutory construction,' we find ourselves unable to discern Congress's meaning."); *see also City of Arlington, Tex. v. FCC*,

569 U.S. 290, 296 (2013) ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."). Because the Final Rule violates the statute's plain text, it should not be allowed to stand.

II. The Secretary's Final Rule Arbitrarily Denies Payment for Many Valuable Home Infusion Services.

Even if the Secretary had identified some relevant ambiguity in BBA18's requirements (which he did not), the Secretary's Final Rule would still be invalid because it is unreasonable. This Court may defer to an agency's interpretation of an ambiguous statutory provision only if the interpretation falls within "the bounds of reasonableness." *Goldstein v. SEC*, 451 F.3d 873, 880–81 (D.C. Cir. 2006). A "reasonable statutory interpretation must account for both 'the specific context in which . . . language is used' and 'the broader context of the statute as a whole.'" *Util. Air Regulatory Grp.*, 573 U.S. at 321 (alteration in original) (quoting *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997)). An agency interpretation that is "'inconsisten[t] with the design and structure of the statute as a whole, . . . does not merit deference.'" *Id.* (internal citation omitted) (quoting *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 353 (2013)).

For all the reasons explained above, the Secretary's Final Rule is based on an impermissible, unreasonable construction of the statute.[10] *See supra* 23–30. Restricting the dates of payment in a way that effectively excludes reimbursement for all but the most severe home infusion therapy services cannot be reconciled with Congress's overarching purpose of providing a "new temporary transitional payment [that] will bridge the potential gap in care for beneficiaries," and allow "home infusion providers [to] continue to administer these therapies

[10] And, for the same reasons the Secretary's Final Rule is unreasonable, it is also arbitrary and capricious. *See* 5 U.S.C. §§ 706(2)(A), (D); *see Judulang v. Holder*, 565 U.S. 42, 52 n.7 (2011) (recognizing the overlap in the analysis under *Chevron* step two and the arbitrary or capricious standard of review).

without going bankrupt." 163 Cong. Rec. H6236 (statement of Rep. Pat Tiberi). Indeed, the entire point of the statute is to reimburse for the full scope of home infusion services to make it *easier* for Medicare beneficiaries to receive home infusion therapy for a variety of diseases and conditions.

Congress understood that home infusion therapy could improve patients' quality of life, while at the same time saving the Medicare program hundreds of millions of dollars by substituting for costlier inpatient or skilled nursing care. *See* CBO Estimated Direct Spending at 2 (Ex. 3) (projecting that the transitional benefit would save the Medicare Trust Fund $910 million dollars during the two-year transition period alone). Accordingly, Congress anticipated, and intended, an increase in Medicare beneficiaries receiving home infusion therapy services after the CURES Act and BBA18. When Congress enacted BBA18, for example, the Congressional Budget Office estimated that under the statute Medicare would pay for approximately 25 million home infusion days in each of 2018 and 2019. CBO Cost Estimate at 3 (Ex. 2).

By contrast, the Secretary estimates that his Final Rule will lead to only 305,595 reimbursable days of care in a given year—less than 2% of the days of payment that Congress had expected. 83 Fed. Reg. at 32,507 (tbl. 66, col. 3, total for "estimated total visits of care"). The Secretary further opined that he "[did] not anticipate an increase in beneficiaries receiving home infusion therapy services" under the Rule. *Id*. at 32,482. This result is so far from what Congress intended that it should have prompted the Secretary to select an alternative approach. *See Bread for the City v. U.S. Dep't of Agric.*, 872 F.3d 622, 625 (D.C. Cir. 2017) (relying on CBO's interpretation of statute with budgetary effect).

Recognizing that his Final Rule essentially guts the separate home infusion therapy professional services benefit, the Secretary has suggested that he is justified in transforming the

benefit into a much narrower nursing benefit because Medicare already pays for pharmacy services through the DME benefit. *See* 83 Fed. Reg. at 32,482 (noting that "existing DME suppliers already provide home infusion therapy services without separate reimbursement"). But the Secretary points to no evidence showing that pharmacy services are included in the DME benefit, much less that the DME reimbursement benefit is adequate for those services. More importantly, the Secretary's interpretation is at odds with the plain language of the statute. Congress explicitly defined the "items and services" to be covered under the separate home infusion benefit as, among other things, "professional services, including nursing services, furnished in accordance with the plan." 42 U.S.C. § 1395x(iii)(2)(A). In adopting such a broad definition, Congress deliberately chose not to include limiting language that would exclude services covered under the DME benefit or elsewhere. *Cf. id.* § 1395x(iii)(2)(B) (covering "training and education (not otherwise paid for as durable medical equipment)"). Instead, Congress made clear that all home infusion professional services—not just nursing services—were to be separately covered and reimbursed within the new home infusion benefit. *Id.* § 1395x(iii)(2)(A); *see also* Ex. B to Noyes Decl. (Ex. 1) (Letter from Sens. Warner & Isakson) ("To the extent that CMS believes these services were covered under the DME benefit, the purpose of the home infusion services payment was to cover them separately as home infusion professional services.").

The Secretary's Final Rule provides no explanation why the language of the *statute* reasonably permits the Secretary to restrict the days of payment only to those days where skilled services were physically provided to the patients in their homes. To be sure, the Secretary conclusory asserts 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." 83 Fed. Reg. at 56,580. But the Final Rule provides no meaningful textual analysis to justify the

Secretary's conclusion that the days of payment are so limited. Instead, the Secretary just quotes provisions of BBA18 and the CURES Act with no explanation. *Id.*

The Secretary's apparent belief that Congress intended all professional services, including pharmacy services, to be bundled into a single payment for the days a nurse is in the home makes no sense. *See* 83 Fed. Reg. at 56,581. Although home infusion therapies require varying levels of in-home nursing services, all home infusion therapies require the supplier to perform an array of remote professional services, including preparing the drug, reviewing patient health records, and monitoring the patient's laboratory test results to ensure that all home infusions are safe and effective. *See supra* 6–12. For this reason, other payers, including commercial insurers, Medicare Advantage plans, and the TRICARE program, typically reimburse home infusion suppliers using a fixed rate for each day the patient receives an infusion medication, as Congress directed in BBA18. Ex. C to Noyes Decl. (Ex. 1), at 4–5. Yet the Secretary offers an interpretation that unreasonably and arbitrarily limits reimbursement for the services entirely based on whether nursing services were provided in the home. As a result, under the Final Rule, payment for services provided to Medicare patients will be less than one third of what exists in the market today for other public payers, Ex. D to Noyes Decl. (Ex. 1), at 3–4, and it will come nowhere close to the level of reimbursement Congress intended to provide in BBA18. The Secretary's reading thus falls outside "the bounds of reasonableness" and must be set aside. *Goldstein*, 451 F.3d at 881.

The Secretary's interpretation is not only beyond any reasonable interpretation of the statute, it also creates statutory conflicts that would not otherwise exist. For example, because the Secretary now requires a "skilled professional" to be "in the home" for reimbursement to occur, he has reworked the home infusion benefit to mirror a different Medicare provision that pays for home health services. *See* 42 U.S.C. § 1395fff. Although the Secretary states in his Final Rule

that "the home infusion therapy services temporary transitional payment is separate from the home health benefit" and recognizes that "[h]ome infusion therapy is excluded from the Medicare home health benefit, and separately payable, beginning January 1, 2019," 83 Fed. Reg. at 56,581, the Secretary did not fully consider the irreconcilable conflict he had created with the home health benefit. Ex. B to Noyes Decl. (Ex. 1), at 9, 31; Ex. D to Noyes Decl. (Ex. 1), at 5. That conflict is apparent in the Secretary's recently released FAQs, which contradict the Final Rule and state that home infusion professional services will not be paid to home infusion providers for patients who are concurrently under the home health benefit. *See* CMS, *Home Infusion Therapy Services Temporary Transitional Payment: Frequently Asked Questions* No. 14 (Feb. 27, 2019), *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Downloads/Home-Infusion-Therapy-Services-Temp-Transitional-Payment-FAQs.pdf. This conflict between the Secretary's policy and his own Final Rule demonstrates the forced unintended consequences of the Secretary's unreasonable interpretation.[11]

Likewise, the Secretary ignored the serious objections that commenter had raised, in which they explained that, under the Final Rule, home infusion suppliers will no longer be able to provide home infusion therapy to Medicare beneficiaries—the very situation Congress intended to prevent with BBA18. Ex. B to Noyes Decl. (Ex. 1), at 15 (noting that the reimbursement gap created by the CURES Act was an "estimated cost of $120 per day per beneficiary in unreimbursed professional services" and reiterating that beneficiaries will lose access to home infusion services if Medicare does not appropriately reimburse); Ex. A to Noyes Decl. (Ex. 1), at 6 (expressing concern that the proposed rule would "make it impractical for home infusion therapy suppliers to

[11] Moreover, the Secretary's recent announcement of this payment rule in the form of a FAQ is invalid; he is required to follow the procedures of notice-and-comment rulemaking to establish a legal standard for payment for services. 42 U.S.C. § 1395hh(a)(12).

continue to provide these services"). Despite recognizing that a variety of professional services are needed to safely administer home infusion therapy, the Secretary ignored the grave consequences of his actions and offered no reasoned explanation for rejecting an approach that would adequately reimburse for those services as Congress directed. *See Int'l Fabricare Inst. v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992) (an agency "is required to give reasoned responses to all significant comments in a rulemaking proceeding").

The Secretary's decision to reimburse suppliers only for the days where a skilled professional is in the patient's home also violates the fundamental requirement that "an agency treat like cases alike." *Westar Energy, Inc. v. FERC*, 473 F.3d 1239, 1241 (D.C. Cir. 2007); *see also Hall v. McLaughlin*, 864 F.2d 868, 872 (D.C. Cir. 1989) ("Reasoned decisionmaking requires treating like cases alike"). The Secretary's Final Rule unfairly and arbitrarily denies some Medicare beneficiaries access to home infusion therapy simply because they do not need infusions of drugs that require in-home nursing services. But there is no reason why Medicare beneficiaries receiving Category I or Category II infused drugs should be treated differently from Category III drugs, just because a nurse is required for one infusion and not the other.

The Secretary's only response—that his Final Rule saves Medicare beneficiaries money in co-payments—is irrational. 83 Fed. Reg. at 56,582. Any potential effect on patient co-payments is irrelevant to the construction of the statute, which addresses Medicare reimbursements to home infusion suppliers and says nothing about patient co-payments. Moreover, the Secretary does not acknowledge that over 75% of beneficiaries have some form of supplemental coverage to significantly reduce, and in some cases virtually eliminate, their co-payments. Ex. D to Noyes Decl. (Ex. 1), at 6. Nor does the Secretary consider the fact that his Final Rule will actually result

in higher costs to Medicare beneficiaries, who will now be forced to receive infusion therapy in much higher cost settings, resulting in even higher co-payments.

By failing to comply with Congress's unambiguous mandate, the Secretary has dramatically reduced the payments Medicare makes for home infusion services. Ironically, although the Secretary has reduced payments for home infusion services, the Medicare program will end up paying hundreds of millions more because 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. There is simply no reasonable basis for the Secretary's Final Rule. Because it is arbitrary and not a product of reasoned decision-making, it must be vacated. *See* 5 U.S.C. § 706(2).

CONCLUSION

The Court should grant summary judgment to NHIA and set aside the Secretary's Final Rule.

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Dated: March 1, 2019

CERTIFICATE OF SERVICE

I hereby certify that on March 1, 2019, a copy of the above Motion was filed electronically via the Court's ECF system, which effects service upon counsel of record.

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