IN THE 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 and Human Services,

Defendant.

Civil Action No. 19-cv-00393-RJL

DEFENDANT'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF HIS OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND MOTION TO DISMISS OR, IN THE ALTERNATIVE, CROSS-MOTION FOR SUMMARY JUDGMENT

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I. Introduction

Plaintiff National Home Infusion Association, a trade association of various home infusion therapy companies, asks the Court to invalidate a regulation that reflects what Congress meant when it said that temporary transitional payments for home infusion therapy services should be issued on an "infusion drug administration calendar day," 42 U.S.C. § 1395m(u)(7)(B)(iv). The Court should decline Plaintiff's invitation to do so for two straightforward reasons.

First, the Court lacks jurisdiction. Plaintiff acknowledges that its members, on whose behalf it sues, have not exhausted the administrative remedies available to them. Yet, exhaustion is a jurisdictional prerequisite under the Medicare Act, and for this independent reason alone, Plaintiff's complaint fails. Second, and should the Court reach the merits, Congress clearly did not intend to issue payments for home infusion therapy services on each day that a patient receives a home infusion. Instead, it explicitly limited those payments to days on which certain services are provided to the patient in the home. And even if the Court holds that Congress did not directly speak to this issue, CMS did not abuse its discretion in defining "infusion drug administration calendar day," 42 C.F.R. § 486.505. CMS acted reasonably, not arbitrarily or capriciously, in interpreting which days the single payments should issue.

II. Background and Statement of Facts

A. Statutory and Regulatory Background

Title XVIII of the Social Security Act, commonly known as the Medicare statute, 42 U.S.C. § 1395 *et seq.*, establishes a program of health insurance for the elderly and disabled. Medicare Part A pays for inpatient hospital services and other institutional care. 42 U.S.C. § 1395c. Medicare Part B is a supplementary program, 42 U.S.C. § 1395j, that covers medical and other health-care services, 42 U.S.C. § 1395k(a)(1). This includes outpatient infusion drugs that are "incident to" a physician's services, provided the drugs are not usually self-administered by the patient. 42 U.S.C.

§ 1395x(s)(2)(A), (B).[1] The Medicare program is administered by CMS through private contractors known as Medicare Administrative Contractors (MAC). 42 U.S.C. §§ 1395u(a), 1395kk-1(a)(4).

1. Home Infusion Therapy

For some time, Medicare has provided a benefit under Part B for home infusion drugs, a type of medication that is administered intravenously or through certain non-oral routes at the patient's home. *See* Home Infusion Therapy Requirements, 83 Fed. Reg. 56,406, 56,414 (Nov. 13, 2018) [hereinafter Final Rule]. In addition to this benefit, which covers the equipment, the supplies and the drug, *see id.* at 56,581, the 21st Century Cures Act added a payment for certain items and services associated with home infusion therapy, effective January 1, 2021. *See* 42 U.S.C. § 1395m(u)(1)(A). From January 1, 2019 until CMS implements a permanent payment system for home infusion therapy services, *id.* § 1395m(u)(1)–(6), Congress has charged the Secretary of Health and Human Services (who has delegated authority on this matter to CMS) with issuing temporary transitional payments for home infusion therapy services. *See id.* § 1395m(u)(7)(A)(i)–(ii). Congress designated three payment categories for home infusion drugs. *See id.* § 1395m(u)(7)(B)(i).

The temporary transitional payment does not issue every day that a patient receives a home infusion drug. Rather, the statute directs the Secretary to issue "a single payment," as specified by the aforementioned categories, on each "infusion drug administration calendar day in the individual's home." *Id.* § 1395m(u)(7)(B)(iv). The term *infusion drug administration calendar day*, which is at the core of Plaintiff's suit, refers to "the date on which professional services (as

[1] Other outpatient drugs are covered by Medicare Part D, a voluntary prescription drug benefit added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 42 U.S.C. § 1395w-101 *et seq.*

described in section 1861(iii)(2)(A)) were furnished to administer [transitional home infusion drugs or home infusion] drugs to [an] individual [by an eligible home infusion supplier or a qualified home infusion therapy supplier]." *Id.* § 1395m(u)(7)(E)(i). The "professional services" that trigger an "infusion drug administration calendar day" are more limited than the "items and services" that are covered under the benefit. In general, the single payment covers *both* (A) "professional services, including nursing services, [that are] furnished in accordance with the plan" *and* (B) "training and education . . . , remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs [that are] furnished by a qualified home infusion therapy supplier." *Id.* § 1395m(u)(1)(A)(i) (citing 42 U.S.C. § 1395x(iii)(2)(A)–(B)). However, the payment is issued only on days when subsection (A) services are "furnished to administer" home infusion drugs to patients (i.e., "professional services, including nursing services, furnished in accordance with the plan"). *Id.* § 1395m(u)(7)(E)(i) (citing *id.* § 1395x(iii)(2)(A)). The statute does *not* provide for payment to be issued on days when only "training and education . . . , remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs [are] furnished by a qualified home infusion therapy supplier." *See id.* § 1395x(iii)(2)(B). Nor are single payments issued on days when "professional services, including nursing services, [are] furnished in accordance with the plan," but not "to administer" home infusion drugs to patients. *See id.* § 1395x(iii)(2)(A).

Consistent with this statute, CMS issued a proposed rule that, in part, implements the definition of "infusion drug administration calendar day." *See* Home Infusion Therapy Requirements, 83 Fed. Reg. 32,340, 32,514 (July 12, 2018) [hereinafter Proposed Rule]. Following a comment period, during which CMS considered the statutory text and various evidence, including comments from Plaintiff and its members, CMS defined "infusion drug administration

calendar day" as "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." Final Rule, 83 Fed. Reg. at 56,631 (codified at 42 C.F.R. § 486.505). The agency further explained, "[t]he skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel." *Id.*

2. Judicial Review and the Medicare Claims Review Process

One of the disputes in this case—indeed, the threshold dispute—concerns the procedures that a healthcare provider must follow before bringing a claim arising under the Medicare Act in federal court. 42 U.S.C. § 405(h), made applicable to the Medicare Act by 42 U.S.C. § 1395ii, strips courts of general federal question jurisdiction, 28 U.S.C. § 1331, for claims arising under the Medicare Act. *See Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 825 (D.C. Cir. 2018). Section 405(h) provides as follows:

> The findings and decision of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under [the Medicare Act].

Accordingly, in *Shalala v. Illinois Council on Long Term Care, Inc.*, the Supreme Court held that a nursing home provider's challenge to certain Medicare regulations may not be brought pursuant to § 1331, but rather, consistent with § 405(h) (as incorporated by § 1395ii), must be channeled through the administrative review provisions of the Medicare Act. 529 U.S. 1, 10, 13 (2000).

The Supreme Court has characterized the § 405(h) bar to other avenues of review as "sweeping and direct," *see Weinberger v. Salfi*, 422 U.S. 749, 757 (1975), and explained that it applies to "all 'claim[s] arising under' the Medicare Act," *Heckler v. Ringer*, 466 U.S. 602, 615 (1984), regardless of the nature of the particular claim, *Ill. Council*, 529 U.S. at 14. *See also Your*

Home Visiting Nurse Servs., Inc. v. Shalala, 525 U.S. 449, 456 (1999) ("judicial review under the federal-question statute, 28 U.S.C. § 1331, is precluded by 42 U.S.C. § 405(h)"). So long as the claim arises under the Medicare Act, it must be channeled through the statute's exhaustion and exclusive judicial review provisions.

Consistent with this statutory process, the Supreme Court has repeatedly rejected efforts to read § 405(h) narrowly. Thus, in *Heckler v. Ringer*, the Court held that an effort to enjoin a Medicare policy on constitutional due process and procedural rulemaking grounds must be channeled through the agency. 466 U.S. at 614–15. And in *Illinois Council*, the Court confirmed that it would not "accept a distinction that limits the scope of [Section] 405(h) to claims for monetary benefits." 529 U.S. at 14. Accordingly, a claim arises under the Medicare Act when that statute "provides both the standing and the substantive basis for" the claim, regardless of whether the claims can be characterized as also arising under other statutes or constitutional guarantees. *Id.* at 11; *Salfi*, 422 U.S. at 760–61.

All of that is to say that a plaintiff cannot bring a claim arising under the Medicare Act in federal court without (1) presenting the claim to the Secretary, and (2) exhausting all available administrative remedies—although the latter requirement may be waived in certain circumstances. These administrative remedies, which are set forth in the Medicare Act and its implementing regulations, afford healthcare providers extensive opportunities for review, including several levels of administrative and judicial review. 42 U.S.C. §§ 1395ff; 42 C.F.R. pt. 405, subpart I.

To begin, a healthcare provider may submit a reimbursement claim—in this case for home infusion therapy services—with a MAC. That MAC issues an initial determination of whether services are covered and the payment amount. 42 U.S.C. § 1395ff(a)(1); 42 C.F.R. §§ 405.904(a)(2), 405.920. If the claimant is dissatisfied with the MAC's initial determination, the

claimant may seek a redetermination from the MAC. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. §§ 405.904(a)(2), 405.940. If dissatisfied with the MAC's redetermination, the claimant may then request a reconsideration of the redetermination by a qualified independent contractor (QIC). 42 U.S.C. § 1395ff(b), (c); 42 C.F.R. §§ 405.904(a)(2), 405.960. When evaluating the redetermination, the QIC reviews the evidence upon which the initial determination and redetermination were based, and any additional evidence submitted by the parties or obtained by the QIC on its own. 42 C.F.R. § 405.968(a). A still dissatisfied claimant may appeal the decision of the QIC to an Administrative Law Judge (ALJ) for a hearing and decision if the amount-in-controversy requirements are met. 42 U.S.C. §§ 405(b), 1395ff(b)(1)(A), (d)(1); 42 C.F.R. §§ 405.1000–405.1058. The ALJ's decision, in turn, may be reviewed by the Medicare Appeals Council of the Departmental Appeals Board. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2); 42 C.F.R. §§ 405.1100–405.1140. The Medicare Appeals Council's decision is the final decision of the Secretary subject to judicial review if the amount-in-controversy requirements are met. 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A); 42 C.F.R. §§ 405.1130, 405.1136. Claimants who are dissatisfied with the pace of proceedings may, at various levels of the administrative process, expedite review of their claims. *See, e.g.*, 42 C.F.R. § 405.1100(b) ("Under circumstances set forth in §§ 405.1016 and 405.1108, the appellant may request that a case be escalated to the [Medicare Appeals] Council for a decision even if the ALJ or attorney adjudicator has not issued a decision, dismissal, or remand in his or her case."); *see also id.* §§ 405.1002(b), 405.1132; 42 U.S.C. §§ 1395ff(c)(3)(C)(ii), 1395ff(d)(3).

B. Reimbursement Claims and Procedural History

Plaintiff is a nonprofit association that represents certain home infusion therapy companies. *See* Decl. of William Noyes ¶ 3, ECF No. 9-2. Shortly after the final rule came into effect, three of Plaintiff's members submitted reimbursement claims for home infusion therapy services on

days when a nurse or other skilled professional was not in the patient's home: Intramed Plus submitted its claim on February 13, 2019; BioScrip, Inc. submitted its claim on February 7, 2019; and Paragon Healthcare, Inc. submitted its claim on February 14, 2019. *See id.* ¶¶ 10, 12, 14. A MAC, acting on behalf of CMS, sent Intramed Plus, BioScrip, Inc., and Paragon Healthcare, Inc. remittance advices that denied payment for their claims. *Id.* ¶¶ 11, 13, 15. Intramed Plus and Paragon Healthcare, Inc. filed for redetermination with the MAC. *Id.* ¶¶ 11, 15. BioScrip, Inc. alleges that it filed for redetermination of some of its claims and "is in the process of filing for redetermination of the remaining claims." *Id.* ¶ 13.

There is no evidence that Intramed Plus, Bioscrip, Inc., or Paragon Healthcare, Inc. have advanced past the redetermination phase of the administrative review process. And there is no evidence that any of Plaintiff's other members have submitted reimbursement claims for home infusion therapy services.

Nevertheless, on February 14, 2019, just days after Intramed Plus and BioScrip, Inc. submitted their claims and the same day Paragon Healthcare, Inc. submitted its claim, Plaintiff filed the complaint on behalf of these members and others, alleging that the final rule unreasonably construes § 1395m(u)(7) and violates the Administrative Procedure Act (APA). The parties filed a joint motion for a briefing schedule, ECF No. 8, which the Court granted. Plaintiff filed a motion for summary judgment on March 1, 2019. ECF No. 9.

III. Legal Standard

Defendant moves to dismiss for lack of jurisdiction pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure. "A federal court's subject matter jurisdiction, constitutionally limited by article III, extends only so far as Congress provides by statute." *Commodity Futures Trading Comm'n v. Nahas*, 738 F.2d 487, 492 (D.C. Cir. 1984). "It is to be presumed that a cause lies outside this limited jurisdiction, . . . and the burden of establishing the contrary rests upon the party

asserting jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). In reviewing a motion to dismiss for lack of subject matter jurisdiction, district courts are not limited to the allegations in the complaint, but rather "may consider materials outside the pleadings." *Jerome Stevens Pharm., Inc. v. FDA*, 402 F.3d 1249 (D.C. Cir. 2005); *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992).

In the alternative, Defendant moves for summary judgment pursuant to Rule 56(a) of the Federal Rules of Civil Procedure. Summary judgment is appropriate when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). When a party seeks review of agency action under the APA, the case can usually be resolved through summary judgment because the reviewing court does not engage in fact finding of its own; rather, the court merely determines whether the agency's action was permissible on the basis of the governing law and the administrative record compiled by the agency. *See Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743–44 (1985).

The legal standard that the Court applies in this case is also affected by the level of deference that the agency is owed. With respect to questions of statutory interpretation, "considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer." *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984). And with respect to review under 5 U.S.C. § 706(2)(A)—whether final agency action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"—courts likewise apply a "highly deferential" standard. *See St. John's United Church of Christ v. FAA*, 550 F.3d 1168, 1172 (D.C. Cir. 2008). Overlaying all of this is the enhanced deference that courts afford the Department of Health and Human Services (HHS) in interpreting the Medicare Act because of the statute's "tremendous complexity." *Cmty. Care Found. v. Thompson*, 318 F.3d

219, 225 (D.C. Cir. 2003); *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994).

IV. Argument

The Court should dismiss the complaint for two independent reasons. First, as a threshold matter under Rule 12(b)(1), the Court lacks jurisdiction because Plaintiff has not exhausted administrative remedies, a prerequisite for judicial review. Second, summary judgment against Plaintiff is appropriate because the statute clearly limited "infusion drug administration calendar days" to days when professional services are provided to administer the drug in the home. Alternatively, CMS did not exceed its statutory authority in defining "infusion drug administration calendar day," nor did it define the term in an arbitrary and capricious manner.

A. The Court Should Dismiss This Case for Want of Jurisdiction Because Plaintiff's Members Have Not Exhausted Their Claims.

At the outset, there is no jurisdictional basis for Plaintiff's suit. Because Plaintiff's standing depends on its members claims for benefits, its members must first channel their claims through the congressionally designed administrative process before coming to federal court. The Court should dismiss the complaint for lack of jurisdiction for the simple reason that Plaintiff's members have not come close to exhausting their administrative remedies.

1. The Medicare Act Provides the Exclusive Jurisdictional Basis for Plaintiffs' Claims

Although Plaintiff invokes federal question jurisdiction pursuant to § 1331, *see* Compl. ¶ 14, the only jurisdictional basis for this Medicare case is § 405(g). As discussed *supra*, a plaintiff raising "any claim arising under" the Medicare Act may invoke *only* § 405(g) as the jurisdictional basis for its suit. 42 U.S.C. §§ 405(h); 1395ii; *see also Ill. Council*, 529 U.S. at 10–15. A claim arises under the Medicare Act if the Act provides "both the standing and the substantive basis" for the claims, *see Salfi*, 422 U.S. at 757–64.

In this case, the Medicare Act furnishes the "standing and substantive basis" for Plaintiff's

claims. Plaintiff itself acknowledges this, invoking § 405(g) as the primary jurisdictional basis of this suit, Compl. ¶ 13, and § 1331 "[i]n the alternative," *id.* ¶ 14. Nor could Plaintiff argue otherwise; all of Plaintiff's claims attack CMS's interpretation of § 1395m(u)(7). *See id.* ¶¶ 59–82. And as relief, Plaintiff seeks "prompt payments of any amounts improperly withheld as a result of the Final Rule." *Id.* at 33. The Supreme Court has held that in such cases, where a plaintiff seeks a monetary benefit from HHS under the Medicare Act, "[t]he statute plainly bars § 1331 review." *Ill. Council*, 529 U.S. at 10. Just so here; § 405(g) is Plaintiff's only ticket to federal court.[2]

2. Plaintiffs Have Not Exhausted Their Claims, a Prerequisite to Judicial Review under the Medicare Act.

Because § 405(g) is the only basis for the Court's jurisdiction, Plaintiff must abide by the statute's requirements. Most importantly for this case, the Medicare Act withholds jurisdiction in federal court until the plaintiff has obtained a "final decision" from the Secretary (i.e., to exhaust administrative remedies). 42 U.S.C. §§ 405(g), 1395ff(b); *see also* 42 C.F.R. §§ 405.1130, 405.1136; *Ill. Council*, 529 U.S. at 5. As discussed above, to obtain a final decision, a provider ordinarily must (1) present a claim to the agency—or more precisely, to a contractor who handles the first line of review for the agency—and receive an "initial determination," (2) request "redetermination" of the claim by the contractor, (3) request reconsideration of the claim by the QIC, (4) request a hearing from an ALJ (if the amount remaining in controversy and other requirements for an ALJ hearing are met), and (5) request that the Medicare Appeals Council review the case and issue a decision. 42 U.S.C. § 1395ff; 42 C.F.R. § 405.904(a)(2).

[2] Any suggestion that Plaintiff has an injury separate from its members is without merit. At most, Plaintiff has asserted that it "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." Compl. ¶ 16. However, "a mere 'interest in a problem,' no matter how longstanding the interest and no matter how qualified the organization is in evaluating the problem, is not sufficient by itself to render the organization 'adversely affected' or 'aggrieved' within the meaning of the APA." *Sierra Club v. Morton*, 405 U.S. 727, 739 (1972).

There is no question that Plaintiff's members have failed to complete these steps. Plaintiff candidly admits that its members have not exhausted the remedies available to them, stating that some of its members have submitted claims for reimbursement of home infusion therapy services to a MAC, but that they have gone only so far as to file for redetermination of the MAC's initial determination. *See* Compl. ¶ 13; Pl.'s Mem. Points Authorities in Support of Pl.'s Mot. Summ. J. 20–21 & n.8, ECF No. 9-1 [hereinafter Pl.'s Mem.]; Decl. of William Noyes Ex. E, ECF No. 9-2 [hereinafter Claims Summary] (indicating that Plaintiff's members filed for redetermination of most claims but that the MAC has not yet issued decisions on these redetermination requests). Assuming that the MAC's redetermination decision is not favorable to Plaintiff's members, before obtaining a final decision that would permit them to invoke this Court's jurisdiction under § 405(g), they must still request reconsideration of their claims by the QIC, request a hearing from an ALJ, and request that the Medicare Appeals Council review the case. *See* 42 U.S.C. § 1395ff; 42 C.F.R. § 405.904(a)(2). Unless and until Plaintiff's members receive a final decision, they have not exhausted their administrative remedies.

3. The Limited Circumstances That Would Justify Waiver of the Exhaustion Requirement Are Not Present Here.

Although it is possible in an exceptional case to excuse the Medicare Act's exhaustion requirement, Plaintiff's footnoted explanation for why its members have not exhausted is far too meager to make this such a case. The Secretary's decision not to waive the exhaustion requirement is entitled to deference. *See Ringer*, 466 U.S. at 618; *Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103, 110 (D.D.C. 2015); *see also Matthews v. Eldridge*, 424 U.S. 319, 330 (1976) (observing that "under s 405(g) the power to determine when finality has occurred ordinarily rests with the Secretary since ultimate responsibility for the integrity of the administrative program is his"). "Exhaustion is generally required as a matter of preventing

premature interference with agency processes, so that the agency may function efficiently and so that it may have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review." *Tataranowicz v. Sullivan*, 959 F.2d 268, 275 (D.C. Cir. 1992) (quoting *Salfi*, 422 U.S. at 765). However, "in certain special cases," a court may excuse the plaintiff from exhausting upon consideration of several factors. *Ringer*, 466 U.S. at 618. Specifically, courts look to (1) whether the plaintiff's claim is collateral to a demand for benefits, *id.*; *Bowen v. City of New York*, 476 U.S. 467, 483 (1986); (2) whether "the claimants . . . would be irreparably injured were the exhaustion requirement now enforced against them," *City of New York*, 476 U.S. at 483; and (3) whether exhaustion would be futile, *Tataranowicz*, 959 F.2d at 274. *See Nat'l Ass'n for Home Care & Hospice, Inc.*, 77 F. Supp. 3d at 110; *Triad at Jeffersonville I, LLC v. Leavitt*, 563 F. Supp. 2d 1, 16 (D.D.C. 2008).

First, Plaintiff has not attempted to argue that its claims are collateral to its members' claims for benefits. *See* Pl.'s Mem. 21 n.8 (arguing that exhaustion should be excused because it would be futile and because Plaintiff would incur "substantial harm"). Nor could it. A claim is collateral to a claim for benefits if it is different in substance. *See, e.g.*, *Eldridge*, 424 U.S. 330–31 (holding that an individual's procedural claim that he was denied due process without a hearing was collateral to his substantive claim that he was entitled to disability benefits). By contrast, a claim is not collateral to a claim for benefits when they raise "precisely the same legal issues." *Suarez v. Colvin*, 140 F. Supp. 3d 94, 100–01 (D.D.C. 2015). This case is clearly in the latter category. Plaintiff's members submitted reimbursement claims "challenging 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." Noyes Decl. ¶¶ 10, 12, 14. And Plaintiff restates this claim almost verbatim in its complaint. Compl. at 2. Because the claims raised in the complaint are not collateral to the underlying reimbursement claims, the first factor weighs strongly in Defendant's favor.

Second, Plaintiff has made no showing that exhaustion would cause irreparable injury. Such a showing in this context is demanding: Congress's decision to channel "virtually all legal attacks through the agency . . . comes at a price, namely, occasional individual, delay-related hardship." *Ill. Council*, 529 U.S. at 13. To bypass the Act's exhaustion requirement, the plaintiff must therefore demonstrate a hardship that "turns what appears to be simply a channeling requirement into *complete* preclusion of judicial review." *Id.* at 22–23. Monetary loss, "ultimately to be recovered, does not usually constitute irreparable injury." *Sampson v. Murray*, 415 U.S. 61, 90 (1974). Indeed, "even if the Secretary's actions were to force a health care provider out of business, the injuries are not necessarily 'irreparable,' considering the risk known to the health care provider when it enters the Medicare program." *Manakee Prof'l Med. Transfer Serv., Inc. v. Shalala*, 71 F.3d 574, 581 (6th Cir. 1995); *Nat'l Ass'n for Home Care & Hospice, Inc.*, 77 F. Supp. 3d at 110 (observing that "even if the Court were to accept [the plaintiff's] assertion that some of its members are likely to go bankrupt as a result of the narrative requirement, even extreme financial difficulty does not necessarily satisfy the irreparable harm requirement"); *Triad at Jeffersonville I, LLC*, 563 F. Supp. 2d at 13–14 (same); *Atl. Urological Assocs., P.A. v. Leavitt*, 549 F. Supp. 2d 20, 32 (D.D.C. 2008) (same).

Here, Plaintiff has provided no evidence—as is its burden at summary judgment—that its members would suffer irreparable injury. *See Nat'l Ass'n for Home Care & Hospice, Inc.*, 77 F. Supp. 3d at 110 (finding no irreparable injury because the plaintiff "provide[d] no evidentiary support for its assertion, such as affidavits or declarations from members describing the narrative

requirement's specific effect on their businesses"). Instead, it circularly asserts that home infusion therapy suppliers and Medicare beneficiaries are suffering "substantial harm." *See* Pl.'s Mem. 21 n.8. This is plainly insufficient. First, only *irreparable* injury may excuse the Medicare Act's exhaustion requirements, not "substantial harm." Second, this statement offers no indication of what that injury is. Before CMS issued its final rule, home infusion therapy suppliers received no payment for home infusion therapy services. Now, suppliers may receive payment for covered services on each "infusion drug administration calendar day," 42 C.F.R. § 486.505. As explained *infra*, this payment covers all "items and services," 42 U.S.C. § 1395x(iii)(2), regardless of whether they occurred on an infusion drug administration calendar day. And, suppliers continue to be reimbursed for the equipment, supplies, and the drugs themselves. *See* Final Rule, 83 Fed. Reg. at 56,581. Third, the relevant inquiry is whether *Plaintiff* or, through associational standing, *its members* have been irreparably injured. The inquiry is not whether Medicare beneficiaries who are not parties to this suit have been irreparably injured. At any rate, beneficiaries are not irreparably injured, particularly under the demanding standard to excuse exhaustion; indeed, beneficiaries may have lower co-payments for home infusion therapy under the final rule than they would under Plaintiff's preferred interpretation. *See* Final Rule, 83 Fed. Reg. at 56,582–83.

Lastly, exhaustion of Plaintiff's claims is not sufficiently futile to overcome the Secretary's decision not to waive it here. The Medicare Act's exhaustion requirement is "something more than simply a codification of the judicially developed doctrine of exhaustion, and may not be dispensed with merely by a judicial conclusion of futility." *Salfi*, 422 U.S. at 766. The key inquiry is rather whether judicial review would interfere with the purposes of the Medicare Act's exhaustion requirement. *See Tataranowicz*, 959 F.2d at 274–75. Thus, judicial review is appropriate only if it "(1) will not interfere with the agency's efficient functioning; (2) will not thwart any effort at self-

correction; (3) will not deny the court or parties the benefit of the agency's experience or expertise; and (4) will not curtail development of a record useful for judicial review." *See id.* at 275. Finally, even if a court determines that it *could* waive the exhaustion requirement because exhaustion would be futile, the court must also decide whether it *should*, especially where, as in this case, expedited appeal procedures are available. *See Ryan v. Bentsen*, 12 F.3d 245, 248 (D.C. Cir. 1993).

Without acknowledging this demanding standard, Plaintiff argues that exhaustion is sufficiently futile to warrant judicial review for one reason: "the Secretary's adjudicators are bound by his rule." Pl.'s Mem. at 21 n.8. The challenged rule is, of course, final and has the force of law. Crucially, however, there is no record upon which the Court can review the rule's application (if any) to the underlying reimbursement claims; at this stage, only a MAC has weighed in on the reimbursement claims and Plaintiff has not attached these claims or the MAC's decisions to its motion for summary judgment. Proceeding directly to judicial review would "curtail development of a record" because there currently is no record of the underlying claims. *See Tataranowicz*, 959 F.2d at 275. Furthermore, Plaintiff's members submitted their reimbursement claims either on the same day or days before the complaint was filed. *See* Claims Summary. Denying HHS even the briefest of opportunities to review these claims cuts against each of the exhaustion purposes articulated in *Tataranowicz*; it interferes with the agency's efficient functioning, the agency has had no opportunity to self-correct, the agency has not provided its experience or expertise to these claims, and it utterly cuts off any chance at developing a record. *See* 959 F.2d at 275.

Even if the Court decides that the futility standard has been satisfied, it should hesitate to override the Secretary's decision not to waive the exhaustion requirement here, as the D.C. Circuit has instructed in *Ryan*, 12 F.3d at 249–50. After the reconsideration stage, the Medicare statute would allow one of Plaintiff's members to request "expedited access to judicial review" in lieu of

an administrative hearing. If the reviewing entity (either ALJs or members of the Medicare Appeals Council) determines that (1) the Medicare Appeals Council does not have authority to decide the question of law or regulation relevant to the matters in controversy and (2) there is no material issue of fact in dispute, Plaintiff's members could seek judicial review. 42 U.S.C. § 1395ff(b)(2); 42 C.F.R. § 405.990. Plaintiff's members have not requested expedited judicial review. Procedures like this benefit the parties and the court: the claimant circumvents full Department review and "when the case reaches the district court there will be no question regarding exhaustion of remedies or applicability of the futility doctrine." *Ryan*, 12 F.3d at 248. This in turn conserves "judicial effort" and focuses the Court on the precise legal question at issue. *Id.* at 249. "When an agency has provided an abbreviated procedure that accelerates the decision-making process, it is in the best interests of the court, the agency and the claimant that the procedure be utilized." *Id.* Plaintiff's members could still avail themselves of this procedure here, and the Court should not excuse them from doing so.

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In light of these factors, the purpose of the Medicare Act's exhaustion requirement, and the Secretary's decision not to waive this requirement in this case, this is not a "special case" that warrants excusal. The Court thus should dismiss this case for lack of jurisdiction.

B. The Court Should Grant Summary Judgment in Defendant's Favor Because CMS's Definition of "Infusion Drug Administration Calendar Day" Is Consistent with § 1395m(u)(7) and Is Not Arbitrary or Capricious.

If the Court determines that it has jurisdiction, Plaintiff's claims fail because Congress expressly limited the "infusion drug administration calendar day" to days when only certain "professional services" were furnished to administer the infusion drug to the patient in the home. In the alternative, CMS did not exceed its statutory authority or act arbitrarily or capriciously in defining "infusion drug administration calendar day." As Plaintiff acknowledges, *see* Pl.'s Mem.

at 23, this Court's review of § 486.505 is governed by *Chevron*, which sets forth a deferential two-step process to review an agency's construction of a statute which it administers. 467 U.S. at 842–43. First, if Congress has unambiguously spoken to the issue in question, the Court must give effect to Congress's intent. *Id.* at 843. Second, if the statute is silent or ambiguous, the Court should accord deference to the agency's construction so long as it is reasonable. *Id.* at 843–44.

CMS's definition of "infusion drug administration calendar day" easily satisfies this deferential standard. The statute provides that payment should issue only on "infusion drug administration calendar days"—that is, days when "professional services, including nursing services," 42 U.S.C. § 1395x(iii)(2)(A), "were furnished to administer [home infusion] drugs to [an] individual." *Id.* § 1395m(u)(7)(E)(i). The statute's command that payment issue on *infusion drug administration calendar days* thus straightforwardly contradicts Plaintiff's view that payment issue every day a patient receives infusion drugs. In fact, the statute clearly states that payment issues on a subset of days when a professional administers infusion drugs in a patient's home. Even if the statute leaves any ambiguity, CMS exercised its authority to define infusion drug administration calendar day reasonably, not arbitrarily or capriciously. Therefore, summary judgment should be awarded to Defendant on all counts.

1. *Chevron* Step One: Congress Has Clearly Stated that the Temporary Transitional Payment Should Issue Only on Days when a Professional Administers Infusion Drugs in a Patient's Home.

This case should be resolved in Defendant's favor at step one: Congress's clear intent was to issue single payments only on infusion drug administration calendar days (i.e., days when a professional provides services needed for the administration of infusion drugs in a patient's home). This clear statement is echoed by the final rule and flatly contradicts Plaintiff's view that the payment issues every day a patient receives an infusion, regardless of whether a professional is present in the patient's home. The first step under *Chevron* concerns whether "Congress has

directly spoken to the precise question at issue." 467 U.S. at 842; *see also Bell Atl. Tel. Cos. v. FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997). To determine whether this is the case, courts employ "traditional tools of statutory construction," *Chevron*, 467 U.S. at 843 n.9, beginning with an examination of the statute's text and followed by the statute's "legislative history, and structure, as well as its purpose." *Petit v. U.S. Dep't of Educ.*, 675 F.3d 769, 781 (D.C. Cir. 2012) (quoting *Bell Atl. Tel. Cos.*, 131 F.3d at 1047.

The precise question at issue in this case is whether the statute clearly provides for the dates on which the transitional payment should issue. The short answer is that it has, but not in Plaintiff's favor: Congress clearly stated that the single payment should issue only on days when a professional provides services needed to administer the drug in the patient's home. Beginning with the plain text, the statute directs Defendant to "establish a single payment amount for each such payment category, in accordance with subparagraph (D), for each infusion drug administration calendar day in the individual's home for drugs assigned to such category." 42 U.S.C. § 1395m(u)(7)(B)(iv). With respect to the phrase "infusion drug administration calendar day," the statute includes a "[c]larification[]":

> 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.

Id. § 1395m(u)(7)(E)(i). The "professional services" mentioned in this subsection is elaborated as "[p]rofessional services, including nursing services, furnished in accordance with the plan." *Id.* § 1395x(iii)(2)(A). Put differently, Congress directed payment to issue on days when "[p]rofessional services, including nursing services," *id.*, "were furnished to administer [home infusion] drugs to [an] individual." *Id.* § 1395m(u)(7)(E)(i). Of particular significance here is the

term *administer*, which has a specific meaning under the Medicare Act: it "refers only to the physical process by which the drug enters the patient's body." CMS, MEDICARE BENEFIT POLICY MANUAL ch. 15 § 50.2.B (Feb. 1, 2019), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-Ioms-Items/Cms012673.html. For example, a nurse who is providing services to "administer" a drug to a patient would physically assess the patient (e.g., ensuring the intravenous access is correctly placed and functional) in order to confirm that the pump is able to correctly infuse the drug into the patient's body. Particularly in light of this definition, the text plainly states that the single payment issue only on days when professional services are furnished to administer infusion drugs in the patient's home.

For the same reason, the text does not bear Plaintiff's interpretation that payment must issue *every* day a patient receives infusion drugs. Rather, Congress directly stated that payment should issue "*only* for the date on which professional services *were furnished to administer* such drugs." 42 U.S.C. § 1395m(u)(7)(E)(i) (emphasis added). Because the statute contemplates that there are some days on which the patient receives infusion drugs *without* professional services being "furnished to administer" them, "infusion drug administration day" cannot mean *every* day a patient receives infusion drugs.

Plaintiff's interpretation appears to stem from the assumption that "professional services" are furnished to administer the drug every day a patient receives infusion drugs. This is not so. To understand why, one must consider the statute's context. *See Petit*, 675 F.3d at 781 (observing that "the meaning we ascribe to statutory text must reflect the statute's 'context'" (quoting *Bell Atl. Tel. Cos.*, 131 F.3d at 1047)). Congress provided for a broader category of "professional services" to be covered by the single payment, *see* 42 U.S.C. § 1395x(iii)(2)(A)–(B), than those "professional services" that trigger an infusion drug administration calendar day, *Id.*

§ 1395x(iii)(2)(A). Specifically, the single payment as a whole covers "[p]rofessional services, including nursing services, furnished in accordance with the plan," *id.*, *in addition to* "[t]raining and education (not otherwise paid for as durable medical equipment (as defined in subsection (n)), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier," *id.* § 1395x(iii)(2)(B). *See id.* § 1395m(u)(7)(A)(i) (referencing subsections (A) and (B)). However, the statute instructs payment for the single payment *only* on days when the professional services defined in subsection (A) are furnished to administer the drug (i.e., professional services, including nursing services). *See id.* § 1395m(u)(7)(E)(i) (referencing subsection (A), but not (B)). By its terms, the statute does not permit payment to issue on days when only "[t]raining and education (not otherwise paid for as durable medical equipment (as defined in subsection (n)), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs [are] furnished by a qualified home infusion therapy supplier," *id.* § 1395x(iii)(2)(B). *See id.* § 1395m(u)(7)(E)(i).

As Plaintiff acknowledges, there are days when subsection (A) services are not furnished to administer infusion drugs but the patient nevertheless receives such drugs. *See, e.g.*, Pl.'s Mem. 28 ("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."). The plain text of the statute provides that payment should not issue on such days. Section 1395m(u)(7)(E)(i) limits payment to days when subsection (A) services are furnished to administer the drug. Therefore, the plain text contradicts Plaintiff's interpretation that payment should issue each day a patient receives infusion drugs.

Notwithstanding the plain text of the statute, Plaintiff argues that the term "including" in subsection (A) suggests a broader group of services than just nursing services. *See* Pl.'s Mem. at

24–25. This is a straw man; CMS's interpretation contemplates that payments would issue on days when professional services other that nursing services are administered in the home, referring more generally to "skilled services" (i.e., skills that are "so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel"). 42 C.F.R. § 486.505. For example, social workers and dieticians who provide their services in the patient's home may trigger an infusion drug infusion calendar day. *See* Proposed Rule, 83 Fed. Reg. at 32,468; *see also Home Infusion Therapy Services Temporary Transitional Payment: Frequently Asked Questions (FAQs)* 4–5 (Feb. 27, 2019), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Downloads/Home-Infusion-Therapy-Services-Temp-Transitional-Payment-FAQs.pdf (providing examples of skilled services that may trigger an infusion drug administration calendar day).

Plaintiff also suggests that it would be redundant to account for variation in the complexity of services furnished in determining the dates on which payment issues because such variation is already accounted for in the payment rates. *See* Pl.'s Mem. at 25–27. There is no dispute that Congress accounted for variation in payment in assigning three payment categories. 42 U.S.C. § 1395m(u)(7)(C). But Plaintiff offers no reason why Congress could not also account for such variation by limiting payment to days when subsection (A) services are furnished to administer the drug. At any rate, that is what Congress unambiguously did. Plaintiff's disagreement with the statute's payment structure is better taken up with Congress, not this Court.

In addition to the plain text, the legislative history confirms that Congress intended for payment to issue only on a subset of days when a professional administered infusion drugs while in the patient's home. Although nothing in the legislative history directly speaks to the meaning

of "infusion drug administration calendar day," there is some indication that Congress intended for payment to issue on only a subset of days. In reporting the Medicare Part B Improvement Act of 2017, which introduced the temporary transitional payment that ultimately was included in the Bipartisan Budget Act of 2018 (BBA 2018), to the House of Representatives, the Committee on Ways and Means referred to the payment as "the new home infusion *nursing* benefit." *See* H.R. Rep. No. 115-254, pt. 1, at 10 (2017) (emphasis added). The Committee's shorthand for "nurses" suggests that the authors of the bill intended for the payment to issue on days when certain skilled professionals (i.e., nurses) administered the infusion drug. And it is consistent with Congress providing for a broad single payment that issues only on days when skilled professionals administer the drug in the patient's home.

Furthermore, the history of home infusion legislation rebuts Plaintiff's assertions that Congress intended to enact a per diem payment. Since 1988, Congress has addressed the issue of Medicare coverage of home infusion therapy through the introduction of several proposed bills. Each of these bills prior to BBA 2018 proposed to pay for home infusion services through a per diem payment. *See, e.g.*, Medicare Home Infusion Site of Care Act of 2015, S. 275, 114th Cong. § 2(b) (directing "a per diem schedule for payment for the professional services (including nursing services), supplies, and equipment"); Medicare Home Infusion Therapy Coverage Act of 2009, H.R. 574, 111th Cong. § 2(b) (directing "a per diem schedule for payment for the professional services, supplies, and equipment"). Significantly, none of these bills were enacted into law. Although Plaintiff would have liked for Congress to use this per diem payment structure, Congress clearly chose instead a payment structure triggered by infusion drug administration calendar days.

Plaintiff points to no contrary legislative history. Congressman Pat Tiberi's statement that "[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, *quoted in* Pl.'s Mem. at 27, does not contradict Defendant's reading of the statute. In the first place, "legislators' remarks during a floor debate, even in the Congress that enacted the legislation, do not control statutory interpretation and generally are not accorded significant weight." *Blitz v. Donovan*, 740 F.2d 1241, 1247 (D.C. Cir. 1984). Furthermore, this statement is wholly consistent with the notion that payments are not issued every day a patient receives home infusion drugs. Under the statute, providers continue to be paid for infusion drugs themselves and the supplies and pumps necessary to administer them. In addition, they now receive a temporary transitional payments for home infusion therapy services. Plaintiff also points to various statements that members of Congress made after the statute passed and in preparation for this litigation. *See* Pl.'s Mem. at 27. Such after-the-fact statements are of no value in statutory analysis and should therefore be ignored. *See Graham Cty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 298 (2010).

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For these reasons, Congress clearly stated that the temporary transitional payment should not issue each day a patient receives infusion drugs. Rather, it clearly stated that the single payment should issue only on days when "[p]rofessional services, including nursing services," 42 U.S.C. § 1395x(iii)(2)(A), "were furnished to administer [home infusion] drugs to [an] individual." *Id.* § 1395m(u)(7)(E)(i). Because the final rule echoes Congress's clear command, "that is the end of the matter" and the Court should award summary judgment in Defendant's favor. *See Chevron*, 467 U.S. at 842. Nevertheless, should "the [C]ourt determine[that] Congress has not directly addressed the precise question at issue, . . . the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. As the following section

explains, CMS's interpretation is permissible at this step as well.

2. *Chevron* Step Two and § 706(2)(A): CMS's Construction of "Infusion Drug Administration Calendar Day" Is Reasonable.

i. CMS's Construction of the Statute is Reasonable.

The next and final question is whether CMS reasonably defined "infusion drug administration calendar day" as "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. Under the highly deferential standard that the Court must apply to answer this question, CMS's interpretation is reasonable. To find an agency's interpretation permissible at step two, the Court "need not conclude that the agency construction was the only one it permissibly could have adopted," *Rust v. Sullivan*, 500 U.S. 173, 184 (1991), or that it is "the best interpretation of the statute," *United States v. Haggar Apparel Co.*, 526 U.S. 380, 394 (1999), or that it is "the most natural reading," *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 702 (1991). The agency's view is deemed to be reasonable so long as it is not "flatly contradicted" by plain language. *Dep't of the Treasury, IRS v. Fed. Labor Relations Auth.*, 494 U.S. 922, 928 (1990). Deference is especially appropriate here given the complex, highly technical nature of the Medicare program. *See Thomas Jefferson Univ.*, 512 U.S. at 512; *Cmty. Care Found.*, 318 F.3d at 225.

As Plaintiff points out, the same standard that governs *Chevron* step two governs review of arbitrary and capricious claims. *See* Pl.'s Mem. at 30 n.10 (citing *Judulang v. Holder*, 565 U.S. 42, 52 n.7 (2011)); *see also Agape Church, Inc. v. FCC*, 738 F.3d 397, 410 (D.C. Cir. 2013). Under § 706(2)(A), final agency action is unlawful if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." As with *Chevron* step two, a reviewing court "is not to substitute its judgment for that of the agency." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009) (quoting *Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Auto.*

Ins., 463 U.S. 29, 43 (1983)). Rather, the court must "defer to the wisdom of the agency, provided its decision is reasoned and rational, and even uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Dillmon v. NTSB*, 588 F.3d 1085, 1089 (D.C. Cir. 2009) (quoting *Chritton v. NTSB*, 888 F.2d 854, 856 (D.C. Cir. 1989)). Again, this deference applies with added force in the Medicare context. *See Thomas Jefferson Univ.*, 512 U.S. at 512; *Cmty. Care Found.*, 318 F.3d at 225.

CMS's definition of "infusion drug administration calendar day" satisfies this highly deferential standard. As CMS explained in the proposed and final rule, the basis of its definition begins with the statutory text:

> Section 1834(u)(7)(E)(i) of the Act states that payment to an eligible home infusion supplier or qualified home infusion therapy supplier for an infusion drug administration calendar day in the individual's home refers to payment only for the date on which professional services, as described in section 1861(iii)(2) of the Act, were furnished to administer such drugs to such individual. This includes all such drugs administered to such individual on such day.

Proposed Rule, 83 Fed. Reg. at 32,464; *accord* Final Rule, 83 Fed. Reg. at 56,580. CMS acknowledged 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." Final Rule, 83 Fed. Reg. at 56,580; *accord* Proposed Rule, 83 Fed. Reg. at 32,464. But, it explained its view that "the BBA of 2018 includes this clarification of 'infusion drug administration calendar day' in order to establish clear parameters so as to explicitly pay for services that occur in the patient's home when the drug is being administered." Final Rule, 83 Fed. Reg. at 56,580; *accord* Proposed Rule, 83 Fed. Reg. at 32,464. It concluded, "Our interpretation of the phrase 'only for the date on which professional services, as described in section 1861(iii)(2) of the Act, 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 by the DME

pump" and 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." Final Rule, 83 Fed. Reg. at 56,580.

CMS further explained that the best reading of the statute is that payments are issued on days when skilled services are furnished that are "so inherently complex that they can only be safely and effectively furnished by, or under the supervision of, professional or technical personnel." *Id.* In support of this definition, CMS noted that § 1395m(u)(7) "states that payment is for professional services furnished 'to administer' such drugs to such individual." Final Rule, 83 Fed. Reg. at 56,581. CMS reasoned, "As the term 'administered' refers only to the physical process by which the drug enters the patient's body, then the professional must be in the patient's home furnishing services specifically related to this process." *Id.* (citing Medicare Benefit Policy Manual, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf). Applying its expertise in this "complex and highly technical regulatory program," *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1229 (D.C. Cir. 1994) (quoting *Thomas Jefferson Univ.*, 512 U.S. at 512), CMS drew from a "skilled services" definition that it uses in similar contexts, *see* 42 C.F.R. § 409.32. *See* Final Rule, 83 Fed. Reg. at 56,580; *accord* Proposed Rule 83 Fed. Reg. at 32,464. CMS explained that this definition is consistent with § 1395m(u)(7), which calls for payment on days when "professional services, including nursing services, [are] furnished in accordance with the plan," 42 U.S.C. § 1395x(iii)(2)(A). First, CMS acknowledged that the skilled services regulation "is not specific to skilled nursing services in a [skilled nursing facility]." Final Rule, 83 Fed. Reg. at 56,581. And, the explicit reference to "nursing services" in § 1395x(iii)(2)(A) was, in CMS's view, a good reason to rely on § 409.32. *See* Proposed Rule, 83 Fed. Reg. at 32,464 ("As section 1861(iii)(2)(A) of the Act refers to the professional services,

including nursing services, we believe this to mean skilled services as set out at 42 C.F.R. § 409.32."); *accord* Final Rule, 83 Fed. Reg. at 56,580.

CMS provided several other explanations for its interpretation. It explained that "requiring that direct patient care services be made in order to receive payment promotes visits that provide direct care to the patient, which may help to mitigate any infusion related reactions or unplanned readmissions or ED visits." Final Rule, 83 Fed. Reg. at 56,583. It explained, "Similar to the physician office and the hospital outpatient setting, Medicare payment is made for direct care services furnished to a patient for infusion drug administration." *Id.* And "clinically, it is occasionally necessary for a nurse to visualize part of the administration of the infusion drug as this is part of his/her overall patient assessment while in the home." *Id.* CMS also reasoned that a payment structure that issued payments every day a patient receives infusion drugs would be unreasonable because, at least in part, it would result in a considerable cost increase for the patient, who is responsible for a 20 percent coinsurance amount. *See id.* at 56,582–83.

For these reasons, CMS did not contradict the statute or act arbitrary or capriciously. As explained *supra*, § 1395m(u)(7)(B)(iv) clearly does not contemplate that the temporary transitional payment will issue on each day that a patient receives infusion drugs; rather, it provides that a single payment should issue only on an "infusion drug administration calendar day in the individual's home," which is "the date on which professional services . . . were furnished to administer such drugs to such individual." 42 U.S.C. § 1395m(u)(7)(E)(i). To the extent that the statute left room for interpretation, it delegated interpretive authority to CMS. CMS is afforded deference in exercising such authority so that it can properly administer the Medicare program, and the above reasoning is sufficient for its interpretation to survive step two and review under § 706(2)(A).

ii. Plaintiff's Piecemeal Attack on CMS's Interpretation Does Not Overcome the Considerable Deference that CMS is Owed.

Plaintiff offers a number of arguments as a final effort to cast doubt on CMS's interpretation. However, in light of the considerable deference that step two, § 706(2)(A), and *Thomas Jefferson University* afford CMS in interpreting "drug infusion administration calendar day," these arguments do not defeat CMS's interpretation.

1. In arguing that the final rule conflicts with the purpose of § 1395m(u)(7), Plaintiff misstates the final rule and imagines a conflict that does not actually exist. The first such argument—that any reference in the final rule to skilled nursing facilities is inappropriate because they are "the environment that home infusion is trying to avoid," Pl.'s Mem. at 28—mistakenly assumes that § 409.32 applies only to nursing services in a skilled nursing facility. As CMS explained in the final rule, "the definition of skilled services is not specific to skilled nursing services in a [skilled nursing facility]." *See* Final Rule, 83 Fed. Reg. at 56,581.

Plaintiff also argues that Congress intended a greater utilization of home infusion therapy than that covered by the final rule, pointing to a Congressional Budget Office (CBO) cost estimate of H.R. 3178, a bill that was subsequently amended and became § 1395m(u)(7). *See* Pl.'s Mem. 31 (citing H.R. 3178 CBO Cost Estimate, ECF No. 9-3). In general, CBO cost estimates are poor evidence of congressional intent: "CBO is not Congress, and its reading of the statute is not tantamount to congressional intent." *See Sharp v. United States*, 580 F.3d 1234, 1239 (Fed. Cir. 2009). This is particularly so when Congress does not ratify CBO's interpretation or when CBO reports on a version of the bill that did not become law. *See id.* Notwithstanding this general rule, the D.C. Circuit has considered CBO reports as evidence of congressional intent in a few circumstances. For instance, in *Bread for the City v. USDA*, the panel cited, among other things, a CBO report to confirm the spending formula of a statute that directed USDA to purchase surplus

food. *See* 872 F.3d 622, 625 (D.C. Cir. 2017). The question presented was whether a subsection of the statute directed the USDA to spend an additional $50 million or an additional $327 million. *See id.* at 624. The panel held that "[t]he most natural reading of the statutory text" was $50 million. *See id.* The panel then confirmed this reading with the Senate and House drafts of the bill, the explanatory statements that accompanied the appropriations bill, and a CBO report, which all expected a $50 million increase. *See id.* at 624–25.

The *Bread for the City* panel's use of the CBO report in that case is in stark contrast to Plaintiff's use of the CBO cost estimate for H.R. 3178. Whereas the CBO report cited in *Bread for the City* was consistent with the statutory text and other legislative history, there is significant reason to doubt Plaintiff's reliance on the CBO cost estimate for H.R. 3178. First, and as referenced above, the CBO cost estimate on which Plaintiff relies is for a different version of the bill than what ultimately passed. The temporary transitional payment in H.R. 3178 was calibrated to five hours of infusion time, whereas the payment in the statute as enacted is calibrated to four hours of infusion time. *Compare* H.R. 3178 § 101(a) (applying one hour/unit of HCPCS codes 96365, 96369, and 96413 with four hours/units of HCPCS codes 96366, 96370, and 96415), *with* 42 U.S.C. § 1395m(u)(7)(D)(ii)–(iv) (one hour/unit of HCPCS codes 96365, 96369, and 96413 with three hours/units of HCPCS codes 96366, 96370, and 96415). Put differently, the temporary transitional payment is smaller under the statute as enacted than it was under H.R. 3178.

Second, the underlying assumptions of CBO's cost estimates are dubious. One line in particular stands out: with respect to its cost estimate of H.R. 3178, CBO stated, "Based on CBO's expectation that Medicare would pay for about 25 million infusions per year in the home setting, CBO estimates that on net, the home infusion provision would increase direct spending by $15 million over the 2018-2027 period." H.R. 3178 CBO Cost Estimate 3, ECF No. 9-3. However,

CBO gives no basis for its estimate either that Medicare would pay for 25 million infusions in the home, nor does it tie that estimate to the increase in direct spending, other than speculating that patients would switch to home infusion from other settings. *Id.* at 2–3. Not only is this estimate unfounded, it is also irrelevant because the statute ties payment to an infusion drug administration calendar day, not number of infusions. The number of infusions per year is not a useful variable to determine the cost of the statute.[3] In short, the CBO cost estimates are unreliable sources on their own and even more unreliable sources of congressional intent.

2. Plaintiff's various arguments that the final rule creates absurd results likewise misstates the statute and the rule. First, Plaintiff is wrong to speculate that "most Medicare beneficiaries will no longer be able to receive home infusion," Pl.'s Mem. 28. Once again, the temporary transitional payment covers all items and services listed in § 1395x(iii)(2) on infusion drug administration calendar days, a benefit that did not exist prior to 2019. And the DME benefit continues to cover equipment, supplies, and the drug. *See* Final Rule, 83 Fed. Reg. at 56,581. To the extent that Plaintiff seeks payment on days other than infusion drug administration calendar days in the individual's home, it ought to ask Congress to rewrite § 1395m(u)(7)(E)(i). This Court cannot do so.

Furthermore, some of the ostensibly absurd results that Plaintiff points to are not absurd at

[3] Plaintiff's reliance on CBO's cost estimate for H.R. 3178 appears to stem from a misreading of the document, which further reduces its usefulness in this briefing. Plaintiff claims that CBO "estimated that under the statute Medicare would pay for approximately 25 million home infusion days in each of 2018 and 2019." Pl.'s Mem. 31. However, as the above quote indicates, CBO said nothing of the sort. It expected "that Medicare would pay for about 25 million *infusions* per year," not infusion *days*. H.R. 3178 CBO Cost Estimate 3 (emphasis added). Thus, Plaintiff's comparison of the cost estimate with CMS's regulatory impact analysis lacks a common variable; Plaintiff compares the number of infusions that CBO "expect[ed]" with the "total visits of care" that CMS estimated. *See* Pl.'s Mem. 31.

all. For example, patients who receive milrinone in a doctor's office typically go to the office once per week. *See* Prescription Analysis, Rulemaking R. at 5839; *see also* Final Rule, 83 Fed. Reg. at 56,621 (assuming that "the initial week of care requires two nurse visits, and all subsequent weeks only require one visit"). As Plaintiff observes, patients who receive milrinone at home are also typically visited by a nurse once per week. *See* Pl.'s Mem. at 29. Contrary to Plaintiff's assertions, it would be absurd if payment for this continuous service under the home infusion therapy services temporary transitional payment was seven times that of the payment for a traditional office visit.[4]

Next, Plaintiff's argument that reimbursement for services is limited to nursing services provided in the home similarly misstates the rule. *See* Pl.'s Mem. at 33. An infusion drug administration calendar day is triggered when "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. As CMS has explained, this is not limited to nursing services. *See* Final Rule, 83 Fed. Reg. at 56,581. Furthermore, as the statute contemplates, the single payment covers all items and services set forth at § 1395x(iii)(2), including remote monitoring. "The requirement that a skilled professional be in the home on a day an infusion drug is administered is only for purposes of determining the days for which the bundled payment for home infusion therapy services is

[4] The Court should be skeptical of Plaintiff's assertion that it spends $43,800 per beneficiary who receives milrinone per year. This figure is from an NHIA study, which proposed a $120 per diem payment for services, equipment, and supplies associated with antibiotic infusion therapy. *See* Edward M. Drozd et al., IMPACT ON MEDICARE EXPENDITURES FROM EXPANDING COVERAGE OF INFUSION THERAPY OF ANTI-INFECTIVE DRUGS TO THE HOME SETTING 2 (Avalere & NHIA 2014), www.nhia.org/resource/legislative/documents/AvalereFinalHomeInfusionReport.pdf.
Significantly, the temporary transitional payment does not cover antibiotics; they are covered under Part D. Furthermore, this study's proposed payment includes not only the services associated with the antibiotic home infusion but also the accompanying equipment and supplies. The temporary transitional payment, on the other hand, does not cover equipment and supplies because they are covered separately under the DME benefit. Thus, the $120 per diem figure would be more reasonable for antibiotics than it would be for milrinone.

made." Final Rule, 83 Fed. Reg. at 56,582.

3. Finally, Plaintiff raises a number of miscellaneous arguments, which can be dismissed in turn. First, Plaintiff has pointed to no statutory conflict that warrants vacating § 486.505. *See* Pl.'s Mem. at 33–34. In support of its argument, Plaintiff argues that CMS has contradicted the final rule in a guidance document, which explained that home infusion professional services will not be paid to home infusion providers for patients who are concurrently under the home health benefit. *See id.* at 34 (citing *Home Infusion Therapy Services Temporary Transitional Payment: Frequently Asked Questions (FAQs)* at 6, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Downloads/Home-Infusion-Therapy-Services-Temp-Transitional-Payment-FAQs.pdf). However, there is no conflict between this guidance and the Final Rule. In fact, CMS explained in the final rule that "the home infusion therapy services temporary transitional payment is separate from the home health benefit, . . . [n]ot until the full implementation of the [home infusion] benefit in 2021 will home health agencies have the option of becoming home infusion suppliers." Final Rule, 83 Fed. Reg. at 56,581. And because the temporary transitional payment may be issued only to "an eligible home infusion supplier," 42 U.S.C. § 1395m(u)(7)(A)(i); *see also id.* § 1395m(u)(7)(F) (defining "eligible home infusion suppliers"), "[f]or the two-year temporary transitional payment period (CYs 2019–2020), home health services covered under the Medicare home health benefit include the in-home services covered under the new home infusion therapy benefit." *See Home Infusion Therapy Services Temporary Transitional Payment: Frequently Asked Questions (FAQs)* at 6.

Plaintiff also argues that CMS ignored a comment that "home infusion suppliers will no longer be able to provide home infusion therapy to Medicare beneficiaries." Pl.'s Mem. at 34. This is wrong for two simple reasons. First, CMS adequately addressed the comment. "In notice and

comment rulemaking, an agency need not respond to every comment so long as it responds in a reasoned manner to significant comments received." *U.S. Satellite Broad. Co. v. FCC*, 740 F.2d 1177, 1188 (D.C. Cir. 1984). In summarizing comments on this issue, CMS explained the general view reflected in this comment, *see* Final Rule, 83 Fed. Reg. at 56,580 ("Commenters expressed concern that tying payment to days for which a nurse provides in-person professional services, would limit payment only to a small subset of the many professional services furnished in connection with home infusion."), and offered a lengthy response—oft repeated in this memorandum—that § 1395m(u)(7) tied payment to a subset of days when professional services were furnished to administer the drug, *see id.* at 56,580–81. Furthermore, it is absurd to suggest that home infusion suppliers will no longer be able to provide home infusion therapy. Suppliers continue to receive payments for furnishing the equipment, the supplies, and the drug. *See* Final Rule, 83 Fed. Reg. at 56,581. And they now also receive payments for covered services on days when professional services are furnished to administer the drug.

In addition, to the extent the rule treats Category 1 and 2 drugs differently than Category 3 drugs, Pl.'s Mem. at 35, this is a product of the statute. The statute creates a separate payment for each category and states that payment should issue on days when professional services are furnished to administer the drug in the patient's home. To the extent that professional services are furnished to administer one category of drug more than another, that is a function of the statute, not the rule. At any rate, CMS explained why cases could reasonably be treated differently: "Considering that we do not expect a visit to be made for each infusion drug administration, we also do not believe the supplier should be paid every day that the medication is infused regardless of whether or not direct care services are furnished." Final Rule, 83 Fed. Reg. at 56,582.

Last, Plaintiff takes issue with CMS's observation that copayments would spike if the

temporary transitional payments were issued each day a patient receives a drug infusion. As CMS explained, "the patient is responsible for 20 percent coinsurance for every home infusion therapy services payment in addition to the 20 percent coinsurance charged for the DME infusion pump supplies and the drug." *Id.* For patient who receive daily infusions, a daily payment would result in a $10,000 annual bill to the beneficiary. *See id.* at 56,583. Far from irrelevant, this consideration further supports CMS's view that Congress did not intend payments to issue every day a drug is infused when so high a cost would be borne by beneficiaries.

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In sum, although Plaintiff disagrees with CMS's interpretation of "infusion drug administration calendar day," this is not enough to defeat the considerable deference that CMS is owed at step two, under the § 706(2)(A), and under *Thomas Jefferson University*. CMS's interpretation is reasonable, and it has not acted arbitrarily or capriciously.

V. Conclusion

For the foregoing reasons, the Court should grant Defendant's motion to dismiss or, in the alternative, cross-motion for summary judgment.

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Respectfully submitted,

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