**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 REPLY MEMORANDUM IN SUPPORT OF HIS MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT**

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## I. Introduction

The Court should dismiss this Medicare case for two independent and straightforward reasons. First, Plaintiff National Home Infusion Association's members have come nowhere close to exhausting administrative remedies. The Medicare statute permits judicial review only when claimants have exhausted such remedies and even provides an expedited process when claims raise purely legal questions and lack a material factual dispute. Plaintiff's members should avail themselves of that expedited process, as the D.C. Circuit has instructed, rather than jumping the line to federal court. Second, Defendant Alex M. Azar II, the Secretary of Health and Human Services, has not exceeded his statutory authority or acted arbitrarily or capriciously. Congress was perfectly clear that the temporary transitional payment issues only on days when professional services are furnished to administer home infusion drugs, not *every day* a patient receives such drugs. And even if there were any ambiguity in Congress's command, the Centers for Medicare and Medicaid Services' (CMS) interpretation of the statute was eminently reasonable.

## II. Argument

### A. The Court Lacks Jurisdiction Because Plaintiff's Members Still Have Not Exhausted Their Claims.

Because Plaintiff's members still have not exhausted their claims, *see* Suppl. Decl. of William Noyes ¶¶ 4–6, ECF No. 15-1 (asserting that Intramed Plus, BioScrip, and Paragon Healthcare are "pursuing [their] appeals of the denied claims, and those appeals remain pending"), the Court should dismiss this case for lack of jurisdiction. Contrary to Plaintiff's framing of the exhaustion legal standard as one under which a court may simply waive the exhaustion requirement when certain factors are met, the Secretary's decision not to waive this requirement may be overcome only "in certain special cases." *See Heckler v. Ringer*, 466 U.S. 602, 618 (1984). This is because Congress, through statute, and HHS, through regulation, have carefully crafted a

system of administrative remedies that claimants must follow before obtaining a "final decision" that permits judicial review. *See* 42 U.S.C. § 405(g); Def.'s Mem. of P. & A. in Supp. of His Opp'n to Pl.'s Mot. Summ. J. & Mot. Dismiss or, in the Alternative, Summ. J. 4–6, ECF No. 13-1 [hereinafter Def.'s Mem.] (describing the system of administrative remedies). In deciding whether to exercise this extraordinary power, courts consider whether the claim is collateral to a demand for benefits, whether the claimant would be irreparably injured if the exhaustion requirement were enforced against it, as well as whether exhaustion would be futile. *See* Def.'s Mem. 12.

**1. Altogether, the Three Exhaustion Factors Weigh in Defendant's Favor.**

Despite recognizing these three factors, *see* Pl.'s Opp'n Def.'s Mot. Dismiss or, in the Alternative, Summ. J. 4, ECF No. 15 [hereinafter Pl.'s Opp'n], Plaintiff has nothing to say regarding the first two, *see id.* at 4–8. This is undoubtedly because the first two factors weigh entirely in Defendant's favor. The allegations in the Complaint are identical, not collateral, to Plaintiff's members' demands for benefits. *See* Def.'s Mem. 12–13. And Plaintiff has not shown, as is its burden, that its members would be irreparably harmed if they exhausted administrative remedies. *See id.* at 13–14.

Instead, Plaintiff focuses entirely on the futility factor, to no avail. Once again, "the ordinary standard for futility in administrative law cases is inapplicable in Medicare cases." *Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 75 (D.D.C. 2018). Rather, this "statutory scheme is . . . one in which the Secretary may specify such requirements for exhaustion as he deems serve his own interests in effective and efficient administration." *Weinberger v. Salfi*, 422 U.S. 749, 766 (1975). "The fact that the agency . . . may lack the power to" resolve certain questions "is beside the point because it is the 'action' arising under the Medicare Act that must be channeled through the agency." *Shalala v. Ill. Council on Long Term Care, Inc*., 529 U.S. 1, 23 (2000). Accordingly, "a court may not substitute its conclusion as to futility for the contrary conclusion of the Secretary."

*Id.* Rather, 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." *Tataranowicz v. Sullivan*, 959 F.2d 268, 275 (D.C. Cir. 1992). As Defendant pointed out in his opening motion, none of these elements is present here because there is no record of the underlying claims; Plaintiff filed its complaint on the same day or days after its members submitted their reimbursement claims. *See* Def.'s Mem. 15.

Without a record, it is impossible to confirm Plaintiff's argument that its members raise pure legal disputes. If they are purely legal disputes and Plaintiff is correct that the agency decision makers are bound by the Secretary's regulation, then Plaintiff's members may avail themselves of expedited access to judicial review, as discussed below. But, some of Plaintiff's characterizations of the final rule call into question whether it correctly understands how the CMS will apply the rule to the underlying claims. Plaintiff appears to believe that the temporary payment issues only on days when a *nurse* is physically present in the home. *See, e.g.*, Pl.'s Mem. of P. & A. in Supp. of Pl.'s Mot. Summ. J. 2, ECF No. 9-1 [hereinafter Pl.'s Mem.]. Yet, as the final rule explains in response to comments that express similar concerns, an infusion drug administration calendar day is not triggered only when a nurse furnishes the applicable services to administer home infusion drugs. The temporary payment issues on days 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. This includes—but is not limited to—days when a nurse furnishes services to administer home infusion drugs. *See* Home Infusion Therapy Requirements, 83 Fed. Reg. 56,406, 56,581 (Nov. 13, 2018) [hereinafter Final Rule]. For instance, social workers and dieticians who provide their services in the patient's home may trigger an infusion drug administration calendar

day. *See* Home Infusion Therapy Requirements, 83 Fed. Reg. 32,340, 32,468 (July 12, 2018) [hereinafter Proposed Rule]. In light of Plaintiff's incorrect description of what triggers an infusion drug administration calendar day, CMS should have an opportunity to ensure that its regulations are correctly applied before its actions are subject to judicial review. This is even more so because Plaintiff has not shown that the underlying demands for benefits are collateral to the complaint or that its members would be irreparably harmed.

**2. The Court Should Decline to Waive the Exhaustion Requirement Because Plaintiff's Members Have Not Requested Expedited Access to Judicial Review.**

Even if the Court determines that it would be permissible to waive the Medicare statute's exhaustion requirement, it should nevertheless decline to do so because Plaintiff's members have not requested the statute's abbreviated procedures. "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." *Ryan v. Bentsen*, 12 F.3d 245, 249 (D.C. Cir. 1994). As detailed in Defendant's opening memorandum, Plaintiffs members may request expedited access to judicial review in lieu of an administrative hearing. And if the reviewing entity determines that the Medicare Appeals Council does not have authority to decide the relevant question of law and there are no disputed material factual issues, Plaintiff's members could seek expedited judicial review. *See* Def.'s Mem. 15–16 (citing 42 U.S.C. § 1295ff(b)(2); 42 C.F.R. § 405.990). This Court should follow *Ryan* and decline to waive the exhaustion requirement because Plaintiff's members have not requested expedited access to judicial review.

Plaintiff attempts to distinguish *Ryan* by arguing that the futility factor weighs in its favor in this case. *See* Pl.'s Opp'n 7. However, asking a court to decide legal questions regarding futility is precisely the inquiry that *Ryan* seeks to avoid. The D.C. Circuit declined to waive the exhaustion requirement in that case because the agency's internal procedures permitted expeditious judicial

review, eliminating the need for "judicial effort on the applicability of the futility doctrine." *See Ryan*, 12 F.3d at 249. The court explained, "Compliance with the [expedited appeals process] is not another wall constructed to stymie a claimant's efforts to obtain judicial review of his claim." *Id.* Rather, it "reflects both considerations already embodied in the Supreme Court's futility decisions and [the D.C. Circuit's] prudential concerns." *Id.* Thus, *Ryan* on its own terms contradicts Plaintiff's attempt to distinguish it. And, because the procedures in *Ryan* are almost identical to those here, *compare id.* at 247–48 (explaining that the expedited appeals process is available when "the only obstacle preventing [the claimant] from receiving benefits is a provision of the Act he alleges is unconstitutional"), *with* 42 C.F.R. § 405.990(a)(2), the Court should follow *Ryan*'s direction and dismiss this case for failure to exhaust.

Three of the four district court decisions that Plaintiff cites to the contrary, *see* Pl.'s Opp'n 7, are irrelevant because they do not discuss the availability of expedited access to judicial review. *American Hospital Association v. Azar*, the only decision that discusses such procedures, simply states that "the Secretary does not explain why [§ 405.990] would prevent a court from waiving 42 U.S.C. § 405(g)'s exhaustion requirement when appropriate, nor does the Secretary cite case law establishing that principle." 348 F. Supp. 3d 62, 74 n.10 (D.D.C. 2018), *appeal filed*, No. 19-5048 (D.C. Cir. Feb. 28, 2019). However, Defendant has done exactly that in this case.

Plaintiff also incorrectly argues that imposing the exhaustion requirement in this case would be especially inappropriate because Plaintiff challenges a temporary benefit. The D.C. Circuit has already rejected this argument in *Ryan*: "The added burden that a claimant [use the expedited appeals process] is not itself futile because the [process] does not involve review of the merits of his claim to benefits." 12 F.3d at 249. The expedited access to judicial review provision was already baked into the Medicare statute, *see* 42 U.S.C. § 1395ff(b)(2), when Congress enacted

the temporary transitional benefit. To the extent that Plaintiff takes issue with the expedited access to judicial review provision, that is an issue for Congress to resolve, not the courts. Therefore, this Court should insist that Plaintiff's members at least request expedited access to judicial review before "expending judicial effort on the applicability of the futility doctrine." *See Ryan*, 12 F.3d at 249. In any event, it is irrelevant that Plaintiff is challenging a temporary benefit. Plaintiff's members' claims are, at bottom, claims for Medicare payment, which, if successful, would be paid (with interest) even if the permanent benefit is already in effect.

### B. The Court Should Grant Summary Judgment in Defendant's Favor Because the Final Rule Did Not Exceed CMS's Statutory Authority and Was Not Arbitrary or Capricious.

Even if the Court reaches the merits, it should award summary judgment in Defendant's favor. The final rule did not exceed CMS's statutory authority; it instead reflects the statute's command that the temporary transitional payment issues only on days when professional services are furnished to administer home infusion drugs. In the alternative, CMS did not act unreasonably, arbitrarily, or capriciously in defining "infusion drug administration calendar day."

#### 1. *Chevron* Step One: Congress Directly Stated that the Temporary Transitional Payment Issues Only on a Subset of Days when Professional Services Are Furnished to Administer Home Infusion Drugs.

Rather than offer any statutory basis for its argument that the temporary transitional payment should issue every day a patient receives home infusion—a plainly incorrect reading of the statute—Plaintiff nitpicks Defendant's step one analysis. Notably, however, Plaintiff does not respond to the statute's clear command that there are some days on which a patient infuses drugs at home when the temporary transitional payment does not issue. For example, the payment does not issue on days when "[p]rofessional services, including nursing services, [are] furnished in accordance with the plan," 42 U.S.C. § 1395x(iii)(2)(A), but are not "furnished *to administer*

[home infusion] drugs," *id.* § 1395m(u)(7)(E)(i) (emphasis added). Likewise, the statute clearly states that the payment does not issue on days when "[t]raining 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," *id.* § 1395x(iii)(2)(B). *Id.* § 1395m(u)(7)(E)(i) (referring only to § 1395x(iii)(2)(A), not § 1395x(iii)(2)(B)). If Congress intended for payment to issue every infusion day, it could have said so. It didn't. Instead, the statute states that the payment issues "*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) (emphasis added). The use of the term *only* indicates that the payment does not occur on other days, when professional services are not furnished to administer the drug. Furthermore, the statute provides that the single payment occurs on "each infusion drug administration calendar day *in the individual's home*." *Id.* § 1395m(u)(7)(B)(iv) (emphasis added), not remotely or from a pharmacy as Plaintiffs would have it. Therefore, Plaintiff's argument that payment issues "each day a drug is infused," Pl.'s Mem. 23, is incorrect.

Plaintiff has no response to this and instead focuses with tunnel vision on the term *furnish* in § 1395m(u)(7)(E)(i). That section, once more, states that "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 1861(iii)(2)(A)) were furnished to administer such drugs to such individual." The term *furnish* has several meanings, one of which, as Plaintiff correctly points out, is "to provide with what is needed" or to "supply, give." *Definition of* Furnish, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/furnish (last visited April 24, 2019). And, as Plaintiff also correctly points out, one can directly or indirectly furnish something. However, the statute does not provide for

payment to issue when professional services are "furnished"; rather, it provides that payment issues when professional services are "furnished *to administer* [home infusion] drugs." 42 U.S.C. § 1395m(u)(7)(E)(i) (emphasis added). Thus, whether one could furnish home infusion drugs directly or indirectly, the use of the additional term *to administer*, which "refers only to the physical process by which the drug enters the patient's body," Rulemaking R. 4472, indicates that payment issues only when professional services are directly furnished (i.e., to administer the drug). Because home infusion drugs, by definition, physically enter the patient's body in the patient's home, professional services that are furnished to administer such drugs necessarily occur in the patient's home as well.

Plaintiff argues in response that Defendant reads the term *furnish* out of the statute. Far from reading it out of the statute, Defendant recognizes that the term is necessary for the sentence to be grammatical. It does not, however, negate the meaning of the term *administer*. Plaintiff also argues that because some professional services that are furnished outside the home are necessary for home infusion, such services must trigger an infusion drug administration calendar day. Not so. Although such services are priced into the temporary transitional payment, *see* 42 U.S.C. § 1395m(u)(7)(A)(i); Final Rule, 83 Fed. Reg. at 56,581 (observing that "that the home infusion therapy services temporary transitional payment is a unit of single payment, meaning all home infusion therapy services furnished, which include professional services, training and education, remote monitoring and monitoring, are built into the payment for the day the professional services are furnished in the home and the drug is being administered"), the plain text of § 1395m(u)(7)(E)(i) requires that payment issue only on days when professional services are furnished to administer the drug. Because one can administer a home infusion drug only in the home, remote monitoring, although covered by the temporary transitional payment, cannot trigger

an infusion drug administration calendar day. The same can be said of § 1395x(iii)(2)(A) services that are not "furnished to administer [home infusion] drugs." *See id.* § 1395m(u)(7)(E)(i).

Plaintiff also argues that Defendant impermissibly narrowed the term *professional services* to *skilled services*. However, Plaintiff mistakenly assumes that the *skilled services* are a subset of *professional services*. Indeed, they are one and the same. *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."). Nor would it make sense for unskilled services to qualify as "professional services": "For the professional services to be necessary for the safe and effective administration of home infusion drugs, they must be furnished by skilled professionals in accordance with individual state practice acts." *Id.* Plaintiff surely does not contend that services furnished by unskilled individuals would qualify as "professional services."

Finally, Plaintiff raises two brief objections to Defendant's use of legislative history. First, and contrary to Plaintiff's suggestion, history of failed legislation sometimes *is* relevant. Although "'[c]ongressional inaction lacks persuasive significance' in most circumstances," *Star Athletica, L.L.C. v. Varsity Brands, Inc.*, 137 S. Ct. 1002, 1015 (2017) (quoting *Pension Benefit Guaranty Corp. v. LTV Corp.*, 496 U.S. 633, 650 (1990)), it "also can inform [courts'] understanding of Congress's intent" in some cases. *Doe v. Rumsfeld*, 683 F.3d 390, 396 (D.C. Cir. 2012). For example, when Congress creates a cause of action against some entities, but not others, courts infer from congressional inaction that Congress did not intend to create a cause of action for those other entities. *See id.* Particularly here, where Congress repeatedly failed to adopt legislation that issued per diem payments and finally enacted a bill that issued payment only on infusion drug administration calendar days, the Court should decline to provide what Congress chose not to.

Second, Plaintiff insists that after-the-fact statements from individual members of Congress are useful at step one because they are part of the rulemaking record. The rulemaking record is, of course, irrelevant at *Chevron* step one, where the question is whether *Congress* directly spoke to the question at issue.

### 2. *Chevron* Step Two: CMS Acted Reasonably, Not Arbitrarily or Capriciously, in Promulgating the Final Rule.

Even if the Court determines that Congress did not directly speak to the question of whether the temporary transitional payment should issue on a subset of days when patients receive home infusion drugs, for all of the reasons stated in Defendant's opening brief, the final rule is eminently reasonable. Although Plaintiff frames its step two arguments as an attack on the reasonableness of this regulation, in truth, they reflect the association's disagreement with § 1395m(u)(7). It is clear that Plaintiff would like for payments to issue on every day that a patient receives home infusion drugs and on the same days regardless of the category of drug. However, this litigation is not a means to effect Plaintiff's policy preferences. Rather, the question at step two is whether, in light of the particular deference owed to CMS, *see Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994), the agency "flatly" contradicted § 1395m(u)(7). *See Dep't of the Treasury, IRS v. Fed. Labor Relations Auth.*, 494 U.S. 922, 928 (1990). If it did not, which is the case here, the regulation must be upheld.

#### i. Plaintiff's Step Two Arguments Incorrectly Assume That the Temporary Transitional Payment Issues on Each Day That a Patient Receives Home Infusion Drugs.

Throughout its opposition memorandum, Plaintiff mistakenly assumes that the temporary transitional payment issues on every day that a patient receives home infusion drugs. As the previous section explained, this plainly is not the case; payment issues only on days when professional services are furnished to administer home infusion drugs. Payment does not issue

when professional services are furnished, but not to administer the drugs. Nor does payment issue when other services, such as remote monitoring, are furnished. Based on Plaintiff's faulty assumption, it argues that the final rule is implausible on its own terms and that Defendant offers no meaningful defense of his statutory interpretation. *See* Pl.'s Opp'n at 15–16. However, the proposed and final rules as well as Defendant's opening brief thoroughly explain CMS's construction of the statute.

Plaintiff's incorrect assumption undermines its next counterargument as well. Plaintiff argues that "pharmacies provide the majority of services needed to infuse these drugs safely in a patient's home," and that Defendant "has no reasonable basis to deny reimbursement for these professional services." *See* Pl.'s Opp'n at 16–17. But Defendant's interpretation does not mean that pharmacies, as eligible home infusion suppliers, receive no payment for such services. "[P]rofessional services, training and education, remote monitoring and monitoring, are built into the payment for the day the professional services are furnished in the home and the drug is being administered." Final Rule, 83 Fed. Reg. at 56,581. And regardless of when an infusion drug administration calendar day takes place, the separate durable medical equipment (DME) benefit provides payment to the pharmacies for the equipment and supplies, which includes the drug. *Id.*

Furthermore, in arguing that the final rule is arbitrary and capricious, Plaintiff assumes that services performed by pharmacists must receive the temporary transitional payment. The legislative history indicates that this is not necessarily the case. In previous unsuccessful versions of home infusion therapy legislation there was clear reference to pharmacy services. *See, e.g.*, Medicare Home Infusion Site of Care Act of 2015, S. 275, 114th Cong. § 2(a) (stating that professional services included [drug] "compounding, dispensing, and distribution" and that a qualified home infusion therapy supplier must have dispensing authority and expertise in the

preparation of parenteral medications); Medicare Home Infusion Therapy Coverage Act of 2009, H.R. 574, 111th Cong. § 2(a) (same). Congress conspicuously left such references out in § 1395m(u)(7), suggesting that it did not intend to include services performed by pharmacists under the benefit. This is likely because such services are provided when furnishing the drug, which is paid under the DME benefit. In the unsuccessful versions of home infusion therapy legislation referenced above, a conforming amendment would have eliminated payment for supplies, which includes the drugs themselves, and equipment under the DME benefit, Medicare Home Infusion Site of Care Act of 2015, S. 275, 114th Cong. § 2(c)(3); Medicare Home Infusion Therapy Coverage Act of 2009, H.R. 574, 111th Cong. § 2(c)(3), instead incorporating payment for the supplies and equipment under the home infusion therapy benefit, Medicare Home Infusion Site of Care Act of 2015, S. 275, 114th Cong. § 2(a); Medicare Home Infusion Therapy Coverage Act of 2009, H.R. 574, 111th Cong. § 2(a). Notably, this change was not included in either the 21st Century Cures Act or the Bipartisan Budget Act of 2018.

It is also clear that Plaintiff would prefer a system where the temporary transitional payment is issued uniformly, regardless of the type of drug and the number of days professional services are furnished to administer the drug. Not only did Congress not mention such a payment structure anywhere in the statute, every indication is that Congress intended something different. Infusion drug administration calendar days are triggered when professional services are furnished to administer home infusion drugs. Because professional services are furnished to administer some home infusion drugs more frequently than others, it follows that the temporary transitional payment also issues more frequently with respect to certain drugs than others. Far from being "cavalier[]," Pl.'s Opp'n 18, CMS takes seriously its duty to interpret the Medicare statute

reasonably. And a reasonable interpretation of the statute can, and in this case does, result in the temporary transitional payment issuing more frequently with respect to certain drugs than others.

Plaintiff appears to argue in response that relying on the statute "is no answer at *Chevron* Step Two." Pl.'s Opp'n 18. This is flatly incorrect. The key question at step two is "whether the [agency] has reasonably explained how the permissible interpretation it chose is 'rationally related to the goals of' the statute." *Petit v. Dep't of Educ.*, 675 F.3d 769, 785 (D.C. Cir. 2012). Focusing on the statute is precisely what CMS is supposed to do. Plaintiff's charge that CMS is "blaming Congress" for its rule therefore is not far off; the agency relied heavily on the plain text of the statute in promulgating the final rule.

**ii. The Purported Negative Effects of the Rule Do Not Render CMS's Interpretation Unreasonable.**

Unsatisfied that CMS focused so strongly on the statutory text, Plaintiff argues that CMS should instead consider certain purported negative effects of the final rule. *See* Pl.'s' Mem. 18–21. First, although such purported effects *could* counsel in favor of a different interpretation of the statute, they are not enough to vacate the final rule at step two. Rather, the question at this step is whether CMS's interpretation was contrary to the statute. *See Fed. Labor Relations Auth.*, 494 U.S. at 928. Even assuming the truth of the purported negative effects of the final rule, such allegations do not contradict CMS's interpretation of the text of the statute.

At any rate, Plaintiff overstates the purported negative effect of the rule. With respect to milrinone, Plaintiff asserts, without any support, that Congress enacted the temporary transitional payment to make up for its reduced price under the DME benefit. *See* Pl.'s Opp'n at 19–20. Not only does Plaintiff lack support for this assertion, it makes no sense. As the opening memorandum states, patients who receive milrinone in a physician's office would typically receive *professional services* (not treatment, as Plaintiff suggests in footnote five of its opposition memorandum) in the

office once per week, even though the infusion is continuous. *See* Def.'s Mem. 31. Likewise, patients who receive milrinone at home also receive such services (i.e., professional services that are furnished to administer the drug) once per week. *See id.* It would be utterly unreasonable under these circumstances for the temporary transitional payment to be seven times that of a traditional office visit.

**iii. Plaintiff's Congressional Intent Arguments Are Unsupported.**

Plaintiff also asserts, without any support, that Congress intended to increase home infusion therapy. In support, it points again to a floor statement of Congressman Pat Tiberi, which as Defendant has already pointed out, has minimal value and does not support Plaintiff's view of congressional intent. *See* Def.'s Mem. 23.

Plaintiff also insists that the Congressional Budget Office (CBO) cost estimate of a bill that was amended and became § 1395m(u)(7) supports its view of legislative intent. Once again, courts generally do not rely on CBO cost estimates to determine congressional intent, particularly when Congress does not ratify CBO's interpretation, *see Thompson v. Kennickell*, 797 F.2d 1015, 1024 (D.C. Cir. 1986) (considering a CBO estimate that was included in the Senate Report of the bill), or when CBO reports on a version of the bill that does not become law. *See Sharp v. United States*, 580 F.3d 1234, 1239 (Fed. Cir. 2009). When the D.C. Circuit does consider CBO estimates, it typically does so to confirm other evidence of congressional intent, not to use as the exclusive evidence congressional intent. *See, e.g.*, *Bread for the City*, 872 F.3d 622, 625 (D.C. Cir. 2017) (confirming the amount of spending allocated in the statute with the amount estimated by the CBO); *Thompson v. Kennickell*, 797 F.2d 1015, 1025 (D.C. Cir. 1986) (observing that "[e]very item in the legislative history" save one supported the court's reading); *In re Jordan*, 745 F.2d 1574, 1576 (D.C. Cir. 1984) (same). Here, by contrast, Plaintiff asks the Court to rely exclusively on the CBO cost estimate of a bill that did not become law to determine that Congress intended

for an increase in home infusion therapy in enacting another bill. No fair reading of D.C. Circuit law supports that request.

At any rate, the Court should be wary of affording significant weight to this particular CBO report because its underlying assumptions are unclear. As Plaintiff acknowledges, the main difference between H.R. 3178 and the statute as enacted was a one hour decrease in the payment amounts (H.R. 3178 paid for five hours of infusion time, whereas BBA 2018 paid for four hours of infusion time). Despite this modest change, CBO changed its estimate from a $15 million *increase* in spending from fiscal years 2018 to 2027, *see* H.R. 3178 CBO Cost Estimate, to a $910 million *decrease* in spending during the same period, *see* BBA 2018 CBO Cost Estimate 2, ECF No. 9-4.[1] But a one hour difference in the payment amounts cannot alone explain CBO's staggering change in cost estimates. In short, without more clarity on the underlying assumptions upon which the CBO cost estimate was based, it is an unreliable source of congressional intent.

**iv. Section 1395m(u)(7) Does Not Require CMS to Consider Payment Practices in the Private Market.**

Last, Plaintiff argues that CMS unreasonably failed to consider payment practices in the private market. However, nothing in the statute's temporary transitional payment provision requires CMS to consider such practices. Plaintiff relies on § 1395m(u)(2), which provides as follows: "In developing the payment system" for the permanent payment, "the Secretary *may* . . . consider payment amounts . . . in the private insurance market for home infusion therapy." 42 U.S.C. § 1395m(u)(2) (emphasis added). First, this section plainly states that CMS may—not must—consider private practices in the applicable context. *See id.* Therefore, it would not be arbitrary or capricious for Defendant to decline to consider this factor. Second, these

[1] Broken down further, CBO estimated that there would be a decrease of $260 million in fiscal year 2019, $490 million in fiscal year 2020, and $160 million in fiscal year 2021. *See* BBA 2018 CBO Cost Estimate 2.

considerations apply to the permanent payment, not the temporary transitional payment. Section 1395m(u)(2), which is located in the permanent payment section, explains the factors that Defendant may consider "[i]n developing the payment system" in that section. By contrast, there is no payment system to develop for the temporary transitional payment because Congress has explicitly created one. *See id.* § 1395m(u)(7)(B)–(D) (setting forth the payment methodology, the payment categories, and the payment amounts). Therefore, the factors that CMS may consider in developing the permanent payment system, including consideration of payment amounts in the private insurance market, do not apply to the temporary transitional payment.[2]

[2] Although CMS appreciates the rulemaking comments identifying practices in the private insurance market, as explained above, the statute constrains CMS's ability to consider such practices in implementing the temporary transitional payment.

## III. Conclusion

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

Dated: April 29, 2019

Respectfully submitted,

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