UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAROLINA MEDICAL SALES, INC. *et al.*,		
Plaintiffs,	Civil Action No.:	07-1298 (RMU)
v.	Document Nos.:	15, 19, 24
MICHAEL LEAVITT, In his official capacity as Secretary of the U.S. Dep't of Health and Human Services *et al.*,		
Defendants.		

MEMORANDUM OPINION

GRANTING THE DEFENDANTS' MOTION TO DISMISS;
DEFERRING RULING ON PLAINTIFFS' MOTION TO STRIKE;
FINDING AS MOOT PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I. INTRODUCTION

The court today considers whether to dismiss a complaint filed by two plaintiffs (Carolina Medical Sales, Inc. and Americare Health Systems) in the business of selling diabetic supplies through mail order to Medicare patients against defendants Michael Leavitt (Secretary of the United States Department of Health and Humans Services ("HHS")) and Leslie Norwalk (Acting Administrator of HHS's Centers for Medicare and Medicaid Services ("CMS")). The four-count complaint alleges that the defendants violated the Administrative Procedure Act ("APA"), 5 U.S.C. § 706 and § 553, and the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA"), 42 U.S.C. § 1395hh, by singling out mail-order diabetic supplies as an item and service for competitive bidding without first conducting notice-and-comment rulemaking and without possessing the necessary statutory authority to distinguish items and services based on delivery method. The defendants urge the court to dismiss the complaint on

the grounds that the MMA precludes judicial review, the issue is not ripe, the plaintiffs lack standing, and the plaintiffs fail to state a claim for relief as the decision is committed to agency discretion and was procedurally lawful. The plaintiffs insist that the court possesses subject-matter jurisdiction and that dismissal for failure to state a claim is premature. Because the court concludes that the MMA insulates the Secretary's decision from judicial review, the court grants the defendants' motion to dismiss and dismisses the plaintiffs' complaint. Because the complaint does not survive the motion to dismiss, the court also denies as moot the plaintiffs' pending motion for a preliminary injunction.

II. BACKGROUND

A. Factual History

Title XVIII of the Social Security Act, commonly known as Medicare, 42 U.S.C. §§ 1395 *et seq.*, establishes a national program of health insurance for the elderly and disabled. In 2003, Congress amended Medicare Part B (the supplementary medical insurance program covering healthcare services such as physical visits; outpatient diagnostic tests; and durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS")) to require the HHS Secretary to replace the current fee-schedule pricing system with a competitive bidding program by which businesses would compete for contracts to supply DMEPOS items and services to Medicare beneficiaries. 42 U.S.C. § 1395w-3.

On May 1, 2006, CMS solicited comments for a proposed rule published in the Federal Register to implement a bidding program for certain DMEPOS items. 71 Fed. Reg. 25654. On April 10, 2007, CMS issued a final rule establishing bidding programs in ten metropolitan areas.

72 Fed. Reg. 17992. The final rule stated that the Secretary would designate "the items that are included in a competitive bidding program through program instructions or by other means." 42 C.F.R. § 414.406(d). Subsequently, the Secretary identified mail-order diabetic supplies as such an item on an agency website. Compl. ¶ 39. To participate in the bidding program, mail-order diabetes suppliers must meet certain accreditation and quality standards and submit a competitively priced bid to furnish an item or service. 42 C.F.R. § 414.412(a). After contracts are awarded to winning suppliers, Medicare beneficiaries can only obtain supplies from an entity that has entered into a contract with HHS. 42 U.S.C. § 1395w-3(b)(6)(A)(i)-(ii). Thus, the program distinguishes between mail-order diabetic suppliers and store-front diabetic suppliers, who are not yet included in the program.

On May 15, 2007, CMS issued a request for bids for the first round of the bidding program. Compl. ¶ 46. The bidding window closed on September 25, 2007. Defs.' Mot. to Dismiss at 6; Pls.' Mot. for Prelim. Inj., Ex. A ("Lachat Decl.") ¶ 28. Plaintiff Carolina Medical Supplies did not submit a bid, allegedly because the process "was exceptionally confusing" and because its sole managing employee underwent surgery. Lachat Decl. ¶ 28. Plaintiff Americare Health Systems did submit a bid but was ultimately not awarded a contract. Pls.' Mot. for Prelim. Inj. at 7. On July 1, 2008, sales under the program will commence, at which time the plaintiffs, having not won contracts with HHS, will be excluded from selling mail-order diabetic supplies to Medicare beneficiaries. *Id.* at 1.

B. Procedural History

The plaintiffs filed this complaint on July 20, 2007. Counts 1 and 2 allege that the defendants' promulgation of the final rule and selection of mail-order diabetic supplies as an item

for competitive bidding exceeds their statutory authority under § 706 of the APA and § 1395hh of the MMA, respectively. Compl. ¶¶ 54, 58. Count 3 claims that the defendants failed to follow notice-and-comment procedures in promulgating the final rule. *Id.* ¶ 63. Count 4, a request for mandamus relief, reiterates Count 3, seeking an order for the defendants to follow notice-and-comment rulemaking. *Id.* ¶ 68. On January 11, 2008, the defendants filed a motion to dismiss. Briefing continued with the plaintiffs' opposition but did not conclude with the defendants' reply, as the plaintiffs filed a motion to strike the defendants' reply. A final round of opposition and reply followed. And, on June 3, 2008, the plaintiffs filed a motion for a preliminary injunction to forestall the implementation of the competitive bidding program scheduled to commence on July 1, 2008. With that concluded, the court turns to the motion to dismiss and the motion to strike.

III. ANALYSIS

A. The Court Defers from Ruling on the Plaintiffs' Motion to Strike

The plaintiffs object to a number of arguments and evidence in the defendants' reply brief. In their opening brief the defendants suggest that "if Plaintiffs failed to submit a comment about HHS's proposal to consider delivery mode in implementing a competitive bidding program, they have waived their right to challenge HHS's determination." Pls.' Mot. to Strike at 1 (quoting Defs.' Mot. to Dismiss at 23). The defendants, inappropriately according to the plaintiffs, elaborated on this argument in their reply, submitting two exhibits purporting to demonstrate that the plaintiffs received adequate notice of the defendants' consideration of delivery mode in the proposed rule. *Id.* at 2. The two exhibits are a letter from Apria Healthcare commenting on the proposed rule and the declaration of Joel Kaiser that HHS received no

comments on the rule from the plaintiffs. Defs.' Reply, Attachs. A, B. The plaintiffs urge the court to ignore the exhibits and waiver argument on the grounds that they raise new issues for the first time in the reply and introduce matters outside the pleadings and therefore non-cognizable in a Rule 12(b)(6) motion to dismiss. *Id.* Alternatively, they request leave to file a sur-reply. *Id.* at 3.

The defendants respond that, as an initial matter, motions to strike address only pleadings, not briefs, motions or exhibits. Defs.' Opp'n to Mot. to Strike at 1. The defendants also insist that their opening brief put the plaintiffs on notice that they were raising a waiver argument. Though the argument was phrased hypothetically, it included a citation with an explanatory parenthetical supporting the legal proposition. *Id.* at 3. The defendants further maintain that the exhibits were not attached to argue an issue of fact but merely to rebut the plaintiffs' argument that the final rule was not a "logical outgrowth" of the proposed rule. *Id.* at 4. Moreover, because the defendants have sought dismissal under Rule 12(b)(1) for subject-matter jurisdiction in addition to Rule 12(b)(6), the court may look beyond the pleadings to resolve disputed jurisdictional facts. *Id.* at 5. In reply, the plaintiffs contend that the content of the attached documents do not support the defendants' position, but they have not had an opportunity to argue this point sufficiently. Pls.' Strike Reply at 1. They further insist that the defendants should not be allowed to rely on material to prove disputed jurisdictional facts intertwined with the merits of the plaintiffs' case when the plaintiffs have not had notice or adequate access to the administrative record. *Id.* at 5.

Because the disputes detailed above do not implicate the analysis of the court's subject-matter jurisdiction, and because the court disposes of this motion on the grounds that the MMA

precludes judicial review of the Secretary's challenged decision to include mail-order diabetic suppliers in the bidding program, the court refrains from ruling on the motion to strike at this time.

B. The Plaintiffs do not Demonstrate that the Court has Subject-Matter Jurisdiction

1. Legal Standard for a Motion to Dismiss Pursuant to Rule 12(b)(1)

Federal courts are courts of limited jurisdiction and the law presumes that "a cause lies outside this limited jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994); *St. Paul Mercury Indem. Co. v. Red Cab Co.*, 303 U.S. 283, 288-89 (1938); *see also Gen. Motors Corp. v. Envtl. Prot. Agency*, 363 F.3d 442, 448 (D.C. Cir. 2004) (noting that "[a]s a court of limited jurisdiction, we begin, and end, with an examination of our jurisdiction").

Because "subject-matter jurisdiction is an 'Art. III as well as a statutory requirement[,] no action of the parties can confer subject-matter jurisdiction upon a federal court.'" *Akinseye v. District of Columbia*, 339 F.3d 970, 971 (D.C. Cir. 2003) (quoting *Ins. Corp. of Ir., Ltd. v. Compagnie des Bauxite de Guinea*, 456 U.S. 694, 702 (1982)). On a motion to dismiss for lack of subject-matter jurisdiction pursuant to Rule 12(b)(1), the plaintiff bears the burden of establishing by a preponderance of the evidence that the court has subject-matter jurisdiction. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). The court may dismiss a complaint for lack of subject-matter jurisdiction only if "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Empagran S.A. v. F. Hoffman-Laroche, Ltd.*, 315 F.3d 338, 343 (D.C. Cir. 2003) (quoting *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957)).

Because subject-matter jurisdiction focuses on the court's power to hear the claim,

however, the court must give the plaintiff's factual allegations closer scrutiny when resolving a Rule 12(b)(1) motion than would be required for a Rule 12(b)(6) motion for failure to state a claim. *Macharia v. United States*, 334 F.3d 61, 64, 69 (D.C. Cir. 2003); *Grand Lodge of Fraternal Order of Police v. Ashcroft*, 185 F. Supp. 2d 9, 13 (D.D.C. 2001). Thus, the court is not limited to the allegations contained in the complaint. *Hohri v. United States*, 782 F.2d 227, 241 (D.C. Cir. 1986), *vacated on other grounds*, 482 U.S. 64 (1987). When necessary, the court may consider the complaint supplemented by undisputed facts evidenced in the record, or the complaint supplemented by undisputed facts plus the court's resolution of disputed facts. *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992).

2. Section 1395w-3(b)(10) of the MMA Precludes Judicial Review

The defendants argue that § 1395w-3(b)(10) of the MMA precludes judicial review of the Secretary's preferred implementation of the competitive bidding program, i.e., his decision to select mail-order (as opposed to all) diabetic suppliers for inclusion in the competitive bidding program. Defs.' Mot. to Dismiss at 8. Section 1395w-3(b)(10) reads:

> There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of--
> (A) the establishment of payment amounts under paragraph (5);
> (B) the awarding of contracts under this section;
> © the designation of competitive acquisition areas under subsection (a)(1)(A) of this section;
> (D) the phased-in implementation under subsection (a)(1)(B) of this section;
> (E) the selection of items and services for competitive acquisition under subsection (a)(2) of this section; or
> (F) the bidding structure and number of contractors selected under this section.

42 U.S.C. § 1395w-3(b)(10). In particular, the defendants propose that §§ 1395w-3(b)(10)(D) and (E) bar review. The former insulates from review the "phased-in implementation under subsection (a)(1)(B)" of the competitive bidding programs. Subsection (a)(1)(B) provides that

the bidding programs:

> (i) shall be phased in among competitive acquisition areas in a manner so that the competition under the programs occurs in--
> (I) 10 of the largest metropolitan statistical areas in 2007;
> (II) 80 of the largest metropolitan statistical areas in 2009; and
> (III) additional areas after 2009; and
> (ii) may be phased in first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.

42 U.S.C. § 1395w-3(a)(1)(B). The latter bars from review the "selection of items and services for competitive acquisition under subsection (a)(2) of this section." 42 U.S.C. § 1395w-3(b)(10)(E). Subsection (a)(2) identifies for inclusion DMEPOS items and services as defined in § 1395m(a)(13), included among which are (by reference to § 1395x(n)) "blood-testing strips and blood glucose monitors for individuals with diabetes" that are "used in the patient's home." 42 U.S.C. § 1395m(a)(13).

The defendants characterize the plaintiffs' complaint as a quarrel not with the Secretary's decision to regulate mail-order diabetic suppliers but with the fact that "the Secretary has not also required storefront providers of diabetic suppliers to participate in competitive bidding." Defs.' Mot. to Dismiss at 11. But this discretion, the defendants insist, is legislatively shielded, as the Secretary may require bidding "first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential." *Id.* (citing 42 U.S.C. § 1395w-3(a)(1)(B)(ii)). The defendants advise that the Secretary has not determined yet whether to require bidding among storefront diabetic suppliers or whether to grant such suppliers an exemption, *id.* at 12, but refer the court to the fact that the Secretary singled out mail-order suppliers first because "over 60 percent of Medicare expenditures for diabetic suppliers are for items furnished by nationwide mail order suppliers,"

id. at 11 (citing 72 Fed. Reg. 17992, 18018).

The plaintiffs insist that § 1395w-3(b)(10)(D) does not bar their complaint because they "are not challenging the Secretary's decision to phase-in mail order diabetic supplies first to the competitive bidding program. Rather, plaintiffs' claim is that the Secretary had no authority under the statute to treat 'mail order' diabetic suppliers differently than store front suppliers at any time." Pls.' Opp'n at 12. The defendants essentially concede the point, arguing that the plaintiffs' argument "turns on whether the definition of 'item' the Secretary adopted permits him to consider delivery type." Defs.' Reply at 9. In other words, the question turns on whether § 1395w-3(b)(10)(E) precludes review.

But the court will tarry here a little longer. "Whether and to what extent a particular statute precludes judicial review is determined not only from its express language, but also from the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved." *Block v. Comty. Nutrition Inst.*, 467 U.S. 340, 345 (1984). Thus, § 1395w-3(b)(10) should be interpreted with both a view to its individual subparts and a mind to its structure as a whole.

Focusing on § 1395w-3(b)(10)(D), the court recognizes that Congress explicitly highlighted for the Secretary's attention the early phase-in of items that, due to volume and cost, have the highest savings potential. 42 U.S.C. § 1395w-3(a)(1)(B)(ii). Moreover, Congress projects a schedule in which the bidding program begins in 10 cities in 2007, expands to 80 in 2009, and thereafter extends elsewhere as cost-effective. 42 U.S.C. § 1395w-3(a)(1)(B). Thus, the defendants found that "over 60 percent of Medicare expenditures for diabetic suppliers are for items furnished by nationwide mail order suppliers," 72 Fed. Reg. 17992, 18018.

Accordingly, they concluded that "the implementation of a separate mail order competitive bidding program would result in significant savings because it would focus on suppliers that can obtain discounts from manufacturers because they furnish a large volume of items to beneficiaries through the mail." *Id.*

While the plaintiffs are correct that the discretion of the Secretary to single out mail-order diabetic suppliers cannot be deduced solely from the language and structure of § 1395w-3(b)(10)(D), the provision clearly indicates that Congress contemplated a detailed, scheduled deployment of the competitive bidding program and imbued the Secretary with the authority – immune from judicial review – to economize by accelerating the introduction of cost-effective items and services. *See Block*, 467 U.S. at 351 (holding that presumption favoring judicial review is overcome whenever congressional intent to preclude review is "fairly discernible in the statutory scheme"). And while Congress did include exceptions to the overall goal of cost-containment, such as solicitude for small-businesses, it nowhere evinced a particular concern for delivery method. *See* 42 U.S.C. § 1395w-3(b)(2)(A)(ii) (requiring the Secretary to "tak[e] into account the needs of small providers" in developing financial standards"). Thus, to the extent that the plaintiffs' interpretation limits that economizing discretion – by, for example, forcing the Secretary to ignore the fact that a majority of Medicare expenditures for diabetic suppliers are for items furnished via mail and that significant cost savings are obtainable due to their distribution method – it pulls against the current of Congress's intentions. *See Painter v. Shalala*, 97 F.3d 1351, 1356 (10th Cir. 1996) (holding that overall structure of new medicare Part B payment scheme calling for accelerated agency decision-making bestowed discretion on Secretary barring judicial review).

Having surveyed section 1395w-3(b)(10)(D), the court shifts its attention to section 1395w-3(b)(10)(E), which precludes review of the Secretary's "selection of items and services for competitive acquisition." 42 U.S.C. § 1395w-3(b)(10)(E). The plaintiffs agree that this provision authorizes the Secretary to include DMEPOS items in the bidding program but maintain that it does not confer discretion "to split the diabetic supplies category based on method of delivery." Pls.' Opp'n at 12. The defendants assert[1] that the plaintiffs' "all-or-nothing" interpretation of "items and services" traduces the Secretary's discretion to issue regulations based on cost-relevant distinctions pertaining to delivery method. Defs.' Mot. to Dismiss at 24. They also worry that the plaintiffs' interpretation would nullify § 1395w-3(a)(1)(3)(B), which authorizes the Secretary to exempt "items and services for which the application of competitive acquisition is not likely to result in significant savings." *Id.* And they further propose that the Secretary possesses discretion to discriminate by delivery method by virtue of § 1395hh(a)(1) of the MMA which directs the Secretary to prescribe "such regulations as may be necessary to carry out the administration" of the bidding program. Defs.' Reply at 5.

The plaintiffs dispute the suggestion that their favored interpretation deprives the Secretary of discretion to select items based on cost-effectiveness. For example, while the Secretary would be prohibited from selecting only mail-order diabetic suppliers in competitive bidding, he would be free to select all diabetic suppliers. Pls.' Opp'n at 29. They make the same point vis-a-vis § 1395w-3(a)(1)(3)(B). *Id.* In further support of their position, the plaintiffs note that Congress explicitly authorized consideration of delivery mode in only three instances: (1) the

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[1] The defendants initial arguments concern the validity of their rulemaking procedure rather than their statutory authority to distinguish items based on delivery making in the first place. Defs.' Mot. to Dismiss at 21-23. They are, therefore, irrelevant.

exemption of rural areas and areas with low population density "that are not competitive, unless there is a significant national market through mail order for a particular item or service," 42 U.S.C. § 1395w-3(a)(3)(A); (2) the establishment of a process for "items and services under which a physician may prescribe a particular brand or mode of delivery of an item or service . . . if the physician determines that use of the particular item or service would avoid an adverse medical outcome on the individual," 42 U.S.C. § 1395w-3(a)(5)(A); and (3) clinical diagnostic laboratory tests performed on specimens "furnished by entities that did not have a face-to-face encounter with the individual," 42 U.S.C. § 1395w-3(e)(1). Pls.' Opp'n at 27. Because the defendants' selection of mail-order diabetic supplies for bidding does not fit any of these categories, the Secretary lacks the discretion to consider delivery method. *Id.* at 28. Moreover, the plaintiffs continue, the MMA defines the items subject to bidding to include DMEPOS items as defined in § 1395m(a), which makes no distinction based on delivery method. *Id.*

The plaintiffs are convinced that Congress's silence in regard to delivery method in the text of §1395w-3(b)(10)(E) denotes an intent to omit it from the ambit of the Secretary's discretion, but they read the statute too ungenerously. The provision itself is broad, unqualified, and clear: "There shall be no administrative or judicial review . . . of . . . the selection of items and services for competitive acquisition under subsection (a)(2)." When Congress uses explicit language such as this, the courts recognize its intent to bar review. *See Am. Soc'y of Cataract and Refractive Surgery v. Thompson*, 279 F.3d 447, 453 (7th Cir. 2002); *Am. Soc'y of Dermatology v. Shalala*, 962 F. Supp. 141, 145 (D.D.C. 1996). The absence of any mention of delivery method here or under the definitions of DMEPOS under subsection (a)(2) does not detract from this conclusion. The plaintiffs proffer no reason why Congress would – after

imbuing the Secretary with unreviewable discretion over establishing payment amounts, awarding contracts, designating competitive acquisition areas, phasing-in implementation and determining the bidding structure and number of contractors – decide to carve out an isolated patch for judicial review of the Secretary's implementation of the competitive bidding program based on the Secretary's consideration of delivery method. Indeed, the motivating force behind the amendments establishing the competitive bidding system was to "combat waste" in the Medicare reimbursement system. H.R. Rep. No. 108-178 (II), at Title III § 302. The scope of the other areas of preclusion indicate a scheme to insulate the entire program from review, as does the broad, general language used. *Cf. Santa Cruz County v. Leavitt*, 2008 WL 686831, at *4 (N.D. Cal. Mar. 11, 2008) (collecting cases supporting proposition that "no review" provision "that directly targets all three core components of the overall formula for Part B fee reimbursement" clearly and comprehensively barred judicial review). The focus of § 1395w-3(b)(10)(D) on timing and cost-effective priority militates against the plaintiffs' restrictive interpretation, as does § 1395w-3(a)(1)(3)(B), which authorizes the Secretary to exempt "items and services for which the application of competitive acquisition is not likely to result in significant savings." 42 U.S.C. § 1395w-3(a)(1)(3)(B).

The plaintiffs attempt to persuade the court that Congress deliberately withheld the discretion to select items and services based on delivery method by referring the court to other areas of the statute explicitly contemplating delivery method. The argument is a thoughtful but ultimately unsuccessful application of the canon *expressio unius est exclusio alterius* – expressing one item of an associated group excludes another left unmentioned. The canon does "not apply to every statutory listing or grouping; it has force only when the items expressed are

members of an associated group or series, justifying the inference that items not mentioned were excluded by deliberate choice, not inadvertence. *Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168 (2003) (internal quotations omitted). Section 1395w-3(a)(3)(A), in which Congress exempts from bidding rural and low-population density areas "that are not competitive, unless there is a significant national market through mail order for a particular item or service," actually cuts against the grain of the plaintiffs' argument by revealing Congress's intent to utilize delivery-method distinctions in the bidding program. This is likewise true of § 1395w-3(e)(1), ordering a competitive bidding demonstration project for clinical diagnostic laboratory tests performed on specimens "furnished by entities that did not have a face-to-face encounter with the individual." 42 U.S.C. § 1395w-3(e)(1). Applied here, *expressio unius* is a straight-jacket, resulting in the contorted interpretation that Congress did intend the Secretary to consider delivery method but only in low population-density markets and for a demonstration project for laboratory tests – a cramped conclusion nowhere else suggested in the statute and at odds with the amendments' broad-based cost-saving statutory scheme. *See Am. Medical Ass'n v. Thompson*, 2001 WL 619510, at *4 (N.D. Ill. May 29, 2001) (holding that preclusion provision barred plaintiffs' challenge when plaintiffs failed to suggest any reason why Congress would want to exempt their attack on sub-components of protected formula – but not the formula itself – from preclusion).

The plaintiffs find no refuge in § 1395w-3(a)(5)(A), either. That section, which concerns "items and services under which a physician may prescribe a particular *brand or mode* of delivery of an item or service . . . if the physician determines that use of the particular item or service would avoid an adverse medical outcome on the individual," refers (in the most natural reading) to the delivery method of medicine into the patient's body not into their commercial

possession. 42 U.S.C. § 1395w-3(a)(5)(A) (emphasis added); *cf.* H.R. REP. No. 108-178(I), at 68 (2003) (requiring an investigation of whether suppliers "are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability); *see, e.g.*, *In the Case Of: Comprehensive Prof'l Home Visits v. Ctrs. for Medicare & Medicaid Servs.*, 2004 WL 1764750, at *8 (July 26, 2004) (indicating that "mode of delivery" for patient's oxygen treatment was "TRACH. MIST").

Finally, the fact that delivery method is not an ancillary or collateral aspect of the Secretary's discretion to select items and services under § 1395w-3(b)(10)(E) buttresses the court's conclusion that preclusion applies. Because storefront and mail-order suppliers face different costs and access to geographical markets, discrimination based on delivery method is not an ancillary policy only implicated by the Secretary's selection of "items and services" – it is encompassed in the very act of identifying and selecting items and services. *Cf. Am. Soc'y of Cataract and Refractive Surgery*, 279 F.3d at 452-53 (holding that regulation setting out formula for calculating relative value units was integral part of Secretary's discretionary determination of relative value units and, therefore protected from judicial review). Consequently, the plaintiffs' challenge to the Secretary's decision to discriminate based on delivery method is a direct attack on the Secretary's selection of items and services. *Cf. McNary v. Haitian Refugee Ctr.*, 498 U.S. 479, 492 (1991) (holding that preclusion turned on whether challenge was a collateral attack on practices and policies used in processing an application or a direct challenge to a determination respecting an application). The selection of items and services for inclusion in competitive bidding – because of the composition of the structure of the marketplace itself and the program's focus on cost-saving – necessarily includes relevant distinctions such as delivery method. Thus,

HHS's proposed definition of "item" included "the services directly related to the furnishing of that product to the beneficiary." 71 Fed. Reg. 25,661.

To allow a civil litigant to parse the definition of "items and services" into individually challengeable sub-components would frustrate Congress's intent and potentially hamstring the Secretary's ability to expeditiously implement the bidding program. *See Am. Soc'y of Anesthesiologists v. Shalala*, 90 F. Supp. 2d 973, 976 (N.D. Ill. 2000) (holding that if plaintiffs' position were accepted, "the congressional mandate against court intervention would be totally frustrated, because the opportunity for parties . . . to launch in-court attacks on the individual strands – the specific items – that are both integral to and essential components of the congressionally-protected determinations that Secretary must make would defeat her ability to make the determinations themselves"). Accordingly, if the type of delivery method had no effect whatsoever on the implementation of the competitive bidding program, then the Secretary's decision to distinguish items and services based on delivery method would likely be arbitrary or irrational, which would support the conclusion that delivery method is an ancillary aspect to the selection of items and services. But the plaintiffs have failed to convince the court that this is so and have, therefore, also failed to defeat the defendants' motion to dismiss.

IV. CONCLUSION

For the foregoing reasons, the court grants the defendants' motion to dismiss. An order consistent with this Memorandum Opinion is separately and contemporaneously issued this 19th day of June, 2008.

RICARDO M. URBINA
United States District Judge