**UNITED STATES DISTRICT COURT**
**DISTRICT OF CONNECTICUT**

| | |
|---|---|
| RICHARD BAGNALL, MICHAEL SAVAGE, LEE BARROWS, GEORGE RENSHAW, SARAH MULCAHY, SHIRLEY BURTON, and DENISE RUGMAN, on behalf of themselves and all others similarly situated,<br><br>Plaintiffs,<br><br>v.<br><br>KATHLEEN SEBELIUS, Secretary of Health and Human Services,<br><br>Defendant. | No. 3:11-cv-1703-AWT |

**MEMORANDUM IN SUPPORT OF MOTION TO DISMISS**

**INTRODUCTION**

Medicine is complicated science. Sometimes, when a patient visits a hospital, it is not immediately clear whether she will quickly improve and be sent on her way, or whether she will need to be admitted to the hospital as an inpatient for more intensive treatments. The Centers for Medicare & Medicaid Services (CMS) – the arm of the United States Department of Health and Human Services (HHS) that administers the Medicare program – recognizes this gray area. Thus, it interprets the Medicare Act to encompass "observation services" as a category of outpatient services for which Medicare will provide reimbursement. *See* CMS, Medicare Benefit Policy Manual ("Policy Manual"), Chap. 6, § 20.6 (Rev. 143, December 29, 2011) (attached as Exhibit 1). Observation services include short term treatments and assessments provided to a patient while a doctor makes the "complex medical judgment" of whether to admit a

patient as an inpatient. *Id.; id.*, Chap. 1, § 10 (Rev. 119, January 15, 2010) (attached as Exhibit 2).

This seems all to the good. But plaintiffs – a group of Medicare beneficiaries or their successors (and a putative class of the same) who claim to have received observation services – disagree with CMS's decision to recognize observation services as outpatient services and allege fault with procedural aspects of CMS's recognition of observation services and physicians' delivery of them. Plaintiffs allege that treatments offered during observation services are basically the same as those furnished to inpatients and, consequently, that observation services should be considered inpatient services. Complaint for Declaratory, Injunctive, and Mandamus Relief (Compl.), November 2, 2011, Doc. No. 1, ¶¶ 4, 99, 103. The difference in classification matters, plaintiffs say, because for most Medicare beneficiaries the reimbursement scheme for inpatient services is financially superior to the regime used for outpatient services. *Id*. ¶ 6. Plaintiffs also contend that recognizing observation services interferes with the practice of medicine, in contravention of 42 U.S.C. § 1395, though they do not specify the causal mechanism. *Id.* ¶¶ 106-107. With regard to procedure, plaintiffs (i) lament the procedures that CMS employed in recognizing observation services, insisting that CMS did not provide notice of the proposed interpretation of the Medicare Act and an opportunity to comment on it before it became final, *id.* ¶¶100-101, (ii) decry the fact that CMS's interpretation recognizing observation services has not been published in the Federal Register, *id.* ¶ 102, (iii) insist that patients should receive notice, nearly instantaneously, of information regarding observation services, *id.* ¶ 104, and (iv) assert that CMS does not provide

administrative review of the determination that a patient received observation services, *id.* ¶ 105.

Plaintiffs are wrong on the merits. But the Court need not – indeed, cannot – reach the merits because no plaintiff with standing has exhausted his or her administrative remedies, and under the Medicare Act, that fact precludes the Court from exercising jurisdiction over plaintiffs' claims. Plaintiffs try to circumvent this fundamental problem by invoking mandamus jurisdiction. This effort is to no avail. Mandamus is an extraordinary remedy, and it is not appropriate here because, among other reasons, plaintiffs have other avenues of relief that are not only available but are statutorily required, namely, the unexhausted administrative remedies. What is more, the only plaintiff to have exhausted his administrative remedies lacks standing because he has no existing financial injury and, like the rest of the plaintiffs, lacks standing to seek prospective relief.

If the Court concludes that it has jurisdiction, then dismissal nonetheless is warranted for failure to state a claim upon which relief can be granted. Plaintiffs cannot prevail on their substantive claims. That treatments furnished to patients receiving observation services sometimes share an affinity with those provided to inpatients does not mean that observation services are inpatient services. The word "inpatient" in the relevant section of the Medicare Act means admitted to the hospital as an inpatient. By definition, a patient receiving observation services has not been admitted as an inpatient: the physician is observing the patient to determine *if* s/he should be admitted as an inpatient. Thus, classifying observation services as outpatient services makes sense. Indeed, it would be odd to do otherwise – a person receiving services necessary to

determine if s/he should be admitted as an inpatient would be an inpatient. With respect to plaintiffs' other substantive claim, interpreting the Medicare Act to cover observation services does not interfere with the practice of medicine. CMS does not prohibit or direct any diagnosis or treatment by reimbursing the cost of observation services.

Plaintiffs' procedural allegations also lack merit. CMS had no obligation to engage in notice and comment rulemaking because the notice and comment requirements do not apply to interpretive rules, and the recognition of observation services as outpatient services is an interpretation of the Medicare Act. Nonetheless, CMS has subjected its regulations addressing observation services for public comment. Also, CMS has published its interpretation in the Federal Register. In any case, CMS did not have an obligation to do so. An interpretation must be published in the Federal Register only if the failure to publish would detrimentally affect the public. That is not the case here: knowledge of the interpretation would not change a patient's behavior. Similarly unavailing is plaintiffs' claim that CMS must provide patients notice, nearly instantaneously, regarding a hospital's decision to provide observation services and the consequences, for reimbursement purposes, of receiving such services. CMS cannot provide notice of a potential decision regarding reimbursement before the claim has been received, and CMS, which directs a massive and complex system, will not have received a claim within the hours-long time frame envisioned by plaintiffs. Finally, contrary to plaintiffs' allegation, CMS provides administrative review of observation service claims.

For the above stated reasons, which are elaborated below, the Court should dismiss plaintiffs' suit.

## BACKGROUND

### I. The Medicare Statutory and Regulatory Framework

The Medicare program, established under Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395*iii*, ("Medicare Act"), is a federal health insurance program that pays for covered medical care provided to eligible aged and disabled persons. Two major parts of Medicare, Part A and Part B, pay for medical items and services provided under the program on a "fee-for-service" basis. Medicare Part A authorizes payments for covered inpatient hospital services and other institutional care, including skilled nursing facility and home health care services. *Id.* §§ 1395c, 1395d, 1395i. Medicare Part B establishes a voluntary supplemental insurance program that pays for various medical and other health services and supplies, including physician services, physical, occupational, and speech therapy services, and hospital outpatient services. 42 U.S.C. §§ 1395k, 1395m, 1395x.

Payment rates differ between Parts A and B, and whether a service is covered under Part A or B can affect the coverage of future services. If a person receives hospital services as an inpatient, then (under Part A) she pays a one-time deductible for the first 60 days in the hospital. 42 U.S.C. § 1395e. But if a person receives hospital services as an outpatient, then (under Part B) she owes a co-payment for each individual covered hospital service received. 42 U.S.C. § 1395cc(a)(2)(A). Also, whether hospital services are categorized as outpatient services or inpatient services can affect whether Medicare will cover care received in a skilled nursing facility. For example, Medicare will cover an individual's post-hospitalization care at a skilled nursing facility only if furnished

"after transfer from a hospital in which [the individual] was an inpatient for not less than 3 consecutive days before his discharge." 42 U.S.C. § 1395x(i).

Whether an individual is an inpatient or outpatient depends on whether a person has been admitted to a hospital as an inpatient. Policy Manual, Chap. 1, § 10 ("An inpatient is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services."); *Landers v. Leavitt*, 545 F.3d 98, 111 (2d Cir. 2009) ("[O]ne is an inpatient for the purpose of § 1395x(i) only if one has been formally admitted to a hospital . . . ."). When deciding whether to admit an individual, "[p]hysicians should use a 24 hour period as a benchmark, *i.e.*, they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis." Policy Manual, Chap. 1, §10**.** That said, "the decision whether to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors, including the patient's medical history and current medical needs, the types of facilities available to inpatients and outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting." *Id.* To be more specific, the physician should consider, among other things, "[t]he severity of the signs and symptoms exhibited by the patient; [t]he medical predictability of something adverse happening to the patient; [t]he need for diagnostic studies that appropriately are outpatient services . . . to assist in assessing whether the patient should be admitted; and[,] [t]he availability of diagnostic procedures at the time when and at the location where the patient presents." *Id.*

To aid patients while physicians make this "complex medical judgment" regarding admission, Medicare provides coverage for "observation services" under Part

B. Policy Manual, Chap. 6, § 20.6. "Observation care is a well-defined set of specific clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital." Policy Manual, Chap. 6, § 20.6(A). The observation period should be short, usually less than 24 hours. *Id.* And while there is no hard and fast time limit on observation service, "[i]n only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours." *Id.* Statistics demonstrate that, in fact, most stays are short; in 2006, 97% of observation periods lasted less than 48 hours. Compl. ¶ 48.

## II. The Medicare Claims Review Process

Most of Medicare's payment and review functions under Parts A and B of the Medicare program are performed by Medicare contractors, generally private insurance companies. *See, e.g.*, 42 U.S.C. §§ 1395h, 1395kk-1, 1395u; 42 C.F.R. § 421.200. These contractors review claims for Medicare payment and determine the amount of Medicare payments due for Medicare-covered services provided to program beneficiaries under the Medicare statute, regulations, rulings and interpretive guidelines published by CMS.[1] *See id.*; 42 C.F.R. §§ 421.3, 421.100.

[1] As an alternative to the traditional fee-for-service program offered by Medicare Parts A and B, Congress added Medicare Part C, which gives qualified Medicare enrollees the option of participating in the Medicare Advantage ("MA") program. *Id.* §§ 1395w-21–1395w-28; 42 C.F.R. Part 422. Through the MA program, the Secretary enters into contracts with MA organizations under which MA organizations receive a predetermined payment amount each month for each of their Medicare enrollees in exchange for providing enrollees with services covered by Medicare Parts A and B. This payment, which is known as the "capitation rate," is intended to cover all of the Medicare-covered

Ordinarily, an individual cannot bring claims arising under the Medicare statute, such as the ones in this case, without exhausting his or her administrative remedies. *Illinois Council*, 529 U.S. at 5. Indeed, to challenge coverage and payment determinations, the Medicare statute and regulations afford program beneficiaries extensive opportunities for review, including several levels of administrative review, and, potentially, judicial review. 42 U.S.C. §§ 1395ff, 1395w-22(g); 42 C.F.R. Part 405, Subpart I; 42 C.F.R. Part 422, Subpart M. For services provided to a Medicare beneficiary under Medicare Parts A and B, a contractor performs the initial determination of whether services are covered and the payment amount. 42 C.F.R. §§ 405.904(a)(2), 405.920. If the beneficiary is dissatisfied with contractor's initial determination of whether or to what extent the services are covered by Medicare, the claimant may seek a redetermination from the contractor. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. §§ 405.904(a)(2), 405.940. If dissatisfied with the contractor's redetermination, the beneficiary may then request a reconsideration of the redetermination by a qualified independent contractor (also QIC). 42 U.S.C. § 1395ff(b), (c); 42 C.F.R. §§ 405.904(a)(2) and 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 beneficiary 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), (E); 42 C.F.R. §§ 405.1000(a), 405.1002. The ALJ's hearing decision, in turn, may be reviewed by the

---

services provided by the organization to the enrollee during the month, regardless of the actual costs of such services. 42 U.S.C. §§ 1395w-23 and 1395mm.

Medicare Appeals Council (also MAC) of the Departmental Appeals Board. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2); 42 C.F.R. § 405.1000, 405.1100, 405.1102, 405.1104, and 405.1110. The MAC'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. § 405.1136; *see also* 42 C.F.R. § 405.1130.[2]

**III. Plaintiffs' Complaint**

Plaintiffs – seven individuals who sue on behalf of themselves (or the estates they administer) and a putative class of similarly situated individuals – allege that CMS has impermissibly interpreted the Medicare statute and regulations in concluding that observation services are outpatient services. Compl. ¶ 4. And, they continue, the Secretary's actions have hurt them or the estate because if observation services were covered as inpatient services under Part A, rather than outpatient services under Part B, they would have benefitted financially. *Id.* ¶ 6. In the alternative, they maintain that even if the Secretary has not erred as a substantive matter, she has erred by failing to afford Medicare beneficiaries adequate procedural protections, such as the use of notice and comment rulemaking. Compl. ¶ 101. By way of remedy, plaintiffs seek an injunction prohibiting the recognition of observation status and requiring the Secretary to: pay for services that would have been covered had the patient not been covered under Part B for observation services, but instead Part A; provide better notice regarding observation services; and furnish administrative review of the decision of whether and to what extent observation services are covered. They also seek a declaration to the effect that the recognition of observation status violates the Medicare statute, 42 U.S.C. § 1395

[2] Beneficiaries who enroll in a MA plan under Part C follow a similar administrative appeals process. *See* 42 U.S.C. § 1395w-22(g); 42 C.F.R. Part 442.

*et seq.*, Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq.*, Freedom of Information Act (FOIA), 5 U.S.C. § 552, and the Due Process Clause, U.S. Const., Amend. 5. Compl., Prayer for Relief, para. 3-4.

## STANDARDS

"Dismissal for lack of subject matter jurisdiction under [Federal] Rule [of Civil Procedure]12(b)(1) is proper when the district court lacks the statutory or constitutional power to adjudicate [a case]." *Austin v. Fischer*, 2011 WL 6450728, at *2 (2d Cir. Dec. 23, 2011). "Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause." *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 94 (1998) (internal quotation marks omitted). When resolving a motion to dismiss for lack of jurisdiction, the Court may consider evidence outside of the pleadings. *Luckett v. Bure*, 290 F.3d 493, 496-97 (2d Cir. 2002). Under Rule 12(b)(6), dismissal of a count is appropriate when it "fail[s] to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6).

## ARGUMENT

### I. The Court Lacks Jurisdiction over Plaintiffs' Claims.

#### A. The Medicare Act Provides the Exclusive Jurisdictional Basis for Plaintiffs' Claims and Requires that Plaintiffs Exhaust.

Judicial review of "any claim arising under" the Medicare Act may be obtained only as provided under the Act, 42 U.S.C. §§ 405(h), 1395*ii*; *see Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 10-12 (2000); a claim arises under the Medicare Act if the Act provides "both the standing and the substantive basis" for the claims, *see Weinberger v. Salfi*, 422 U.S. 749, 757-64 (1975). The Act provides that district courts have jurisdiction to conduct judicial review of Medicare claims only if the

claimant has obtained a "final decision" from the Secretary. 42 U.S.C. §§ 405(g), 1395ff(b), 1395w-22(g)(5); *see also* 42 C.F.R. §§ 405.1130, 405.1136; *Illinois Council*, 529 U.S. at 5.

Under the Medicare statute and regulations, to obtain a final decision (*i.e.*, to exhaust administrative remedies), a beneficiary 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 Qualified Independent Contractor, (4) request a hearing from an administrative law judge (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).

While a final decision ordinarily comprises these five elements, the final four elements may be waived by the Secretary or, in exceptional circumstances not present here, a court. *Mathews v. Eldridge*, 424 U.S. 319, 328, 330 (1976). But the first element – the presentment requirement – is nonwaivable. *Illinois Council*, 529 U.S. at 15 ("Section 405(g) contains the nonwaivable and nonexcusable requirement that an individual present a claim to the agency before raising it in court."). And judicial review under the general federal question jurisdiction statute, 28 U.S.C. § 1331, which plaintiffs invoke, *see* Am. Compl. ¶ 10, is simply unavailable. *See* 42 U.S.C. §§ 405(h), 1395*ii*; *Ill. Council on Long Term Care*, 529 U.S. at 10-25.

The Supreme Court has characterized the § 405(h) bar to other avenues of review as "sweeping and direct," *see Salfi*, 422 U.S. at 757, 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 on Long Term Care*, 529 U.S. at 14. *See also Your Home Visiting Nurse Serv., 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 exhaustion and exclusive judicial review provisions of the Medicare statute.

The Supreme Court has repeatedly rejected efforts to read Section 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 614-615. 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; Salfi*, 422 U.S. at 760-761.[3]

In this case, the Medicare Act furnishes the "standing and substantive basis" for plaintiffs' claims. That the Medicare Act provides the alleged basis for plaintiffs' standing is clear from plaintiffs' allegations that interpreting the Medicare Act to cover

[3] *See Salfi*, 422 U.S. at 760-61 ("It would, of course, be fruitless to contend that appellees' claim is one which does not arise under the Constitution, since their constitutional arguments are critical to their complaint. But it is just as fruitless to argue that this action does not also arise under the Social Security Act."); *Ringer*, 466 U.S. at 616, 621-22 ("Ringer's claim may well 'aris[e] under' the APA in the same sense that Salfi's claim arose under the Constitution, but we held in Salfi that the constitutional claim was nonetheless barred by § 405(h).").

observation services as outpatient services under Part B supposedly denied plaintiffs of the financial benefits of coverage under Medicare Part A. *See* Compl. ¶ 6. It is similarly clear that the Medicare Act provides the "substantive basis" for plaintiffs' claims. Plaintiffs' substantive claims rest on the premise that interpreting the Medicare Act to cover observation services as outpatient services violates the Act, and as relief for these claims, plaintiffs seek injunctions requiring the payment of Medicare Part A benefits, *see Ringer*, 466 U.S. at 615-16. Plaintiffs' procedural claims – regarding the notice and/or publication requirements of the APA, Medicare Act, FOIA, and Due Process Clause – too "aris[e] under" the Medicare Act. *See Ringer*, 466 U.S. at 614-15. The claims phrased in terms of the Medicare Act speak for themselves. Compl. ¶¶ 101, 104-105. The APA claims depend, among other things, on whether defendant's policies regarding observation services amount to a legislative rule or an interpretative one. *Id.* ¶¶ 100, 102. This assessment requires an interpretation of statutory provisions to determine if the rule derives meaning from the text of the Act or creates law where the Medicare Statute left a gap. *See Sweet v. Sheahan*, 235 F.3d 80, 91 (2d Cir. 2000); *Ill. Council on Long Term Care*, 529 U.S. at 14. The FOIA publication claim requires knowledge of the challenged interpretation of the Medicare Act and its likely effects, as publication is required only if the failure to publish would have detrimental effects. And plaintiffs' Due Process related claims require knowledge of the limited entitlement protected by the Medicare Act, the operation of the claim reimbursement system, and the notice currently given beneficiaries, which again implicates the Medicare Act. *Id.* ¶¶ 104, 105. In this way, plaintiffs' assertions are all "inextricably intertwined" with the Medicare Act and thus arise under it. *Ringer*, 466 U.S. at 614-15.

Five of the six plaintiffs have not obtained decisions from the Medicare Appeals Council and, thus, have not exhausted their administrative remedies. See Compl. ¶¶56-95. Only one of the named plaintiffs – Lee Barrows – has obtained a decision from the Medicare Appeals Council. Notice of Administrative Decisions, Jan. 6., 2012, Doc. No. 22, Ex. 1. But the MAC ruled in Mrs. Barrows' favor, concluding, as a factual matter, that her now-deceased husband's stay at the hospital was an inpatient stay. *Id.* at 6. Concomitantly, the MAC held that his inpatient stay and subsequent SNF care would be covered under Part A. *Id.* at 11-12. This holding eliminated any past financial harm and, by extension, standing to seek retrospective relief. *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352, (2006) ("[A] plaintiff must demonstrate standing separately for each form of relief sought.") (internal quotation marks omitted); Compl., Prayer for Relief, ¶¶ 4(d), (e). And none of the plaintiffs has standing to seek prospective relief, including Mrs. Barrows; Mrs. Barrows represents an estate, and an estate could never be furnished observation services. *See* Section I.B. below. Thus, no plaintiff *with standing* has obtained a decision from the MAC.[4]

B. This Court Lacks Mandamus Jurisdiction Over Plaintiffs' Claims.

As a fallback position, plaintiffs invoke mandamus jurisdiction. Compl. ¶¶ 96-98. Under 28 U.S.C. § 1361, the "district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." Mandamus "is an extraordinary

[4] Notably, it appears that none of the plaintiffs have raised with the agency the issue on which they now sue, namely, whether observation services may be classified as outpatient services. Compl.¶¶ 56-95. Rather, they appear to have challenged the conclusion that they received observation services. *See, e.g.*, Compl. ¶ 77 ("Mr. Renshaw's estate requested reconsideration of the determinations that his hospital stay was for observation status and therefore covered under Part B rather than Part A. . . .").

remedy available only in extraordinary circumstances[.]" *Aref v. United States*, 452 F.3d 202, 206 (2d Cir. 2006) (quotation marks and citations omitted). Mandamus "may be awarded only if the plaintiff proves that (1) there is a clear right to the relief sought; (2) the Government has a plainly defined and peremptory duty to perform the act in question; and (3) there is no other adequate remedy available." *Benzman v. Whitman*, 523 F.3d 119, 132-33 (2d Cir. 2008).

Mandamus jurisdiction is unavailable to plaintiffs. For one thing, the named plaintiffs have another adequate remedy, which Congress provided, indeed required: review under the Medicare Act. "Our holding that the plaintiffs must exhaust their administrative remedies also disposes of plaintiffs' alternative argument for mandamus relief because one of the requisites for obtaining a writ of mandamus is that the plaintiffs have exhausted all other adequate remedies." *Abbey v. Sullivan*, 978 F.2d 37, 47 (2d Cir. 1992). All of the named plaintiffs with any standing to sue had or have administrative remedies available to them under CMS regulations. Thus, they all have another adequate remedy. Mandamus would hardly be an extraordinary remedy if it were available to everyone who neglected to pursue their administrative remedies. Plaintiffs similarly cannot establish the other prerequisites to mandamus relief. For example, plaintiffs' substantive claims depend on the contention that the Medicare Act cannot be interpreted to permit observation services to be classified as outpatient services. But plaintiffs have not identified the statutory text that prohibits this interpretation, and none is evident. Relatedly, as plaintiffs cannot show a clear right to relief (i.e., cannot demonstrate that observation services must be considered inpatient services), they cannot demonstrate that the Secretary has a clear duty to consider observation services as inpatient services.

In short, the Court lacks jurisdiction over this action because the named plaintiffs cannot establish jurisdiction under the Medicare Act or the mandamus statute.

C. Plaintiffs Lack Standing to Seek Prospective Relief Because They Do Not Face Imminent Future Injury.

All of the plaintiffs lack standing to the extent they seek prospective relief. Plaintiffs seek prospective relief in the form of injunctions regarding the recognition of observation services, the notice that must be provided to Medicare beneficiaries receiving observation services, and the administrative review procedures available to those who received observation services. Compl., Prayer for Relief, ¶¶ 4(a), (b), (c). To obtain prospective relief a plaintiff must face the imminent prospect of being injured by the allegedly improper conduct. *See, e.g., Los Angeles v. Lyons*, 461 U.S. 95, 107-08 (1983). The estate plaintiffs cannot seek prospective relief because they will never seek medical care, and therefore will never be potentially harmed by the recognition of observation services or any of the alleged procedural defects related to the provision of these services. *Stauber v. City of New York*, 2004 WL 1593870, at *17 (S.D.N.Y. July 19, 2004); *Blake v. Southcoast Health Sys.*, 145 F. Supp. 2d 126, 136-37 (D. Mass. 2001). The two non-estate plaintiffs, like the plaintiff in *Lyons*, have not pleaded that they are imminently likely to be harmed by the challenged decision (here that observation services are outpatient services). And even if they had made such an allegation, they have provided no support for the proposition that the odds that they imminently will visit the hospital and be furnished observation services "are sufficient to make out a federal case for equitable relief." *Lyons*, 461 U.S. at 108. Thus, the Court should dismiss the claims for prospective relief for lack of standing.

## II. Plaintiffs Fail to State a Claim Upon Which Relief May Be Granted.

### A. Count I Should Be Dismissed Because Recognition of Observation Services as Outpatient Services Comports with the Medicare Statute.

Plaintiffs allege that "defendant violates" 42 U.S.C. § 1395d(a) of "the Medicare statue and the purpose of Medicare Part A, which is to provide coverage for hospitalization and for follow up SNF care after hospitalization for an acute event," by "allowing observation status . . . to deprive intended beneficiaries of Part A coverage." Compl. ¶ 99.

This claim fails because plaintiffs misread Part A and misunderstand observation status. The Medicare Act does not require coverage for all care in a hospital under Part A, as plaintiffs suggest. *Id.* Rather, the Medicare Act specifies, in relevant part, that Part A covers "inpatient" hospital care (with exceptions). 42 U.S.C. § 1395d(a). Indeed, the section of the statute cited by plaintiffs is entitled "Entitlement to payment for *inpatient hospital services*, post-hospital extended care services, home health services, and hospice care." *Id.* The word "inpatient" has a well-defined meaning: It means admitted to the hospital as an inpatient.[5] *See* CMS, Medicare Benefit Policy Manual ("Policy Manual") Chap. 1, § 10 (Rev. 119, Jan. 15, 2010) ("An inpatient is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services."); *Landers v. Leavitt*, 545 F.3d 98 (2d Cir. 2009) (upholding CMS's definition of "inpatient" in a related context).[6] Thus, Part A does not cover everything done within the

[5] The decision whether to admit a patient as an inpatient rests initially with a patient's doctors, as reflected by the Policy Manual which discusses the factors that a doctor must consider in making this medical judgment.

[6] CMS's interpretation of the word "inpatient" cannot be seriously challenged: (i) it is longstanding, *see Landers*, 545 F.3d at 107-08; (ii) it is consistent with the interpretation of the same word in other parts of the statute, *id.* at 108, (iii) it is relatively formal

confines of a hospital, even when a patient stays overnight: it does not cover emergency room services (in most instances), Policy Manual, Chap. 6, § 20.5.1; it does not cover outpatient diagnostic tests performed at the hospital, *id.*, Chap. 6, § 20.4(A); and it does not cover observation services, *id.*, Chap. 6, § 20.6. Patients receiving these services – including observation services – are not inpatients. *Id.*, Chap. 6, § 20.6(A). Indeed, patients receive observation services specifically so that doctors can make the "complex medical judgment" of whether to admit them as an inpatient. *Id.*, Chap. 1, §10; Chap. 6, § 20.6. And nothing in the Medicare statute indicates that hospitals must instantly make inpatient admission decisions. In short, as the Second Circuit already decided in *Landers*, observation status does not deprive patients of Part A coverage for time spent in the hospital because, by definition, persons receiving observation services have not been admitted as inpatients and are not covered by Part A.

The other aspect of plaintiffs' allegation in paragraph 99 similarly lacks merit. Part A does not cover all SNF care "after hospitalization for an acute event." Compl. ¶ 99. Rather, the Medicare Act dictates that coverage of SNF care under Part A is available after 3 days of hospitalization as an *inpatient*. 42 U.S.C. §§ 1395d(a)(2), 1395x(i); *Landers*, 545 F.3d at 103. Again, plaintiffs ignore the fact that care received in a hospital is not synonymous with inpatient care. More specifically, a patient receiving observation services is not an inpatient. And to the extent plaintiffs disagree with the conclusion that

---

(insofar as it appears in a generally applicable, published guidance manual), *id.* at 110; (iv) it is consistent with statutory text, *id.* at 111; (v) it is consistent the Second Circuit's decision on a nearly identical issue, *id.* at 111-23; and (vi) "HHS interpretations, in particular, should receive more respect than the mine-run agency interpretations" because it is "a highly expert agency [ ] administer[ing] a large complex regulatory scheme in cooperation with many other institutional actors," *id.* at 107 (quotation marks and citation omitted).

observation services are inpatient services insofar as later SNF care is concerned, they run headlong into *Landers*, in which the Second Circuit upheld the Secretary's determination that days spent receiving observation and emergency services did not count toward the three-day minimum inpatient requirement. 545 F.3d at 111-12. Plaintiffs cannot relitigate *Landers* in this Court.[7]

B. Counts II and III Fail Because Notice and Comment Obligations Apply to Legislative Rules, Not Interpretative Rules Like the One at Issue Here, and CMS submitted the Rule for Notice and Comment.

In Count II, plaintiffs contend that "defendant's policy of allowing hospitals to place beneficiaries on observation status violates the notice and comment requirements of the [APA]" because CMS did not first publish a proposed rule and allow members of the public to comment on it. Compl. ¶ 100. Count III is to similar effect, but it alleges a violation of the Medicare Act's notice and comment requirements. *Id.* ¶ 101. The same standard applies to notice and comment claims brought under these two statutes, so they are addressed together. *See Baptist Health v. Thompson*, 458 F.3d 768, 776 n.8 (8th Cir. 2006) (citing *Erringer v. Thompson*, 371 F.3d 625, 633 (9th Cir. 2004)).

It is not clear exactly what "rule" plaintiffs contend should have been promulgated by notice and comment, as they never identify a specific provision. Defendant's best guess is that plaintiffs mean to challenge the conclusion in the Policy Manual that "when a physician orders that a patient receive observation care, the patient's status is that of an outpatient." Policy Manual, Chap. 6, § 20.6(B); see Compl. ¶¶ 4,6. If plaintiffs intend to challenge this statement (or related ones in the Policy Manual), then

[7] Plaintiffs' counsel in this case were the plaintiffs' counsel in *Landers*, but they did not argue in that case that observation services should be considered in-patient services in all contexts. 598 F.3d at 104.

their claims fail because these Policy Manual provisions are interpretive, not legislative, and therefore not subject to notice and comment requirements. In any case, CMS has solicited comments on observation services.

Notice and comment requirements apply to legislative rules, not interpretative rules. 5 U.S.C. § 553(b). Legislative rules "are those that create new law, rights, or duties, in what amounts to a legislative act." *Sweet v. Sheahan*, 235 F.3d 80, 91 (2d Cir. 2000) (quotation marks and citation omitted). On the other hand, "interpretive rules . . . do not create rights, but merely clarify an existing statute or regulation." *Id.* (quotation marks and citations omitted). *See also White v. Shalala*, 7 F.3d 296, 303 (2d Cir. 1993).

The apparently challenged statement in the Policy Manual is an interpretive rule. It does not create new law. Rather, it clarifies the meaning of 42 U.S.C. § 1395d(a)(1), which limits Part A coverage to "inpatient hospital services." That is, in specifying that a patient receiving observation services is an outpatient, it makes clear that the phrase "inpatient hospital services" means those services furnished to a patient who has been admitted to the hospital as an inpatient. Policy Manual, Chap. 6, § 20.6(B). (Individuals receiving observation services have not been admitted as inpatients, of course, because the purpose of observation services is to allow a physician to determine whether a patient should be admitted to a hospital as an inpatient.) *Landers* leaves no doubt that this task is interpretative. *Landers* resolved a dispute over the meaning of the word "inpatient" in a related context – *i.e.*, in the context of the statutory provision that requires a beneficiary to spend three consecutive days as an "inpatient" to have post-hospitalization SNF care covered – and deemed the task an interpretative one. *See, e.g.*, *Landers*, 545 F.3d at 104-05. Indeed, another court in this circuit has explained that "the Medicare Benefit Policy

Manual . . . [is] issued by the Centers for Medicare and Medicaid Services [ ] as an interpretive guide to the Medicare statute and regulations." *Kaplan ex rel. Estate of Kaplan v. Leavitt*, 503 F. Supp. 2d 718, 722 (S.D.N.Y. 2007). Thus, the notice and comment requirement is inapplicable to the interpretive Policy Manual provision, and plaintiffs' claims fail.

In any case, plaintiffs' claim fails because CMS has solicited comments on observation services in many rulemakings. *See, e.g.*, 63 Fed. Reg. 47552, 47570 (Sept. 8, 1998); 65 Fed. Reg. 18434, 18448 (Apr. 7, 2000); 69 Fed. Reg. 50448, 50532 (Aug. 16, 2004); 69 Fed. Reg. 65682, 65828 (Nov. 15, 2004); 70 Fed. Reg. 42674, 42742-45 (July 25, 2005); 70 Fed. Reg. 68516, 68688-95 (Nov. 10, 2005). *See also* 70 Fed. Reg. 29070, 29098-100 (May 19, 2005) (addressing observation services in context of Medicare SNF coverage), 70 Fed. Reg. 45026, 45050 (Aug. 4, 2005) (same).

C. Count IV is Meritless Because CMS had Published the Interpretation in the Federal Register, and the FOIA Requires Federal Register Publication of Only Those Interpretations That Detrimentally Affect the Public.

Plaintiffs maintain that "observation status" is invalid because "[t]he Freedom of Information Act requires publication in the Federal Register 'of substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency,'" and "observation status meets this criterion, but it has not been published in the Federal Register." Compl. ¶ 102 (quoting 5 U.S.C. § 552(a)(1)(D)).

This claim lacks merit.[8] First, CMS has published its interpretation of the Medicare statute (*i.e.*, that observation services are outpatient services) in the Federal Register. *See, e.g.*, 71 Fed. Reg. 67960, 68151 (Nov. 24, 2006) ("[A]ll hospital observation services, regardless of the duration of the observation care, that are medically reasonable and necessary are covered by Medicare, and hospitals receive either packaged or separate OPPS [outpatient prospective payment system] payment for these covered observation services.").

Second, the FOIA, in any case, does not require publication. As explained earlier, the challenged Policy Manual provision is not a legislative, or substantive, rule. *Sweet*, 235 F.3d at 91 n.7 (explaining that the term "substantive rule" is a synonym for "legislative rule"). Thus, the question is whether the provision is an "interpretation of general applicability" that must be published in the Federal Register. The answer to that question is no. The Second Circuit has held that "the requirement for publication attaches only to matters which if not published would adversely affect a member of the public." *State of New York v. Lyng*, 829 F.2d 346, 354 (2d Cir. 1987). The public would not be adversely affected by the failure to publish the Policy Manual provision in the Federal Register. Publication of the conclusion that observation services are not inpatient services in the Federal Register would not allow a member of the public to alter her behavior to her benefit, or, for that matter, to alter a doctor's decision to place her in observation status. A patient receives observation services because a doctor needs more time to make the "complex medical judgment" of whether to admit the patient as an

[8] Plaintiffs again fail to specify the precise target of this claim, so defendant again understands plaintiffs to be challenging the Policy Manual provision discussed in relation to the previous claim.

inpatient. Policy Manual, Chap. 1, §10. Knowing that observation services are covered by Part B rather than Part A would not change this situation in any way.[9] In short, CMS had no obligation to publish the interpretation in the Federal Register.

D. Count V Should Be Dismissed Because Policies Cannot Be Challenged in the Abstract and CMS's Interpretation of the Medicare Act Must be Upheld.

Count V states that "[d]efendant's policy of allowing hospitals to limit or prevent Medicare coverage to which beneficiaries are otherwise entitled, by allowing beneficiaries to be deemed on observation status, violates the [APA's] prohibition against agency action that is arbitrary, capricious, or an abuse of discretion, 5 U.S.C. § 706(2)(A)." Again, plaintiffs miss the mark. Under the APA, a plaintiff can challenge only discrete actions, not "policies"; courts are not über-administrative bodies put in place to second guess agency policy decisions. In any case, the interpretation embodied in the Policy Manual, assuming that is the target of plaintiffs' fire, is proper.

Plaintiffs assail "defendant's *policy* of allowing hospitals to place beneficiaries on observation status." Compl. ¶ 100 (emphasis added). But "the federal courts are not authorized to review agency policy choices in the abstract." *Fund for Animals, Inc. v. U.S. Bureau of Land Mgmt.*, 460 F.3d 13, 18 (D.C. Cir. 2006). Under the APA, Courts review only final agency actions. *Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 62 (2004). Plaintiffs do not specify what specific final agency action they challenge. Is it some statement in the Policy Manual? A regulatory provision? Something else? Plaintiffs cannot leave the Court and defendant guessing. Ignoring statutory limitations

[9] What is more, the interpretation of the statute to the effect that observation services are outpatient services is publicly available in the Policy Manual and in a bulletin put out by Medicare, CMS, "Are You a Hospital Inpatient or Outpatient?," available online at http://www.medicare.gov/publications/pubs/pdf/11435.pdf. It is also consistent with the publicly available holding in *Landers*.

that confine courts to reviewing discrete agency actions risks entangling courts in "abstract policy disagreements which [they] lack both expertise and information to resolve." *Id.* at 66. The risk is particularly great in the Medicare context because of the complexity of the legal regime at issue. *See, e.g.*, *Illinois Council*, 529 U.S. at 13 (describing Medicare as a "massive, complex health and safety program). Accordingly, plaintiffs' request that the Court weigh in to any policy dispute they have with CMS is inappropriate; courts review discrete, final agency actions. This is most particularly true in Medicare case where Congress has provided for review of final decisions of the Secretary. *Heckler*, 466 U.S. at 614-615. Plaintiffs have not identified any such action.[10]

If plaintiffs mean to challenge as "arbitrary and capricious" the conclusion that observation services are outpatient services – and, therefore, not covered by Part A – then that claim fails for the reasons that Count I fails. Part A covers certain inpatient medical services. 42 U.S.C. § 1395d(a). The word "inpatient" refers to a person admitted to the hospital as an inpatient. *See* Policy Manual, Chap. 1, § 10 ("An inpatient is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services."). Indeed, the Second Circuit upheld this very interpretation of inpatient in a related context, concluding that "one is an inpatient for the purpose of [42 U.S.C.] § 1395x(i) only if one has been formally admitted to a hospital. *Landers*, 545 F.3d at 111-12. And observation services are provided to determine if an individual should be admitted as an inpatient; they are not furnished to persons admitted as inpatients. Policy Manual, Chap. 6, § 20.6. Given that Part A covers inpatient services, and observation services by definition are not provided to inpatients, the conclusion that

[10] This argument applies to all of plaintiffs' claims in which they challenge defendant's "policy," rather than a specified agency action.

observation services are outpatient services – and, therefore, covered by Part B rather that Part A – is ineluctable, not "arbitrary or capricious."

E. Count VI Fails Because Plaintiffs Either Already Receive the Notice They Seek, or Seek Notice to Which They Are Not Entitled.

Plaintiffs assert that "defendant's fail[ ] to provide written notification to Medicare beneficiaries . . . of their placement on observation status, of the consequences of that placement for their Medicare coverage, and of their right to challenge the placement" and that this violates the Medicare statute and the Due Process Clause of the Fifth Amendment. Compl. ¶ 104. This claim should be dismissed. Depending on how it is interpreted, plaintiffs either already receive all that they ask for, or ask for something to which they have no entitlement.

Plaintiffs' own complaint sows the seeds of the demise of one possible version of this claim. Earlier in the complaint, plaintiffs admit that patients receive a written notice informing them that they received observation services and of the "consequence of that" fact (*i.e.*, that these services are covered by Part B, rather than Part A). "Their first formal notification from Medicare occurs when they receive the [Medicare Summary Notice], which summarizes all of their Medicare activity for the most recent three-month period, including an indication that they were covered under Part B (if they were in original Medicare) while they were hospitalized." Compl. ¶ 42. The MSN also informs plaintiffs of their right to challenge the determination that they received observation services covered by Part B. An MSN states that, to appeal "any claims decision on this notice," the beneficiary should "[c]ircle the item(s) you disagree with and explain why

you disagree." Sample Part B MSN, at 2 (attached as Exhibit 3).[11] Thus, the MSN provides plaintiffs with all the information to which they claim an entitlement.

Plaintiffs may mean to allege that they are entitled to a notice, such as the MSN, while they are in the midst of or before receiving observation services. *See* Compl. ¶42. This allegation is incorrect. The Medicare Act does not require that plaintiffs be given instantaneous notice of a potential claims determination that has not yet been made, such as the decision to cover observation services under Part B. Such determinations need only be made (at the earliest) within 30 days of the receipt of a standard, error-free claim. 42 U.S.C. § 1395ff(a); 42 C.F.R. § 405.922.

Nor does the Due Process Clause require plaintiffs' unrealistic requested notice. "[N]o person may be deprived of life, liberty, or property by an adjudicatory process without first being afforded notice and a full opportunity to appear and be heard, appropriate to the nature of the given case." *In re the Drexel Burnham Lambert Group*, 995 F.2d 1138, 1144 (2d Cir. 1993). Importantly, the "notice requirement" should not be interpreted so as to make it an "impractical or impossible obstacle." *Id.* To the extent a Medicare beneficiary has an interest protected by the Due Process Clause, it is a property interest in the "entitlement to have payments made on his behalf." 42 U.S.C. § 1395d(a). A patient receiving observation services has not been deprived of any benefit because the government has not made any decision on the beneficiary's claim for benefits. Indeed, it would not even have received the claim in the short window that a patient receives

[11] The MSN may be considered in resolving the Rule 12(b)(6) motion both because the MSN is incorporated by reference in the Complaint, *see* Compl. ¶ 42, and is judicially noticeable as a public record. *See Sira v. Morton*, 380 F.3d 57, 67 (2d Cir. 2004) (discussing consideration of documents incorporated by reference); *Pani v. Empire Blue Cross Blue Shield*, 152 F.3d 6, 75 (2d Cir. 1998) (discussing judicial notice of public records under Rule 12(b)(6)).

observation services, especially as they would be ongoing. Thus, plaintiffs seek to make the notice requirement an impossible obstacle: Plaintiffs ask that CMS provide notice of a possible decision before it has been presented with the claim requiring a decision. Neither law nor reason countenances such a practice.[12] Plaintiffs may respond that Medicare beneficiaries have a right to notice of the interpretive rule embodied in Policy Manual. But this assertion also fails. Plaintiffs have identified no property interest in receiving notice about an interpretative rule, well in advance of any determination regarding their claims. *Cf. Schulz v. Green County, State of Wis*., 645 F.3d 949, 952 (7th Cir. 2011).

F. Count VII Should be Dismissed Because Defendant's Policy is to Provide Medicare Beneficiaries with the Right to Administrative Review.

Plaintiffs allege that "[d]efendant's policy of not providing Medicare beneficiaries with the right to administrative review, including expedited review, of their placement on observation status violates the Medicare statute . . . and the Due Process Clause of the Fifth Amendment." Compl. ¶ 105. This claim may be dispatched quickly: It is the policy of CMS to provide administrative review of determinations regarding payment and coverage under Medicare Part B. The MSN informs a Medicare beneficiary that s/he received observation services, which are covered by Part B. Compl. ¶ 42. And, fatal to plaintiffs' claim, the MSN also informs the beneficiary that "any claims decision on this notice" can be appealed by "[c]ircl[ing] the item(s) you disagree with and explain[ing] why you disagree." Sample Part B MSN, at 2. Indeed, according to plaintiffs' own

[12] It is important to note that (i) observation services are not categorically exempt from reimbursement, but rather are covered by Medicare Part B, not Part A, and (ii) a Medicare beneficiary dissatisfied with an initial determination regarding the coverage of observation services may avail herself of a panoply of administrative remedies before a final reimbursement determination is made.

allegation, six of the seven named plaintiffs have administratively appealed the determination that they received observation services. Compl. ¶¶ 56-88. Moreover, Mrs. Barrows won her appeal: The MAC concluded that, as a factual matter, Mr. Barrows – on whose behalf Mrs. Barrows sues – had not received observation services, but that his stay had been an inpatient stay. Notice of Administrative Decisions, Jan. 6., 2012, Doc. No. 22, Ex. 1, at 6**.** Only one plaintiff has not been allowed to appeal that determination, according to plaintiffs' allegations. Compl. ¶ 95. But as demonstrated by the text of the MSN, if true, that is at worst a mistake – not a policy. *See Bowen v. Yuckert*, 482 U.S. 137, 157 (1987) (O'Connor, J., concurring) (explaining that the "Secretary faces an administrative task of staggering proportions in applying" the Medicare statute to process all Medicare claims, and "[p]erfection in processing millions of such claims annually is impossible."); *Mercer v. Birchman*, 700 F.2d 828, 835 (2d Cir. 1983) ("[i]t has never been expected that" a "vast" claims-processing department of government "can achieve absolute procedural perfection").

G. Counts VIII and IX Lack Merit Because CMS Has Not Supervised or Controlled the Practice of Medicine.

Plaintiffs maintain that defendant has interfered with the practice of medicine, in violation of 42 U.S.C. § 1395, by (i) "allowing hospitals to place Medicare beneficiaries on observation status based on criteria that are not publicly known" and (ii) "allowing hospitals, through their utilization review committees, to reverse the decision of a beneficiary's physician to formally admit the beneficiary as an inpatient, and to retroactively place that beneficiary on observation status[.]" Compl. ¶¶ 106-107.

Little time needs to be spent on these claims, as defendant's actions have not "infringe[d] on [the] professional judgment" of physicians. *Home Health Care, Inc. v.*

*Heckler*, 717 F.2d 587, 591 (D.C. Cir. 1983). Section 1395 provides, in relevant part, that "[n]othing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided. . . ." Sensibly, then, when evaluating a claim that the government had impermissibly interfered with the practice of medicine, the Second Circuit looked to whether the challenged regulation "direct[ed] or prohibit[ed] any kind of treatment or diagnosis." *Goodman v. Sullivan*, 891 F.2d 449, 451 (2d Cir. 1989).

Under this standard, neither of plaintiffs' claims withstands even the mildest scrutiny. Recognition of observation services as outpatient services does not "direct" or "prohibit" any kind of treatment or diagnosis; it simply provides coverage under Part B for services furnished to a patient while a doctor and hospital make the complex medical judgment of whether to admit a Medicare beneficiary as an inpatient.[13] The physician can still make any diagnosis and recommend any treatment that s/he thinks is appropriate. Nor does allowing utilization review committees to reverse a physician's decision of how to classify services rendered "direct" or "prohibit" any diagnosis or treatment. (A utilization review committee is a committee of private medical professionals, including at

[13] Contrary to plaintiffs' allegations, the basic criteria for the receipt of observation services are not publicly unknown. The Policy Manual, which is available online, explains that "Observation care is a well-defined set of specific clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital." Policy Manual, Chap. 6, § 20.6(A). Also, Medicare has posted a bulletin on the internet explaining observation services: "Observation services are hospital outpatient services given to help the doctor decide if the patient needs to be admitted as an inpatient or can be discharged." CMS, "*Are You a Hospital Inpatient or Outpatient?*," available online at http://www.medicare.gov/publications/pubs/pdf/11435.pdf.

least two doctors, who assess hospital admissions and stays to determine if they are medically necessary. 42 C.F.R. §§ 482.30(b), (c); *see Blum v. Yaretsky*, 457 U.S. 991 (1982)). The decision reflects a judgment, by a group of health care professionals, on how care should be administratively classified; it does not constitute a decision by CMS that certain treatment or diagnosis is favored or verboten. Even if one thinks the decision to classify observation services as outpatient care influences some medical decisions, that influence does not constitute impermissible interference with the practice of medicine, because "if tangential influence alone violates § 1395, then the Secretary would scarcely be able to regulate the Medicare program at all." *Goodman*, 891 F.2d at 451.

## CONCLUSION

For the reasons stated above, the Court should dismiss plaintiffs' suit.

Dated: January 9, 2012

Respectfully submitted,

TONY WEST
Assistant Attorney General

DAVID B. FEIN
United States Attorney

SHEILA LIEBER
Deputy Branch Director

s/Justin M. Sandberg
JUSTIN M. SANDBERG (Fed. Bar # phv01491)
U.S. Dept. of Justice, Civil Division
Federal Programs Branch
20 Massachusetts Ave., N.W., Rm. 7302
Washington, DC 20001
Telephone: (202) 514-5838
Facsimile: (202) 616-8202
justin.sandberg@usdoj.gov

Attorneys for Defendant

**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF CONNECTICUT**

| | | |
|---|---|---|
| RICHARD BAGNALL, *et al.*, on behalf of themselves and all others similarly situated,<br><br>Plaintiffs,<br><br>v.<br><br>KATHLEEN SEBELIUS, Secretary of Health and Human Services,<br><br>Defendant. | ) | Case No. 3:11-CV-1703 (AWT)<br><br>January 9, 2012 |

**CERTIFICATE OF SERVICE**

I hereby certify that on January 9, 2012, a copy of the Memorandum in Support of the Motion to Dismiss and the accompanying exhibits were served on all parties via ECF-system generated e-mails sent to the following individuals:

Alice Bers
Judith A. Stein
Mary T. Berthelot
Gill W. Deford
Center for Medicare Advocacy, Inc.
P.O. Box 350
Willimantic, CT 06226

Respectfully submitted,

TONY WEST
Assistant Attorney General

DAVID B. FEIN
United States Attorney

SHEILA LIEBER
Deputy Branch Director

s/Justin M. Sandberg
JUSTIN M. SANDBERG (Fed. Bar # phv01491)

U.S. Dept. of Justice, Civil Division
Federal Programs Branch
20 Massachusetts Ave., N.W., Rm. 7302
Washington, DC 20001
Telephone: (202) 514-5838
Facsimile: (202) 616-8202
justin.sandberg@usdoj.gov

Attorneys for Defendant