UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

RICHARD BAGNALL, et al., Plaintiffs, v. KATHLEEN SEBELIUS, Secretary of Health and Human Services, Defendant.	No. 3:11cv1703 (MPS)

MEMORANDUM OF DECISION

A lot turns on whether a Medicare recipient is classified as an "inpatient" when she is hospitalized. The inpatient classification matters because, under Medicare, reimbursement rates for otherwise identical services differ dramatically for inpatients and outpatients. Under Medicare Part A—which covers inpatient hospital services and certain post-hospital extended care, including care at a skilled nursing facility ("SNF"), *see* 42 U.S.C. §§ 1395d(a), 1395x(i)—a beneficiary whom a hospital admits as an inpatient pays a one-time deductible for the first sixty days in the hospital; by contrast, under Medicare Part B, which applies to hospital services provided to beneficiaries who are not "inpatients," the beneficiary owes a co-payment for every individual hospital service. The inpatient/outpatient classification also affects the cost of post-hospitalization care at a SNF, as Medicare covers such care only "after transfer from a hospital in which [the individual] was an *inpatient* for not less than 3 consecutive days before his discharge." *Id.* § 1395x(i) (emphasis added).

The Medicare statute leaves the critical term "inpatient" undefined, but Defendant Kathleen Sebelius, Secretary of the Department of Health and Human Services, has interpreted the term to mean "*a person who has been admitted to a hospital* for bed occupancy for purposes of receiving inpatient hospital services." Centers for Medicare and Medicaid Services ("CMS"),

Medicare Benefit Policy Manual ("Policy Manual"), CMS Pub. No. 100-02. Ch. 1, § 10 (emphasis added). In other words, the Secretary leaves the classification to the discretion of doctors and hospitals by tying it to their determination as to whether formally to admit a beneficiary.

The Secretary's decision to make this critical benefits classification hinge on whether a beneficiary has been formally admitted to a hospital has cost each of the fourteen plaintiffs in this case thousands of dollars, because each spent several nights in the hospital without being formally admitted (two of the plaintiffs were initially admitted but their admission was later revoked) and, thus, each was denied Part A coverage. Unfortunately for these plaintiffs, however, the Second Circuit already upheld the Secretary's decision to define "inpatient" status by reference to formal hospital admission in *Estate of Landers v. Leavitt*, 545 F.3d 98 (2d Cir. 2008).

In an attempt to circumvent *Landers*, the plaintiffs target not the definition of "inpatient" but a related classification—known as "observation status"—that was applied to each of them while in the hospital. Observation status is a classification that hospitals apply to beneficiaries who are receiving certain services in a hospital while the decision about whether to admit the beneficiary is pending. Plaintiffs claim that the Secretary's recognition or "use" of this classification operates to deny them Part A coverage to which they are entitled, and also violates various procedural requirements. Plaintiffs cannot fully sidestep *Landers*, however, as many of their claims rest on theories that *Landers* rejected when it upheld the Secretary's decision to tie Part A coverage to formal admission. And those of Plaintiffs' claims not foreclosed by *Landers* fail as a matter of law. For reasons detailed below, the Court grants the Secretary's Motion to Dismiss [Dkt. # 23] under Rule 12(b)(6) as to all causes of action stated in the Plaintiffs'

Complaint [Dkt. # 1] and Complaint in Intervention [Dkt. # 53], and denies as moot Plaintiffs' Motions for Class Certification and Appointment of Class Counsel [Dkt. ## 2, 51] and Defendant's Motion to Stay Discovery [Dkt. # 35].

I. Background

A. The Medicare Framework

Medicare provides health insurance to the nation's elderly and is codified under Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1. Medicare contains four distinct programs, referred to as "parts." *See Landers*, 545 F.3d at 103. Two of these programs—Part A and Part B—are at issue in this case. Part A covers inpatient hospital services and various other institutional care, including SNF care. *See* 42 U.S.C. § 1395d. More specifically, Section 1395d(a) creates an entitlement to Part A coverage for "inpatient hospital services" and "post-hospital extended care services." The statute provides in relevant part:

> The benefits provided to an individual by the insurance program under [Part A] shall consist of entitlement to have payment made on his behalf or, in the case of payments referred to in section 1395f(d)(2) of this title to him (subject to the provisions of this part) for—
>
> (1) inpatient hospital services . . .
>
> (2) (A) post-hospital extended care services . . . .

42 U.S.C. § 1395d(a).

Both "inpatient hospital services" and "post-hospital extended care services" are statutorily defined terms, and both definitions make reference to "inpatient," a term left undefined. The term "inpatient hospital services" is defined to mean:

> the following items and services *furnished to an inpatient of a hospital* . . . —
>
> (1) bed and board;

(2) such nursing services and other related services, such use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients, and such drugs, biologicals, supplies, appliances, and equipment, for use in the hospital, as are ordinarily furnished by such hospital for the care and treatment of inpatients; and

(3) such other diagnostic or therapeutic items or services, furnished by the hospital . . . as are ordinarily furnished to inpatients either by such hospital . . . .

42 U.S.C. § 1395x(b) (emphasis added). And "[t]he term 'post-hospital extended care services' means extended care services furnished to an individual after transfer from a hospital *in which he was an inpatient* for not less than 3 consecutive days before his discharge from the hospital in connection with such transfer." *Id.* § 1395x(i) (emphasis added).

Part B establishes a voluntary program of supplemental medical insurance—for which enrollees pay a monthly premium—covering an assortment of medical services, including physician services, nurse practitioner services, home health care, and hospital outpatient services. *Id.* §§ 1395k, 1395m, 1395x. Hospital services may be covered under Part A or Part B, depending on whether the Medicare beneficiary received inpatient or outpatient services.

The payment mechanisms differ under Part A and Part B, with significant financial consequences for beneficiaries depending on whether the services provided to them are classified as inpatient or outpatient services. Under Part A, a beneficiary pays a one-time deductible for "inpatient hospital services," as defined above, furnished during the first sixty days spent in the hospital. *Id.* § 1395e. By contrast, Part B requires that a Medicare beneficiary make a copayment for any outpatient hospital services she receives. *Id.* § 1395cc(a)(2)(A). In addition, a component of Part A benefits is coverage for qualifying post-hospitalization SNF care for up to one hundred days. *See id.* §§ 1395d(a)(2), 1395x(i). As the definition set forth above makes clear, however, eligibility for this SNF care is limited to those beneficiaries who have been hospital inpatients for at least three consecutive calendar days prior to their discharge from the

hospital. *Id.* § 1395x(i). Under this statutory framework, a Medicare beneficiary covered under Part A would pay dramatically less than a Part B enrollee would pay for equivalent hospital or SNF care. Thousands of dollars may turn on whether a beneficiary received inpatient or outpatient hospital services.

The statutory provisions governing Part A do not define the term "inpatient." *See id.* §§ 1395d(a), 1395x(b), 1395x(i). Nonetheless, the Secretary, through CMS, an office within the Department of Health and Human Services that administers Medicare, has defined the term as follows in the Medicare Benefit Policy Manual issued by CMS:

> An inpatient is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. Generally, a patient is considered an inpatient if formally admitted as inpatient with the expectation that he or she will remain at least overnight and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight.

Policy Manual, Ch. 1, § 10. The Policy Manual states that the decision whether to admit a patient is a "complex medical judgment" that should be made by the "physician or other practitioner responsible for a patient's care at the hospital," and that "[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." *Id.* Acknowledging the complexity of the determination, the Policy Manual articulates "a number of factors" that a physician should consider, "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.*

Rather than admitting an individual as an inpatient, the hospital may instead place the individual on "observation status," in which case the services she receives will be considered "observation services." The Medicare Policy Manual defines "observation care" as follows:

> 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. Observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge.

Policy Manual, Ch. 6, § 20.6(A). Thus, according to the Policy Manual, observation care is provided for the purpose of monitoring a patient to determine whether he or she should be formally admitted as an inpatient. *Id.* § 20.6(B) ("The purpose of observation is to determine the need for further treatment or for inpatient admission."). Because patients on observation status are not yet "inpatients," the services they receive while on observation status are covered under Part B as outpatient services. (Compl. [Dkt. # 1] at ¶ 4); Policy Manual, Ch. 6, § 20.6(B) ("When a physician orders that a patient receive observation care, the patient's status is that of an outpatient."); *see also id.* § 20.2 ("A hospital outpatient is a person who has not been admitted by the hospital as an inpatient"). The consequence is that beneficiaries who are placed on observation status have a greater financial responsibility for the hospital services they receive—and for any subsequent SNF stay—than if they had been admitted as inpatients and the services were covered under Part A. (Compl. [Dkt. # 1] at ¶ 6.)

B. Individual Plaintiffs

The Plaintiffs are fourteen Medicare beneficiaries, or representatives of their estates, who were taken to a hospital for various acute medical conditions between 2009 and 2011.[1] (*See* Compl. [Dkt. # 1] at ¶¶ 56-95; Compl. in Intervention [Dkt. # 53] at ¶¶ 57-90.) Several of the

[1] Seven of the fourteen named Plaintiffs moved to intervene in this action. As part of an order permitting their intervention, the Court adopted the parties' stipulation that all of the Secretary's arguments in her motion to dismiss, which was pending at the time, would apply to the Intervenor Plaintiffs. (*See* Order [Dkt. # 52] at 2.) The Complaint in Intervention alleges the same claims for relief as the original complaint. (Compl. in Intervention [Dkt. # 53].)

Plaintiffs were hospitalized after suffering a fall, having a seizure, or after surgery, while others were hospitalized for dizziness, weakness, nausea, hypertension, and severe pain. (*Id.*) Each of the Plaintiffs was hospitalized for periods ranging from three to seven days, and while in the hospital the Plaintiffs received diagnostic, monitoring, and treatment services, including EKGs, CT scans, x-rays, IV fluids, IV medication, oral medication, physical therapy, occupational therapy, consultations with specific medical departments, and prophylactic measures to prevent the development of other conditions such as deep-vein thrombosis. (*Id*.) Rather than being formally admitted to the hospital as inpatients, most of the Plaintiffs were placed on observation status for the duration of their hospital stay, despite receiving services similar to those provided to admitted patients. (*Id.*) Two of the Plaintiffs, Lawrence Barrows and Martha LeYanna, were initially admitted to the hospital but later had their status changed to observation during their hospital stay. (Compl. in Intervention [Dkt. # 53] a ¶¶ 78-81; Compl. [Dkt. # 1] at ¶¶ 67-71.)

Each of the Plaintiffs suffered serious financial consequences as a result of the fact that they were not admitted and were instead placed on observation status. Because they were not considered inpatients, the medical services that Plaintiffs received while in the hospital were covered under Medicare Part B rather than Part A. (Compl. [Dkt. # 1] at ¶¶ 58, 63, 69, 76-77, 80, 86, 92; Compl. in Intervention [Dkt. # 53] at ¶¶ 59, 65, 70, 75, 80, 84, 89.) As a result, most of the Plaintiffs were required to make coinsurance payments, ranging in amounts from $335, (Compl. [Dkt. # 1] at ¶ 81), to $825, (Compl. in Intervention [Dkt. # 53] at ¶ 59).[2] In addition, after being discharged from the hospital, each of the Plaintiffs received post-hospitalization care

[2] Plaintiffs received notice of Part B coverage and coinsurance charges via Medicare Summary Notices ("MSNs"), which they typically received several weeks or months after being discharged from the hospital. It is a fair inference from the Complaint that many of the Plaintiffs were not aware, during their period of hospitalization, that they were on observation status rather than admitted inpatients. For most, if not all, of the Plaintiffs, the MSN was the first indication that the services would be covered under Part B, not Part A.

at a SNF. (*See* Compl. [Dkt. # 1] at ¶¶ 59, 64, 70, 76, 81, 87, 93; Compl. in Intervention [Dkt. # 53] at ¶¶ 60, 65, 70, 75, 80, 84, 90.) Because they were on observation status during their hospital stays, and therefore were not considered "inpatients," Plaintiffs' subsequent SNF care was not covered under Medicare Part A. (*See id.*) Plaintiffs' out-of-pocket costs arising from their SNF care ranged from just under $4,000 (Compl. in Intervention [Dkt. # 53] at ¶ 75) to over $30,000 (Compl. [Dkt. # 1] at ¶ 70).

Plaintiff Sarah Mulcahy's experience is illustrative. After being taken to the emergency room for severe pain, urinary incontinence, and nausea, Ms. Mulcahy was hospitalized from June 25 to June 29, 2010. (Compl. [Dkt. # 1] at ¶ 79.) During her hospitalization she received IV medications for nausea and vomiting. (*Id.*) The doctor also ordered incentive spirometry (a device to assist lung functioning) to prevent respiratory infection and venodynes (compression cuffs) to prevent deep vein thrombosis. (*Id.*) She had chest and rib X-rays and a CT scan of the head. (*Id.*) Ms. Mulcahy was initially placed on observation status and remained in that status for the entire duration of her stay. (*Id.* at ¶ 80.) Several weeks later, she received a Medicare Summary Notice stating she was responsible for approximately $335 in Part B coinsurance payments for outpatient claims. (*Id.*) Because she was never formally admitted to the hospital and therefore did not satisfy the three-day rule, her subsequent SNF care, from June 29 to October 7, 2010, was not covered by Medicare. The cost of that care, which she paid for out of pocket, was about $30,000. (*Id.* at ¶ 81.)

C. Plaintiffs' Claims

Plaintiffs bring this putative class action against the "use" of observation status, which, according to Plaintiffs, deprives "thousands of Medicare beneficiaries annually of Part A coverage for their hospitalization and [denies] coverage of their follow-up nursing home care."

(Pls.' Opp'n [Dkt. # 39] at 1.) According to Plaintiffs, "[b]oth the incidence of placing beneficiaries on observation status and the average time period in which beneficiaries are on observation status have been increasing dramatically in recent years." (Compl. [Dkt. # 1] at ¶ 5.) The growth in the use of observation status, say Plaintiffs, stems from financial incentives created by a Medicare billing rule: "If a beneficiary is admitted but that admission is later found to be improper, the hospital must refund the Part A payment to Medicare but cannot rebill under Part B. Consequently, hospitals have an incentive to place patients on observation status because that placement at least ensures that the hospital will receive some payment for the stay in the hospital." (Compl. [Dkt. # 1] at ¶ 46.) Plaintiffs do not challenge this particular Medicare billing rule, which the Secretary recently revised. *See* 42 C.F.R. § 414.5.

Instead, Plaintiffs challenge the Secretary's "use" of "observation status," alleging that it violates the Medicare statute, both substantively and procedurally (First, Third, Sixth, Seventh, Eighth, and Ninth Causes of Action); violates the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 553 and 706(a)(2) (Second and Fifth Causes of Action); violates the Freedom of Information Act ("FOIA") (Fourth Cause of Action); and violates the Due Process Clause of the Fifth Amendment (Sixth and Seventh Causes of Action, again). More specifically, the First Cause of Action alleges that "[b]y allowing observation status, a billing mechanism, to deprive intended beneficiaries of Part A coverage," the Secretary violates the Medicare statute and "the purpose of Medicare Part A, which is to provide coverage for hospitalization and for follow-up SNF care . . . as established in 42 U.S.C. § 1395d(a)." (Compl. [Dkt. # 1] at ¶ 99.) The Second and Third Causes of Action allege that the Secretary's "policy of allowing hospitals to place beneficiaries on observation status" violates the notice-and-comment requirements of the Administrative Procedure Act and the Medicare statute, respectively. (*Id.* at ¶¶ 100-01.) The

Fourth Cause of Action alleges that "observation status" has not been published in the Federal Register in violation of the Freedom of Information Act, 5 U.S.C. § 552(a)(1)(D). (*Id.* at ¶ 102.) The Fifth Cause of Action alleges that the Secretary's "policy of . . . allowing beneficiaries to be deemed on observation status" violates the Administrative Procedure Act's prohibition against agency action that is arbitrary, capricious, or an abuse of discretion. (*Id.* at ¶ 103.)

The Sixth Cause of Action alleges that, by not requiring that beneficiaries receive written notification of their placement on observation status, the consequences of that status, and their "right to challenge" that status, the Secretary violates both the Medicare statute's notice requirements and the Due Process Clause of the Fifth Amendment. (*Id.* at ¶ 104.) The Seventh Cause of Action alleges that the Secretary'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. (*Id.* at ¶ 105.) The Eighth Cause of Action alleges that the Secretary's "policy of allowing hospitals to place Medicare beneficiaries on observation status based on criteria that are not publicly known interferes with the practice of medicine in violation of the Medicare statute, 42 U.S.C. § 1395." (*Id.* at ¶ 106.) Finally, the Ninth Cause of Action alleges that the Secretary's "policy of allowing hospitals, through their utilization review committees," to reverse the decision to admit the beneficiary as an inpatient, and retroactively to place that beneficiary on observation status, "interferes with the practice of medicine in violation of the Medicare statute, 42 U.S.C. § 1395." (*Id.* at ¶ 107.)[3]

[3] Plaintiffs assert these claims on behalf of themselves and all other person similarly situated. Accordingly, Plaintiffs have filed motions to certify a class and appoint class counsel under Rule 23 of the Federal Rules of Civil Procedure. [Dkt. # 2, 51]. Plaintiffs have requested certification of the following class: "All Medicare beneficiaries who, on or after January 1, 2009, have had or will have had any portion of a stay in a hospital treated as observation status and

II. Standard of Review

The Secretary moves to dismiss Plaintiffs' claims under Rule 12(b)(1) and Rule 12(b)(6). The standard for ruling on a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1) is well established. "A case is properly dismissed for lack of subject matter jurisdiction . . . when the court lacks the statutory or constitutional power to adjudicate it." *Makarova v. U.S.*, 201 F.3d 110, 113 (2d Cir. 2000). On a motion to dismiss under Rule 12(b)(1), the party asserting subject matter jurisdiction bears the burden of proving by a preponderance of the evidence that jurisdiction exists. *See id.* The Court may refer to evidence outside the pleadings to assist in its determination. *See id.*

On a motion to dismiss under Rule 12(b)(6), the Court accepts as true all factual allegations in the complaint and draws all reasonable inferences from those allegations in the light most favorable to the plaintiff. *See Harris v. Mills*, 572 F.3d 66, 71 (2d Cir. 2009). To survive a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks and citation omitted).

III. This Court Has Jurisdiction under the Doctrine of Judicial Waiver

The Secretary argues that the Court lacks subject matter jurisdiction because Plaintiffs—with the exception of the Barrows estate—have not exhausted their administrative remedies. (Def.'s Mem. of Law [Dkt. # 24] at 10-14.) All Plaintiffs have presented their claims to the Secretary, however, and the remaining pertinent pre-suit requirement—that each Plaintiff complete the administrative adjudication process by obtaining a "final decision" of the Secretary

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therefore not covered under Medicare Part A." (Pl.'s Mem. in Supp. Mot. to Cert. Class [Dkt. # 2-1] at 3.)

before coming to federal court—is subject to "judicial waiver" because of the nature of Plaintiffs' claims. The Court thus has jurisdiction and denies the Secretary's Rule 12(b)(1) motion.

Medicare borrows the judicial review procedures of the Social Security Act. *See* 42 U.S.C. § 1395ii (adopting procedures). The Supreme Court described the operation of these provisions as follows: "42 U.S.C. § 405(h) precludes federal-question jurisdiction in an action challenging denial of claimed benefits. The only avenue for judicial review is 42 U.S.C. § 405(g), which requires exhaustion of the administrative remedies . . . ." *Mathews v. Eldridge*, 424 U.S. 319, 327 (1976); *see* 42 U.S.C. § 405(h) ("No action against . . . the [Secretary] . . . shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter."); *see also Shalala v. Ill. Council on Long Term Care Inc.*, 529 U.S. 1, 10-12 (2000). Section 405(g) review is available where the claimant has obtained a "final decision" from the Secretary. 42 U.S.C. § 405(g). In light of this jurisdictional framework, the Secretary argues that the Court lacks jurisdiction under § 405(g) because Plaintiffs have not obtained final decisions from the Secretary, and that the Court cannot hear the claims under 28 U.S.C. § 1331 because they arise under the Medicare Act and thus fall within the jurisdictional bar of § 405(h).

The exhaustion requirement, however, is subject to judicial waiver. As the Supreme Court explained in *Mathews*, the "final decision" requirement embodied in § 405(g):

> consists of two elements, only one of which is purely "jurisdictional" in the sense that it cannot be "waived" . . . . The waivable element is the requirement that the administrative remedies prescribed by the Secretary be exhausted. The non-waivable element is the requirement that a claim for benefits shall have been presented to the Secretary.

424 U.S. at 328; *see also City of N.Y. v. Heckler*, 742 F.2d 729, 734 (2d Cir. 1984), *aff'd sub nom. Bowen v. City of N.Y.*, 476 U.S. 467 (1986). The Secretary does not dispute that Plaintiffs

have met the (non-waivable) presentment requirement. The question, then, is whether waiver of the exhaustion requirement is appropriate for those Plaintiffs who, unlike the Barrows estate, have not exhausted their administrative remedies.

If the Secretary has not waived § 405(g)'s exhaustion requirement, a court may do so "where a claimant's interest in having a particular issue resolved promptly is so great that deference to the agency's judgment [not to waive the requirement] is inappropriate." *Mathews*, 424 U.S. at 330; *see also Heckler*, 742 F.2d at 736 ("[The exhaustion requirement] may be waived . . . , in appropriate circumstances, by the courts."). Three factors inform whether a court should waive the exhaustion requirement: "collaterality," irreparable harm, and futility. *Heckler*, 742 F.2d at 736. That is, courts may waive the requirement "where [a] plaintiff's legal claims are collateral to the demand for benefits, where exhaustion would be futile, or where the harm suffered pending exhaustion would be irreparable." *Id.* Observing that the waiver inquiry is a "practical" one, the Second Circuit has "taken the view that no one factor is critical" and that courts should instead balance "competing considerations to arrive at a just result under the circumstances presented." *Id.*

Judicial waiver of the exhaustion requirement is appropriate in this case. To begin with, Plaintiffs' claims are substantially—though not wholly—collateral to their claims for Medicare benefits. In the Second Cause of Action, for example, Plaintiffs allege that the Secretary's "policy of allowing hospitals to place beneficiaries on observation status violates the notice-and-comment requirements" of § 553 of the APA. (Compl. [Dkt. # 1] at ¶ 100.) This claim is based on statutory authority distinct from the provisions of the Medicare statute that form the basis of Plaintiffs' claims to benefits, and prevailing on the § 553 claim would not automatically entitle Plaintiffs to Medicare benefits. The Second Cause of Action is therefore collateral—i.e., it is

separate and distinct from Plaintiffs' claims to Medicare benefits. *See Landers v. Leavitt*, 232 F.R.D. 42, 46 (D. Conn. 2005) ("[T]he agency's policy . . . is collateral to the plaintiffs' claims. To prevail on the claim raised here is not to prove eligibility for benefits.").[4] So too with many of Plaintiffs' other claims: the Third Cause of Action, which alleges violations of Medicare's notice-and-comment requirements; the Fourth Cause of Action, which asserts violations of FOIA; the Sixth and Seventh Causes of Action, which allege that the Secretary provided inadequate notice and insufficient administrative review in violation of the Medicare statute and the Due Process Clause of the Fifth Amendment; and the Eighth and Ninth Causes of Action, which assert that two different aspects of the Secretary's policy "interfere[] with the practice of medicine in violation of the Medicare statute." (Compl. [Dkt. # 1] at ¶¶ 101-02, 104-07.) These claims are based on statutory or constitutional provisions distinct from the statutory provisions governing Plaintiffs' eligibility for Part A benefits, and, if Plaintiffs prevailed, they would not automatically be entitled to the Medicare benefits they seek. *See Landers*, 232 F.R.D. at 46.[5]

To be sure, the First Cause of Action is closely related to Plaintiffs' claims for Medicare benefits, as it asserts that the Secretary's use of observation status "violates the Medicare statute and the purpose of Medicare Part A," in that it deprives them of Part A coverage for hospitalization and follow-up SNF care under 42 U.S.C. § 1395d(a). (Compl. [Dkt. # 1] at ¶ 99.)[6] And the same goes for the Fifth Cause of Action, which alleges that the Secretary's policy

[4] Although the District Court's decision in *Landers* was appealed (as discussed below), the jurisdictional issue was apparently not raised on appeal.

[5] Some of these causes of action are based on provisions of the Medicare statute; however, they raise claims that are fundamentally distinct from Plaintiffs' claims for benefits.

[6] There is, to be sure, a distinction between an individual claim for benefits that asserts that a particular beneficiary should have been formally admitted instead of being placed on "observation status," on the one hand, and a global claim that the use of the designation, "observation status," is inconsistent with the Medicare statute as a general matter. As the Court understands it, the former claim is the specific claim each plaintiff is pressing in the

"of allowing hospitals to limit or prevent Medicare coverage to which beneficiaries are otherwise entitled, by allowing beneficiaries to be deemed on observation status," is arbitrary and capricious. (*Id.* at ¶ 103.) Unlike the claims discussed above, the First and Fifth Causes of Action are not collateral to Plaintiffs' claims for benefits, because they challenge the substantive standard applied to their benefit determinations, specifically, they challenge the Secretary's decision to deny Part A coverage to persons placed on "observation status," i.e., persons who are not formally admitted to the hospital but are receiving hospital services substantively identical to those provided to persons who have been admitted.

With respect to irreparable harm—the second so-called *Eldridge* factor—Plaintiffs have made "a colorable claim of irreparable harm." At the district court level in *Landers*, Judge Hall found in circumstances nearly identical to this case that the plaintiff–Medicare beneficiaries made "a colorable claim of irreparable harm where denial of benefits potentially subjected claimants to deteriorating health, and possibly death." 232 F.R.D. at 46 (internal quotation marks and alterations omitted). All of the Medicare beneficiaries in this case faced grave and deteriorating health conditions, and possible death, during their hospitalization and at subsequent SNF stays. At least one of the beneficiaries described in the complaint, Nettie Jean Sapp, was forced to transfer out of SNF care—which Medicare did not cover—and into an assisted living facility because she could no longer afford the out-of-pocket costs of SNF care.[7] Ms. Sapp later

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administrative proceedings, while the latter claim is, as the First Cause of Action, the claim Plaintiffs are pressing in Court. Nonetheless, both types of claims would, if successful, lead to the beneficiary's being found entitled to the benefits at issue. Accordingly, both types of claims are non-collateral.

[7] Ms. Sapp was hospitalized from April 21 through April 26, 2010, after experiencing weight loss, weakness, memory loss, and several falls. (Compl. [Dkt. #1] at ¶¶ 83-85.) Because she was on observation status for the duration of her hospital stay, her subsequent care in a SNF, from April 26 through June 24, 2010, was not covered by Medicare. (*Id.* at ¶ 87.) Ms. Sapp's

died at the assisted living facility. (Compl. [Dkt. #1] at ¶ 87.) Like Ms. Sapp, some Plaintiffs may be forced to forego needed medical care in the future, causing further health deterioration, while an administrative appeal is pending. For these Plaintiffs, winning an administrative appeal would not remediate the harm done to them by an initial denial of benefits. *See Fox v. Bowen*, 656 F. Supp. 1236, 1243-44 (D. Conn. 1987) ("Many of the plaintiffs who discontinued their physical therapy prematurely so as not to exhaust their personal financial resources will never be able to achieve as complete a recovery as would have been possible had their benefits not been initially denied.").

The Supreme Court has made clear that "[t]he ultimate decision of whether to waive exhaustion should not be made solely by mechanical application of the *Eldridge* factors, but should also be guided by the policies underlying the exhaustion requirement." *Bowen v. City of N.Y.*, 476 U.S. at 484.[8] This is not a case where "a claimant [alleges] mere deviation from the applicable regulations in his particular administrative proceeding." *Id.* In such cases (i.e., those predicated merely on an alleged *misapplication* of established standards), individual administrative errors "are fully correctable upon subsequent administrative review since the claimant on appeal will alert the agency to the alleged deviation," and "[b]ecause of the agency's expertise in administering its own regulations, the agency ordinarily should be given the opportunity to review application of those regulations to a particular factual context." *Id.* at 484-85; *see also Abbey v. Sullivan*, 978 F.2d 37, 45 (2d Cir. 1992) ("The policies favoring exhaustion are most strongly implicated by actions . . . challenging the *application* of concededly valid

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family paid roughly $9,200 out of pocket to the skilled nursing facility before Ms. Sapp moved to an assisted living facility because she could no longer afford SNF care. (*Id.*)

[8] As Plaintiffs observe, (Pls.' Opp'n [Dkt. # 39] at 17), this policy-based analysis is often referred to as a consideration of "futility." *See Abbey v. Sullivan*, 978 F.2d 37, 45 (2d Cir. 1992) ("[S]aying that exhaustion would be futile is merely another way of stating that the policies underlying the exhaustion requirement do not apply in a given case.").

regulations." (emphasis in the original)). By contrast, the main thrust of Plaintiffs' claims targets not the Secretary's *application* of standards but the standards themselves (First and Fifth Causes of Action), the procedural steps taken by the Secretary to establish the standards (Second, Third, and Fourth Causes of Action), the adequacy of the notice and hearings provided to beneficiaries in the administration of the standards (Sixth and Seventh Causes of Action), and the effects of the standards on the practice of medicine (Eighth and Ninth Causes of Action). With claims such as these, "the policy of permitting an agency to correct its own errors is chimerical" because the challenges are "to regulations promulgated and consistently enforced by the agency, and which the agency has either no power, or no inclination, to correct." *Abbey*, 978 F.2d at 45. As Judge Hall observed before waiving the exhaustion requirement for claims—similar to those here—brought by the Medicare beneficiaries in *Landers*, "[e]xhaustion would be futile in the face of an agency policy irreversible by any individual Administrative Law Judge." 232 F.R.D. at 46.

Plaintiffs' claims therefore qualify for judicial waiver, giving the Court subject matter jurisdiction over them under § 405(g). As a result, it is unnecessary to consider Plaintiffs' alternative assertion that the Court may exercise mandamus jurisdiction over this action pursuant to 28 U.S.C. § 1361.

IV. Plaintiffs' Claims Fail as a Matter of Law

In this case, Plaintiffs attack the Secretary's "use" of "observation status," rather than the "qualifying stay" rule at issue in the Second Circuit's decision in *Landers*. Nonetheless, because Plaintiffs advance some of the same theories the court considered and rejected in that case, it is helpful to begin the analysis of Plaintiffs' claims by examining the *Landers* decision in some detail.

A. The *Landers* Decision

The plaintiffs in *Landers* each spent at least three days in the hospital but were discharged less than three days after having been formally admitted, because each had spent at least one night either in the emergency room or on "observation status" – the very status that is the subject of this lawsuit – before being formally admitted. *Estate of Landers v. Leavitt*, 545 F.3d 98, 104 (2d Cir. 2008). As a result, CMS determined that, under Section 1395x(i) (and a regulation implementing that provision known as the "three midnight rule," 42 C.F.R. § 409.30(a)(1)), the plaintiffs were not eligible for Part A benefits for the post-hospitalization SNF care. *Id.* at 103-04. The plaintiffs challenged CMS's interpretation of the "qualifying hospital stay requirement" in a putative class action. *Id.* at 104. "They sought a permanent injunction and a writ of mandamus prohibiting the Secretary from excluding Medicare beneficiaries' time in the emergency room and on observation status from counting toward the qualifying stay requirement." *Id.*

In appealing the district court's ruling granting summary judgment to the Secretary, the *Landers* plaintiffs first argued that "the Medicare statute entitles them to coverage for their post-hospitalization SNF stays." *Id.* Because the Medicare statute provides coverage for a post-hospitalization SNF stay for a beneficiary who has been "an inpatient for not less than three consecutive days" in a hospital, 42 U.S.C. §1395x(i), and because each of the plaintiffs had been in the hospital for three consecutive days, the Second Circuit focused on whether the plaintiffs had been "inpatients" for at least three days. *See id.* Noting that the statute did not define the term "inpatient," the court recognized that resolution of this issue turned on whether it should "credit the interpretation of the [Medicare] statute that [CMS] has set forth in the policy manual,"

i.e., the Secretary's interpretation that an "inpatient" is "a person who has been formally admitted to a hospital." *Id.*

The court first found that the policy manual provision should be analyzed as a non-legislative agency interpretation rather than a legislative rule, thereby entitling it to deference under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944) rather than *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). *Id.* at 106. Applying *Skidmore*, the court concluded that "CMS's interpretation is entitled to a great deal of persuasive weight" and that "a Medicare beneficiary is not an inpatient within the meaning of Section 1395x(i) unless he or she has been formally admitted to a hospital." *Id.* at 107, 111.

In reaching this conclusion, the Second Circuit made several findings that, as shown below, undermine Plaintiffs' claims in the present case. First, the court treated the policy manual provision setting forth CMS's definition of "inpatient" as a "nonlegislative rule" rather than a legislative one. *See id.* at 106-07 & n.2 (citing cases holding that statements in the policy manuals of HHS and other agencies are "interpretive" rules). Second, the court found that CMS had "recently reconsidered its position on the public record," inviting comments in 2005 on "whether it should consider the possibility of counting the time spent in observation status toward meeting the SNF benefit's qualifying 3-day hospital stay requirement." *Id.* at 109 (quoting from HHS Notice in Federal Register) (internal quotation marks omitted). The court went on to summarize CMS's 2005 discussion of "observation status" in the Federal Register, in a passage that foreshadows Plaintiffs' claims in this case:

> [CMS] observed, further, that the medical practice of placing patients on observation status before formally admitting them has grown in prevalence since Congress enacted the Medicare statute in 1965, that some commentators have suggested that patients on observation status receive qualitatively the same type of care as admitted patients, and that some view it as unfair for Medicare reimbursement decisions to turn on a distinction that they believe to be a "mere

> recordkeeping convention on the part of the hospital rather than a substantive change in the actual care that the beneficiary receives there."

Id. at 109 (quoting from HHS Notice in Federal Register). The court noted that CMS had received comments on the observation status issue, but ultimately declined to change its interpretation in part because "it did not want to adopt a reimbursement guideline that conflicted with what it viewed as Congress's intent" in establishing the "qualifying stay" requirement, "namely, that the SNF benefit 'serve as a less expensive alternative to what would otherwise be the final, convalescent portion of an acute care stay of several days as an inpatient at a hospital.'" *Id.* The court observed that although "CMS's statement with respect to observation status may be less than wholly satisfying," "it is not so deficient that it lacks persuasive force." *Id.* CMS's recent consideration of the issue was one of the factors cited by the court in its decision to credit CMS's interpretation of the statutory term "inpatient." *Id.* at 109-110.

Third, the court observed that it had concluded that "a Medicare beneficiary is not an inpatient within the meaning of Section 1395x(i) unless he or she has been formally admitted to a hospital . . . not only because our decision is informed by CMS's highly persuasive interpretation, but also because it accords with the statutory text and our governing precedents." *Id.* at 111. In the passage following this observation, the court rejected an argument that, as will be shown in Section IV.B below, is essentially identical to one Plaintiffs make in this case:

> The statutory definition of inpatient hospital services enumerates such services as "bed and board," 42 U.S.C. § 1395x(b)(1), "nursing services," *id.* § 1395x(b)(2), and "other diagnostic services" *id.* § 1395x(b)(3). The plaintiffs urge us to credit their argument that anyone who receives these services in the hospital is receiving inpatient hospital services and is therefore an inpatient. In light of the statutory text, however, this argument is ultimately question-begging. The statute defines inpatient hospital services to include the aforementioned items and services when they are "furnished *to an inpatient of a hospital* and … by the hospital." *Id.* § 1395x(b) (emphasis added). Thus, services cannot be inpatient hospital services unless they are furnished to an inpatient.

Id.

B. Analysis of Plaintiffs' Specific Claims

1. First and Fifth Causes of Action

The First and Fifth Causes of Action are based on similar theories. The Court will therefore treat them together.

In their First Cause of Action, Plaintiffs allege that, by "allowing observation status . . . to deprive intended beneficiaries of Part A coverage," the Secretary violates 42 U.S.C. § 1395d(a) of "the Medicare statute 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." (Compl. [Dkt. # 1] at ¶ 99.) More specifically, Plaintiffs argue that they received the same "full range" of hospital services that a formally admitted "inpatient" would have received, and thus that using the "observation services" label to deny them Part A coverage elevates form over substance: "Beneficiaries like the plaintiffs … who receive the full range of inpatient hospital services (e.g., bed and board, nursing services, medical treatment, medications, supplies and appliances, and social services) clearly fall under the Part A hospital benefit as enunciated in the [Medicare] statute." (Pls.' Opp'n [Dkt. # 39] at 22; *see also* Compl. [Dkt. # 1] at ¶ 4 ("Beneficiaries on observation status generally receive the same treatment as beneficiaries who have been formally admitted, but they are considered outpatients by the Secretary.").)

As illustrated by the language quoted above, however, the *Landers* court rejected Plaintiffs' "form over substance" argument. 545 F.3d at 111 ("The plaintiffs urge us to credit their argument that anyone who receives these services in the hospital is receiving inpatient hospital services and is therefore an inpatient. In light of the statutory text, however, this argument is ultimately question-begging . . . [and] would read the words 'to an inpatient of a

hospital' out of the statutory text."). *Landers* upheld as a valid interpretation of the Medicare statute the Secretary's decision to tie Part A coverage to formal hospital admission, rather than to the nature of the services provided. Thus, the denial of Part A coverage to the Plaintiffs did not violate the Medicare statute, even if they received services that were identical to those provided to admitted inpatients. The First Cause of Action is therefore dismissed.

The Fifth Cause of Action fails for similar reasons. Plaintiffs allege that the Secretary'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)." (Compl. [Dkt. # 1] at ¶ 103.) Under 5 U.S.C. § 706(2)(A), an agency's action "may be set aside if found to be 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41 (1983). Although Plaintiffs do not clearly articulate their *State Farm* claim, it appears that they rely on two distinct theories: (1) that the Secretary acted capriciously by classifying individuals who are on observation status—and thus are "hospitalized patients" who "spen[t] weeks receiving hospital services," (Pls.' Opp'n [Dkt. # 39] at 33)—as outpatients;[9] and (2) that the Secretary has "allowed observation status . . . to become a significant factor in the hospitalization process for Medicare beneficiaries," (*id.* at 34), i.e., that the Secretary should

[9] It is not entirely clear what action of the Secretary the Plaintiffs are challenging here – a theme that recurs in Plaintiffs' complaint and their brief in opposition to the Motion to Dismiss. Of course, hospitals and doctors, rather than the Secretary, make the decision to place beneficiaries on observation status in lieu of admitting them to the hospital. The only action or decision the Secretary has taken with respect to observation services is the decision to adopt Manual provisions that define "observation services" and clarify that a patient receiving such services is an "outpatient." Policy Manual, Ch. 6, § 20.6(A), (B). Thus, the Court will presume that to be the action that Plaintiffs challenge.

have taken action, such as reinterpreting the term "inpatient," in response to the increasing use of observation services over the past decade.

The first theory fails for essentially the same reasons that the First Cause of Action fails. Plaintiffs' argument that it is "irrational" that beneficiaries such as the plaintiffs might spend "weeks" in the hospital receiving "hospital services" but still be denied Part A benefits because they were on "observation status," (*id.* at 33), is another way of saying that Part A coverage should turn on the "substance" of the services provided rather than the "form[ality]" of hospital admission. As shown, *Landers* rejected that argument. *See*, 545 F.3d at 111. While Plaintiffs' Fifth Cause of Action makes a claim under the APA, rather than under the Medicare statute, the result is the same: This Court can hardly find that the Secretary's interpretation of "inpatient" is arbitrary or capricious when the Second Circuit has concluded that the "interpretation is entitled to a great deal of persuasive weight" and "accords with the statutory text [of the Medicare statute] and our governing precedents." *Landers*, 545 F.3d at 107.

The second theory—that the Secretary has failed to respond to the increasing frequency with which hospitals are using observation status due to underlying financial incentives—is essentially a complaint about the Secretary's nonfeasance. Plaintiffs complain that, despite being aware of the growing use of observation status, the Secretary "has taken no action." (Pls.' Opp'n [Dkt. # 39] at 34.) Although the APA does allow for challenges to an agency's "failure to act,"[10] this theory would have to proceed under 5 U.S.C. § 706(1) to "compel agency action unlawfully withheld or unreasonably delayed." But a § 706(1) claim can "proceed only where [a plaintiff] asserts that an agency failed to take a *discrete* agency action"—such as issuing a "rule,"

[10] *See* 5 U.S.C. § 702 ("A person suffering legal wrong because of agency action . . . is entitled to judicial review thereof."); 5 U.S.C. § 551(13) (defining "agency action" to include "failure to act").

"order," or "sanction"—"that it *is required to take*." *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 62-64 (2004) (emphasis in the original). Plaintiffs do not point to any such action.[11] The Fifth Cause of Action is therefore dismissed.

2. Second and Third Causes of Action

Like the First and Fifth Causes of Action, Plaintiffs' Second and Third Causes of Action are based on similar theories and will be addressed together.

The Second Cause of Action alleges that the Secretary's "policy of allowing hospitals to place beneficiaries on observation status" violates the notice-and-comment requirements of the APA. *See* 5 U.S.C. § 553; (Compl. [Dkt. #1] at ¶ 100.) Although it is not entirely clear which "policy" Plaintiffs have in mind, the Court can discern from the Complaint and Plaintiffs' opposition brief the following three "policies" that might be the subject of this claim: (1) the Policy Manual provisions defining "observation services" and stating that its recipients are "outpatients," (2) the policy of allowing hospitals to place beneficiaries who are receiving the same services as "inpatients" in an "outpatient" status that denies them Part A coverage, and (3)

[11] The Court also notes that the Secretary has recently promulgated a rule designed to curb the underlying financial incentive that Plaintiffs identify as a cause of the increasing use of observation status. (Compl. [Dkt. # 1] at ¶ 46.) Under the new rule, if a hospital determines that the beneficiary's inpatient admission was not reasonable and necessary, and the beneficiary should have been treated as a hospital outpatient rather than admitted as an inpatient, hospitals may nonetheless seek reimbursement under Part B provided the beneficiary is enrolled in Medicare Part B and the hospital timely submits the Part B claim. 42 C.F.R. § 414.5; *see also* 78 Fed. Reg. 50496, 50906-15 (Aug. 19, 2013). Regarding hospital admission, the Secretary has created a "two-midnight benchmark" and a "two-midnight presumption." Under the two-midnight benchmark, hospital visits that are expected to last less than two midnights are generally considered inappropriate for inpatient admission; hospital visits that are expected to last two midnights or longer are considered appropriate for admission. 42 C.F.R. § 412.3(e)(1). Under the two-midnight presumption, "inpatient hospital claims with lengths of stay greater than 2 midnights after the formal admission following the order will be presumed generally appropriate for Part A payment." *See* 78 Fed. Reg. at 50952 (finalizing the foregoing rule). According to CMS, these new rules are "interrelated and were designed to work together to reduce the frequency of extended observation care when it may be inappropriately furnished." *Id.* at 50908.

the policy of allowing hospitals to make increasing use of the observation status category. In any event, as explained below, Plaintiffs' § 553 claim turns on whether the "policy" at issue is considered "legislative" or "interpretive."

When an agency engages in "rulemaking," it is required under § 553(b) to provide public notice of the proposed rule in the Federal Register, followed by an opportunity for public comment. *Sweet v. Sheahan*, 235 F.3d 80, 90 (2d Cir. 2000); 5 U.S.C. §§ 553(b), (c). This procedure is commonly referred to as "notice-and-comment rulemaking." The APA provides an exception to the usual notice-and-comment rulemaking procedures when a rule is "interpretative." 5 U.S.C. § 553(b)(3)(A). Although the APA does not define "interpretative" rules—commonly referred to as "interpretive rules"—courts have developed several formulations to distinguish interpretive rules from what have been termed "legislative" rules, which, unlike interpretive rules, are subject to the notice-and-comment requirements in § 553. *See Sweet*, 235 F.3d at 91. Notably, the Second Circuit has held that the legislative/interpretive distinction does not depend on whether a rule is "substantive," because interpretive rules sometimes have "substantive effects." *White v. Shalala*, 7 F.3d 296, 303 (2d Cir. 1993). Instead, "legislative" rules "are those that create new law, rights, or duties, in what amounts to a legislative act." *Sweet*, 235 F.3d at 91. "Interpretive" rules, on the other hand, "do not create rights, but merely clarify an existing statute or regulation." *Id.* In addition, the Second Circuit has quoted favorably a "more comprehensive" test articulated by the D.C. Circuit:

> [I]nsofar as our cases can be reconciled at all, we think it almost exclusively on the basis of whether the purported interpretive rule has "legal effect", which in turn is best ascertained by asking (1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties, (2) whether the agency has published the rule in the Code of Federal Regulations, (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the

> rule effectively amends a prior legislative rule. If the answer to any of these questions is affirmative, we have a legislative, not an interpretive rule.

Id. (quoting *Am. Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1110-12 (D.C. Cir. 1993)).[12] Application of the tests from *American Mining* and *Sweet* shows that none of the possible iterations of Plaintiffs' argument states a claim based on 5 U.S.C. § 553.

As explained above, it is possible that the "policy" or "policies" Plaintiffs challenge are the statements about observation services in Chapter 6 of the Policy Manual, including the statement that patients receiving observation care are considered "outpatients" and the definition of "observation services" in section 20.6(A). Policy Manual, Ch. 6, § 20.6(B) ("When a physician orders that a patient receive observation care, the patient's status is that of an outpatient."); *id.* § 20.6(A) ("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."). Under the tests articulated in *Sweet* and *American Mining*, these "policies" are interpretive, not legislative. With respect to the factors in *American Mining*, factors 2-4 are all answered in the negative.[13] Under the first factor—whether in the absence of the rules there would not be an adequate legislative

[12] The *Sweet* court noted that the D.C. Circuit subsequently modified its holding with respect to the second criterion, publication in the Code of Federal Regulations. *Sweet*, 235 F.3d at 91 n.8 (citing *Health Ins. Ass'n of Am., Inc. v. Shalala*, 23 F.3d 412, 423 (D.C. Cir. 1994) (stating that in no case had the court taken publication in the C.F.R. as "anything more than a snippet of evidence of agency intent" with regard to whether a rule has legal effect)).

[13] It is worth noting that the Secretary published the statements regarding observation status in the Policy Manual, rather than the Code of Federal Regulations, and that several courts have found Policy Manual provisions to be interpretive rather than legislative rules. *See Landers*, 545 F.3d at 106-07; *St. Mary's Hosp. of Troy v. Blue Cross & Blue Shield Ass'n/Blue Cross & Blue Shield of Greater N.Y.*, 788 F.2d 888, 891 (2d Cir. 1986) ("[m]anual rules have consistently been held to be 'interpretive rules,' and thus exempt from the notice and comment requirements").

basis for enforcement action or other agency action to confer benefits or ensure the performance of duties—there would be adequate legislative authority for the agency action at issue here in the absence of the statements in section 20.6(A) and 20.6(B). The denial of Part A benefits, which owes at least in part to the fact that the Plaintiffs were not admitted, rested on the statutory term "inpatient" and CMS's interpretation of that term upheld in *Landers*, i.e., an inpatient is one who has been admitted. *See* 42 U.S.C. § 1395d(a) (beneficiaries entitled to Part A coverage for, among other things, "inpatient hospital services"); Policy Manual, Ch. 1, § 10 (defining "inpatient" as "a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services"). In other words, because the Secretary's Part A coverage determination as to Plaintiffs hinged on whether each had been admitted,[14] the Secretary could lawfully have made the same determination even in the absence of the Policy Manual provisions defining a category of "observation services" and stating that beneficiaries receiving observation services are considered "outpatients." Because all four factors are answered in the negative, the rule is interpretive under the test articulated in *American Mining*.

Applying *Sweet's* more general definition of "legislative" and "interpretive," i.e., rules that "create new law, rights, or duties" versus rules that "do not create rights, but merely clarify an existing statute or regulation" yields the same result. *See* 235 F.3d at 91 (internal quotation marks and citations omitted). The statements regarding observation status in Chapter 6 of the

[14] (*See, e.g.*, Compl. [Dkt. #1] at ¶ 64 ("Because [Mildred Savage] was not formally admitted to the hospital until her return stay and therefore did not satisfy the three-day rule, her subsequent care in a skilled nursing facility . . . was not covered by Medicare."); *id.* at ¶ 70 ("Because [Lee Barrows] was not formally admitted to the hospital and therefore did not satisfy the three-day rule, his subsequent care in a skilled nursing facility . . . was not covered by Medicare."); *id.* at ¶ 76 ("Because [Charles Renshaw] was not formally admitted to the hospital and therefore did not satisfy the three-day rule, his subsequent care in a skilled nursing facility . . . was not covered by Medicare."); *id.* at ¶ 81 ("Because [Sarah Mulcahy] was not formally admitted to the hospital and therefore did not satisfy the three-day rule, her subsequent care in a skilled nursing facility . . . was not covered by Medicare.").)

Policy Manual, including the definition of observation services in section 20.6(A) and the rule that patients receiving observation services are outpatients in section 20.6(B), do not "create new rights" to Part A coverage or abrogate existing rights to such coverage (and thereby "create new law") because, had they been removed from the Policy Manual, Plaintiffs would still not have *legally* been entitled to Part A coverage unless and until they were admitted. Therefore, adoption of sections 20.6(A) and 20.6(B) of the Policy Manual did not deprive them of a right to coverage or otherwise create new law. Rather, those sections clarify the statutory term "inpatient," and just as the Second Circuit in *Landers* found the Secretary's definition of that term to be interpretive, rather than legislative, this Court makes a similar finding about the Secretary's clarification of that term in its Policy Manual statements about observation services. In particular, the definition of observation services and the statement that patients receiving observation services are outpatients classifies a particular set of hospital services given at a particular time, i.e., "ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients," Policy Manual, Ch. 6, § 20.6(A), as falling outside the set of "inpatient" services. The statements thus clarify the extent of the statutory term. *Compare White*, 7 F.3d at 304 (holding that, for purposes of determining eligibility for SSI benefits, rule interpreting "veteran's benefits" to include veteran benefits received by a dependent is interpretive rule because it "clarifies an ambiguous term" in the relevant statute).

The second possible "policy" that Plaintiffs may be challenging is the Secretary's allowing hospitals to place beneficiaries who are receiving the same services as "inpatients" in an "outpatient" status that denies them Part A coverage. In other words, the "policy" at issue is the fact that the Secretary has allowed hospitals to classify patients receiving services normally

reserved for inpatients as outpatients instead of inpatients and thus, in effect, to deny them Part A coverage. A § 553 claim based on that policy fails as well. This would appear to be yet another way of arguing that Part A coverage should be based on the substance of the services received rather than on the "form[ality]" of hospital admission. As explained above, the court in *Landers* found that the Secretary's contrary approach was consistent with the Medicare statute; any such "policy" thus does not create new rights, duties or law but, as *Landers* held, faithfully interprets the statute.

A final possible interpretation of Plaintiffs' Second Cause of Action is that the Secretary's "allowing" hospitals to make increasing use of the observation status category is, in effect, a "rule" that is subject to the notice-and-comment rulemaking procedures. Assuming that agency inaction might be considered a legislative "rule," the Court concludes that the Secretary's failure to respond to a particular industry trend—in this case, the way in which hospitals react to financial incentives created by the Secretary's policies—is not a "rule" that "create[s] new law, rights, or duties." This is illustrated by applying the first factor of the *American Mining* test – in the absence of the Secretary's failure to respond, there would nonetheless be an adequate legislative basis to take the action at issue, namely, to deny Part A benefits to any beneficiary who has received hospital services but has not been formally admitted as an "inpatient."

Plaintiffs also make a separate argument in support of their Second Cause of Action: that the Secretary's "embracing of observation status" was required to undergo notice-and-comment rulemaking procedures because it constitutes a change in the Secretary's position. According to Plaintiffs' brief, "[t]he rule prior to the Secretary's embracing of observation status as a means to limit Medicare hospital coverage to Part B was that beneficiaries receiving a hospital level of care in a hospital were covered under Part A." (Pls.' Opp'n [Dkt. # 39] at 28.) Plaintiffs argue

that, even if the rule they challenge is only interpretive, the Secretary was nonetheless required to promulgate it using notice-and-comment procedures because it represented "a change in position." (*Id.*)

This argument fails for two reasons. First, aside from the vague assertion of a previous policy, Plaintiffs fail to identify the source or basis of the "policy" that the Secretary has allegedly changed, and they do not provide any information about when the asserted "policy" on observation services was adopted. Instead, the Complaint states that the Secretary "*has long had a policy* under which Medicare beneficiaries in hospitals, instead of being formally admitted, are placed on what is commonly referred to as 'observation status.'" (Compl. [Dkt. # 1] at ¶ 2) (emphasis added). Moreover, the alleged prior policy conflicts with the Secretary's definition of "inpatient" as requiring formal admission—which has apparently been around since 1965. What the allegations do make clear, however, is that any change is the result of action taken not by the Secretary but by hospitals. Plaintiffs claim that hospitals have been responding to financial incentives by increasingly placing beneficiaries on "observation status" rather than formally admitting them. (*See, e.g.*, *id.* at ¶¶ 45-50.) Because it does not appear that any change was made by the *Secretary*, however, no notice and comment was required.

Second, even if there had been a "previous policy" as Plaintiffs allege, Plaintiffs cite no authority for the proposition that, in these circumstances, any change in that policy was subject to notice and comment. The cases Plaintiffs cite hold that a change in an agency's interpretation of its own *regulation* is, itself, subject to notice and comment because it is an amendment of the regulation and, thus, requires promulgation via notice and comment, just as the adoption of the initial regulation does. *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 100 (1995) (interpretive rule in Medicare manual provision would require APA rulemaking if it "adopted a new position

inconsistent with any of the Secretary's existing regulations"); *Alaska Prof'l Hunters Ass'n, Inc. v. FAA*, 177 F.3d 1030, 1034 (D.C. Cir. 1999) (agency's change in interpretation of a "regulation" requires notice and comment). Nowhere, however, do Plaintiffs suggest that the Secretary's "previous policy" emanated from a *regulation* adopted by the Secretary, and the Court is unaware of any such regulation. Accordingly, the Second Cause of Action is dismissed.

The Third Cause of Action is similar to the Second in that it alleges that the Secretary was required to initiate notice-and-comment rulemaking before adopting a policy of "allowing hospitals to place beneficiaries on observation status." (Compl. [Dkt. #1] at ¶ 101.) The only difference is that the Third Cause of Action is based on provisions in the Medicare Act rather than the APA. Under 42 U.S.C. § 1395hh(a)(2), the Secretary cannot promulgate "a rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals . . . to . . . receive services or benefits under this subchapter . . . unless it is promulgated by the Secretary through notice-and-comment rulemaking." *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 75 (2d Cir. 2006) (internal quotation marks omitted).

The parties disagree about whether this provision is broader than the notice-and-comment requirement found in the APA, but the Court need not reach that question. Again, although Plaintiffs are not clear about what rule or policy was subject to notice-and-comment rulemaking, this Cause of Action fails under any of the possibilities outlined above. Like the APA, sections 1395hh(b)(2)(C)[15] and 1395hh(c)[16] exempt, at least implicitly, "interpretive rules" from notice-

[15] 42 U.S.C. § 1395hh(b) states:

and-comment requirements. *See Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 814 n.2 (D.C. Cir. 2001); *Warder v. Shalala*, 149 F.3d 73, 79 (1st Cir. 1998). As discussed above, insofar as Plaintiffs argue that the statements in Chapter 6 of the Policy Manual regarding observation services were subject to the Medicare Act's notice-and-comment requirements, those statements are "interpretive" rules, and are therefore exempt. Insofar as Plaintiffs argue that the Secretary's failure to act constituted a policy subject to notice-and-comment requirements, for the same reasons such a policy did not "create new law, rights, or obligations," it did not constitute the "establish[ment]" or "change[]" of a substantive legal standard. The Third Cause of Action is

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(b) Notice of proposed regulations; public comment

(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where—

. . .

(C) subsection (b) of section 553 of Title 5 does not apply pursuant to subparagraph (B) of such subsection.

[16] 42 U.S.C. § 1395hh(c) states:

(c) Publication of certain rules; public inspection; changes in data collection and retrieval

(1) The Secretary shall publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, *interpretative rules*, statements of policy, and guidelines of general applicability which—

(A) are promulgated to carry out this subchapter, but

(B) are not published pursuant to subsection (a)(1) of this section and have not been previously published in a list under this subsection.

(emphasis added).

therefore dismissed.[17]

3. Fourth Cause of Action: FOIA, 5 U.S.C. § 552(a)(1)

The Fourth Cause of Action alleges that "observation status" is "void and of no force and effect," because, as a "substantive rule of general applicability adopted as authorized by law," or a "statement of general policy or interpretation of general applicability formulated and adopted by the agency," it must be published in the Federal Register. (Compl. [Dkt. #1] at ¶ 102.) The Freedom of Information Act ("FOIA") requires federal agencies to "separately state and currently publish in the Federal Register" any "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." 5 U.S.C. § 552(a)(1)(D). Plaintiffs argue that "observation status meets [the] criterion" set forth in § 552(a)(1)(D), namely, that it is a "substantive rule of general applicability" or "statement[] of general policy or interpretation[]." (Compl. [Dkt. #1] at ¶ 102.)

This claim fails for two reasons. First, as *Landers'* summary of CMS's 2005 discussion in the Federal Register makes clear, both the concept of observation services and the decision to classify such services as outpatient services *have* been published 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."); *see also* 70 Fed. Reg. 29070, 29098-100 (May 19, 2005) (discussing "observation status," defining it, citing relevant

[17] Congress enacted 42 U.S.C. § 1395hh(a)(2) as a non-retroactive amendment to the Medicare Act in 1987. Thus, § 1395hh(a)(2) does not apply to the definition of "inpatient," which was established by the Secretary in 1965.

Policy Manual provisions, and stating that it is covered "under the outpatient prospective payment system," i.e., Part B rather than Part A). Indeed, CMS considered some of the same claims Plaintiffs advance in this lawsuit in the 2005 Federal Register discussion – and declined to make regulatory changes to address those claims. *Landers*, 545 F.3d at 109 (noting that although CMS acknowledged that "the medical practice of placing patients on observation status before formally admitting them has grown in prevalence since Congress enacted the Medicare statute in 1965" and that "some commentators have suggested that patients on observation status receive qualitatively the same type of care as admitted patients", CMS "declined to change its interpretation" of the statutory term "inpatient"). Contrary to Plaintiffs' assertions, then, the Secretary, through CMS, has given clear notice in the Federal Register of her position concerning the meaning and impact of "observation services," and her unwillingness to make changes that would diminish the effect of the "observation status" designation on Part A coverage. *Landers*, 545 F.3d at 109.[18]

Second, the Second Circuit has held that "the requirement for publication [in the Federal Register] attaches only to matters which if not published would adversely affect a member of the

[18] Plaintiffs assert that "the policy" the Secretary was required to publish in the Federal Register was "the *use* of observation status to replace Part A coverage with Part B coverage," rather than simply the statement that "observation services are outpatient services." (Pls.' Opp'n [Dkt. # 39] at 32) (emphasis added). But the statement in the Policy Manual that "[w]hen a physician orders that a patient receive observation care, the patient's status is that of an outpatient," Policy Manual, Ch. 6, § 20.6(B), is just another way of saying that a patient on "observation status" is not an "inpatient" and thus does not qualify for Part A coverage because he or she has not yet been admitted. Apart from rhetoric, then, it is difficult to see any daylight between the "use of observation status to replace Part A coverage with Part B coverage" and the statement that beneficiaries who receive observation care are considered outpatients. Moreover, to the extent Plaintiffs are genuinely complaining about "use" of observation services, they are not complaining about an action by the Secretary. It is not the Secretary who "uses" observation status – it is hospitals. And, of course, hospitals' use of observation status—even if it is increasing—is not a "substantive rule of general applicability adopted as authorized by law," or a "statement of general policy or interpretation of general applicability formulated and adopted by the agency," § 522(a)(1), and thus does not require publication in the Federal Register.

public." *State of N.Y. v. Lyng*, 829 F.2d 346, 354 (2d Cir. 1987). Any failure to publish the statements about "observation status" would not have made any difference in the level of Medicare coverage afforded to Plaintiffs, each of whom was denied Part A benefits because he or she was not admitted to the hospital (or had his or admission revoked) and thus was not considered an "inpatient." (*See, e.g.*, Compl. [Dkt. # 1] at ¶ 81.) To put it another way, there is no suggestion in Plaintiffs' complaint that the physicians and hospitals charged with their care would have been more likely to make the "complex medical judgment" to admit them had the statements about "observation status" been published more prominently or more clearly.

4. Sixth and Seventh Causes of Action

Plaintiffs' Sixth and Seventh Causes of Action are also based on similar theories. Plaintiffs' sixth cause of action alleges that:

> Defendants' failure to provide written notification to Medicare beneficiaries, or to require that they receive written notification, of their placement on observation status, of the consequences of that placement for their Medicare coverage, and of their right to challenge that placement violates the Medicare statute, 42 U.S.C. §§ 1395ff and 1395w-22(g), and the Due Process Clause of the Fifth Amendment.

(Compl. [Dkt. # 1] at ¶ 104.) Plaintiffs' seventh cause of action alleges that Defendant's failure to provide administrative review, including expedited review, of their placement on observation status violates the same sections of the Medicare statute and the Due Process Clause of the Fifth Amendment. (*Id.* at ¶ 105.) Because the two causes of action are overlapping, the Court will treat them together.

a. Claim Under the Medicare Statute

i. Content of the Notices

Plaintiffs argue that the content of the notices provided to beneficiaries who receive observation services is inadequate under the Medicare Act. The Act requires that beneficiaries

receive written notice of "initial determinations" as to whether they are entitled to Medicare coverage, and whether coverage will be provided under Part A or Part B. 42 U.S.C. § 1395ff(a)(1). If an initial determination results in the denial of benefits, the written notice of the determination must include: (1) the reasons for the determination, including whether a local medical review policy or a local coverage determination was used; (2) the procedures for obtaining additional information concerning the determination; and (3) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination. *Id.* § 1395ff(a)(4)(A). In addition, the written notice must be "provided in printed form and written in a manner calculated to be understood by the individual." *Id.* § 1395ff(a)(4)(B).

The written notice that beneficiaries receive comes in the form of a Medicare Summary Notice ("MSN"). According to Plaintiffs, the MSNs received by beneficiaries who are on observation status "usually do not contain the words 'observation status' or 'observation services.'" (Pls.' Opp. [Dkt. # 39] at 37.) Instead, the MSNs list the hospital claims as covered Part B outpatient claims without explaining why the hospital claims are considered outpatient claims. Plaintiffs also complain that there is no "explanation of the causal link between these Part B covered services and the denial of part A post-hospital SNF coverage that beneficiaries are also probably facing." (*Id.*)

The Court declines to reach the merits of this issue because Plaintiffs do not have standing to challenge the adequacy of the notices of initial determination. Standing requires that Plaintiffs have suffered an "injury in fact" that is "fairly traceable to the challenged action of the defendant." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Plaintiffs have alleged an injury in fact: their services were covered under Part B instead of Part A, a difference with

serious financial consequences. There is no "causal link" between that injury, however, and the alleged inadequacy of the MSNs. *See id.* The purpose of the requirements set forth in 42 U.S.C. § 1395ff is to provide beneficiaries with notice of an initial determination of benefits so that they can appeal that decision. Here, Plaintiffs' injuries were not caused by their inability to appeal their initial determinations of benefits. Despite the alleged inadequacy of the notices, each Plaintiff *did* appeal his or her initial determination. Because the conduct complained of—i.e., the alleged inadequacy of the notices—did not cause Plaintiffs' injuries, they lack standing to challenge the content of the notices.

ii. Timing of the Notices and Expedited Determination

Plaintiffs also complain that the timing of the notices and unavailability of expedited determination violate the Medicare Act. Although it is not entirely clear, Plaintiffs seem to argue that beneficiaries are entitled to notice of "their rights, including potential coverage or non-coverage of post-hospital services," at the time they are placed on observation status. (Pls.' Opp'n [Dkt. # 39] at 38.) Except in the case of beneficiaries who are initially admitted and then later placed on observation status, *see* 42 U.S.C. § 1395ff(b)(1)(F), 42 C.F.R. § 405.1205, however, nothing in the statute or the applicable regulations requires such notice when beneficiaries are placed on observation status. Indeed, the statute only requires notice of an initial determination within the "45-day period beginning on the date the fiscal intermediary or the carrier, as the case may be, receives a claim for benefits." 42 U.S.C. § 1395ff(a).

Plaintiffs also seem to argue that 42 U.S.C. § 1395ff(b)(1)(F) allows for an "expedited determination" at the time beneficiaries are placed on observation status. The Act provides for expedited determination of Medicare coverage only if a provider plans to "*terminate services* provided to an individual and a physician certifies that failure to continue the provision of such

services is likely to place the individual's health at significant risk," or if the provider plans to "*discharge* the individual from the provider of services." 42 U.S.C. § 1395ff(b)(1)(F) (emphasis added). It is clear that an individual who has been placed on observation status, i.e., a patient who receives observation services and has not yet been admitted, has not experienced a "terminat[ion]" of services or a "discharge." *See* 42 C.F.R. § 405.1205(a)(2) (defining "discharge" as the "formal release of a beneficiary from an inpatient hospital"). Thus, Plaintiffs' argument that beneficiaries are entitled to expedited determination upon being placed on observation status is meritless.

Plaintiffs correctly state, and the Secretary does not appear to contest, that beneficiaries whose status is changed from inpatient to observation are entitled to expedited determination under 42 C.F.R. § 405.1206(a). That section states that a beneficiary has a right to an expedited determination when "a hospital (acting directly or through its utilization review committee), with physician concurrence, determines that inpatient care is no longer necessary." 42 C.F.R. § 405.1206(a). Accordingly, the Policy Manual states that "[h]ospitals must notify Medicare beneficiaries who are hospital inpatients about their hospital discharge appeal rights." Policy Manual, Ch. 30, § 200.3. The Policy Manual interprets hospital discharge to include not only physical discharge, but also discharge "on paper," i.e., the beneficiary remains in the hospital, "but at a lower level of care." Policy Manual, Ch. 30, § 200.1.

According to Plaintiffs, the notice to beneficiaries who have been re-classified from inpatient to observation status usually does not issue. (*See* Compl. [Dkt #1] at ¶ 44; Pls.' Opp'n [Dkt. # 39] at 38.) The Complaint also alleges that one Plaintiff, Mr. Barrows, was formally admitted before having his status changed to observation, but did not receive any notice regarding any appeal rights. (*Id.* at ¶ 68.) In addition, Plaintiff LeYanna *did* receive notice when

she was re-classified from inpatient to observation status, but the notice did not contain any information about her appeal rights.[19] (Compl. in Intervention [Dkt. # 53] ¶ 79.) But these allegations do not state claims against the Secretary. The regulations place the responsibility of giving notice on the *hospitals*. *See* 42 C.F.R. §§ 405.1205(b)(1) ("*hospitals* must deliver valid, written notice of a beneficiary's rights as a hospital inpatient"). Because there is no allegation that any alleged failures in notice are attributable to the *Secretary*—the Defendant in this action—this claim is dismissed.

b. Due Process Claim

Plaintiffs also claim that the Secretary violated their rights to due process by: (1) not requiring that beneficiaries receive written notification of their placement on observation status, the consequences of that status, and their "right to challenge" that status, (Compl. [Dkt. # 1] at ¶ 104), and (2) not providing Medicare beneficiaries with the right to administrative review, including expedited review, of their placement on observation status, (*id.* at ¶ 105.)

The Due Process Clause of the Fifth Amendment "imposes constraints on governmental decisions which deprive individuals of 'liberty' or 'property' interests within the meaning" of that Amendment. *Mathews v. Eldridge*, 424 U.S. 319, 332 (1976); U.S. Const., Amdt. 5 ("No person shall . . . be deprived of life, liberty, or property, without due process of law"). In order to state a Due Process claim, a plaintiff must show that: (1) state action (2) deprived him or her of liberty or property (3) without due process of law. "The first inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest in 'property' or

[19] 42 C.F.R. § 405.1205(b)(2)(ii) requires that the discharge notice include information about the beneficiary's "right to request an expedited determination of the discharge decision including a description of the process under § 405.1206."

'liberty.'" *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59, 119 S. Ct. 977, 989, 143 L. Ed. 2d 130 (1999). The Court will therefore address the Plaintiffs' asserted property interest first.

It is well-settled that recipients of government benefits, including Medicare benefits, can possess a property interest in those benefits sufficient to implicate due process rights. *See, e.g.*, *Goldberg v. Kelly*, 397 U.S. 254, 262 (1970) (holding that procedural due process applies to the termination of welfare benefits because they are "a matter of statutory entitlement for persons qualified to receive them"); *Kraemer v. Heckler*, 737 F.2d 214, 222 (2d Cir. 1984) (holding that plaintiffs stated a due process claim based on termination of Medicare benefits). A "mere 'unilateral expectation' of receiving a benefit," however, is not enough to create a property interest protected by the Due Process Clause; instead, "a property interest arises only where one has a 'legitimate claim of entitlement' to the benefit." *Kapps v. Wing*, 404 F.3d 105, 113 (2d Cir. 2005) (quoting *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 577 (1972)).

Courts look to the statutes, regulations, and other "rules and understandings" governing the distribution of particular benefits to determine whether a particular benefits regime creates a "legitimate claim of entitlement." *Id.*; *Perry v. Sindermann*, 408 U.S. 593, 602 (1972) (legitimate claim of entitlement can be supported by "rules and understandings . . . promulgated and fostered by state officials"). A "legitimate claim of entitlement" is created by "placing substantive limitations on official discretion." *Ky. Dep't of Corr. v. Thompson*, 490 U.S. 454, 462 (1989). That is, the applicable statutes and regulations must contain "explicitly mandatory language, *i.e.*, specific directives to the decision-maker that if the regulations' substantive predicates are present, a particular outcome must follow." *Id.* at 463 (internal quotation marks omitted). Thus, "entitlement to the benefit occurs only when official discretion is so narrowly confined as to virtually guarantee conferral of the benefit." *Furlong v. Shalala*, 156 F.3d 384,

394 (2d Cir. 1998). If, on the other hand, the applicable rules merely authorize a particular benefit, and vest significant discretion over the conferral of a benefit, the benefit is not an "entitlement" that receives constitutional protection. *Sealed v. Sealed*, 332 F.3d 51, at 56 (2d Cir. 2003); *Kelly Kare, Ltd. v. O'Rourke*, 930 F.2d 170, 175 (2d Cir. 1991).

In *Furlong*, the plaintiff-physicians claimed that the application of the so-called "one-and-one-half" rule to a procedure called "concurrent invasive monitoring" deprived them of a property right without due process in violation of the Fifth Amendment. 156 F.3d at 392-93. Under the applicable Medicare rules at issue in *Furlong*, reimbursement of multiple "surgical" procedures performed during the same operation was governed by the "one-and-one-half" rule, which provided that a secondary, less expensive "surgical" procedure performed during a larger operation would be reimbursed at only half the statutory fee. *Id.* at 388-89. As a result, physicians performing heart or other major surgery were reimbursed at half the statutory fee for "concurrent invasive monitoring" that was performed as part of the larger surgery. *Id.* at 389. The physician-plaintiffs argued that they had a property interest in full reimbursement for the procedure because "concurrent invasive monitoring" was a "medical" rather than a "surgical" procedure, and thus not subject to the "one-and-one-half" rule. *Id.* at 393-94. The Second Circuit rejected that argument, finding that no rule conclusively categorized concurrent invasive monitoring as either "medical" or "surgical" and that, instead, the decision of how to categorize the procedure was left up to the discretion of the carriers, who were free to interpret the service as "surgical." *Id.* at 394.

Furlong stands in stark contrast with *Kapps v. Wing*, 404 F.3d 105 (2d Cir. 2005). In *Kapps*, applicants for New York's Home Energy Assistance Program ("HEAP") claimed that the administrators of the HEAP program violated their procedural due process rights when they

denied applications for HEAP benefits without affording the applicants a hearing. The Second Circuit found that New York state law set "fixed," "objective" eligibility criteria for the receipt of HEAP benefits, such as income, household size, and enrollment in certain other welfare programs. *See id.* at 114; *see also* N.Y. Comp. Codes R. & Regs. tit. 18, § 393.4(c) (setting forth standard eligibility criteria for the receipt of HEAP benefits, and indicating that "once determined eligible a household will receive a regular HEAP benefit"). Those criteria were precisely the type of "discretion-limiting substantive predicates that are the hallmarks of protected property rights." *Id.* at 113. In addition, there was no indication that "discretionary factors" entered into the determination of HEAP eligibility, or that HEAP administrators had any discretionary control over the objective factors. *Id.* at 114. Thus, because state law "mandate[d] award of the benefit upon satisfaction of specific criteria," the Second Circuit held that the applicants possessed a property interest in HEAP benefits. *Id.* at 116.

Here, Plaintiffs argue that they fit squarely into the *Kapps* mold because, "[i]f they meet the eligibility requirements for Part A coverage, they have a right to that coverage at both the hospital and nursing facility." (Pls.' Supp. Mem. [Dkt. # 93] at 2.) It is true that entitlement to Part A coverage is demonstrated upon the showing of a specific substantive predicate: whether the beneficiary received inpatient services. But, as explained above, only "inpatients" can receive inpatient services, and to be an inpatient, one must be formally admitted to the hospital instead of being placed on observation status. If the applicable administrative scheme—i.e., the Medicare statute and regulations, and the Secretary's interpretations of those statutes and regulations—"virtually guarantees" inpatient status by mandating formal admission upon the meeting of certain "substantive predicates," then Plaintiffs would have a legitimate claim of entitlement to inpatient status, and by extension, Part A benefits. The Policy Manual makes

clear, however, that formal admission is not mandatory under any conditions; instead, the decision to admit a patient is considered a "complex medical judgment" left to the doctor's discretion.

It is clear that the statute itself does not create a property interest in inpatient status. Although the Medicare Act entitled beneficiaries to Part A coverage for "inpatient services" rendered to an "inpatient," it leaves the term "inpatient" undefined. *Landers* held that the Secretary has adopted a valid interpretation of the term "inpatient" as being dependent upon formal admission to the hospital. Thus, the heart of the matter is whether beneficiaries have any right to formal hospital admission. Because admission is governed by the Policy Manual, the Court looks to the Policy Manual to determine whether admission is mandatory upon meeting certain substantive predicates.

Chapter 1, Section 10 of the Policy Manual sets forth the framework for determining whether a patient is to be admitted:

> The physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient. Physicians *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. However, the decision 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 to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting.

(emphasis added). The Manual goes on to state that "factors to be considered when making the decision to admit *include such things as*:" (1) the severity of the signs and symptoms exhibited by the patient, (2) the medical predictability of something adverse happening to the patient, (3) the need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in

assessing whether the patient should be admitted, and (4) the availability of diagnostic procedures at the time when and at the location where the patient presents. *Id.* (emphasis added).

The plain language of the Policy Manual vests substantial discretion in the treating physician to determine whether a patient should be admitted. Unlike in *Kapps*, there are no fixed, objective eligibility criteria that, upon being met by the beneficiary, require hospital admission. The only factor that is arguably a "substantive predicate" governing the admission of a patient is the 24-hour "benchmark."[20] Meeting that benchmark, however, does not "virtually guarantee" formal admission under the rule. *Furlong*, 156 F.3d at 394. The benchmark is prefaced with the statement that a patient *should* be admitted if he or she meets the 24-hour standard. The absence of any "must" or "shall" language makes clear that a physician is not required to admit a patient if he or she meets the 24-hour benchmark, and that instead the decision remains within the physician's discretion. *See Sullivan v. Town of Salem*, 805 F.2d 81, 84 (2d Cir. 1986) (finding that the presence of the word "may" as opposed to "shall" meant the relevant action was discretionary, not mandatory, for purposes of property interest analysis). Thus, there is no "explicitly mandatory language" present. *See Ky. Dep't of Corr.*, 490 U.S. at 463.

Furthermore, immediately after setting forth the 24-hour benchmark, the Policy Manual states, "*However*, the decision to admit a patient is a *complex medical judgment* which can be made only after the physician has considered a number of factors." Policy Manual, Ch. 1 § 10

[20] Because all of the Plaintiffs were denied Part A benefits before the new rules described in footnote 11, *supra*, were adopted, and because there is no indication that the new rules apply retroactively, the recently-promulgated rules do not affect the question of whether the Plaintiffs *in this case* possessed a property interest in Part A benefits. The Court expresses no opinion on whether the new rules have created a property interest in Part A benefits going forward.

(emphasis added). In other words, the Policy Manual provides an escape hatch from the 24-hour benchmark, *i.e.*, even if the physician believes the patient will need at least 24 hours of hospital care, the physician can decline to admit the patient if he or she makes the "complex medical judgment" that admission is inappropriate in light of a slew of factors that are broadly worded and laced with discretionary judgment. The Policy Manual does not specify how the factors should be weighed, or which conditions favor admission and which do not. The Policy Manual does not even limit the physician to considering the factors listed. *Id.* ("factors to consider . . . *include such things as* . . ."). It follows that a physician could be presented with a patient she believes will need over 24 hours of hospital treatment, but ultimately decide not to admit the patient based on factors *not* enumerated in the Policy Manual. Thus, the Policy Manual does not mandate or "virtually guarantee" hospital admission upon the satisfaction of certain substantive predicates; rather, it simply *authorizes* formal admission and encourages the physician to consider certain factors. Ultimately the decision to admit is up to the physician based on his or her medical judgment. Because the Policy Manual does not "meaningfully channel official discretion" by mandating that certain patients be formally admitted, it does not entitle beneficiaries to formal admission, or, by extension, inpatient status and Part A benefits.[21]

[21] There was some discussion at oral argument about whether there is a material difference, with respect to the property interest question, between those Plaintiffs who were never admitted and those Plaintiffs (namely, Plaintiff Barrows and Intervenor-Plaintiff LeYanna) who were admitted before being re-classified to observation status. The same requirements for finding a property interest—i.e., "a legitimate claim of entitlement" and lack of official discretion—apply regardless of whether an individual is already receiving benefits or whether he or she is merely applying for benefits. *See, e.g.*, *Kelly Kare, Ltd*, 930 F.2d at 176 (medical providers did not possess property interest in *continued* participation in Medicare because they could be removed from the program without cause and at the discretion of the government agency); *see also Mallette v. Arlington Cnty. Emps.' Supp. Ret. Sys. II*, 91 F.3d 630, 638 (4th Cir. 1996) (rejecting the "application/revocation distinction"); *Kelly v. R.R. Ret. Bd.*, 625 F.2d 486, 490 (3d Cir. 1980) (due process attaches to determination of benefits eligibility whether before or after benefits have been received). Because there is no indication that the decision to re-

Plaintiffs have therefore failed to establish a property right in formal hospital admission, inpatient status, and Part A benefits. Because Plaintiffs do not possess a property right sufficient to support their Due Process claim, the Court finds it unnecessary to address the other two elements of the Due Process analysis that were both briefed by the parties: (1) state action, and (2) the process due.

Plaintiff's sixth and seventh causes of action are therefore dismissed.

5. Eighth and Ninth Causes of Action

Plaintiffs' Eighth and Ninth Causes of Action allege violations of 42 U.S.C. § 1395, which prohibits the Secretary from interfering with the practice of medicine:

> Nothing 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, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.

Although both causes of action allege that the Secretary has improperly interfered with the practice of medicine, each cause of action complains about different conduct. The Court will therefore treat them separately.

a. Eighth Cause of Action: Allowing Hospitals to Use Observation Status Based on Criteria Not Publicly Known

The Eighth Cause of Action alleges that "Defendant's policy of allowing hospitals to place Medicare beneficiaries on observation status based on criteria that are not publicly known" interferes with the practice of medicine in violation of 42 U.S.C. § 1395. (Compl. [Dkt. # 1] at ¶ 106.) The Court is not persuaded that "allowing hospitals to place Medicare beneficiaries on

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classify a patient from inpatient to observation status is *not* discretionary, there is no property interest in inpatient status once it is conferred. The distinction between the two classes of plaintiffs is thus immaterial with respect to the Due Process claim.

observation status" interferes with the practice of medicine. First, it is not apparent how using "criteria that are not publicly known," assuming that to be true, advances Plaintiffs' argument. Whether the criteria used by hospitals are known by the public or not has no bearing on whether Defendant is interfering with the practice of medicine. Moreover, insofar as Plaintiffs argue that the Secretary's decision to cover observation services under Part B instead of Part A violates 42 U.S.C. § 1395, that decision does not interfere with the practice of medicine either. *See Goodman v. Sullivan*, 891 F.2d 449, 451 (2d Cir. 1989) (refusal to provide Medicare reimbursement for MRI procedures, which were still considered experimental, did not "direct or prohibit any kind of treatment or diagnosis"). Although covering observation services under Part B "may influence some medical decisions," the Second Circuit has held that such "tangential influence alone" does not violate section 1395. *Id.* Rather, to interfere with the practice of medicine, the Secretary's action must "direct or prohibit" a particular kind of treatment or diagnosis. *Id.* Because allowing hospitals to place beneficiaries on observation status, and reimbursing services received while on observation status under Part B, do not "direct or prohibit" any kind of treatment, such actions do not violate section 1395. Plaintiffs' Eighth Cause of Action is therefore dismissed.

b. Ninth Cause of Action: Allowing Utilization Review Committees to Reverse Admission Decisions

The Ninth Cause of Action alleges that "Defendant's policy of 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," interferes with the practice of medicine. (Compl. [Dkt. # 1] at ¶ 107.) Plaintiffs assert that two factors, taken in combination, are driving the increase in the unnecessary and inappropriate use of observation status: (1) reversals of admission decisions by

Utilization Review Committees ("URCs") and Recovery Audit Contractors ("RACs") based on a finding that admission was not "reasonable and necessary," and (2) the Secretary's policy that providers who have their admission decisions reversed must return Part A Medicare payments and may not then seek reimbursement under Part B.[22] Thus, the argument seems to be that *ex post* review of observation status has combined with the requirement to repay Part A benefits in a way that significantly influences physicians' medical judgment about whether beneficiaries should be admitted as inpatients or placed on observation status. This argument is foreclosed by *Goodman*, too.

Regardless of whether Plaintiffs are right about the cause of the increased use of observation status, the retroactive reversal of admission decisions by URCs and RACs, even when combined with the Secretary's policy of not reimbursing hospitals when such reversals occur, does not "actually direct or prohibit any kind of treatment or diagnosis." *Goodman*, 891 F.2d at 451. Instead, "[i]t only refuses subsequent Medicare reimbursement for certain kinds of services," i.e., services that were later found to be unnecessary by a URC or RAC. *Id.* "This

[22] This observation is also echoed in the American Hospital Association's *amicus* brief:

> The RACs' intense focus on short inpatient stays has made it costly for hospitals to admit patients for such stays. When a RAC questions a claim, the hospital must submit medical records and other documentation supporting the billing classification; challenge and appeal the RAC's denial; and repay the funds in question if the denial is upheld. Where physicians and hospitals previously may have erred on the side of more care for vulnerable Medicare patients, who often are quite elderly and have multiple and chronic illnesses, the added enforcement risks appear to be forcing health care providers to place beneficiaries in observation status and see if it suffices.

(Am. Brief of American Hospital Association [Dkt. # 77] at 7-8.) As noted above, *supra* note 11, the Secretary has recently promulgated new regulations to address this issue. *See* 42 C.F.R. § 414.5; 42 C.F.R. § 412.3(e)(1); *see also* 78 Fed. Reg. at 50906-15, 50952.

may *influence* some medical decisions, but if tangential influence alone violates § 1395, then the Secretary would scarcely be able to regulate the Medicare program at all." *Id.* (emphasis added).

The Court also notes that the Medicare statute itself *requires* hospitals to institute URCs to review "admissions to the institution . . . with respect to the medical necessity of the services, and . . . for the purpose of promoting the most efficient use of available health facilities and services." 42 U.S.C. § 1395x(k)(1). Similarly, the Medicare Integrity Program empowers RACs to conduct medical, utilization, and fraud reviews of Medicare payments and identify overpayments and underpayments. 42 U.S.C. § 1395ddd. Thus, the Medicare statute expressly permits URCs and RACs to conduct "medical" and "utilization" reviews post-payment. Accordingly, because such reversals are expressly permitted by the Medicare statute, URC and RAC reversals of hospital admissions do not by themselves violate section 1395. Moreover, administrative review of the decision to admit and recoupment of benefits that were erroneously paid are both permitted as well. *See* 42 U.S.C. § 1395gg (stating that future payments to beneficiaries can be adjusted if an incorrect amount is paid and the "amount cannot be recouped" from the provider); *Mount Sinai Hosp. of Greater Miami, Inc. v. Weinberger*, 517 F.2d 329, 344 modified, 522 F.2d 179 (5th Cir. 1975) (holding that recoupment of overpayments from providers does not violate 42 U.S.C. § 1395).

Plaintiffs' Ninth Cause of Action is therefore dismissed.

V. Conclusion

For the reasons stated above, the Court GRANTS Defendant's Motion to Dismiss [Dkt. # 23]. The remaining motions [Dkt. ## 2, 35, 51] are DENIED as moot.

IT IS SO ORDERED.

/s/
Michael P. Shea, U.S.D.J.

Dated: Hartford, Connecticut
September 23, 2013