UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

CHRISTINA ALEXANDER, *et al.*, Plaintiffs, v. ALEXANDER M. AZAR, II, Secretary of Health and Human Services, Defendant.	No. 3:11-cv-1703 (MPS)

MEMORANDUM OF DECISION

In this class action, Medicare beneficiaries seek to require the Secretary of Health and Human Services to afford them a hearing to challenge a critical decision made by others when they are hospitalized—whether to admit them as inpatients or whether to place them on "observation status." That decision does not always affect the types of medical services they receive at the hospital, but it can have an enormous impact on their pocketbooks. If they are discharged from the hospital to a skilled nursing facility (SNF), Medicare will cover their stay only if they spent at least three consecutive days as a hospital inpatient. The named Plaintiffs in this class action spent multiple days in the hospital and were discharged to SNFs, but were designated as outpatients receiving observation services for some or all of their hospital stays. As a result, they were forced to pay for their SNF care out of pocket. The Plaintiffs brought this action against the Secretary on their own behalf and on behalf of all beneficiaries placed on observation status, claiming that his failure to afford any hearing or other administrative review of the decision to deny them inpatient status violates the Due Process Clause of the Fifth Amendment. The history of this case is protracted, and I summarize some of it below. Now before me are the Secretary's (1) second motion for summary judgment; (2) motion for class

decertification; and (3) motion to dismiss for lack of subject matter jurisdiction. For reasons I will explain, the motions are DENIED. After almost eight years of litigation, this case will finally proceed to trial.

PROCEDURAL HISTORY

I assume familiarity with the allegations in the complaints, (ECF Nos. 1, 53, 123), my ruling on the parties' earlier cross motions for summary judgment, *Alexander v. Cochran*, 2017 WL 522944 (D. Conn. Feb. 2, 2017), ECF No. 196, my ruling on the Plaintiffs' motion for class certification, *Alexander v. Price*, 275 F. Supp. 3d 313 (D. Conn. 2017), ECF No. 242, and reconsideration of that ruling, (ECF No. 250). I summarize some of the procedural history below to provide context for my analysis of the present motions.

I. Dismissal and Appeal

On November 3, 2011, seven Medicare beneficiaries or their estates filed a complaint challenging the Secretary's use of observation status. (ECF Nos. 1, 2.) They alleged violations of the Medicare Act, Administrative Procedure Act, and Due Process Clause. The Secretary moved to dismiss the complaint. (ECF No. 23.) Seven intervenor plaintiffs joined the case on April 9, 2012. (ECF No. 53.) On September 23, 2013, I granted the Secretary's motion to dismiss the Plaintiffs' original complaint and first intervenor complaint for failure to state a claim on which relief could be granted. With respect to their Due Process claims, I concluded that the Plaintiffs had not alleged facts sufficient to show that they had a protected property interest in being admitted as inpatients rather than placed on observation status. In particular, I determined that the Secretary, acting through the Centers for Medicare and Medicaid Services ("CMS"), left the decision to admit a Medicare beneficiary as an inpatient to the medical judgment of treating physicians. *Bagnall v. Sebelius*, 2013 WL 5346659, at *1 (D. Conn. Sept. 23, 2013). Concluding that CMS's Medicare

Policy Manual did not mandate that a physician order admission, but instead left the decision to the doctor's discretion, I held that the Plaintiffs had failed to allege a property interest in being admitted as inpatients. *Id.* at *21–*22. The Plaintiffs appealed.

The Second Circuit affirmed in part, vacated in part, and remanded the case.[1] The Court of Appeals held that, notwithstanding the discretionary language in the Medicare Policy Manual, the Plaintiffs had alleged facts suggesting that the decision to admit a patient to the hospital was "made through rote application of 'commercially available screening tools,' as directed by [CMS], which substitute[d] for the medical judgment of treating physicians." *Barrows*, 777 F.3d at 114. The court explained:

> If plaintiffs can prove their allegation that CMS "meaningfully channels" the discretion of doctors by providing fixed or objective criteria for when patients should be admitted, then they could arguably show that qualifying Medicare beneficiaries have a protected property interest in being treated as "inpatients." However, if the Secretary is correct and, in fact, admission decisions are vested in the medical judgment of treating physicians, then Medicare beneficiaries would lack any such property interest.

Id. at 115.

II. Proceedings on Remand

On remand, as directed by the Court of Appeals, I ordered a period of discovery "focused on . . . whether [the P]laintiffs possessed a property interest in being admitted to their hospitals as 'inpatients' . . . ." *Id.* at 116; (ECF No. 120 at 1). Shortly after discovery began, Dorothy Goodman filed a motion to intervene. (ECF No. 121.) Her motion stated that she had been placed on

[1] On appeal to the Second Circuit, the Plaintiffs challenged only the dismissal of Counts Six and Seven of their complaint, which alleged that they were entitled to expedited notice and administrative review of the decision to place them on observation status under the Medicare Act and the Due Process Clause. The Court of Appeals affirmed my decision with respect to the Medicare Act but vacated and remanded with respect to the Due Process Clause. *See Barrows v. Burwell*, 777 F.3d 106 (2d Cir. 2015). Accordingly, I discuss only the Due Process claims that remain after remand.

observation status in 2014 under policies the Secretary had adopted after the case had been dismissed and while the appeal was pending. (*Id.* at 2–3.) The Secretary did not object, and I granted the motion on May 8, 2015 (ECF No. 122). Ms. Goodman filed the Second Intervenor Complaint three days later. (Second Intervenor Compl., ECF No. 123.) The Second Intervenor Complaint alleged that the Secretary had promulgated new regulations governing inpatient admissions in October 2013. (*Id.* ¶¶ 37–42.) The regulations established the Two Midnight Rule, which allegedly created a new standard by which the Secretary would evaluate the propriety of inpatient admission orders for reimbursement under Medicare Part A. (*Id.* ¶ 37.) The Second Intervenor Complaint also alleged that the Secretary's evaluation under the Two Midnight Rule was, in practice, guided by commercial screening tools. (*Id.* ¶¶ 44, 72.)

After the initial period of discovery closed, the parties filed cross motions for summary judgment addressing whether the Plaintiffs had a protected property interest in being admitted as inpatients. (ECF Nos. 160, 164.) The Secretary also moved to dismiss the Plaintiffs' complaints, arguing that the Plaintiffs had failed to allege facts sufficient to support an inference of state action or to show that they were entitled to additional procedural protections. (*See* ECF No. 160-1 at 27–33.) I held oral argument on the motions, at which I raised concerns about standing and mootness in light of the fact that several Plaintiffs had passed away or had been reimbursed for their hospitalizations under Medicare Part A after pursuing administrative appeals. I directed the parties to file supplemental briefs addressing those concerns. (*See* ECF Nos. 189, 190.)

On February 8, 2017, I denied both parties' motions for summary judgment and granted in part and denied in part the Secretary's motion to dismiss. First, I found that all named Plaintiffs had standing, and their claims were not moot. *See Alexander v. Cochran*, 2017 WL 522944, at *4–*6 (D. Conn. Feb. 8, 2017) Second, I found that neither party was entitled to summary judgment

because there were material disputes of fact about (1) the extent to which inpatient admission decisions were dictated by the application of commercial screening tools and (2) the extent to which the Secretary directed hospitals to use those screening tools in making admission decisions. *See Id.* at *10–*14. Third, I held that the Plaintiffs' complaints "plausibly alleged that the inpatient admission decision is the result of 'significant encouragement' from the Secretary, through CMS," and denied the Secretary's motion to dismiss on state action grounds. *Id.* at *15–*16. Fourth, I found that the NOTICE Act, which required hospitals to provide written and oral notice to patients receiving observation services for more than 24 hours, 42 U.S.C. § 1395cc(a)(1)(Y), had rendered moot the Plaintiffs' claim seeking expedited notice about their observation status. *Id.* at *17–*18. Finally, I held that the Plaintiffs had adequately alleged a deprivation of Due Process by pleading that "there are *no* administrative review procedures for Medicare beneficiaries who seek to challenge their placement on observation status." *Id.* at *18.

On February 28, 2017, I held a telephonic status conference to discuss scheduling for the remainder of the case. On the call, both parties agreed that they were not seeking additional discovery in connection with class certification, and the record was sufficient to allow me to decide whether a class should be certified. (Transcript of Conf., ECF No. 251 at 12:23–13:10.) Three days later, the Plaintiffs filed a motion for class certification and appointment of class counsel. (ECF No. 203.) The Secretary opposed the motion. (ECF No. 213.) After oral argument and supplemental briefing, I granted the motion. *See Alexander v. Price*, 275 F. Supp. 3d 313 (D. Conn. 2017). After making two technical adjustments at the Plaintiffs' request, I certified the following class under Fed. R. Civ. P. 23(b)(2):

> All Medicare beneficiaries who, on or after January 1, 2009: (1) have received or will have received "observation services" as an outpatient during a hospitalization; and (2) have received or will have received an initial determination or Medicare Outpatient Observation Notice (MOON) indicating that the observation services are covered (or subject to

> coverage) under Medicare Part B. Medicare beneficiaries who meet the requirements of the foregoing sentence but who pursued an administrative appeal and received a final decision of the Secretary before September 4, 2011, are excluded from this definition.

(ECF No. 250.) Discovery then proceeded, as required by the Second Circuit, "on the other two prongs of the due process analysis—*i.e.*, 'state action' and 'due process.'" *Barrows*, 777 F.3d at 116.

III. Pending Motions

Discovery closed on June 15, 2018. The Secretary filed a letter notifying the Court of his intention to file a second motion for summary judgment addressing (1) whether the Plaintiffs could establish the existence of a property interest for individuals hospitalized after 2015; and (2) whether the Plaintiffs could adduce evidence of a risk of erroneous deprivation under *Mathews v. Eldridge*, 424 U.S. 319 (1976). (ECF No. 305 at 1–3.) The Secretary also provided notice of his intent to file a motion to decertify the class. (*Id.* at 3–6.)

I held a telephonic status conference to discuss the potential filings. On the call and in a subsequent order, I declined to allow the Secretary to file a motion for summary judgment on the existence of a property interest. I explained that the issue had been decided in my previous ruling and that the Secretary had not moved for reconsideration of that decision. (ECF No. 311.) I also discouraged the Secretary from filing a motion to decertify the class as I did not think that such a motion would further the interest of judicial economy. (*Id.*) Finally, I encouraged the Secretary to confine any motion for summary judgment "to the second *Mathews* factor, 'the risk of an erroneous deprivation of [the private interest] through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards.'" (ECF No. 311 (quoting *Mathews*, 424 U.S. at 335).)

The Secretary filed a second motion for summary judgment on July 30, 2018, and a motion for class decertification on August 24, 2018. (ECF Nos. 319, 323.) I held oral argument on the motions on November 26, 2018. At the argument, it became clear that the Plaintiffs intended to rely primarily on the Two Midnight Rule, rather than the use of commercial screening tools, as the basis of a property interest in inpatient admission for Medicare beneficiaries hospitalized after October 2013. (*See* Oral Arg. Transcr., ECF No. 363 at 67:11–14 (Plaintiffs' counsel: "I see the classes divided into 2009 up to the point where the Two Midnight Rule was introduced in 2013. So Two Midnight Rule [as the basis of a property interest] for 2013 forward, and commercial screening tools for the period before that.").) Because neither this Court nor the Second Circuit had addressed whether the Two Midnight Rule provided the type of fixed or objective criteria that could create a property interest, I permitted the parties to file supplemental briefs addressing the Plaintiffs' theory based on the Two Midnight Rule. (ECF No. 361.) The Secretary also filed a motion to dismiss the complaints for lack of subject matter jurisdiction. (ECF No. 370.)

To summarize, pending before me are (1) the Secretary's second motion for summary judgment, with supplemental briefing (ECF Nos. 319, 368); (2) the Secretary's motion for class decertification (ECF No. 323); and (3) the Secretary's motion to dismiss for lack of subject matter jurisdiction (ECF No. 370).[2]

MOTION FOR SUMMARY JUDGMENT

I. Factual and Regulatory Background

[2] I address the Secretary's motion to dismiss for lack of subject matter jurisdiction last because portions of his argument are relevant only if I grant his motion for class decertification.

The following facts are taken from the parties' Local Rule 56(a) statements and are undisputed unless otherwise noted.[3] Additional disputed facts are discussed as relevant in Section III.

A. Observation Services and Inpatient Hospitalizations

Inpatient hospitalizations are covered under Medicare Part A, while outpatient services, including observation services provided in a hospital setting, are covered under Medicare Part B. *Alexander v. Cochran*, 2017 WL 522944, at *6; (Defendant's Local Rule 56(a)(1) Statement ("56(a)(1) Stmt."), ECF No. 319-6 ¶ 4; Plaintiffs' Local Rule 56(a)(2) Statement ("56(a)(2) Stmt."), ECF No. 331-1 at 4.) Patients have different out-of-pocket obligations depending on whether their care is covered under Part A or Part B.

Under Medicare Part A, a beneficiary is required to pay for hospital services up to a one-time deductible for each "spell of illness" or "benefit period." (*See* 56(a)1 Stmt. ¶ 5; 56(a)2 Stmt. at 4–5.) The deductible covers the beneficiary's share of the cost for the first 60 days of the hospitalization. *Id.* If an inpatient is discharged from the hospital and re-admitted within 60 days of discharge, he is not responsible for paying any deductible for the re-hospitalization. (56(a)1 Stmt. ¶ 7; 56(a)2 Stmt. at 5–6.) The Plaintiffs assert that the 60-day period begins upon discharge from the hospital *or* from SNF care, whichever is later. (56(a)(2) Stmt. at 6 (citing 42 U.S.C. § 1395x(a)).) In 2018, the Part A inpatient deductible was $1,340. (56(a)1 Stmt. ¶ 6, 56(a)2 Stmt. at 5.)

Before 2016, a beneficiary placed on "observation status" was required to pay a co-pay equal to 20% of the cost of each service he or she received in the hospital. (56(a)(1) Stmt. ¶ 8;

[3] I also assume familiarity with the summary judgment record considered in my ruling on the parties' cross motions for summary judgment. *See Alexander v. Cochran*, 2017 WL 522944 at *6–*9 (D. Conn. Feb. 2, 2017), ECF No. 196 at 10–17.

56(a)2 Stmt. at 6.) The Plaintiffs assert that beneficiaries also had to pay the cost of any self-administered drugs. (56(a)2 Stmt. at 6 (citing 42 U.S.C. § 1395y(c)).) On January 1, 2016, CMS established a new, pre-set bundled rate for all covered observation services provided during a hospitalization lasting at least 8 hours. (56(a)1 Stmt. ¶ 11; 56(a)2 Stmt. at 7.) Thus, beneficiaries placed on observation status are now required to pay a co-pay equal to 20% of the bundled rate. (56(a)1 Stmt. ¶ 12; 56(a)2 Stmt. at 7–8.) In 2018, the 20% co-payment for observation services under Part B ($469.93) was less than the deductible for inpatient hospitalizations under Part A ($1,340.00). (56(a)1 Stmt. ¶ 11; 56(a)2 Stmt. at 7–8; Baugh Decl., ECF No. 319-18 ¶ 36.)

The Plaintiffs assert that beneficiaries placed on observation status may incur other expenses beyond the co-pay for the bundled observation services. For example, beneficiaries may be responsible for the cost of self-administered drugs and any services that are not included in the pre-determined bundle of observation services. (56(a)2 Stmt. at 7–8 (citing Medicare Claims Processing Manual Ch. 4 §§ 290.2.2, 290.5.3, ECF No. 334-12 at 3–4, 5–7).)

When a patient is discharged from the hospital, he or she may require additional care at a skilled nursing facility ("SNF"). Medicare Part A covers SNF care upon discharge from the hospital for individuals who spent at least three consecutive days in the hospital as inpatients. (56(a)(1) Stmt. ¶ 14; 56(a)(2) Stmt. at 9.) Beneficiaries placed on observation status under Part B, including those who were subsequently admitted as inpatients but remained hospitalized for fewer than three days after the inpatient order, are not eligible for SNF coverage under Medicare. (56(a)(2) Stmt. at 15.)

B. The Two Midnight Rule[4]

[4] The parties did not describe the Two Midnight Rule in their Local Rule 56(a) statements. This section is drawn from my ruling on the parties' cross-motions for summary judgment and from the regulations themselves except where noted.

In October 2013, CMS adopted the "Two-Midnight Rule" to address "high rates of error for hospital services rendered in a medically-unnecessary setting (*i.e.* inpatient rather than outpatient)." (ECF Nos. 164-1 ¶ 7; 176-1 ¶ 7 (quoting CMS Fact Sheet dated June 7, 2015, ECF No. 164-10 at 2).) As originally promulgated, the Rule provided, in part

> Surgical procedures, diagnostic tests, and other treatment are generally appropriate for inpatient admission and inpatient hospital payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights. The expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration.

42 C.F.R. § 412.3(e)(1) (Oct. 1, 2013). The Rule required that a formal, written inpatient order be "present in the medical record" and "supported by the physician admission and progress notes." *Id.* § 412.3(a). The written inpatient order had to be "furnished at or before the time of the inpatient admission." *Id.* § 412.3(d).

The Rule contained two exceptions. First, if a patient's hospitalization was not expected to cross two midnights, it would still be appropriate to admit the patient (and to submit a claim for reimbursement under Medicare Part A) if the patient underwent a test, procedure, or other treatment designated as "inpatient only under [42 C.F.R.] § 419.22(n)." *Id.* Second, if the patient's hospitalization did not span two midnights due to "unforeseen circumstances" such as "a beneficiary's death or transfer," it would still be appropriate for inpatient hospital payment under Part A provided that a physician reasonably expected the admission to span two midnights when entering the admission order. *Id.* § 412.3(e)(2). CMS also acknowledged that in "rare and unusual circumstance[s]" it might recognize further exceptions to the Rule. *Medicare Program Fiscal Year 2014 Payment Policies Related to Patient Status*, 78 FR 50496, 50946 (Aug. 19, 2013). In January 2014, CMS adopted the first and only such exception to date, recognizing that

a patient receiving "newly initiated mechanical ventilation" would be appropriate for inpatient admission, and therefore payment under Part A, even if her hospitalization did not span two midnights. *Medicare Program Short Inpatient Hospital Stays, Provider Administrative Appeals and Judicial Review*, 80 Fed. Reg. 70298, 70540 (Nov. 13, 2015).

It was this version of the Two Midnight Rule that was in effect when Plaintiff Dorothy Goodman was hospitalized from January 31, 2014 through February 4, 2014. (Defendant's Supplemental 56(a)(1) Stmt. ("Supp. 56(a)(1)"), ECF No. 369 ¶ 2; Plaintiffs' Supplemental 56(a)(2) Stmt. ("Supp. 56(a)(2)"), ECF No. 372-1 at 3.)

In December 2015, the Secretary promulgated regulations amending the Two Midnight Rule. As a result of these amendments, the amended Rule now provided

> [A]n inpatient admission is generally appropriate for payment under Medicare Part A when the admitting physician expects the patient to require hospital care that crosses two midnights.
>
> > (i) The expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration.

42 C.F.R. § 412.3(d)(1) (2016). The amended rule maintained the "inpatient only" and "unforeseen circumstances" exceptions noted above. It also included an additional exception:

> Where the admitting physician expects a patient to require hospital care for only a limited period of time that does not cross 2 midnights, an inpatient admission may be appropriate for payment under Medicare Part A based on the clinical judgment of the admitting physician and medical record support for that determination. The physician's decision should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. In these cases, the factors that lead to the decision to admit the patient as an inpatient must be supported by the medical record in order to be granted consideration.

42 C.F.R. § 412.3(d)(3) (2016).

The Secretary again amended the Two Midnight Rule in August 2018. *See Medicare Program; Hospital Inpatient Prospective Payment Systems and Physician Certification and Recertification of Claims*, 83 Fed. Reg. 41144, 41507–08 (Aug. 17, 2018). The amendment removed the requirement of a formal, written inpatient order. *See* 42 C.F.R. § 412.3(a) (2019) (removing the requirement that the inpatient order be "present in the medical record and be supported by the physician admission and progress notes").

C. Changes to Government Review of Medicare Claims

After a hospital admits a Medicare beneficiary as an inpatient or places the beneficiary on observation status, it submits a claim for reimbursement under the Medicare program. *Alexander v. Cochran*, 2017 WL 522944, at *7 (D. Conn. Feb. 8, 2017). A hospital's claim for Medicare reimbursement undergoes several layers of review. Before October 1, 2015, Medicare Administrative Contractors ("MACs") made the initial determination about whether a hospital's claim was appropriate for payment under Part A. *Id.* Since that date, medical review of claims submitted under the Two Midnight Rule has been delegated to Beneficiary & Family Centered Care Quality Improvement Organizations ("QIOs"). (*See* Supp. 56(a)(1) ¶ 10; Supp 56(a)(2) Stmt. at 4); *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems*, 80 Fed. Reg. 70298, 70545 (Nov. 13, 2015) ("We indicated . . . [that] no later than October 1, 2015, we would be changing the medical review strategy and planned to have QIO contractors, rather than the MACs, conduct these reviews of short inpatient stays."). These QIO evaluations are known as "short stay reviews." (Supp. 56(a)(1) ¶ 10; Supp. 56(a)(2) at 4.)

Before the Two Midnight Rule, CMS engaged Recovery Audit Contractors ("RACs") to perform targeted post-payment audits of claims approved by MACs and paid to hospitals. *Alexander v. Cochran*, 2017 WL 522944, at *7 (D. Conn. Feb. 8, 2017). RAC audits were

suspended from October 1, 2013 through December 31, 2015. (Supp. 56(a)(1) ¶ 9; Supp. 56(a)(2) at 4.) RAC audits began again in January 2016, but are now authorized only upon referral by QIOs for providers exhibiting persistent noncompliance with Medicare policies. (Supp. 56(a)(1) ¶ 11; Supp. 56(a)(2) at 5.)

II. Legal Standard

"Summary judgment is appropriate only if the movant shows that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." *Tolan v. Cotton*, 134 S.Ct. 1861, 1866 (2014) (internal quotation marks and citations omitted). "In making that determination, a court must view the evidence in the light most favorable to the opposing party." *Id*. (quotation marks omitted). On summary judgment a court "must resolve all ambiguities and draw all reasonable inferences against the movant." *Caronia v. Phillip Morris USA, Inc.*, 715 F.3d 417, 427 (2d Cir. 2013). The moving party bears the burden of demonstrating that no genuine issue exists as to any material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–25 (1986). If the moving party carries its burden, "the opposing party must come forward with specific evidence demonstrating the existence of a genuine dispute of material fact." *Brown v. Eli Lilly & Co.*, 654 F.3d 347, 358 (2d Cir. 2011).

III. Discussion

The Secretary argues that he is entitled to summary judgment because (1) the Plaintiffs have failed to adduce evidence demonstrating that they face a risk of erroneous deprivation of a protected property interest; (2) the Plaintiffs have failed to demonstrate that additional procedures could remedy any deprivation; and (3) the Plaintiffs' private interest is outweighed by the likely

burden of implementing additional procedures.[5] Because the existence of a property interest is logically antecedent to any risk of deprivation, I first address the issue raised in the parties' supplemental briefs, *i.e.*, whether the Two Midnight Rule can form the basis of a protected property interest.

A. Protected Property Interest under the Two Midnight Rule

It is well established that recipients of government benefits, including Medicare, may possess a property interest that is protected under the Due Process Clause of the Fifth Amendment. *See Kraemer v. Heckler*, 737 F.2d 214, 222 (2d Cir. 1984) (due process claim based on termination of Medicare benefits). "A mere unilateral expectation of receiving a benefit, however, is not enough—a property interest arises only where one has a legitimate claim of entitlement to the benefit." *Barrows*, 777 F.3d at 113 (quotation marks and footnotes omitted). A legitimate claim of entitlement exists when a regulatory or statutory scheme "plac[es] substantive limitations on official discretion," *Ky. Dep't of Corr. v. Thompson*, 490 U.S. 454, 462 (1989) (citation and quotation marks omitted), or "meaningfully channel[s] official discretion by mandating a defined administrative outcome." *Sealed v. Sealed*, 332 F.3d 51, 56 (2d Cir. 2003). I find there is evidence in the summary judgment record sufficient to allow a reasonable factfinder to conclude that the Two Midnight rule, as implemented, "meaningfully channels" the discretion of doctors and

[5] The Secretary filed a motion *in limine* to exclude the opinions of Professor Theodore Marmor, urging that Prof. Marmor should be precluded from testifying at trial and that I should also decline to consider his opinions on summary judgment. (ECF No. 354.) The Secretary filed his motion more than three months after filing his second motion for summary judgment, and nearly two months after the Plaintiffs filed their brief in opposition. I find that there is sufficient evidence in the record to deny summary judgment without considering Prof. Marmor's opinions. The Secretary's motion *in limine* is therefore DENIED without prejudice. The Secretary may file an updated motion for trial in accordance with the instructions available on the Court's website. *See* Trial Preferences: Procedural Motions and Arguments, http://www.ctd.uscourts.gov/content/michael-p-shea.

hospitals in deciding whether to admit a beneficiary as an inpatient. *Barrows*, 777 F.3d 106, 113 (2d Cir. 2015)

1. Physician Discretion under the Two Midnight Rule

The Secretary first argues that the Two Midnight Rule cannot form the basis of a protected property interest because it requires physicians to make a "discretionary determination[]" based on "complex medical factors." (Def. Supplemental Brief, ECF No. 368 at 12.) He asserts that the Second Circuit's decision in this case makes clear that when a decision is made based on a "complex medical judgment," no property interest arises. Specifically, the Second Circuit stated as follows:

> [D]rawing all reasonable inferences in favor of plaintiffs, these allegations show that the Secretary—acting through CMS—has effectively established fixed and objective criteria for when to admit Medicare beneficiaries as "inpatients," and that, *notwithstanding the Medicare Policy Manual's guidance*, hospitals apply these criteria when making admissions decisions, rather than relying on the judgment of their treating physicians.
> …
> *However, if the Secretary is correct and, in fact, admission decisions are vested in the medical judgment of treating physicians, then Medicare beneficiaries would lack any such property interest.*
> ….
> On remand, the District Court is directed to supervise a limited period of discovery . . . focused on the sole issue of whether plaintiffs possessed a property interest in being admitted to their hospitals as "inpatients," which, as stated above, turns on a factual determination—*namely, whether the decision to admit these patients to these hospitals was a "complex medical judgment" left to the treating physicians' discretion, or whether, in practice, the decision was made by applying fixed criteria set by the federal government.*

Barrows, 777 F.3d at 114–15 (emphases added). Although the "complex medical judgment" language quoted in the ruling comes from the pre-Two Midnight Rule version of the Medicare Policy Manual in effect at the time, it remains in the current version of the Manual describing the Two Midnight Rule and is at least arguably implicit in the regulation embodying the Rule. *Compare* Medicare Policy Manual, Ch. 1, Sec. 10 (pre-Two Midnight Rule: "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 . . . . 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 outpatients, the hospital's by-laws and admission policies, and the relative appropriateness of treatment in each setting…."); *with id.* (post-Two Midnight Rule: "Physicians should use the expectation of the patient to require hospital care that spans at least two midnights . . . as a benchmark, i.e., they should order admission for patients who are expected to require a hospital stay that crosses two midnights . . . . 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 . . . ."), *and* 42 C.F.R. § 412.3(d)(1) (effective October 1, 2018) ("Inpatient admission is generally appropriate for payment under Medicare Part A when the admitting physician expects the patient to require hospital care that crosses two midnights. (i) The expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event."); 42 C.F.R. § 412.3(d)(3) (explaining that inpatient admission may be appropriate even where physician does not expect hospitalization crossing two midnights "based on the clinical judgment of the admitting physician . . . .").

The Secretary thus argues that the Second Circuit's ruling left the plaintiffs a "narrow path" for establishing a property interest, one that leads away from "complex medical judgments" and towards "fixed and objective criteria." Because the Two Midnight Rule continues to characterize the physician's decision as involving "clinical judgment" applying "complex medical factors," this argument goes, the plaintiffs veered off the narrow property interest path defined by the Second Circuit when they selected the Rule as their new lodestar.

There are two problems with this argument. First, although the language of the Two Midnight Rule is similar to the then-effective language of the Medicare Policy Manual quoted by the Second Circuit, it is not identical, and the Second Circuit's opinion thus does not dictate my analysis of the Two Midnight Rule. Indeed, the Second Circuit's actual holding was simply that the facts alleged in the original and intervenor complaints concerning the use of commercial screening tools were sufficient to state a plausible claim for deprivation of a property interest. Second, and more importantly, the Second Circuit's opinion teaches that for purposes of deciding whether there is a property interest, the legal language surrounding a decision is not dispositive if there is evidence that the decision is actually made in a different manner. *Barrows*, 777 F.3d at 115 ("[T]hese allegations show that the Secretary—acting through CMS—has effectively established fixed and objective criteria for when to admit Medicare beneficiaries as 'inpatients,' and that, notwithstanding the Medicare Policy Manual's guidance, hospitals apply these criteria when making admissions decisions, rather than relying on the judgment of their treating physicians."); *see also Alexander v. Cochran*, 2017 WL 522944, at *10 ("Although property interests are most commonly created by statutes, regulations, or other formal policy, they may also 'be established through such diverse sources as unwritten common law and informal institutional policies and practices.'") (quoting *Furlong v. Shalala*, 156 F.3d 384, 395 (2d Cir. 1998).

Beginning with the language of the Two Midnight Rule, I find that it is a close question whether the language of the regulation, considered alone, creates a property interest. The Secretary points to the terms of the Rule that suggest discretion, arguing that they foreclose a property interest. *See, e.g.*, 42 C.F.R. § 412.3(d)(1) ("[I]npatient admission is generally appropriate for payment under Medicare Part A when the admitting physician expects the patient

to require hospital care that crosses two midnights. (i) The expectation of the physician should be based on such complex medical factors as …."); *id*. § 412.3(d)(3) ("inpatient admission may be appropriate" even when the physician expects a hospitalization that does not cross two midnights "based on the clinical judgment of the admitting physician …."). But the incorporation of discretion into a legal standard does not necessarily prevent the standard from creating an interest protected by the Due Process Clause. *See Fleury v. Clayton*, 847 F.2d 1229, 1232 (7th Cir. 1988) ("[T]he inclusion of elastic items in a list of criteria does not destroy a property interest."); *see also Eidson v. Pierce*, 745 F.2d 453, 462 (7th Cir. 1984) (stating in dicta that "[w]e do not mean to suggest that any element of discretionary judgment in determining the receipt of public benefits would defeat an asserted property interest. Elements of discretion or judgment are often involved in the application of legal criteria, and a hearing or judicial review might ensure that the discretion was exercised in accordance with the relevant criteria."). In *Fleury*, for example, the Seventh Circuit held that a statute establishing criteria for the professional discipline of physicians created a property interest in "a blemish-free license to practice medicine." 847 F.2d at 1232. While the statute established criteria requiring the Illinois Medical Disciplinary Board to make complex, discretionary judgments about a physician's conduct, it limited the Board's ability "to censure on any ground it chose . . . ." *Id*. at 1233. Thus, a property interest attached and censuring a physician without first providing an opportunity for a hearing deprived the physician of due process. *Id*.; *see also Mallette v. Arlington Cty. Employees' Supplemental Ret. Sys. II*, 91 F.3d 630, 635 (4th Cir. 1996) (holding that an employee had a property interest in retirement disability benefits because a local ordinance required benefits for individuals who met particular criteria, even though the medical examining board exercised discretion in determining whether those criteria had been met).

Fleury and other cases assessing whether a legal standard creates a property interest also draw upon case law conducting a similar analysis to determine whether there is a liberty interest protected by the Due Process Clause. For example, *Fleury* cites *Bd. of Pardons v. Allen*, 482 U.S. 369 (1987), where the Supreme Court analyzed a Montana statute directing the state Board of Pardons to release on parole any prisoner

> [W]hen in its opinion there is reasonable probability that the prisoner can be released without detriment to the prisoner or to the community . . . . A prisoner shall be placed on parole only when the board believes that he is able and willing to fulfill the obligations of a law-abiding citizen.

Id. at 377 (quoting Mont. Code. Ann. § 46-23-201 (1985). The Court recognized that the statute required the Board to make a decision that was "subjective and predictive," and the Board's discretion in making that decision was "very broad." *Id.* at 381. Nevertheless, the Court explained that the statute created a liberty interest because it "made release mandatory upon certain findings . . . ." *Id.* at 380.

In reaching this conclusion, the Court distinguished between "between two entirely distinct uses of the term discretion." *Id.* at 375. In one sense, an official has "discretion" when he or she is "simply not bound by standards set by the authority in question." *Id.* (quotation marks and citation omitted). In another, an official has discretion when he or she "must use judgment in applying the standards" or where "the standards set by a statutory or regulatory scheme cannot be applied mechanically." *Id.* The Montana statute, conferring the latter form of "discretion," supported the existence of a liberty interest. That is, because the statute *required* release when the Board made certain findings, it established standards creating a liberty interest even though the Board exercised significant discretion in making those findings.

Even under these cases, it is debatable whether the language of the Two Midnight Rule, on its own, sufficiently channels physician discretion to create a property interest. The Rule does not

use the word "shall," it relies on a physician's "expectation," it describes what that expectation "should" be based on, and it delineates circumstances in which inpatient admission is "generally appropriate." But I need not resolve that debate—as I explain below, the Plaintiffs have submitted evidence from which a reasonable factfinder could conclude that, *in practice*, the Two Midnight Rule is less discretionary than its language might suggest and does in fact create a legitimate claim of entitlement.

2. The Evidence in the Record Shows that CMS "Meaningfully Channels" Hospital and Physician Discretion

There is a genuine dispute of fact about the extent to which the Two Midnight Rule cabins physician discretion and dictates inpatient admission decisions. The Plaintiffs have adduced evidence that applying the Rule is "a billing decision divorced from physician judgment." (*See* Sheehy Decl., ECF No. 334-70 ¶ 7; Sheehy Report, ECF No. 334-71 at 11–13.) The Plaintiffs have also submitted evidence of CMS guidance suggesting that the Two Midnight Rule is to be applied in a rigid, formulaic manner. (*See, e.g.*, Ctrs. for Medicare & Medicaid Servs., *Reviewing Short Stay Hospital Claims for Patient Status: Admission On or After January 1, 2016* (Dec. 31, 2015), ECF No. 334-1 at 4–7 (providing step-by-step guidance on when an inpatient admission is appropriate and therefore payable under Medicare Part A).) CMS has developed a "2 Midnight Claim Review Guideline" for QIOs reviewing hospitals' inpatient claims, which consists of an "algorithm" or decision tree based on the Two Midnight Rule. (HCQIS Memorandum: Task 13 Short Stay Reviews, ECF No. 331-2 at 5.) According to the algorithm, if a patient is hospitalized for a period crossing two midnights following a "valid inpatient order," then QIOs will approve the claim for reimbursement under Part A without further inquiry. (*Id.*) If the hospitalization does not cross two midnights, or if it does but there is no inpatient admission order, and there is no

evidence of an "unforeseen circumstance" like death or transfer, QIOs will assess whether it was reasonable for the admitting physician to have expected that the patient would receive medically-necessary services for more than two midnights. (*Id.*) The algorithm also directs QIOs to approve inpatient claims in special cases where the hospitalization did not cross two midnights but satisfied one of the exceptions to the rule. (*Id.*) Each step in the decision tree poses a "yes" or "no" question followed by an arrow pointing to one of two boxes depending on the answer: (1) "claim is payable under Part A" or (2) "claim is not payable under Part A." (*Id.*) But there is no branch on that tree suggesting that a patient satisfying the criteria in the Two Midnight Rule should not have been treated as an inpatient. As in *Allen*, 482 U.S. 369, then, once the criteria included in the guidance prescribed by the Secretary for the review of inpatient claims are deemed satisfied, a determination of Part A coverage is required. The formulaic, step-by-step character of this decision tree suggests that the decision as to inpatient admission is not discretionary.

Further, in conducting the medical necessity review, QIOs rely on commercially available screening tools. (Ctrs. for Medicare & Medicaid Servs., BFCC-NCC Questions and Answers Form, ECF No. 331-4 at 11–12 ("The BFCC-QIO may use evidence-based commercial screening criteria for the medical necessity review of the selected claims. One example would be the use of InterQual©, a nationally recognized commercial screening tool, to determine medical necessity.").) As indicated in my earlier summary judgment ruling, "commercial screening tools . . . analyze patient status using an algorithm that processes objective information from the medical record." *Alexander v. Cochran*, 2017 WL 522944 at *7.

All this evidence would allow a reasonable fact finder to conclude that a physician's decision to admit a Medicare beneficiary as an inpatient (and therefore to submit a claim for payment under Medicare Part A) or to place the patient on observation status (and to submit a

claim for payment under Medicare Part B) is meaningfully constrained by fixed criteria used by the Secretary and his agents to implement the Two Midnight Rule. Indeed, it would allow a reasonable factfinder to infer that meeting the two-midnight threshold guarantees that a Medicare beneficiary's hospitalization will be covered under Part A notwithstanding the ostensibly discretionary language in the regulation.

CMS has also communicated that inpatient hospitalizations will *always* be covered under Part A where the hospitalization crossed two midnights. (*See Short Stay Review Guidance*, ECF No. 334-1 at 1 ("[I]npatient hospital claims with lengths of stay greater than 2 midnights after the formal admission following the order are *presumed* to be appropriate for Medicare Part A payment.") (emphasis added).) If a patient is initially placed on observation status, CMS has advised that physicians should enter an order admitting the patient once it becomes clear that he or she will remain in the hospital through a second midnight. *Medicare Program Fiscal Year 2014 Payment Policies Related to Patient Status*, 78 FR 50496, 50946 (Aug. 19, 2013) ("[T]he decision to admit becomes easier as the time approaches the second midnight, and beneficiaries in medically necessary hospitalizations should not pass a second midnight prior to the admission order being written.").

Finally, there is evidence in the record suggesting that (1) CMS has taken steps to ensure that hospitals implement the Two Midnight Rule in accordance with its instructions, and (2) hospitals consequently treat the Rule as non-discretionary. The Secretary requires hospitals participating in Medicare to develop a utilization review ("UR") plan to ensure compliance with Medicare regulations, and specifically requires hospitals to review inpatient admission orders. 42 C.F.R. § 482.30(c)(1)(i) (2019). Hospitals that fail the apply the Two Midnight Rule consistently with CMS guidance have their claims for reimbursement denied and may be subject to referral for

RAC audits. (Supp. 56(a)(1) ¶ 11; Supp. 56(a)(2) at 5.) The Plaintiffs have pointed to evidence that hospitals have adopted standards for inpatient admission, at least for Medicare patients, that treat the two-midnight threshold as dispositive. For example, the Rule 30(b)(6) deponent for Mercy Hospital, where one named plaintiff was treated, testified that nurses reviewing patient records *automatically* end their analysis (and presumably approve the claim for submission to CMS for payment) for any patient with an inpatient order who has been hospitalized for a period spanning two midnights. (*See* ECF No. 331-28 at 8:6–8:18, 18:22–19:6 ("Q: So I'm trying to summarize based on your answer and the chart. If a patient covered by this flow chart has an inpatient order and two midnights have passed since arrival, is the review complete? A: Yes Q: And is that in accordance with a Medicare rule? . . . A: Yes.").) If the patient has not yet passed a second midnight, the file is flagged for further monitoring and the patient may be changed to observation status unless the patient reaches the threshold or other documentation supports the inpatient admission order. (*Id.* at 19–20.) Similarly, the Plaintiffs have produced the "Guidelines for Utilization Review of Medical Admissions" at Abington-Jefferson Hospital. (ECF No. 373-9 at 2.) The Guidelines suggest that patients are admitted as inpatients if a physician expects their hospitalization to cross two midnights regardless of whether the patient satisfies the hospital's other "nationally recognized" criteria for admission. (*See id.* (noting that the "failure to meet inpatient level of care [based on nationally accepted criteria] can be offset by a physician's reasonable expectation that the patient will require two medically necessary inpatient midnights of care.").) Thus, although the Two Midnight Rule itself states that inpatient admission is "generally appropriate" when the physician expects the patient to require a two-night stay in the hospital, Abington-Jefferson hospital apparently treats that circumstance as a guarantee of admission.

In sum, based on the foregoing evidence, a reasonable factfinder could conclude that the Two Midnight Rule, as applied by CMS and hospitals, effectively mandates inpatient admission for Medicare beneficiaries who meet the standards it establishes, and thus that he Plaintiffs have a protected property interest in being admitted as inpatients.

B. How Much Process Is Due?

The next question is how much process is due before the Plaintiffs may be deprived of their property interest. *See Mathews*, 424 U.S. at 333 ("This Court consistently has held that some form of hearing is required before an individual is finally deprived of a property interest."). The inquiry requires balancing three factors:

> First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

Id. at 335.

The Secretary asserts that he is entitled to summary judgment because the private interest in being admitted as an inpatient is "limited at best," the Plaintiffs cannot show that there is any risk of an erroneous deprivation under existing procedures, and the administrative burden to the Government of implementing appeal procedures would be substantial. But I find that these issues cannot be resolved on summary judgment. There is evidence in the record that would allow a reasonable factfinder to conclude that there is at least some risk that Medicare beneficiaries have been, and will be, erroneously designated as outpatients rather than inpatients and thus wrongly deprived of benefits under Medicare Part A. There is also evidence both that the private interest at stake is weighty and that the Government would incur significant costs if ordered to put in

place a review mechanism; and I conclude that I cannot conduct the balancing of those conflicting interests without a trial.

1. Risk of an Erroneous Deprivation

a. Systemic Evidence Regarding Decisionmaking Bias and the Value of Procedural Safeguards

The Plaintiffs have adduced evidence suggesting that CMS's review process pressures hospitals to place patients on observation status rather than admitting them as inpatients. Hospital claims for inpatient reimbursement under Medicare Part A are subject to review by QIOs, while claims for outpatient reimbursement are not. (Supp. 56(a)(1) ¶ 10; Supp 56(a)(2) Stmt. at 4; *see* Mercy Hospital Dep., ECF No. 331-28 at 6 ("Q: Does [the QIO] ever review observation claims for appropriateness of [payment] . . . . [A:] Not that I'm aware of.").)) If a QIO identifies a hospital that consistently fails to apply the Two Midnight Rule appropriately, that hospital may be referred to a RAC for more intensive scrutiny. (Supp. 56(a)(1) ¶ 11; Supp. 56(a)(2) at 5.) In fiscal year 2014, RACs "recouped" from hospitals $1.2 billion in improper inpatient claims. *Alexander v. Cochran*, 2017 WL 522944, at *7. RACs review only claims that are submitted as inpatient claims under Part A. *See id.* ("RACs do not, however, review *outpatient* claims to determine whether they should have been paid as an inpatient."). Similarly, the Office of the Inspector General for the Department of Health and Human Services audits hospitals' inpatient claims, but not outpatient claims. *Alexander v. Cochran*, 2017 WL 522944, at *7. Hospitals can avoid these additional layers of review, then, by classifying close cases as outpatients receiving observation services. The Plaintiffs' expert, Dr. Ann Sheehy, opines that CMS thus exerts "significant pressure" on hospitals to classify patients as observation rather than inpatients. (Sheehy Decl., ECF No. 334-70 ¶ 2.)

The record supports an inference that, at least in close cases, hospitals err against classifying beneficiaries as inpatients to avoid review and reversal. In another Medicare case in which there was evidence that pressure stemming from the Secretary's coverage policies affected decision making by providers, the Second Circuit suggested that such pressure may increase the risk of an erroneous deprivation under the *Mathews* test:

> [T]here appear to be significant differences between *Eldridge* and this case with respect to the fairness and reliability of the existing pretermination procedures and the probable value of additional procedural safeguards. 424 U.S. at 343. It is true that termination in both cases turns . . . upon routine and (hopefully) unbiased medical reports by physicians. *See id*. at 344. However, as our earlier discussion of the government nexus indicated, there are serious factual questions about the effects of governmental regulations and directives on the medical judgments of URCs. If the appellants' allegations on these matters are borne out, then we think the case would be sufficiently different from *Eldridge* to require different, additional safeguards.

Kraemer, 737 F.2d at 222.

The Plaintiffs have also adduced evidence that would allow a reasonable factfinder to conclude that additional procedural safeguards would help to identify and correct any errors that occur. If a RAC or QIO denies a hospital's claim for inpatient reimbursement because the claim does not meet CMS's standards under Part A, the hospital has a statutory right to appeal the denial through multiple layers of administrative and judicial review. *See generally Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183, 185 (D.C. Cir. 2016) (summarizing the administrative appeal process for hospitals); 80 Fed. Reg. 70298, 70546 (noting that providers may appeal from QIO denials "under the provisions of section 1869 of the [Medicare] Act and procedures in 42 CFR part 405."). The Plaintiffs' expert cites sources suggesting that hospitals are successful in up to 62% of appeals. (Sheehy Decl., ECF No. 334-70 ¶ 16.) The core issue in a hospital's appeal is whether it was appropriate for the hospital to admit a Medicare beneficiary as an inpatient—the same issue the Plaintiffs propose to litigate in the hearing they seek. The substantial rate of

success in provider appeals suggests, at the very least, that the question is amenable to reconsideration upon further review. A reasonable factfinder could therefore conclude that additional procedures would be valuable in preventing or remedying erroneous deprivations.

b. Evidence of Potential Erroneous Deprivations under the Two Midnight Rule

Although the Plaintiffs need only show a "risk" of an erroneous deprivation, here they have also produced evidence supporting an inference that Medicare beneficiaries have actually been erroneously designated as outpatients under the Two Midnight Rule. For example, one Medicare beneficiary testified that he was hospitalized with a shoulder injury after he fell on December 31, 2015. (Kanefsky Dep., ECF No. 334-54 at 7.) He was discharged to SNF on January 5, 2016. (*Id.* at 14.) Thus, his hospitalization crossed at least five midnights. Upon his discharge from SNF, he received a bill for the SNF services, indicating that Medicare would not cover his stay. (*Id.* at 18.) He contacted the hospital and was told that "the powers that be" had placed him on observation status. (*Id.* at 15.) He testified that his treating physician appeared "aghast" upon learning that his inpatient order had been overridden. (*Id.*)

The Plaintiffs have also produced the medical records of a Medicare beneficiary who was admitted to the hospital as an inpatient on April 13, 2017 at 6:48 PM. (Niemi Med. Record, ECF No. 334-57 at 14.) A physician entered an order the same day that stated "ADMIT TO INPATIENT" and indicated that her expected length of stay was "Past Midnight tomorrow." (*Id.*) At 3:30 PM the next day, a case manager entered the following note:

> The Utilization Review Committee Physician Advisor recommends changing this patient from inpatient to observation based on the Committee's findings that this patient does not require an inpatient level of care. Refer to history and physical, progress notes, and discharge summary as appropriate to review care provided to the patient. Co-Signature of the attending physician indicates concurrence with this recommendation.

(*Id.* at 17.) As a result, she was placed on observation status. A different physician later entered an order re-admitting her as an inpatient on April 24, 2017. (*Id.* at 15–16.) That order was again reversed the next day, with an identical note describing the recommendation of the Utilization Review Committee. (*Id.* at 19.) The record suggests that the patient's treating physician believed she required SNF placement, but the patient could not afford SNF care out of pocket and Medicare would not cover SNF care because she had not "met 3 midnight 'Inpatient status' criteria." (*Id.* at 20.) She remained hospitalized on observation status until May 22, 2017—a total of 39 midnights. (*Id.* at 14.)

If either of these individuals had a right to appeal, they likely could have met the requirements of the Two Midnight Rule unless the care they received was not medically necessary. In each case, there is evidence that a physician had entered an order indicating that the beneficiary should be admitted as an inpatient and noting an expectation that the beneficiary's hospital stay would cross two midnights. (ECF No. 334-54 at 15; ECF No. 334-57 at 14.) In each case, the beneficiary's stay actually did cross two midnights. (ECF No. 334-54 at 7, 14; ECF No. 334-57 at 14–15.) Yet in each case, the beneficiary was ultimately placed on observation status. Viewed in the light most favorable to the Plaintiffs, the record would allow a reasonable factfinder to conclude that there is a non-trivial risk that some Medicare beneficiaries have been, and will be, deprived of coverage for hospital services and SNF care under Medicare Part A despite meeting the requirements of the Two Midnight Rule.

c. Evidence of Potential Erroneous Deprivation under Commercial Screening Tools

The Secretary next contends that he is entitled to summary judgment because the pre-October 2013 Plaintiffs cannot identify the criteria in the commercial screening tools on which

their property interest is founded, and therefore cannot demonstrate that additional procedures would reduce the risk of an erroneous deprivation. Even without knowing those criteria, however, a reasonable factfinder could conclude that there is some risk of an erroneous deprivation, and that some administrative review would reduce that risk.[6] The Plaintiffs have adduced evidence that commercial screening tools utilize information extracted from a patient's medical record. (Charlberg Dep., ECF No. 334-47 at 4 (Question: "So how would you use Milliman to do the review?" Answer: "We would access the guidelines and look for the specific context of that presentation – that admission – that observation presentation." Question: "So would you have to read the patient's medical record and then take information from it and put it into the software?" Answer: "Yes."); Mulcahy ALJ Hearing, ECF No. 334-64 at 14 (explaining that a patient diagnosed with a urinary tract infection would not qualify for inpatient treatment under InterQual criteria because "InterQual only recognizes a systemic or an organ infection"); Duvall Dep., ECF No. 334-16 at 7–8 (explaining factors included in InterQual guidelines).) There is also evidence suggesting that medical records may be incomplete or inaccurate, or that staff screening the records may overlook details that could alter the patient's status. (*E.g.*, Vedere

[6] Nonetheless, if these plaintiffs cannot identify the commercial screening tool criteria, their claim to a property interest based on those criteria may founder. Although I previously determined that the Plaintiffs who were relying on commercial screening tools as the source of their property interest had raised genuine issues of material fact warranting a trial, *Alexander v. Cochran*, 2017 WL 522944, at *14, that was before I learned that the Plaintiffs apparently declined to use the discovery process to determine what those criteria were. The hearing required by the Due Process clause generally focuses on the question whether a claimant satisfied the substantive predicates that form the basis of his or her property interest. *See Perry v. Sindermann*, 408 U.S. 593, 601 (1972) ("A person's interest in a benefit is a 'property' interest for due process purposes if there are such rules or mutually explicit understandings that support his claim of entitlement to the benefit *and that he may invoke at a hearing*.") (emphasis added). While the existence of a property interest based on screening tool criteria is not at issue in the current motion for summary judgment, I note that any failure by the Plaintiffs to identify those substantive predicates at trial may undermine the claims of those who rely on commercial screening tool criteria as the source of their property interests.

Dep., ECF No. 334-51 at 5 (Question: "At Saint Raphael have you ever disagreed with recommendations from utilization review?" Answer: "I have called a couple of times. Like, Hey, this patient is mentioned as observation. I think, you know, this and this also is going on, maybe they missed this number or they did not tell me about those . . . .").)[7] Thus, a reasonable factfinder could conclude that there is a risk of an erroneous deprivation based on the prospect of clerical errors and the absence of *any* form of review. *See Mackey v. Montrym*, 443 U.S. 1, 15 (1979) (holding that a pre-license-suspension hearing was not required for drivers who refused a breathalyzer test upon being arrested for driving under the influence, because drivers could already request a "same day" hearing before the state registrar of motor vehicles, among other things, "to obtain correction of clerical errors" in the police report of the arrest); *id.* at 16

[7] CMS has acknowledged that clerical errors have resulted in hospitals' claims for Part A reimbursement being incorrectly denied. *See Medicare Program; Hospital Inpatient Prospective Payment Systems and Physician Certification and Recertification of Claims*, 83 Fed. Reg. 41144, 41507 (Aug. 17, 2019) ("[I]t has come to our attention that some medically necessary inpatient admissions are being denied payment due to technical discrepancies with the documentation of inpatient admission orders. Common technical discrepancies consist of missing practitioner admission signatures, missing co-signatures or authentication signatures, and signatures occurring after discharge. We have become aware that, particularly during the case review process, these discrepancies have occasionally been the primary reason for denying Medicare payment of an individual claim."). A reasonable factfinder could infer that similar "technical discrepancies" occurred when applying commercial screening tools, and that beneficiaries could identify and correct those discrepancies if given the opportunity.

CMS sought to reduce the impact of clerical errors under the Two Midnight Rule by removing the requirement that a *written* inpatient order be present in the medical record. Thus, CMS now reviews claims to determine "[i]f other available documentation, such as the physician certification statement when required, progress notes, or the medical record as a whole, supports that all the coverage criteria (including medical necessity) are met . . . ." *Id.* The change suggests that contractors are charged with reviewing a patient's "medical record as a whole" to determine whether that patient was appropriately treated as an inpatient under the Rule. I note that this shift arguably bolsters the claim of the Two Midnight Rule plaintiffs that there is a risk of erroneous deprivation: A reasonable factfinder could conclude that the newly-required holistic inquiry, while reducing the risk of denials based on "technical discrepancies," still carries a risk of error, one that would be reduced with input from the beneficiary at a hearing.

(explaining that independent review by the registrar of the police officer's report of refusal, which was required by state law, was already likely to detect "genuinely material" "clerical errors.").

A reasonable factfinder could infer that creating some form of review procedure would prevent or correct errors in applying commercial screening tools. For example, a barebones "hearing" at which Medicare beneficiaries could review their medical records and request that clerical errors be corrected and then the records reevaluated using screening tools could reduce the risk of erroneous inpatient denials. Given that there is currently *no* formal procedure for review, even evidence of a modest benefit is sufficient to preclude summary judgment. *See Mathews*, 424 U.S. at 333 ("This Court consistently has held that *some form of hearing is required* before an individual is finally deprived of a property interest.") (emphasis added).

2. The Private Interest and Likely Administrative Burden of an Appeals Process

I indicated after a telephone conference with counsel last summer that I was "skeptical" that the first and third *Mathews* factors were susceptible to decision on summary judgment in this case. (ECF No. 311.) Nevertheless, the Secretary addressed all three factors in his brief in support of his motion for summary judgment. (Brief in Support of Second Motion for Summary Judgment, ECF No. 319-1 33–36.) *Mathews* establishes a *balancing* test, and on summary judgment, I may not weigh the evidence. *See St. Pierre v. Dyer*, 208 F.3d 394, 404 (2d Cir.2000) ("In ruling on [a summary judgment motion], the court is not entitled to weigh the evidence."). In any event, there is sufficient evidence with respect to the first and third factors to create a genuine dispute of material fact about the appropriate resolution of the *Mathews* balancing test.

First, the private interest in this case is substantial, including significant out-of-pocket costs for Medicare beneficiaries who receive post-hospital SNF care without Part A coverage and the difficult decision to forego recommended treatment for those who cannot afford to pay those costs. (*See* Sheehy Decl., ECF No. 334-70 ¶ 18 (noting that the "estimated out-of-pocket cost for SNF care after a non-qualifying hospitalization is $10,503")); *see also Kramer*, 737 F.2d at 222 ("In applying the balancing test, the private interest at stake should be weighed more heavily than in *Eldridge* because of the astronomical nature of medical costs.").

Second, although the Secretary has pointed to evidence that the Government would incur costs and additional claims-processing delays if required to afford the type of administrative hearing the Plaintiffs seek, his evidence on this point is somewhat general. (*See, e.g.*, 56(a)(1) Stmt. ¶ 30 ("If any new workload is prioritized (because it involves appeals by beneficiaries), it would divert resources away from existing categories of pending appeals, many of which have been awaiting adjudication for years.") In any event, these costs will ultimately have to be balanced against what appears to be a weighty private interest. The record on summary judgment does not provide sufficiently precise tools to perform that balancing. *See Kraemer*, 737 F.2d at 222–23 ("We fully appreciate that *Eldridge* throws onto the scale consideration of the additional administrative and financial burdens entailed by procedures such as pretermination notification, the opportunity for written or oral submissions and provision for a tentative assessment accompanied by reasons therefor. We leave these matters for further development in the record, simply noting that the plaintiff class has stated a colorable claim on the merits, for which summary judgment is inappropriate.")

For all these reasons, a trial is necessary to determine whether the Plaintiffs have a property interest and how to strike the balance of the *Mathews* factors in this case.

MOTION FOR CLASS DECERTIFICATION

The Secretary has also filed a motion for class decertification. He argues that the class must be decertified because the facts developed in discovery show that (1) the class currently includes some members who lack Article III standing; (2) the Plaintiffs cannot show that the currently-certified class meets the commonality and typicality requirements under Fed. R. Civ. P. 23(a); and (3) there is no final injunctive relief that would be appropriate for the class as a whole.[8] Although I agree that the facts developed through discovery pose problems for the class as it is currently defined, I find that these problems can be addressed by narrowing the class.

I. Legal Standard

The party seeking class certification bears the burden of establishing that the class meets the requirements of Federal Rule of Civil Procedure 23. *See Wu v. Pearson Educ. Inc.*, No. 09-cv-6557 (KBF), 2012 WL 6681701, at *5 (S.D.N.Y. Dec. 21, 2012) (noting that the same burden applies for decertification as for initial certification). Rule 23(a) requires a showing that

> (1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class.

In addition to these four explicit conditions, the Second Circuit has recognized an implied requirement that the class be ascertainable. That is, it must be "defined using objective criteria that establish a membership with definite boundaries." *In re Petrobras Sec.*, 862 F.3d 250, 257 (2d Cir. 2017).

[8] The Secretary also now asserts that it was inappropriate to certify a class in the first instance without allowing the parties to take discovery on class certification issues. (*See* ECF No. 323-1 at 7 n.1.) But at the time, counsel for the Secretary explicitly confirmed that the Secretary was not seeking discovery in connection with the Plaintiffs' motion for class certification and indicated that the existing factual record was sufficient to allow me to decide that motion. (ECF No. 251 at 12:23–13:10.)

The Plaintiffs must also satisfy one of the three paragraphs of subsection (b) of Rule 23. I certified the existing class under Rule 23(b)(2). To satisfy the requirements of Rule 23(b)(2), the Plaintiffs must demonstrate that "the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole." Fed. R. Civ. P. 23(b)(2).

"[B]ecause the results of class proceedings are binding on absent class members . . . the district court has the affirmative duty of monitoring its class decisions in light of the evidentiary development of the case." *Mazzei v. Money Store*, 829 F.3d 260, 266 (2d Cir. 2016). Thus, a court retains discretion to alter, amend, or decertify the class at any time before final judgment. Fed. R. Civ. P. 23(c)(1)(C); Fed. R. Civ. P. 23(c)(1) advisory committee's note to the 2003 amendment ("Decertification may be warranted after further proceedings.").

II. Discussion

A. Standing of Class Members

The Secretary argues that being placed on observation status does not always have negative financial consequences for a Medicare beneficiary, and some class members therefore lack Article III standing because they have not suffered an injury in fact. (ECF No. 323-1 at 31.) Although individual class members need not submit particularized evidence of personal standing, "no class may be certified that contains members lacking Article III standing." *Denney v. Deutsche Bank AG*, 443 F.3d 253, 263 (2d Cir. 2006).[9] The class must therefore be defined in such a way that any given member of the class has suffered, or will suffer, an injury in fact. *Id.* at

[9] I set forth the requirements for Article III standing in greater detail in the portion of this ruling addressing the Secretary's motion to dismiss, *infra*.

264. In light of the record now before me, it is apparent that not all members of the class have standing under Article III.

The Secretary has provided evidence that, on average, Medicare beneficiaries placed on observation status face lower out-of-pocket costs per hospitalization than those admitted as inpatients. (*See* Blaugh Decl., ECF No. 323-10 ¶ 35.) Further, beginning in 2016, Medicare altered co-payments for beneficiaries receiving observation services under Medicare Part B. *See* Motion for Summary Judgment, *supra*, Part I.B. Because of these regulatory changes, the baseline out-of-pocket cost for a Medicare beneficiary with both Part A and Part B coverage is lower if he is placed on observation status while in the hospital than if he is admitted as an inpatient. In 2018, for example, an individual admitted as an inpatient under Medicare Part A would be required to pay a deductible of $1,340.00 while a beneficiary treated as an outpatient receiving observation services would be subject to a co-pay of $469.93 plus the cost of self-administered medication expenses. (Baugh Decl., ECF No. 319-18 ¶ 36.)[10] The existing class therefore includes beneficiaries who not only lack any financial injury, but who would incur additional costs if they were instead admitted as inpatients.

These standing issues are better addressed by redefining the class than by decertifying it entirely. Class decertification is disfavored at a late stage of litigation when it could unfairly prejudice existing class members. *See Gortat v. Capala Bros.*, No. 07-CV-3629-ILG-SMG, 2012 WL 1116495, at *2 (E.D.N.Y. Apr. 3, 2012), *aff'd*, 568 F. App'x 78 (2d Cir. 2014) ("Courts assessing a motion to decertify a previously certified class should also consider the stage of the litigation and whether an eve-of-trial decertification could adversely and unfairly prejudice class

[10] In 2014, the average self-administered medication cost for Part B beneficiaries was $207. *Id.*

members, who may be unable to protect their own interests.") (quotation marks omitted). I certified a class in this case on July 31, 2017. *Alexander v. Price*, 275 F. Supp. 3d 313 (D. Conn. 2017). Since that time, class members may have foregone the opportunity to pursue individual claims because those claims were encompassed by this suit. *See Woe by Woe v. Cuomo*, 729 F.2d 96, 107 (2d Cir. 1984) ("We are also concerned about possible prejudice to members of a class who failed or were unable to take independent steps to protect their rights precisely because they were members of the class.")

In any event, class decertification is not necessary here. The Plaintiffs have identified two groups of Medicare beneficiaries for whom placement on observation status *always* causes injury, and the class can be narrowed to encompass only those groups. *See id.* ("Indeed, it is an extreme step to dismiss a suit simply by decertifying a class, where a potentially proper class exists and can easily be created.") (internal quotation marks omitted). First, beneficiaries who are hospitalized for three or more consecutive days, but admitted as inpatients for fewer than three consecutive days, are not eligible for SNF care under Medicare Part A. When these beneficiaries require SNF care, they must cover the costs out of pocket. All of the named Plaintiffs fall within this group (*see* ECF Nos. 1, 53, 123; 56(a)(2) Stmt. at 36–37 (summarizing the experience of Martha Leyanna)), as do two of the class members whose experiences the Plaintiffs summarized in their opposition to summary judgment. (56(a)(2) Stmt. at 33–36 (summarizing the experiences of Ervin Kanfesky, Nancy Niemi).) [11]

[11] In certifying the original class in this case, I discussed at length my conclusion that the named Plaintiffs' claims were typical of the class as a whole, including individuals who suffered financial harm but did not require SNF care. *See Alexander v. Price*, 275 F. Supp. 3d. at 324–25. The present redefinition narrows the class in this regard to include only those who would be eligible for SNF care but for their placement on observation status, plus beneficiaries who lack Part B coverage. To be clear, the class would continue to embrace individuals who would be or

Second, approximately 6% of Medicare beneficiaries are enrolled in coverage under Part A but not Part B. (56(a)(2) Stmt. at 9 (citing AARP Public Pol'y Inst., *Fact Sheet: The Medicare Population* at 1 (2009), https://assets.aarp.org/rgcenter/health/fs149_medicare.pdf).) These individuals are financially responsible for the full cost of their hospitalization if they are placed on observation status. For example, the Plaintiffs have identified one class member who chose not to enroll in Part B coverage because he could not afford the additional monthly payments. (*See* Roney Dep., ECF No. 334-66 at 13 (Question: "Is there any reason why you have decided not to enroll in the past for Part B?" Answer: "I wasn't really sure that I could afford the monthly payments. . . . .").) He was hospitalized on September 17, 2016. (*Id.* at 3.) During his hospitalization, he believed that he had been admitted as an inpatient. (*Id.* at 9.) At some point during his hospitalization, though, he was placed on observation status. (*Id.* at 12). Because he was not covered under Part B, he was billed for the full cost of his hospitalization—$3,500. Such an individual plainly has suffered an injury in fact from his placement on observation status.

I acknowledge that narrowing the class to include only these two groups fails to cover some individuals who might suffer a financial injury because of their placement on observation status. For example, this definition does not include individuals covered under both Part A and Part B who incur greater expenses while on observation status because the services they received

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were eligible for SNF care but for their placement on observation status, including those who decide to forego SNF care. As I explained in my previous decision,

> It is true that plaintiffs have emphasized that an expedited administrative appeals process is important because it would give SNF-eligible individuals the ability to challenge their observation placement before incurring high SNF costs. They have noted that the lack of expedited administrative review can force individuals who need SNF but cannot afford it to forgo critical care. For individuals making the weighty decision of whether to seek SNF care after a hospitalization, the additional procedural safeguard of expedited review could be more valuable, and thus could receive significant weight in the *Mathews v. Eldridge* balancing test.

Alexander v. Price, 275 F. Supp. 3d at 323.

were not included under the bundled observation rate. The definition also fails to include individuals who face additional costs because they are placed on observation status and re-hospitalized within 60 days.[12] I nonetheless decline to expand the class to cover these two groups. According to a study cited by the Plaintiffs, only about 1 in 4 observation patients who are re-hospitalized face cumulative costs greater than the standard inpatient deductible, even across both stays. (*See* 56(a)(2) Stmt. at 10–11 (citing Shreya Kangovi et al., *Patient Financial Responsibility for Observation Care*, 10 J. Hospital Med. 718, 720 (2015).)[13] And merely stating that these individuals *could* suffer adverse financial consequences from the "observation" designation, as the Plaintiffs do (56(a)(2) Stmt. at 9), is insufficient to establish standing. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) ("Although imminence is concededly a somewhat elastic concept, it cannot be stretched beyond its purpose, which is to ensure that the alleged injury is not too speculative for Article III purposes—that the injury is *certainly* impending. . . . Thus, we have repeatedly reiterated that threatened injury must be *certainly impending* to constitute injury in fact, and that allegations of *possible* future injury are not sufficient.") (internal quotation marks omitted). Standing to seek prospective relief requires a showing of an "actual or imminent" injury, *Lujan*, 504 U.S. at 560. This is not a showing these individuals could make, at least unless and until they had stayed at the hospital for three nights. I am not aware of evidence about any class member who experienced either of these situations,

[12] Some of these beneficiaries might fall within the first definition above—*i.e.*, individuals who require SNF care but are ineligible because they were placed on observation status.

[13] This study addresses the period *before* CMS adopted regulations standardizing co-pays for hospitalizations on observation status under Part B. As noted above, the baseline co-pay for a beneficiary placed on observation status is substantially lower than the Part A inpatient deductible. (Baugh Decl., ECF No. 319-18 ¶ 36.) In other words, this group is currently likely to be smaller than 1 in 4 re-hospitalized observation patients.

and any such persons could only be identified retrospectively by reference to the amount they were ultimately billed after discharge. Because such persons would not have standing by virtue of their initial designation as "observation status," they cannot be included in a class that seeks prospective relief in the form of a hearing to contest that designation.

B. Commonality, Typicality, and Appropriate Class-Wide Relief

The Secretary next argues that the Plaintiffs cannot bear their burden of demonstrating commonality and typicality because the evidence in the record suggests that their claims are not susceptible to class-wide proof. He also argues that no single injunction could provide relief for the whole class. In support of these assertions, he points to testimony by physicians demonstrating heterogeneity in the way that hospitals approach inpatient admission versus observation status. (*See generally* ECF No. 323-1 at 6–15 (summarizing the views of Dr. Christopher Baugh, ECF No. 323-10; Dr. Christopher Steevens, ECF No. 323-3; Dr. Harvey Lee, ECF No. 323-4; Dr. Cheryl Laffer, ECF No. 323-5; Dr. Ann Sheehy, ECF No. 323-2; utilization review nurse Cathi Charlberg, ECF No. 323-7; and Dr. Swarupa Reddy, ECF No. 323-8).)

This evidence of varying practices, however, pales next to the solid core of common factual and legal questions that cut across the class as a whole. As I explained in initially certifying a class

> All proposed class members . . . have core factual questions in common, such as "How is the inpatient status determination made within hospitals?" and "To what extent does CMS influence hospital decision-making?" The fundamental legal questions in this case are also common, for example: "Do Medicare beneficiaries ha[ve] a protected property interest in being treated as inpatients in the hospital?" "Does the inpatient vs. observation decision constitute state action?" All of these questions are best suited for class-wide resolution.

Alexander v. Price, 275 F. Supp. 3d 313, 324 (D. Conn. 2017). The same is true of the other legal questions considered in today's summary judgment ruling: If there is a property interest, does the absence of any review of the inpatient decision create a risk of erroneous deprivation? What is the private interest at stake for those who must pay for SNF care out of pocket and for

those without Part B coverage? What is the burden to the Government of creating a hearing procedure? I have already held that there are material disputes of fact about all of these questions. The Secretary's evidence about the diversity of hospital and physician approaches will likely be relevant at trial on the question of whether there is state action, but it does not warrant decertification at this late stage.

The Secretary's reliance on *Wal-Mart Stores v. Dukes*, 564 U.S. 338 (2011), is also misplaced. In that case, the district court had certified a nationwide class of all current and former female Wal-Mart employees suing the retailer for employment discrimination. The Supreme Court reversed, explaining that "[t]he only corporate policy that the plaintiffs' evidence convincingly establishe[d was] Wal–Mart's 'policy' of allowing discretion by local supervisors over employment matters." *Id.* 564 U.S. at 355. Because the plaintiffs could not identify a company-wide policy of discrimination, they could not establish that Wal-Mart acted discriminatorily in each of the millions of employment decisions at issue. *Id.* at 357 ("Other than the bare existence of delegated discretion, respondents have identified no 'specific employment practice'—much less one that ties all their 1.5 million claims together.") In contrast, here, the Plaintiffs have adduced evidence that *all* hospitals participating in Medicare are compelled to apply the standards for inpatient admission decisions that CMS dictates, and it is undisputed that the agency has no formal procedure through which any class members can challenge those decisions. Regardless of the circumstances surrounding the decision to place each class member on observation status, all class members described in the modified class definition below have a strong interest that is affected by the inpatient/observation decision and yet lack formal procedural recourse to challenge that decision. They have therefore met their burden of demonstrating the existence of common questions of law or fact across the entire class.

C. Modified Class Definition

For the foregoing reasons, the Secretary's motion for class decertification is denied, and I adopt the following modified class definition:

> All Medicare beneficiaries who, on or after January 1, 2009: (1) have received or will have received "observation services" as an outpatient during a hospitalization; (2) have received or will have received an initial determination or Medicare Outpatient Observation Notice (MOON) indicating that the observation services are not covered under Medicare Part A; and (3) either (a) were not enrolled in Part B coverage at the time of their hospitalization; or (b) stayed at the hospital for three or more consecutive days but were designated as inpatients for fewer than three days. Medicare beneficiaries who meet the requirements of the foregoing sentence but who pursued an administrative appeal and received a final decision of the Secretary before September 4, 2011, are excluded from this definition.

* * * *

More modifications may be necessary. Specifically, in light of my ruling today on summary judgment, it appears that it may be necessary to subdivide the current class. As currently defined, the class comprises two arguably-distinct groups: (1) Medicare beneficiaries hospitalized before October 2013 who assert a property interest based on the use of commercial screening tools; and (2) Medicare beneficiaries hospitalized after October 2013 who assert a property interest under the Two Midnight Rule. (*See* Oral Arg. Transcr., ECF No. 363 at 67:11–14 (Plaintiffs' counsel: "I see the classes divided into 2009 up to the point where the Two Midnight Rule was introduced in 2013. So Two Midnight Rule [as the basis of a property interest] for 2013 forward, and commercial screening tools for the period before that.").) Although there are undoubtedly common questions of law and fact for both groups, their interests do not universally align. The administrative burden of providing a hearing for beneficiaries hospitalized before 2013 would be significantly lower given that the group could only include beneficiaries hospitalized during a four-year period. In contrast, nearly six years have elapsed since the Two Midnight Rule was promulgated, and the post-October 2013 group is

open-ended—it includes individuals who will be hospitalized under the Rule in the future. Although a single injunction could potentially redress the procedural deprivation and financial injuries suffered by both groups, each might have reason to seek a different form of hearing depending on the standard that applies. For example, I may determine that the nature of the property interest under commercial screening tools warrants only a brief review of the patient's record. In contrast, a hearing under the Two Midnight Rule could be more involved as the standard arguably requires more expert input. Further, the groups may rely on different facts to demonstrate that CMS implemented the relevant standards in a way that dictated hospitals' inpatient admission decisions, and the determination whether there is a property interest at all may be different for the two groups.

If the differences noted above create "a fundamental conflict among class members," I would be required to divide the class into subclasses and appoint separate counsel for each. *Charron v. Wiener*, 731 F.3d 241, 252 (2d Cir. 2013); *see* Fed. R. Civ. P. 23(c)(5) ("When appropriate, a class may be divided into subclasses that are each treated as a separate class under this rule."). In the absence of "fundamental conflict," I may alternatively divide the class for case management purposes without formally creating subclasses requiring separate counsel. *See Am. Timber & Trading Co. v. First Nat. Bank of Oregon*, 690 F.2d 781, 786 (9th Cir. 1982) ("The creation of subclass IV was within the district court's broad power under Fed. R. Civ. P. 23(d) to adopt procedural innovations to facilitate management of the class action.").

The parties have not yet had an opportunity to brief whether the differences between these two groups warrant further modifications to the class definition. Therefore, within 21 days of this decision, the Plaintiff shall file a response on the docket, not to exceed 12 pages, addressing whether I should (1) create formal subclasses pursuant to Fed. R. Civ. P. 23(c)(5) and

appoint separate counsel for each; (2) subdivide the class only for purposes of case management under Fed. R. Civ. P. 23(d); or (3) allow the case to proceed to trial with a single class under the newly-certified class definition. The Secretary may respond within 14 days of the Plaintiffs' filing in a brief confined to 12 pages.[14] No replies will be allowed. I will determine whether to hold a status conference or oral argument once both parties have filed briefs.

MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

The Secretary has also filed a motion to dismiss for lack of subject matter jurisdiction. (ECF No. 370.) He argues that Plaintiffs lack standing because (1) their injuries are not "fairly traceable" to the lack of procedures for challenging their observation status, and (2) their injuries are not redressable by the Secretary. He also asserts that all of the named Plaintiffs' claims are moot.

I. Standing and Mootness

Article III of the U.S. Constitution restricts the power of federal courts to "Cases" and "Controversies." U.S. Const. Art. III. A plaintiff has standing under Article III's case-or-controversy requirement when (1) she has suffered an "injury in fact" (2) that is "fairly traceable to the challenged action of the defendant" and (3) it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) (citations, quotation marks, and alterations omitted). A plaintiff bears the burden

[14] I will *not* consider further argument at this point on the merits of class certification in general or on the issues addressed in the summary judgment ruling, and the parties are not authorized to file further briefs on these issues. Nor will I consider argument that either of the two sub-groups I have identified should be excluded from the class definition or decertified. I have already considered lengthy briefs and oral arguments on these matters and have identified sufficient questions of material fact to warrant a trial for both of these groups. The question for supplemental briefing is simply intended to determine the best way to protect the interest of all class members.

of proving these elements "in the same way as any other matter on which the plaintiff bears the burden of proof . . . ." *Id.*

It is "not enough that a dispute was very much alive when suit was filed; the parties must continue to have a personal stake in the ultimate disposition of the lawsuit." *Chafin v. Chafin*, 133 S. Ct. 1017, 1023 (2013) (citation and quotation marks omitted). A claim generally becomes moot when subsequent events eliminate the controversy between the parties: "when the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome." *Id*. (citation and quotation marks omitted). Once a class is certified, however, the named plaintiffs' claims may become moot without similarly mooting the entire suit. *Sosna v. Iowa*, 419 U.S. 393, 402 (1975) ("The controversy may exist, however, between a named defendant and a member of the class represented by the named plaintiff, even though the claim of the named plaintiff has become moot.")

II. Discussion

A. Action Fairly Traceable to the Secretary

The Secretary first argues that the Plaintiffs' injures are not "fairly traceable" to him because inpatient admission decisions are made by hospitals and physicians. I disagree for two reasons. First, the complaints in this case "plausibly alleged that the inpatient admission decision is the result of 'significant encouragement' from the Secretary, through CMS." *Alexander v. Cochran*, 2017 WL 522944, at *16. In other words, the Plaintiffs alleged that hospitals and physicians making inpatient admission decisions for Medicare beneficiaries are state actors within the Secretary's control. Further, the summary judgment record shows that here are disputes of fact about the extent to which those allegations are true. *See id.* at *12–*14; Summary Judgment Ruling, *supra*, Part III.A.2. The Plaintiffs have therefore made a sufficient showing at this stage

that the injuries of class members are fairly traceable to the Secretary. Second, the Secretary ignores the procedural component of the Plaintiffs' claims. The Plaintiffs do not assert that the Secretary is liable because he deprived them of their right to be admitted as inpatients; rather, he is liable because they face a risk that they will be erroneously deprived of that interest without due process. The lack of nation-wide administrative review is attributable to the Secretary through CMS.

B. Redressability

The Secretary asserts that the Plaintiffs' injures are not redressable through an injunction in this case because beneficiaries may receive Part A benefits only if they are formally admitted as inpatients, and he lacks the authority to require hospitals to admit patients. Even if I accepted the premise that the Secretary lacks such authority and otherwise has no authority to reimburse beneficiaries under Part A who have mistakenly been denied hospital admission as inpatients, the Secretary's conclusion does not follow. The redressability prong of the standing analysis is relaxed in the case of a procedural deprivation. "When a litigant is vested with a procedural right, that litigant has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant." *Massachusetts v. E.P.A.*, 549 U.S. 497, 518 (2007). The Plaintiffs have raised a genuine dispute of fact about whether they meet that lower bar. Under current regulations, if CMS or its contractors determine that a hospital's claim for reimbursement is improper under Part A, the claim is denied; however, the hospital is permitted to resubmit the claim for reimbursement under Part B. *See* CMS Ruling No. CMS-1455-R (Mar. 13, 2013). One possible remedy, then, would be to require CMS to implement the opposite procedure: If a patient appealed his observation status and successfully established that he met the criteria for inpatient admission, CMS could inform the patient's hospital

that any claim for outpatient reimbursement under Part B would be denied and an inpatient claim under Part A would be approved. Hospitals would have a choice between submitting a bill under Part A or foregoing reimbursement entirely.[15] There is at least "some possibility" that, under these circumstances, hospitals and physicians would reconsider the decision to place a patient on observation status.

In addition, recent regulatory developments have sapped the Secretary's redressability objection of some of its force. Until recently, the Two Midnight Rule required *both* that the order of the physician admitting the beneficiary as an inpatient "be furnished at or before the time of the inpatient admission," 42 C.F.R. § 412.3(c) (2018), *and* that it be "present in the medical record . . . ." 42 C.F.R. § 412.3(a) (2017). And because it was "longstanding Medicare policy to not permit retroactive [inpatient] orders," *Medicare Program; Hospital Inpatient Prospective Payment Systems and Physician Certification and Recertification of Claims*, 83 Fed. Reg. 41144, 41508 (Aug. 17, 2018), the absence of a formal admission order in the medical record at the time services were provided was not a gap that the Secretary or anyone else could fill after the fact. Last year, however, the Secretary eliminated the requirement that the physician order be "present in the medical record," thereby "removing the requirement that written inpatient admission orders are a specific requirement for Medicare Part A payment." *Id*. 41507. As long as "other available documentation, such as the physician certification statement when required, progress notes, or the medical record as a whole, supports that all the coverage criteria (including medical necessity) are met," payment under Medicare Part A will no longer be denied

[15] This decision should be easy for hospitals given that "Medicare pays considerably more for short inpatient stays than for observation services." *Health Policy Brief: The Two Midnight Rule* 2, Health Aff. (Jan. 22, 2015) ("For example, for patients with chest pain, Medicare paid $870 more for short inpatient stays in 2012 than it paid for observation stays.").

due to the absence of a physician order. *Id.*; *see also id.* at 41509 ("It is our intention that this revised policy will properly adjust the focus of the medical review process towards determining whether an inpatient stay was medically reasonable and necessary and intended by the admitting physician rather than towards occasional inadvertent signature or documentation issues unrelated to the medical necessity of the inpatient stay or the intent of the physician.") Thus, at least for those beneficiaries who can point to evidence in "the medical record as a whole" that a physician intended that they be admitted as inpatients—which, as discussed above, includes many of the named plaintiffs as well as class members Kanefsky and Nieimi—there would be nothing preventing the Secretary from reinstating the physician's original intent.

More broadly, however, the Secretary's redressability objection must yield to the Plaintiffs' constitutional rights, assuming that they can prove that those rights have been violated. At trial, the Plaintiffs will have to establish that physicians and hospital URCs make inpatient admission decisions based on fixed criteria established by the Secretary. Thus, Plaintiffs will be required to prove that physicians and hospitals are effectively state actors for purposes of determining Medicare Part A benefits. *See Kraemer*, 737 F.2d at 220 ("If the facts prove to be as appellant contends, the government's use of URC determinations may well provide the state action that was missing in *Blum*."). If the Plaintiffs carry that burden and prove the other elements of their Due Process claim, then the Secretary will not be able to avoid affording relief simply by pointing to regulatory limits on his own authority. More specifically, if the Secretary has effectively created a property interest and physicians/hospitals, as his agents, are depriving Medicare beneficiaries of that interest without a hearing, then he must not only afford a hearing, but also ensure that a beneficiary who prevails at such a hearing receives meaningful relief. *See Marbury v. Madison*, 1 Cranch 137, 163 (1803) ("The government of the

United States has been emphatically termed a government of laws, and not of men. It will certainly cease to deserve this high appellation, if the laws furnish no remedy for the violation of a vested legal right.").[16] Thus, to the extent the Secretary contends that the Two Midnight Rule regulation would prevent him from affording relief even if a property interest is found to have been wrongfully denied after a hearing, then the Rule would be unconstitutional as applied. *Cf. People for Ethical Treatment of Prop. Owners v. United States Fish & Wildlife Serv.*, 852 F.3d 990, 997–99 (10th Cir. 2017) (holding that a landowners' group satisfied the redressability requirement of standing even though their challenge to an Endangered Species Act regulation would have left in place another, broader ESA regulation, because their challenge was grounded on a claim that Congress lacked constitutional authority to delegate rulemaking as to the Utah prairie dog, an intrastate species). I need not determine the precise contours of the hypothetical remedy at this stage—it is enough to conclude that the Plaintiffs have raised a material dispute of fact about the availability of relief.

The Secretary also argues that the pre-October 2013 Plaintiffs cannot show that they would have been successful had they been provided with an opportunity to appeal their observation status. But "[a] litigant who alleges a deprivation of a procedural protection to which he is entitled never has to prove that if he had received the procedure the substantive result would have been altered. All that is necessary is to show that the procedural step was connected to the substantive result." *Sugar Cane Growers Cooperative of Fla. v. Veneman*, 289 F.3d 89, 94–95 (D.C. Cir. 2002) (alterations omitted) (cited and quoted in *Massachusetts v. E.P.A.*, 549 U.S. at 518). Here, the

[16] As the Secretary notes, (ECF No. 376 at 11 n.2), it is true that there are well-recognized exceptions to the principle that there is a remedy for every violation of a legal right, including various immunity doctrines. It is just as true, however, that no one has suggested that any of those exceptions apply in this case.

Plaintiffs contend that they incurred additional hospital costs because they were denied a hearing or other review procedure by which they could contest their "observation status." Given that they currently lack *any* means to contest that status, the opportunity at least to bring clerical errors to the attention of a reviewing body raises "some possibility" that the review procedure they seek will prompt reconsideration of the denial of inpatient status. As a result, they have met their burden to establish redressability.

C. Mootness

Finally, the Secretary argues that the claims of the pre-October 2013 are moot due to the adoption of the Two Midnight Rule. The Secretary relies on reasoning that I have already rejected in this case. While "[p]ast exposure to illegal conduct does not in itself show a present case or controversy regarding injunctive relief if unaccompanied by any continuing, present adverse effects," *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983), these Plaintiffs "are injured by the *continuing* lack of . . . an appeals process, which, to this day, is preventing them from requesting and receiving monetary refunds for care that was not covered." *Alexander v. Cochran*, 2017 WL 522944 at *4 (emphasis added); *see also Alexander v. Price*, 275 F. Supp. 3d at 323 n.5 ("The parties have pointed out that, if the plaintiffs ultimately prevail in this case, named plaintiffs and other class members who received observation services in the past would be able to seek (presumably non-expedited) administrative review related to past out-of-pocket costs."); 42 C.F.R. § 405.952(b)(4)(i) (noting that a request for redetermination of Medicare benefits is dismissed after a beneficiary dies only if "[t]he beneficiary's surviving spouse or estate has no remaining financial interest in the case"). Similarly, I find it unnecessary to revisit my conclusion that the named Plaintiffs who received full refunds may act as class representatives. *See Alexander v. Cochran*, 2017 WL 522944 at *5. The controversy between at least some class members and the defendant

remains live, *see Sosna*, 419 U.S. at 402, and removing the named Plaintiffs who have received refunds would have no practical effect.

CONCLUSION

The Secretary's second motion for summary judgment (ECF No. 319), motion for class decertification (ECF No. 323), and motion to dismiss for lack of subject matter jurisdiction (ECF No. 370) are DENIED. The parties shall file supplemental briefs addressing the need to subdivide the class as described above.

This case is now approaching its eighth year. It has been to the Circuit and back, through two motions to dismiss, through two lengthy periods of discovery, and survived two rounds of summary judgment. I have certified a class, reconsidered that decision, and declined to *de*certify the class. All of the named Plaintiffs who were alive when the case was filed have since passed away. The time for motion practice is over. I will hold a telephonic status conference on April 3, 2019 at 11:00 AM to choose a trial date. I will not move that date once it is established.

IT IS SO ORDERED.

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

Dated: Hartford, Connecticut
March 27, 2019