UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

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

MEMORANDUM OF DECISION

I. INTRODUCTION

An elderly person's arrival at a hospital is a stressful moment. The person might arrive in an ambulance. He or she might be in pain, suffering shortness of breath, or showing other troubling symptoms. Worried family members might wonder if their sick parent or grandparent will ever see the outside world again once he or she passes through the hospital's doors. One question that might not be uppermost in their minds at that moment—but that may soon emerge to add to the stress of the experience—is who will pay for the elderly person's medical care. It is that question that is at the heart of this case. More specifically and in legal terms, this case asks whether the Constitution's Due Process Clause requires the U.S. Secretary of Health and Human Services to afford the elderly patient a means to challenge decisions made at the hospital affecting his or her coverage under the Medicare program, the nation's public health insurance program for persons 65 or over.

On arriving at the hospital, the elderly patient will be examined by a physician who, in addition to determining the patient's course of treatment, will decide whether to admit the patient formally as a hospital inpatient or whether, instead, to place the patient on "observation status." Although the patient might not know it, this is a critical decision, because formal admission to a

hospital is a pre-condition to payment both for hospital services and for post-hospital skilled nursing services under Part A of Medicare, a portion of the Medicare program that is free to most Medicare beneficiaries. If the patient is placed on "observation status" instead of being admitted as an inpatient, the patient will have to pay for both the hospital services and the post-hospital skilled nursing services out of pocket, unless he or she has other insurance coverage, such as Medicare Part B (for which premiums must be paid and which covers outpatient hospital services but not post-hospital skilled nursing services) or private insurance. Under current Medicare regulations, the patient has no right to a say in the doctor's decision about whether to admit him or her as an inpatient, and no means to challenge it.

The physician's decision whether to admit the patient as an inpatient is not, however, the final word on the matter. That decision will be reviewed by the hospital's "utilization review staff," a team each hospital participating in the Medicare program must have in place to review whether the physician's decision is correct under mandatory, nationwide standards set by the Centers for Medicare and Medicaid Services ("CMS"), which is part of the U.S. Department of Health and Human Services. Sometimes, the utilization review staff will disagree with the physician's decision and ask him or her to change it, and often the physician will do so. But the patient has no right to a say in the hospital's review process either, and has no means to challenge a decision by the review staff, for example, a decision that the physician's order admitting the patient as an inpatient should be changed to one placing the patient on "observation" status.

The plaintiffs in this case are a nationwide class of Medicare beneficiaries who were placed on observation status after entering the hospital. Some were placed on observation status at the outset, while others were put on observation at the behest of the hospital's utilization

review staff after a physician had initially designated them as inpatients. Many of the plaintiffs remained in the hospital on observation status for days. And many suffered serious financial or other consequences as a result of these decisions. Some were responsible for paying for the hospital services themselves, because they lacked Medicare Part B or private coverage. Others ended up paying the costs of a post-hospital skilled nursing facility themselves, because they went to the facility after an extended hospital stay in which they were not designated as inpatients. Still others, despite a recommendation by their physicians, chose to forgo care at a post-hospital skilled nursing facility, realizing that Medicare would not pay the associated costs because their physician or the hospital had designated their hospital stay as "observation" rather than inpatient. All of these plaintiffs seek a procedure to challenge the coverage-altering decision to classify them as "observation," and argue that the Secretary is depriving them of their property interest in Medicare benefits without due process by failing to afford them such a procedure.

After almost nine years of litigation, including a bench trial held in August 2019, I reach a split decision. I find that some class members, specifically, those who were initially admitted as inpatients by a physician but whose status during their stay was changed to observation, have demonstrated that the Secretary is violating their due process rights. The trial evidence showed that such changes are invariably caused by utilization review staff applying mandatory, nationwide standards set by CMS, in response to significant pressure from the Secretary. For class members whose inpatient status was changed to observation, then, there is enough involvement by the government to find that the deprivation of their property interest in Part A coverage was fairly attributable to the Secretary and thus a product of "state action," a necessary element of a due process claim. Just as the Secretary cannot deprive these beneficiaries of Part A

coverage directly without affording them the procedural protections to which the Constitution entitles them, the Secretary cannot do so indirectly, through a hospital's utilization review process. These class members must be afforded some means to challenge the decision that effectively stripped them of their property interest in Part A benefits.

But I find that the remaining class members—those whose physicians initially placed them on observation status and who were never admitted as inpatients—have failed to prove their due process claims, because the physicians' decisions generally did not constitute state action. These class members have also failed to prove a separate property interest in inpatient admission, because a physician's admission decision is not governed by the sort of mandatory standards that can create a property interest under the law.

Accordingly, I order the Secretary to establish a procedure that will allow the following modified class of Medicare beneficiaries to challenge decisions by hospitals to place them on "observation" status:

> All Medicare beneficiaries who, on or after January 1, 2009: (1) have been or will have been formally admitted as a hospital inpatient, (2) have been or will have been subsequently reclassified as an outpatient receiving "observation services"; (3) 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 (4) 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, unless more than 30 days has passed after the hospital stay without the beneficiary's having been admitted to a skilled nursing facility. 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.

The reasons for my decision, and the details of the order I issue to the Secretary, are set forth in the findings of fact and conclusions of law that follow. Because of the length of this decision, I have provided a table of contents for ease of reference.

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II. PROCEDURAL HISTORY

A. Dismissal and Appeal

On November 3, 2011, seven Medicare beneficiaries filed a complaint alleging that they had been "deprived of Medicare Part A coverage by being improperly classified as outpatients." ECF No. 1 at ¶ 1. They alleged that the Secretary "has long had a policy under which Medicare beneficiaries in hospitals, instead of being formally admitted, are placed on what is commonly referred to as 'observation status' (which the Secretary refers to as 'observation services'). In some instances, beneficiaries who have been formally admitted have their status retroactively changed to observation." ECF No. 1 at ¶ 2. "Beneficiaries on observation status generally receive the same treatment as beneficiaries who have been formally admitted, but they are considered outpatients by the Secretary." *Id.* at ¶ 4. The Plaintiffs alleged violations of the Medicare Act, Administrative Procedure Act, and the 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 failed to allege facts sufficient to show that they had a protected property interest in "formal admission, or, by extension, inpatient status and Part A benefits." ECF No. 106 at 45.

The Second Circuit affirmed in part, vacated in part, and remanded the case for further proceedings on the due process claim. The Court of Appeals held that, notwithstanding 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 v. Burwell*, 777 F.3d 106, 114 (2d Cir. 2015). 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.

B. Proceedings on Remand

On remand, as directed by the Court of Appeals, I ordered a period of discovery focused on the property interest issue. 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 observation status in 2014 under policies the Secretary had adopted 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. 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. The Second Intervenor Complaint alleged that "Beneficiaries who are placed on observation status are not informed that they have any appeal rights to challenge that placement and to contend that they should be formally admitted and be covered under Part A." *Id.* ¶ 47. The Second Intervenor Complaint further alleged that the Secretary's "policy of not providing Medicare beneficiaries with the right to administrative review, including expedited review, of their placement on observation status violates the Due Process Clause of the Fifth Amendment." *Id.* ¶ 103.

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 various remedies. 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 March 3, 2017, 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 on the other two prongs of the due process analysis—*i.e.*, state action and the amount of process due.

Discovery closed on June 15, 2018. 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., 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 created 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.

On March 27, 2019, I denied the Secretary's second motion for summary judgment. ECF No. 378. First, I found that "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 the Plaintiffs have a protected property interest in being admitted as inpatients." *Id.* at 24. Second, I found that factual disputes prevented me from determining without a trial the amount of process due under the factors set forth in *Mathews v. Eldridge*, 424 U.S. 319 (1976). *Id.* at 24-25. On the same day, I also denied the Secretary's motion to decertify the class but adopted a modified class definition.[1] *Id.* at 41.

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[1] The modified class definition I adopted is as follows:

> 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.

Finally, I also denied the Secretary's motion to dismiss for lack of subject matter jurisdiction. *Id.* at 50.

In August of 2019—nearly eight years after this case began—I held a seven-day bench trial. The Plaintiffs filed their post-trial brief, including proposed findings of fact and conclusions of law, on September 19, 2019, ECF No. 427; the Secretary filed his post-trial brief on October 31, 2019, ECF No. 430; and the Plaintiffs filed a reply brief on November 26, 2019. The parties submitted supplemental briefing, at the request of the Court, in February of 2020. ECF Nos. 435-38.

III. FINDINGS OF FACT[2]

A. Statutory and Regulatory Framework

1. Background

1. Medicare is the federal government's health insurance program for people age 65 or older. *Medicare Program – General Information*, CMS.gov (Nov. 13, 2019).[3] It is administered by the Centers for Medicare and Medicaid Services ("CMS"), which is part of the Department of Health and Human Services ("HHS"), and consists of four parts, only two of which are relevant here—Part A and Part B. Medicare Part A is a hospital insurance program and helps cover inpatient care in hospitals and skilled nursing facilities. *Id.* Most eligible individuals don't pay a premium for Part A, which is funded through the Medicare payroll tax. *Id.* Medicare Part B helps cover doctors' services and outpatient care. *Id.* Part B is a voluntary program that requires

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ECF No. 378 at 41.

[2] To the extent that any Finding of Fact reflects a legal conclusion, it shall to that extent be deemed a Conclusion of Law, and vice-versa.

[3] URL: https://www.cms.gov/Medicare/Medicare-General-Information/MedicareGenInfo/index. Medicare also covers people under age 65 with certain disabilities and people of all ages with End-Stage Renal Disease. *Id.*

the payment of a monthly premium. *Original Medicare (Part A and B) Eligibility and Enrollment*, CMS.gov (Nov. 16, 2019).[4]

2. The Scope of Part A Hospital Coverage and the Definition of "Inpatient"

2. The scope of Medicare Part A is defined by statute, regulation, and sub-regulatory guidance. Specifically, eligible individuals are entitled to coverage for—as relevant here—certain "inpatient hospital services" and "post-hospital extended care services." 42 U.S.C. § 1395d(a)(1)-(2). "Inpatient hospital services" are, in turn, defined as those services "furnished to an inpatient of a hospital." 42 U.S.C. § 1395x(b).

3. During all relevant time periods, CMS has defined "inpatient" to require *formal* inpatient admission. Prior to 2013, this requirement was set forth in sub-regulatory guidance. *See Estate of Landers v. Leavitt*, 545 F.3d 98, 104 (2d Cir. 2008), *as revised* (Jan. 15, 2019) (applying *Skidmore* deference to uphold the formal admission requirement). Effective October 1, 2013, the requirement of formal admission was codified at 42 C.F.R. § 412.3(a). That provision states that, "for purposes of payment under Medicare Part A, an individual is considered an 'inpatient of a hospital' . . . if formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner." 42 C.F.R. § 412.3(a).

3. The 24-Hour Benchmark

4. CMS has long offered sub-regulatory guidance related to when inpatient admission is appropriate. For example, the Medicare Benefit Policy Manual in effect in 2009—the beginning of the class period—established a 24-hour benchmark for inpatient admissions. More specifically, the Manual provided that "[p]hysicians should use a 24-hour period as a benchmark, i.e., they should order admission for patients who are expected to need hospital care for 24 hours

[4] URL: https://www.cms.gov/Medicare/Eligibility-and-Enrollment/OrigMedicarePartABEligEnrol/index.

or more, and treat other patients on an outpatient basis." DX539-006.[5] The Manual notes, however, that "the decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors, including the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting."[6] *Id.*

4. The Two Midnight Rule

5. In 2013, CMS refined and codified its guidance related to inpatient admission. As originally promulgated, the relevant provision specified:

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[5] Citations to the Secretary's trial exhibits include the exhibit number (e.g., DX539) and the page number (e.g., 006), separated by a hyphen.

[6] The full text of the relevant portion of the Manual is as follows:

> An inpatient is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. Generally, a patient is considered an inpatient if formally admitted as inpatient with the expectation that he or she will remain at least overnight and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight.
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> The physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient. Physicians should use a 24-hour period as a benchmark, i.e., they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis. However, the decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors, including the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting. Factors to be considered when making the decision to admit include such things as:
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> • The severity of the signs and symptoms exhibited by the patient;
> • The medical predictability of something adverse happening to the patient;
> • The need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and
> • The availability of diagnostic procedures at the time when and at the location where the patient presents.

DX 539-006.

> Except as specified in paragraph (e)(2) of this section,[7] when a patient enters a hospital for a surgical procedure not specified by Medicare as inpatient only under § 419.22(n) of this chapter, a diagnostic test, or any other treatment, and the physician expects to keep the patient in the hospital for only a limited period of time that does not cross 2 midnights, the services are generally inappropriate for inpatient admission and inpatient payment under Medicare Part A, regardless of the hour that the patient came to the hospital or whether the patient used a bed. 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.

78 Fed. Reg. 50496, 50965 (Aug. 19, 2013), *formerly codified at* 42 C.F.R. § 412.3(e)(1) (effective October 1, 2013 to December 31, 2014). This provision is commonly referred to as the "Two Midnight Rule."[8]

6. CMS did not view the Two Midnight Rule as a significant departure from its previous policy establishing a 24-hour benchmark for inpatient admissions. In its notice of final rulemaking accompanying the Two Midnight Rule, it explained that the Two Midnight Rule

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[7] Section (e)(2) provides that "[i]f an unforeseen circumstance, such as a beneficiary's death or transfer, results in a shorter beneficiary stay than the physician's expectation of at least 2 midnights, the patient may be considered to be appropriately treated on an inpatient basis, and hospital inpatient payment may be made under Medicare Part A." 78 Fed. Reg. 50496, 50965 (Aug. 19, 2013), *formerly codified at* 42 CFR § 412.3(e)(2) (effective October 1, 2013).

[8] In December of 2016—more than three years after the Two Midnight Rule became effective—CMS updated the language in the Medicare Benefit Policy Manual based on the Two Midnight Rule. The language remained largely unchanged, except that "Generally, a patient is considered an inpatient if formally admitted as inpatient *with the expectation that he or she will remain at least overnight*," was changed to, "Generally, a patient is considered an inpatient if formally admitted as inpatient *with the expectation that he or she will require hospital care that is expected to span at least two midnights*" (emphasis added), and "Physicians *should use a 24-hour* period as a benchmark, i.e., they should order admission for patients who *are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis*," was changed to, "Physicians should use *the expectation of the patient to require hospital care that spans at least two midnights* period as a benchmark, i.e., they should order admission for patients who *are expected to require a hospital stay that crosses two midnights and the medical record supports that reasonable expectation*." DX541-006 (2015 version); DX 540-005 (2016 version). The language indicating that "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" remained unchanged. *Id.*

"simply modifies our previous guidance to specify that the relevant 24 hours are those encompassed by 2 midnights." 78 Fed. Reg. 50496, 50945 (Aug. 19, 2013).

7. In the preamble to the final rule, CMS repeatedly stated that the Two Midnight Rule does *not* dictate the medical care that a patient is eligible to receive, and the physician retains the discretion to order medical services and to determine the level of nursing care and the patient's location in the hospital based on the patient's clinical needs. *See, e.g.*, *id.* at 50945 ("[T]here are no prohibitions against a patient receiving any individual service as either an inpatient or an outpatient, except for those services designated by the Outpatient Prospective Payment System (OPPS) Inpatient-Only list as inpatient-only services . . . . [T]he physician is expected to continue to use his or her complex clinical judgment in determining whether a beneficiary needs to stay at the hospital, what services and level of nursing care (for example, low-level, monitored, or one-one-one) the beneficiary will need, and what location (unit) is most appropriate."); *id.* at 50946 ("In applying [the 2-midnight benchmark],[9] we have been clear that this instruction does not override the clinical judgment of the physician to keep the beneficiary at the hospital, to order specific services, or to determine appropriate levels of nursing care or physical locations within the hospital."); *id.* at 50948 ("We have expected and continue to expect that physicians will make the decision to keep a beneficiary at the hospital when clinically warranted and will order all appropriate treatments and care in the appropriate location based on the beneficiary's individual medical needs.").

[9] CMS and the parties have used both "two-midnight benchmark" and "Two Midnight Rule" to refer to the language set forth in 42 U.S.C. § 412.3(d)(1). In this ruling, I use these terms interchangeably. Both terms are distinct from the "Two Midnight Presumption," discussed below, *see infra* ¶ 26.

5. Amendments to the Two Midnight Rule

8. Section 412.3, which includes the Two Midnight Rule, has been amended twice since it was originally promulgated in 2013. In November of 2015, the language of the Two Midnight Rule, which had been moved from subsection (e) to subsection (d) in 2014,[10] was amended. Paragraphs (d)(1) and (d)(2) were modified "for clarity," and a new paragraph (d)(3) was added, establishing a case-by-case inpatient admission exception, "based on the clinical judgment of the admitting physician and medical record support for that determination," even when there was neither a two-midnight expectation nor an inpatient-only procedure. 80 Fed. Reg. 70298, 70541 (Nov. 13, 2015).

9. As reformulated, Section 412.3 explicitly recognized three pathways for inpatient admission for purposes of Part A coverage: inpatient admission based on a physician's expectation that a patient "will require hospital care that crosses two midnights" under (d)(1); "inpatient admission for a surgical procedure specified by Medicare as inpatient only" under (d)(2); and inpatient admission "based on the clinical judgment of the admitting physician and medical record support for that determination," *i.e.*, the case-by-case exception, under (d)(3). 80 Fed. Reg. 70298, 70541(Nov. 13, 2015), *formerly codified* at 42 C.F.R. § 412.3(d) (effective Jan. 1, 2016).[11] In all cases, Section 412.3 continued to require that a patient be "formally admitted

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[10] 79 Fed. Reg. 66770, 67030 (Nov. 10, 2014) (removing paragraph (c) of Section 412.3, not relevant here, and redesignating paragraphs (d) and (e) as paragraphs (c) and (d), respectively).

[11] The full text of 42 C.F.R. § 412.3(d), as of January 1, 2016, was as follows:

> (d)(1) Except as specified in paragraphs (d)(2) and (3) of this section, an 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.
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> (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.
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> (ii) If an unforeseen circumstance, such as a beneficiary's death or transfer, results in a shorter beneficiary stay than the physician's expectation of at least 2 midnights, the patient may be considered to be

as an inpatient pursuant to an order for inpatient admission" in order to be considered an inpatient for purposes of Part A payment; that the physician order "be present in the medical record and be supported by the physician admission and progress notes"; and that "[t]he physician order . . . be furnished at or before the time of the inpatient admission." 80 Fed. Reg. 70298, 70541(Nov. 13, 2015), *formerly codified* at 42 C.F.R. § 412.3(a),(c) (effective Jan. 1, 2016).

10. Section 412.3 was amended a second time in August of 2018 to remove the language making the presence of an inpatient physician order in the medical record a prerequisite to Medicare Part A payment. 83 Fed. Reg. 41144, 41700 (Aug. 17, 2018), *codified at* 42 C.F.R. § 412.3(a). Prior to the amendment, Section 412.3(a) provided that the "physician order must be present in the medical record and be supported by the physician admission and progress notes, in order for the hospital to be paid for hospital inpatient services under Medicare Part A." 42 C.F.R. § 412.3(a) (effective until Oct. 1, 2018). The August 2018 Amendment did not, however, eliminate the language in Section 412.3(a) defining "inpatient" for purposes of payment under Medicare Part A as an individual who has been "formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner," 42 C.F.R. §

> appropriately treated on an inpatient basis, and payment for an inpatient hospital stay may be made under Medicare Part A.
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> (2) An inpatient admission for a surgical procedure specified by Medicare as inpatient only under § 419.22(n) of this chapter is generally appropriate for payment under Medicare Part A, regardless of the expected duration of care.
>
> (3) 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.

80 Fed. Reg. 70298, 70541(Nov. 13, 2015), *formerly codified* at 42 C.F.R. § 412.3(d) (effective Jan. 1, 2016).

412.3(a), nor did it eliminate the requirement that "[t]he physician order must be furnished at or before the time of the inpatient admission," 42 C.F.R. § 412.3(c); *see also* 83 Fed. Reg. 41144, 41507 (Aug. 17, 2018) ("Our proposal does not change the requirement that, for purposes of Part A payment, an individual becomes an inpatient when formally admitted as an inpatient under an order for patient admission"); *id.* at 41508 ("The order must be furnished at or before the time of the inpatient admission."). Rather, the intent of the 2018 Amendment was to address denials of Part A payment due to "technical discrepancies," such as "missing practitioner admission signatures, missing co-signatures or authentication signatures, and signatures occurring after discharge." *Id.* at 41507. For technically defective inpatient orders to be deemed sufficient under the new policy, CMS explained that "there can be no uncertainty regarding the intent, decision, and recommendation by the ordering practitioner to admit the beneficiary as an inpatient, and no reasonable possibility that the care could have been adequately provided in an outpatient setting." *Id.* at 41509.

6. Eligibility for SNF Coverage under Medicare Part A

11. The requirements for Part A payment for care in a skilled nursing facility ("SNF"), or "post-hospital extended care services," are set forth in regulations separate from those governing Part A payment for hospital services. 42 C.F.R. §§ 409.30-36, 424.20.[12] Under CMS regulations, for a beneficiary to receive Part A coverage for post-hospital SNF care, the beneficiary must have been "hospitalized . . . for medically necessary inpatient hospital or inpatient [critical access hospital] care, for at least 3 consecutive calendar days, not counting the

[12] "Post-hospital extended care services" are statutorily defined as "extended care services furnished an individual after transfer from a hospital in which he was an inpatient for not less than 3 consecutive days before his discharge from the hospital in connection with such transfer." 42 U.S.C. § 1395x(i). The statute defines "extended care services" to mean "services furnished to an inpatient of a skilled nursing facility." *Id.* § 1395x(h).

date of discharge." 42 C.F.R. § 409.30(a)(1). In addition, to qualify for SNF coverage, a beneficiary must generally "be in need of post-hospital SNF care, be admitted to the facility, and receive the needed care within 30 calendar days after the date of discharge from a hospital or [critical access hospital]." *Id*. § 409.30(b)(1).

12. In 2008, the Second Circuit affirmed CMS's interpretation of the statutory definition of "post-hospital extended care services" to preclude SNF coverage for individuals who were not formally admitted to the hospital as inpatients for at least three days, even when the individual's total stay at the hospital, including time spent as an outpatient receiving observation services, was three days or more. *See Estate of Landers*, 545 F.3d at 108-09. Thus, a patient such as Dorothy Goodman, whose estate is a named Plaintiff in this case and who is alleged to have been formally admitted as an inpatient for two days before being placed on observation for her third day at the hospital, ECF No. 123 at ¶¶ 77, 84, would not qualify for SNF coverage.

7. Coverage for Observation Services Under Medicare Part B

13. Outpatient "observation services" are covered under Medicare Part B, a voluntary supplemental insurance program that pays for hospital outpatient services as well as other medical services and supplies. *See* 42 U.S.C. §§ 1395k, 1395m.[13] The Medicare Benefit Policy Manual defines "observation services" as a "well-defined set of specific, clinically appropriate services, which include ongoing short-term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital." DX548-020.[14] The Manual

[13] While "observation services" are generally covered under Medicare Part B, if and when a patient is subsequently admitted as an inpatient, any observation services received in the three days prior to admission are "bundled" into the Part A claim rather than being separately covered under Part B. *See* 42 U.S.C. § 1395ww(a)(4).

[14] Prior to May 22, 2009, the Manual sometimes referred to "observation status" in addition to "observation services." *See* DX543-004. References to "observation status" were removed on May 22, 2009. *See* DX544-005.

explains that "[w]hen a physician orders that a patient receive observation care, the patient's status is that of an outpatient." *Id.* It further provides that "[o]bservation services are covered only when provided by the order of a physician or [other authorized individual]." *Id.* Because observation services are covered "only when provided by the order of a physician," *id.*, when a hospital's inpatient claim under Part A is denied, the hospital cannot re-bill the same services under Medicare Part B as "observation services."[15] DX548-003.

14. Hospitals are required to provide the Medicare Outpatient Observation Notice ("MOON") to all Medicare beneficiaries receiving observation services for more than 24 hours. 42 U.S.C. § 1395cc(a)(1)(Y). The MOON explains that a beneficiary is an outpatient receiving observation services, rather than an inpatient, as well as the reasons for and financial implications of that status. *Id.* The MOON template provided to hospitals by CMS explains that Medicare Part A "generally doesn't cover outpatient hospital services, like an observation stay." PX234. It also states that placement on observation can affect a beneficiary's eligibility for SNF care, which requires a three-day *inpatient* hospital stay. *Id.* The MOON template does not contain any guidance regarding whether or how a beneficiary can appeal his or her placement on observation status, nor does the relevant statute require any such guidance. *See* PX234; 42 U.S.C. § 1395cc(a)(1)(Y).

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[15] In general, when a hospital's Part A claim is denied because an inpatient admission did not meet Medicare criteria, the hospital may instead bill Medicare for some of the services under Part B, but not as "observation services." 78 Fed. Reg. 50496, 50908-15 (Aug. 19, 2013); 42 C.F.R. § 414.5. Similarly, if a hospital determines, prior to discharge, that a patient does not satisfy Medicare criteria for inpatient admission, the hospital may, with a treating physician's consent, change the patient's status to outpatient and bill Medicare under Part B using Condition Code 44. Medicare Claims Processing Manual ("MCPM"), ch. 1, § 50.3, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf. In neither case, however, may a hospital bill for observation services provided prior to a physician order for observation services. *Id.* ("Like all hospital outpatient services, observation services must be ordered by a physician. The clock time begins at the time that observation services are initiated in accordance with a physician's order."); 42 C.F.R. § 414.5; 78 Fed. Reg. 50496, 50912 (Aug. 19, 2013) ("[W]e are finalizing our proposal to exclude observation services, outpatient DSMT, and hospital outpatient visits from payment as Part B inpatient services when the inpatient admission is determined not reasonable and necessary for Part A payment and the hospital bills Part B.").

B. CMS Enforcement of Part A Eligibility Requirements

15. Hospitals are generally paid more for treating an inpatient covered under Part A than an outpatient covered under Part B, even if similar services are provided to both patients. *See, e.g.*, PX149 at 11.[16] This creates an incentive for hospitals to admit more patients as inpatients. CMS has long been concerned about improper payments for inpatient stays that should have been provided in an outpatient setting and, through its contractors, has sought both to prevent such improper payments and to recoup past improper payments. DX577-003. As discussed below, to advance these objectives, CMS has used a variety of contractors, whose roles have shifted over the course of the class period, and the HHS Office of Inspector General ("OIG") and the Department of Justice have also played a role in furthering these objectives.

1. The Role of the MACs

16. Once a Medicare claim under Part A or Part B is submitted, a Medicare Administrative Contractor ("MAC") processes the claim and makes an initial determination regarding payment. ECF No. 424 at 89-90; ECF No. 425 at 21, 80. The initial determination is conveyed to both the provider, in the form of a remittance advice, and to the beneficiary, in the form of a Medicare Summary Notice. 42 C.F.R. § 405.921.

17. Sometimes, a Medicare claim may be subject to further review after the claim has already been processed and paid. Trial Transcript ("Tr.") 972:19-973:8 (Duvall).[17] During the period relevant to this case, various contractors have been responsible for post-payment reviews of Part

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[16] Citations to the Plaintiffs' trial exhibits are to the page number of the electronic PDF document, unless the page number begins with the prefix "HHS," in which case the citation is to the BATES page number.

[17] Citations to the trial transcript are to the continually paginated page numbers. Transcripts for the seven-day trial have been posted to the public docket. *See* ECF No. 419 (day one) (Tr. 1-261); ECF No. 420 (day two morning) (Tr. 261-390); ECF No. 421 (day two afternoon) (Tr. 391-448); ECF No. 422 (day three) (Tr. 449-624); ECF No. 413 (day 4) (Tr. 624-708); ECF No. 423 (day five) (Tr. 709-878); ECF No. 424 (day six) (879-1060); ECF No. 425 (day seven) (1061-1212).

A hospital claims, including MACs, Beneficiary and Family Centered Care – Quality Improvement Organizations ("QIOs"), and Recovery Audit Contractors ("RACs"). Tr. 557:11-18 (Iwugo); Tr. 941:4-12, 972:19-25 (Duvall).

18. From approximately 2008 to 2015, MACs had the responsibility of conducting post-payment reviews of Part A hospital claims. Tr. 972-73 (Duvall). In conducting these reviews, MACs would look at whether the inpatient hospital services were covered under Medicare Part A, including whether they were reasonable and necessary, and also whether the claim was coded correctly. Tr. 971. CMS issued guidelines it required MACs to follow in reviewing Part A claims. For inpatient admissions not on the inpatient-only list, the guidelines directed the MACs to evaluate "whether, at the time of the admission order, it was reasonable for the admitting practitioner to expect the beneficiary to require medically necessary hospital services (including inpatient and outpatient services) over a period of time spanning at least 2 midnights." PX072 at 5.

19. From October 1, 2013, to October 1, 2015, immediately after promulgation of the Two Midnight Rule, MACs' post-payment reviews of Part A hospital claims were limited by the "Probe and Educate" initiative. Tr. 973. Normally, a MAC can, on its own initiative, undertake to review 50% or even 100% of a category of claims if the MAC determines that there is a high risk of costly error. Tr. 973-74. Under Probe and Educate, MACs were instructed to conduct post-payment patient status reviews of only a very small sample of Part A hospital claims (the "probe") and then, based on that sample, educate providers if there were instances where claims were inconsistent with Medicare statutes, regulations, or guidance. Tr. 958, 972-74. The purpose of the Probe and Educate initiative was to give providers time to adjust to the new rules. Tr. 974.

2. The Role of the QIOs

20. As of October 1, 2015, responsibility for post-payment reviews of Part A hospital claims transitioned to the QIOs. PX117.[18] These post-payment reviews are known as "short-stay reviews" because they focus on claims for hospital inpatient stays that lasted less than two midnights. Tr. 556 (Iwugo). In conducting short-stay reviews, QIOs evaluate whether the claim is appropriate for Medicare Part A payment under the Two Midnight Rule. Tr. 557-58 (Iwugo).

21. The current policies governing QIOs' review of Part A hospital claims are set forth in a CMS document titled "Reviewing Short Stay Hospital Claims for Patient Status: Admissions On or After January 1, 2016." Tr. 561 (Iwugo); DX579 (the "Review Guideline"). The Review Guideline elaborates on each of the three pathways for an inpatient admission to qualify for Part A payment: (1) the two-midnight benchmark, 42 C.F.R. § 412.3(d)(1), (2) the inpatient only list,[19] 42 C.F.R. § 412.3(d)(2), and (3) the case-by-case exception, 42 C.F.R. § 412.3(d)(3). DX579. The document explains the application of the two-midnight benchmark, set forth in 42 C.F.R. § 412.3(d)(1), as follows:

> When a patient enters a hospital for a surgical procedure, diagnostic test, or any other treatment and the physician expects the beneficiary will require medically necessary hospital services for 2 or more midnights (including inpatient and pre-admission outpatient time), and orders admission based upon that expectation, the services are generally <u>appropriate</u> for inpatient payment under Medicare Part A. QIOs will approve these cases so long as other requirements are met.

DX579-004.

22. The applicable standard of review under the Two Midnight Rule, according to the Review Guideline, is reasonableness. That is, the role of the QIO reviewer is not to substitute

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[18] On May 4, 2016, CMS temporarily suspended the short-stay reviews to "ensure accuracy and consistency" in the QIOs' application of the Two Midnight Rule. Tr. 523-24; PX135.

[19] There is no suggestion that any of the Plaintiffs in this case underwent a procedure that was on the inpatient only list. This pathway to inpatient status is thus beyond the scope of this case.

the reviewer's own medical judgment for the admitting physician's to determine whether a patient was likely to require a two-midnight hospital stay. Rather, the reviewer's task is to determine whether it was *reasonable* for the admitting physician to expect the beneficiary to require medically necessary hospital care lasting 2 midnights. *See, e.g.*, DX579-004 ("In other words, if the reviewer determines, based on documentation in the medical record, that it was reasonable for the admitting physician to expect the beneficiary to require medically necessary hospital care lasting 2 midnights, the inpatient admission is generally appropriate for payment under Medicare Part A . . . ."); DX579 (repeatedly characterizing the "reasonableness" of the physician's expectation as the focus of the inquiry); DX521-003 (Dr. Michael Handrigan of CMS: "Was what the physician chose to do unreasonable? Something that a prudent physician would not do? . . . [I]t may not be what I would do in the same scenario, but is the argument reasonable? We're [sic] they diligent enough to make that clear in the record? If so, then it would be payable."); PX158 at 7 ("Was it reasonable for the admitting physician to expect the patient to require medically necessary hospital services for 2 Midnights or longer including all out-patient/observation and inpatient care time?").

23. One implication of the "reasonableness" standard is that there can be more than one acceptable course of action under the Two Midnight Rule. *See, e.g.*, DX511-006 (Dr. Handrigan of CMS to QIOs: Placing the patient on observation and then admitting later was reasonable, "[b]ut, it would also have been appropriate to admit in this case at the outset since there was an expectation of 2MNs, so either way in this case it would have been okay.").

24. The reasonableness determination made by the QIOs is based on the "information known to the physician at the time of admission," and entries in the medical record after the point of admission "are only used in the context of interpreting what the physician knew and expected at

the time of admission." PX117; *see also* DX511 (CMS official: Inquiry is "whether what the physician decided to do was reasonable at that time. . . . If it was a reasonable choice at the time, then it would not be denied."); Tr. 523:9-12 (Iwugo) (focus of the review is whether the physician's expectation at the time of admission was reasonable). Accordingly, "[i]f an unforeseen circumstance results in a shorter beneficiary stay than the physician's reasonable expectation of at least 2 midnights, hospital inpatient payment may still be made under Medicare Part A despite the actual length of stay being less than 2 midnights." PX117.

25. The Review Guideline further makes clear that the Two Midnight rule also requires a showing of medical necessity, because the inquiry is focused on "the physician's expectation of the required duration of *medically necessary* hospital services," and not simply the expected duration of a patient's hospital stay. PX117 ("In other words, if the reviewer determines, based on documentation in the medical record, that it was reasonable for the admitting physician to expect the beneficiary to require *medically necessary* hospital care lasting 2 midnights, the inpatient admission is generally appropriate for payment under Medicare Part A.") (emphasis added); *id.* (inquiry includes both "[e]xpectation of time and the determination of the underlying need for medical care at the hospital").

26. CMS directed QIOs to limit short-stay reviews to those claims that involved inpatient stays of less than two midnights. That is, for the purposes of the short-stay reviews, when a patient stayed at the hospital for two midnights after being formally admitted as an inpatient, the claim would be presumed to satisfy the Two Midnight Rule and would not be subject to further review. This policy is known as the "Two Midnight Presumption." PX117 at 1 ("Under the 2-midnight presumption, inpatient 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 and are not the focus of medical review efforts."); PX158 at 7 ("Step 1: Did the inpatient stay from the point of a valid inpatient order to discharge last '2 midnights'?" If yes, the claim is "presumed to meet the 2 MN requirement and [is] Appropriate for Part A Payment . . . all other claims are to go through the Review Guideline.").[20] The Two Midnight Presumption, unlike the Two Midnight Benchmark, is not a rule defining eligibility for payment; rather, it is a strategy adopted by CMS to direct its contractors' limited resources to those Part A claims it views as most likely to be improper. Tr. 517-18 (Iwugo).

27. When a QIO determines that Part A payment was not appropriate, it initiates a conversation with the provider. Tr. 561 (Iwugo); *see, e.g.*, PX131. If, after that conversation, the QIO still finds that Part A payment was not appropriate, it communicates the final decision to the hospital and beneficiary and sends the claim to the MAC to effectuate the denial of payment. Tr. 561 (Iwugo). In issuing denials based on a failure to satisfy the Two Midnight Rule, QIOs use language prescribed by CMS, which indicates that the claim was denied because it "did not have supporting documentation of a two-midnight expectation requiring medically necessary hospital services." *See, e.g.*, PX166 (sample denial letter); PX165 at 4 (CMS template prescribing the language).

[20] While the Two Midnight Presumption—which determines whether a QIOs will review a claim in more detail, and not whether a claim in fact satisfies the Two Midnight Rule—does not count time spent at the hospital as an outpatient toward the two midnights, the Two Midnight Rule itself *does* count such time toward the requisite two-midnight expectation. PX117 at 5. For example, if a patient received observations services as an outpatient for one midnight, was admitted the next day based on the expectation that the patient would need to stay an additional midnight, and was then discharged after staying two midnights, the resulting claim would *not* satisfy the Two Midnight Presumption (and could thus be subject to detailed review). But assuming the physician's expectation was reasonable, the claim *would* satisfy the Two Midnight Rule (sometimes referred to as the Two Midnight Benchmark to differentiate it from the Two Midnight Presumption), and would thus be payable under Part A. The Two Midnight Presumption is not codified in the Code of Federal Regulations, unlike the Two Midnight Benchmark or Rule.

28. In conducting post-payment reviews of Part A claims, QIOs act as agents of CMS. Detailed contracts between the QIOs and CMS govern the QIOs' work. *See, e.g.*, PX076-080. CMS maintains a detailed manual that QIOs are required to follow. *See* PX092 (Quality Improvement Organization Manual). CMS engages in ongoing efforts to control and standardize the manner in which QIOs apply the Two Midnight Rule, including, for example: issuing guidelines and developing step-by-step instructions governing how short stay reviews are to be conducted, *see* PX158 at 7, PX136 at 4; conducting conference calls with QIOs to provide detailed guidance on how to apply the Two Midnight Rule consistently, *see, e.g.*, DX514; DX522, DX530; and issuing memoranda "instructing" and "directing" QIOs to perform various tasks, PX136 at 1-2. CMS views the Two Midnight Rule as sufficiently objective to demand that QIOs apply the rule with a high degree of consistency, and has threatened consequences if QIOs fail to maintain a 95% accuracy rate. *See, e.g.*, PX187 (warning QIOs that the "failure to maintain an accuracy rate of 95%" as an organization would result in the need to prepare a corrective action plan, and requiring QIOs to implement an individual corrective action plan for individual reviewers with accuracy rates of less than 90%); *see also* DX519-004 (explaining CMS's aim to ensure that "CMS Patient Status reviews are conducted consistently across the [QIOs] so that there is no variability").

3. The Role of the RACs

29. RACs are Medicare contractors charged with identifying areas where there is a high risk of improper Medicare payment, auditing the claims that lead to such payments, and recovering any overpayments. *Id.*; *see generally* PX241. The RAC program was established by Congress. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 306, 717 Stat. 2066, 2256 (2003). It began in 2005 and ran for three years as a

demonstration program. Tr. 977 (Duvall). When the demonstration program expired in 2008, the full program commenced and all the contracts were in place by 2009. Tr. 977-78. There are four RAC contracts, which cover different areas of the country. Tr. 966.

30. Prior to the Two Midnight Rule, RACs regularly conducted post-payment reviews of Part A claims, focusing on short inpatient stays, to determine whether Part A payment was appropriate. Tr. 175:12-176:4, 179:13-180:4 (Pafford); PX020 (RAC denial of a short-stay claim); PX021 (one RAC's review guidelines for whether an inpatient admission was appropriate for Part A payment); Tr. 306:21-307:23 (indicating that RACs audited 8% of Part A inpatient claims according to a study of three hospitals); Tr. 912:15-914:25 (Duvall) (describing the nature of RAC reviews of Part A inpatient claims); Tr. 180:16-19 (Pafford) (indicating that RACs reviewed inpatient claims about ten times more frequently than outpatient claims). If a RAC determined that a payment was inappropriate, it would notify the provider and the beneficiary, and there would be a discussion period during which the provider could offer additional information supporting the claim. Tr. 323:8-11; 334:1-10 (Sheehy); PX241 at 24. If, after the discussion period, the RAC still found the payment inappropriate, it would notify the provider and the beneficiary, and notify the MAC to recover payment. Tr. 334:2-335:4 (Sheehy); 993:18-994:6 (Duvall). These RAC reviews resulted in the denial of a substantial number of Part A claims and placed a significant burden on hospital administrative staff. Tr. 183:15-24 (Pafford) (estimating that RACs denied 35% of one hospital's Part A claims); Tr. 178:11-179:8 (describing the administrative burden on hospitals from facilitating RAC reviews); Tr. 188:2-190:14 (describing the process of appealing RAC denials as "very expensive" for hospitals); Tr. 177:13-16 (Christiana hospital was audited by a RAC every 45 days). Conversely, there is no evidence that RACs reviewed outpatient claims to determine whether they should have instead been billed

as inpatient claims. The Medical Audit Manager at one hospital testified, for example, that no outpatient claims that her hospital submitted were rejected on the grounds that they should have been inpatient claims. Tr. 184:14-17 (Pafford).

31. Following the promulgation of the Two Midnight Rule, which became effective October 1, 2013, CMS suspended RAC reviews of Part A hospital claims, while the MACs conducted the Probe and Educate initiative. Tr. 374:10-16 (Sheehy), 981:18-982:5 (Duvall). That suspension was ultimately extended through December 31, 2015. 80 Fed. Reg. at 70540; *see also* Tr. 982:1-5 (Duvall); DX579-001.

32. Currently, RACs may conduct reviews of Part A hospital claims only upon referral from a QIO. DX579-001; Tr. 374:21-25 (Sheehy). A QIO may refer a provider to a RAC if, following review and education, the QIO determines that the provider is not able to adhere to Medicare payment policy. Tr. 596:16-19 (Iwugo); DX579-001. Specifically, a provider may be referred for "exhibiting persistent noncompliance with Medicare payment policies, including, but not limited to, consistently failing to adhere to the Two-Midnight Rule, or failing to improve their performance after QIO educational intervention." DX579-001. As of the time of trial, however, there had been no such referrals. Tr. 596:16-22 (Iwugo).

33. RACs, like QIOs, act as agents of CMS, and CMS continually directs their activities. Tr. 159:16-18 (Performant, a RAC, was "charged by Medicare" to "carry[] out" statutory mandates); DX581-006 (directing RACs to use commercial screening tools in reviewing claims); Tr. 944:13-945:7 (CMS required RACs to submit review guidelines for CMS's review prior to conducting audits); PX241 (statement of work for RAC contract with CMS).

4. The Role of OIG and DOJ

34. The Department of Justice (DOJ) has investigated hospitals for submitting inpatient hospital claims that it claims should have been billed as outpatient claims. Tr. 221:16-21 (Schwartz). HHS has worked with DOJ on these investigations, Tr. 221:22-222:1; Tr. 899:4-25 (Duvall), and CMS contractors sometimes make referrals to DOJ, Tr. 903:11-13 (Duvall).

35. The HHS Office of the Inspector General (OIG) performs audits of hospitals to ensure compliance with CMS rules and regulations, including reviewing short inpatient stays to ensure they were reasonable and necessary. *See, e.g.*, PX029 at 1, 14. In response to OIG audits, hospitals sometimes intensify their own internal utilization review activities to prevent the submission of inpatient claims that don't satisfy CMS's inpatient criteria. *Id.* at 20-21 (In response to an OIG audit, one hospital's utilization review team began receiving "daily reports from its consultants regarding the appropriate level of care. This information is communicated to our ordering physicians when a determination has been made that the documentation does not support an admission. These reports strengthen our level-of-care determinations and ensure the ordering physicians receive feedback on the appropriate settings for patient care.")

5. The Use of Screening Tools in the Review Process

36. Throughout the relevant time period, CMS has required its contractors to incorporate the use of commercial screening tools—hard-copy or electronic resources created by private companies setting forth criteria for inpatient admission for a variety of medical conditions—into their processes for reviewing whether inpatient hospital claims were appropriate for Part A payment. For example, throughout the relevant period, CMS's Program Integrity Manual has specified that when assessing inpatient hospital claims for Part A payment, "[t]he reviewer shall use a screening tool as part of their medical review." DX556-027; *see also* DX553-005. In

addition, since 2011, the Program Integrity Manual has stated that RACs "shall use screening tools and disclose their use to the provider community consistent with the requirements in their statements of work." DX552-008.[21]

37. CMS does not, however, permit its contractors to rely solely on screening tools to conduct reviews. For example, the Program Integrity Manual requires that "[i]n all cases, in addition to screening instruments, the reviewer applies his/her own clinical judgment to make a medical review determination based on the documentation in the medical record." DX556-027. Elsewhere, the Program Integrity Manual provides that "MACs shall not deny a payment for a service simply because the claim fails a single screening tool criterion." DX552-008. Rather, "the reviewer shall make an individual determination on each claim." *Id*.

38. Thus, while RACs could use screening tools to decide which claims merited further review, they were not permitted to deny a claim based on a screening tool result alone. Tr. 938:20-939:4, 965:16-25 (Duvall); *see* DX553-005; DX556-027. In other words, "having gone through the screening tool, the contractor could decide, I don't want to use additional resources to review this one further, because it is no longer high risk." Tr. 965:25-966:3 (Duvall). However, the RAC could not deny a claim without first doing a clinical assessment based on the documentation in the medical record—an "in-depth review of . . . the entire chart." Tr. 965:2-11, 966:4-7 (Duvall); DX553-005; DX556-027; *see also* PX021 at 5-8 (indicating that one RAC approved the claims that passed the screening tool (provided other requirements, such as the presence of a formal inpatient order, were also satisfied) and conducted further review on claims

[21] CMS does not mandate the use of any particular screening tool. *See, e.g.*, DX556-027 ("CMS does not require that [the reviewer] use a specific criteria set."). There are two major commercially available screening tools—InterQual and Milliman (now called MCG)—but some hospitals also use their own, internally developed screening tools. Tr. 639-41 (Laucks).

that did not); Tr. 947:19-948:12 (Duvall); Tr. 146:23-24 (Dolan) ("[C]ommercial decision support softwares . . . were only utilized for screening purposes."); *id.* at 147:8-13 ("While [the RAC reviewer] would take into consideration what popped out of the commercial screening tool algorithms, that did not make their decision in terms of deciding whether or not the claim was billed wrong.").

39. The Court was presented with limited evidence regarding the operation and content of commercial screening tools. No commercial screening tool was actually introduced at trial, and there was no other evidence that offered a comprehensive picture of the content of any screening tool or of the criteria it used. There was some evidence, however, from which the Court can infer that screening tools include objective criteria for inpatient admission for a variety of medical conditions. *See, e.g.*, Tr. 148:24-149:3 (Dolan). For example, for a patient experiencing chest pain, InterQual lists a number of clinical parameters that would qualify such a patient for inpatient admission, including objective factors such as whether a patient has "positive cardiac enzymes" or "EKG changes." Tr. 427:16-428:8 (Wilson).

C. Admission Practices of Physicians and Hospitals

40. The Plaintiffs complain of being placed on observation status without being afforded procedural protections. The evidence at trial showed that the process through which a patient is placed on observation—and, accordingly, is denied formal inpatient admission and Part A coverage—varies somewhat, largely depending on whether the patient receives observation services in an emergency department observation unit ("EDOU"). The evidence further showed that, even after a treating physician has decided to order inpatient admission, the patient faces a second admission decision by the utilization review team, which can, in effect, override the initial decision by the treating physician. Accordingly, I have divided the findings below into

three parts. The first part is dedicated to admission practices in EDOUs, including a general discussion of observation care; the second is dedicated to admission practices in other settings, such as inpatient wards; and the third is dedicated to the role of the hospital utilization review committee ("URC") in the admission process.

1. Observation Services and Admission Practices in EDOUs

41. Observation medicine is a recognized field of study within the medical community. The Secterary's expert, Dr. Christopher Baugh, credibly testified that "observation care" generally refers to "the care that patients receive while they're getting additional treatments or testing to determine if they require inpatient admission." Tr. 765:19-22. It is the subject of at least two textbooks, several annual conferences, and at least two sections of professional societies. Tr. 764 (Baugh).

42. Observation care is sometimes delivered using condition-specific protocols that identify both which patients would benefit from observation care and which treatments or tests might be appropriate once it is determined that observation care is appropriate. Tr. 766.[22] These protocols are created by the physicians and other medical staff at a particular hospital, but are often shared and discussed with physicians and medical directors at other hospitals, including at meetings of professional societies. Tr. 770:5-771:23. Observation patients are also sometimes clustered together in an observation unit, which is often within or adjacent to the emergency department, in which case the observation unit is known as an emergency department observation unit or EDOU.[23] Tr. 766-68. Observation care can thus be delivered in one of four basic settings based

[22] For example, at Brigham & Women's Hospital in Boston, Massachusetts, where Dr. Baugh works, there are twenty-three separate protocols, including a protocol for asthma and another for chest pain. There is also a "generic" protocol for patients who don't fit neatly into one of the condition-specific protocols. Tr. 768.

[23] According to a 2009 national survey, just less than half of all hospitals nationally had access to an observation unit. Tr. 780:8-11. And the nationwide average length of stay for an emergency department observation unit visit is

on the intersection of the above two factors: (1) whether observation patients are clustered together in an observation unit and (2) whether the care involves the use of protocols. Tr. 765-67.[24]

43. In emergency department observation units (EDOUs), the decision by the physician to order observation services, as opposed to formal inpatient admission, is generally made based on the capabilities of the EDOU, the clinical judgment of the treating physician, and the application of observation care protocols, and not by applying the Two Midnight Rule or any other government-specified criteria. For example, Dr. Baugh testified that, at Brigham and Women's Hospital in Boston, a patient is assigned to the EDOU, and thus placed on observation, when "the attending emergency physician . . . determine[s] that their care would be best served in that setting." Tr. 782:6-11 (Baugh). This decision is made based on "the clinical scenario [the emergency department physicians] are presented with," irrespective of a patient's insurance coverage, and without the approval or participation of the hospital's billing or compliance staff. Tr. 784:3-7 (Baugh). The decision is informed by condition-specific protocols, developed by the physicians at Brigham and Women's, that identify which patients would benefit from observation care. Tr. 766:1-771:23 (Baugh).

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approximately fifteen hours. Tr. 828:9-11. The overlap between patients who are expected to stay at least two nights at the hospital and patients who are treated in EDOUs is thus limited, and Dr. Baugh testified that a patient expected to require medically necessary hospital care for two midnights or more would not usually get assigned to an EDOU. Tr. 828:23-829:23.

[24] According to this taxonomy, in a "Type 1" setting, patients are clustered together in an observation unit, typically within or adjacent to an emergency department, and physicians deliver care according to protocols. Tr. 766. In a "Type 2" setting, patients are clustered together in some manner, but the treating physicians do not follow observation care protocols. Tr. 768. In a "Type 3" setting, patients are not clustered (i.e., patients may be distributed throughout the hospital), but treating physicians do follow protocols for providing observation care. Tr. 766-67. Finally, in a "Type 4" setting, patients are not clustered, nor do treating physicians follow observation care protocols. Tr. 767.

44. Emergency department physicians, in fact, often do not even have the authority to order inpatient admission. For example, when Dr. Baugh determines that observation care in his EDOU is not appropriate for a patient, and that the inpatient service[25] would be the more appropriate treatment setting, Dr. Baugh can transfer the patient to the inpatient service, but he cannot formally admit the patient as an inpatient. The latter decision is reserved for the physicians working in that department, although Dr. Baugh can make a recommendation at the time of the transfer that the patient be treated as an inpatient. Tr. 785:3-25. Accordingly, a decision by Dr. Baugh to treat a patient in his EDOU as an outpatient receiving observation services has the effect of preventing that patient from being formally admitted to the hospital as an inpatient, while a decision by him to transfer a patient to the inpatient service does not guarantee that the patient will be formally admitted.

2. Admission Practices in Other Settings

45. For patients who receive observation services outside of an EDOU and during the time period after the promulgation of the Two Midnight Rule, the evidence at trial showed that physicians generally decide whether to formally admit a patient as an inpatient, as opposed to ordering observation services, by applying the Two Midnight Rule. That is, physicians generally issue an inpatient order if they "expect[] the patient to require hospital care that crosses two midnights," and they base this expectation 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)(1).[26] For example, Plaintiffs' expert Dr. Ann Sheehy

[25] The inpatient service is the department of the hospital that cares for inpatients. However, a patient on an inpatient service may be treated as a formally admitted inpatient or as an outpatient receiving observation services.
[26] Although there was no evidence that treating physicians refer to or consciously apply the text of the Two Midnight Rule, the evidence concerning physicians' decision-making process was generally consistent with the language of the rule, including reliance on the Rule's non-exhaustive list of "complex medical factors."

credibly testified that hospitalists[27] "typically" write inpatient orders based on whether or not they "think [a patient] need[s] two midnights of care." Tr. 305:3-9. Similarly, Dr. Baugh acknowledged that on an inpatient service (which is also sometimes referred to as a hospitalist service), as opposed to in an EDOU, he understood the admitting team to be "following the Two-Midnight Rule, which is based on physician discretion around whether they need two or more midnights of hospital services." Tr. 824:20-22 (Baugh); *see also* Tr. 123:17-20 (Dr. Julia Kyle ordered inpatient admission if a patient "has medical needs that may exceed two midnights in the hospital."); Tr. 1007:10-14 (Dr. Swarupa Vedere indicated that if a patient was expected to stay "more than 48 hours," the patient would be admitted as an inpatient, though she also indicated that "the complexity of the patient care" was also a factor.[28]).

46. Physicians determine whether they expect a patient to require a two-midnight hospital stay by applying medical judgment. Their decision-making process is not reducible to any set of

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[27] "[H]ospitalists [are physicians who] deliver the majority of inpatient care for general medicine patients around the country now. Hospitalists also deliver the majority of observation care around the country." Tr. 304:17-20.

[28] The role that the "complexity" of the care required by the patient plays in physicians' decision-making process was not always clear at trial. At times, physician witnesses described it as an independent factor they considered in determining whether to write an inpatient order, separate from their expectation regarding the anticipated length of a patient's stay, as in the above-cited testimony of Dr. Vedere. *See also* Tr. 124:2-6 (Kyle) ("Q: In fact, you use a variety—consider a variety of factors, including the anticipated length of stay, the complexity of the patient, and the type of care the patient's going to need; correct? A: Yes."). But other evidence suggested that complexity of care—a patient's "medical needs" in the language of the Two Midnight Rule—is *not* an independent factor informing the admission decision, but rather a factor that informs the physician's expectation regarding whether a two-midnight hospital stay will be necessary. The language of the Two Midnight rule itself frames the analysis in this manner, describing the ultimate criterion for admission as the admitting physician's expectation that "the patient require[s] hospital care that crosses two midnights," and listing a patient's "current medical needs" as one of the factors a physician's two-midnight expectation "should" be based on. 42 C.F.R. § 412.3(d)(1); *see also* PX034. Other testimony by the same physicians showed that they understood this feature of the Two Midnight Rule. For example, Dr. Vedere testified that even when patients are in an intensive care unit, indicating that they require the highest level of care, they may still be classified as an outpatient receiving observation services if "they can get better in a day," as with some drug overdose patients. Tr. 1020:13-1021:1 (Vedere); *c.f.*, 78 Fed. Reg. 50496, 50947 (Aug. 19, 2013) ("We do not believe beneficiaries treated in an intensive care unit should be an exception to this standard, as our 2-midnight benchmark policy is not contingent on the level of care required or the placement of the beneficiary within the hospital."). Inpatient admission based on complexity of required care or similar factors alone, without the expectation of a two-midnight stay, may, however, be appropriate under the case-by-case exception, codified at 42 C.F.R. § 412.3(d)(3), but application of the case-by-case exception appears to be rare and CMS provides limited guidance as to its applicability. Tr. 349-50 (Sheehy).

uniform, objective criteria. *See, e.g.*, Tr. 123:17-124:1 (Kyle) (acknowledging that "it is difficult" to provide exact criteria used in the admission decisions and that admissions decisions are made based on the medical needs of the patient); Tr. 1015:16-23 (Vedere) (characterizing the decision to change a patient's status as based on an "overall assessment" of the patient, with no set trigger); Tr 305:5-9 (Sheehy) ("We typically write an order based on the presumption of two midnights. And that order is based on how—what I think the circumstances of that patient's care are going to be at that time to determine whether or not I think they need two midnights of care."). Nor was there any evidence that physicians themselves relied on commercial screening tools in making admissions decisions.

47. At the same time, physicians' decision-making process under the Two Midnight Rule is far from wholly subjective. The application of medical judgment under the Rule generally involves the consideration of various objective factors, such as a patient's signs, symptoms, medical history, and test results, and the application of a shared body of scientifically derived medical knowledge, as well as a physician's own professional experience, to formulate a treatment plan and an attendant expectation regarding how long a patient will require hospital care. *See, e.g.*, Tr.1013:21-1015:15 (Vedere) (describing the decision-making process). As noted, the factors that the physicians who testified actually considered are consistent with the non-exhaustive list set forth in the Two Midnight Rule, *i.e.*, "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)(1).

48. In some cases, physicians consult with hospital case managers prior to determining whether a patient should be admitted as an inpatient or placed on observation. For example, Dr. Vedere testified that, at Yale-New Haven Hospital, "if we have any doubt, we always call the

utilization review manager[s]," who are "trained," "have all the Medicare guidelines," and are "available 24/7." Tr. 1011-12; *see also* Tr. 407-08 (Wilson). This is in line with CMS's intent, as CMS has repeatedly indicated that "hospitals should have case management and other staff available at all times to assist the physician in making the appropriate initial admission decision." 78 Fed. Reg. 50496, 50914 (Aug. 19, 2013); *see also* PX093 at HHS0007574-78.[29]

49. Physicians are not, strictly speaking, bound by the Two Midnight Rule. To be sure, evidence showed that physicians outside of EDOUs view applying the Two Midnight Rule as part of their job. *See, e.g.*, Tr. 124:15-20 (Kyle) ("[W]e have to answer [the Two Midnight Rule question] on every admission."); Tr. 1008:6-8 (Vedere) (Q: ". . . [D]id you have to make decisions whether to admit patients as inpatients? A: We do as a physician. So because I need to put the admission order . . . . I need to mention inpatient or observation."). And Plaintiff's expert Dr. Sheehy opined that the Rule binds physicians and dictates a particular outcome in each case. Tr. 324:3-8 (Sheehy) ("So if a patient meets the two-midnight requirement, they are an inpatient. If they don't meet the two-midnight requirement, they are under observation. And I am bound to follow Medicare regulations."). CMS's sub-regulatory guidance, however, makes clear that CMS does not *require* a physician to admit a beneficiary as an inpatient once he or she develops the expectation that the beneficiary will require 2 or more midnights of medically necessary hospital care. PX034 ("Q4.10: Is the physician required to admit the beneficiary as an inpatient once he or she develops the expectation that the beneficiary will require 2 or more

[29] For example, in the preamble to the 2014 IPPS Final Rule, CMS notes that "changes in patient status from inpatient to outpatient should be few because hospitals should have case management and other staff available at all times to assist the physician in making the appropriate initial admission decision. Use of Condition Code 44 or Part B inpatient billing pursuant to hospital self-audit is not intended to serve as a substitute for adequate staffing of utilization management personnel or for continued education of physicians and hospital staff about each hospital's existing policies and admission protocols. As education and staffing efforts continue to progress, inappropriate admission decisions, and the need for hospitals to correct inappropriate admissions or report Condition Code 44, should become increasingly rare." 78 Fed. Reg. 50496, 50914 (Aug. 19, 2013).

midnights of medically necessary hospital care? A4.10: . . . . CMS does not require the treating physician to admit the beneficiary as an inpatient in these or any other circumstances. . . . [W]here the treating physician expects a beneficiary to require medically necessary hospital care spanning 2 or more midnights, we encourage the physician to consider ordering an inpatient admission, with the understanding that such a claim will not be denied by a Medicare review contractor for inappropriate status if all other requirements are met."). Similarly, CMS has stated that it does not *prohibit* a physician from admitting a beneficiary as an inpatient absent the expectation of a two-midnight stay (or any other qualifying criterion). *See*, *e.g.*, 78 Fed. Reg. 50496, 50949 (Aug. 19, 2013) (In response to concerns that the Two Midnight Rule conflicts with some state laws requiring inpatient admission after 24 hours at a hospital, CMS explained that "[t]he 2-midnight benchmark does not prohibit physicians from ordering inpatient admission in accordance with state law; rather, this policy indicates when Medicare payment will be deemed appropriate.").

50. For the period before the promulgation of the Two Midnight Rule, there was insufficient evidence presented at trial from which to draw any meaningful conclusions as to physicians' decision-making processes with regard to formal inpatient admission. All of the four physicians who testified focused on the period after the Two Midnight Rule. No physician testified about how he or she decided whether to admit a patient as an inpatient before the adoption of the rule, *i.e.*, when the governing standard was the 24-hour benchmark set forth in the Medicare Benefit Policy Manual.

3. Review by the Utilization Review Team

51. The initial decision by the treating physician to order inpatient admission or to place a patient on observation does not represent the end of the decision-making process. Rather,

physician admission decisions undergo extensive review by other hospital staff through a process known as "utilization review."

52. To comply with the Medicare statute and regulations, hospitals must have a utilization review ("UR") plan that provides, *inter alia*, for review of inpatient admissions and the duration of stays for medical necessity. *See* 42 U.S.C. § 1395x(k)(1); 42 C.F.R. § 482.30; *see also* Tr. 634:3-9 (Laucks) ("[U]tilization review is . . . a requirement for Medicare, [wherein] nurses, clinical case managers, screen patients via an evidence-based tool."). Hospitals must have a utilization review committee (URC), which is responsible for executing the UR plan.[30] 42 U.S.C. § 1395x(k)(2); 42 C.F.R. § 482.30(b). The URC must include at least two physicians, but a physician member of the URC may not be involved in the care of the patient whose case is being reviewed. 42 C.F.R. § 482.30(b). While implementation of the UR plan is formally the responsibility of the hospital's URC, in practice, much of the UR process is conducted by hospital UR personnel such as case managers and individual members of the URC. In fact, CMS "encourages and expects hospitals to employ case management staff to facilitate the application of hospital admission protocols and criteria, to facilitate communication between practitioners and the UR committee or Quality Improvement Organization (QIO), and to assist the UR committee in the decision-making process," PX093 at HHS0007575, and permits individual physician members of the URC to initiate patient status changes on behalf of the URC, *id.* at HHS0007576.

53. At each hospital as to which evidence was presented at trial, once an inpatient admission or observation order is entered by the treating physician, case managers or other UR personnel

[30] If having a properly functioning staff committee is impracticable due to the small size of an institution, the URC may be a group outside the institution, established by the local medical society or by a group of hospitals. 42 C.F.R. § 482.30(b).

review the order for compliance with CMS rules. *See, e.g.*, PX118 at 6 (John Dempsey Hospital Utilization Review Plan provides for the review of every admission by case management "within the first working day of admission" to "determine if the patient meets CMS admission criteria"[31]); Tr. 634:21-23 (Laucks); *see also* PX096; PX200 (Allina Health System's protocols for reviewing admission orders).

54. There are generally two levels of review. The first level of review is performed by case managers with nursing backgrounds and involves the use of a commercial screening tool. *See, e.g.*, PX118 ("The Case Management staff [at John Dempsey Hospital] conducts an admission review."); Tr. 636:21-637:20, 644:2-25 (Laucks) (initial screening at John Dempsey is performed by a nurse case manager); Tr. 419:12-25 (Wilson) (utilization manager nurses at Allina Health use MCG, a commercial screening tool, to perform an initial review of admission orders).[32] If the treating physician orders inpatient admission and the case manager finds that the commercial screening tool's inpatient criteria are met, the review is generally deemed complete and the treating physician's order is left undisturbed. *See, e.g.*, PX200 at 8 (indicating that, at Allina Health System, if there is an inpatient order and inpatient screening tool criteria are met, the review is complete); Tr. 420:1-4 (Wilson) (same).[33]

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[31] According to John Dempsey Hospitals' Utilization Review Plan (2015-2016), a review may result in discharge or the change of the patient's status from inpatient to observation. PX118 at 6.

[32] The Director of Care Management at one hospital testified that while CMS does not mandate the use of a particular screening tool, hospitals must use some type of screening criteria as a condition of participation in the Medicare program. Tr. 639:18-24 (Laucks).

[33] Allina relied on a commercial screening tool called Interqual until around 2015, at which point it switched to a different screening tool—MCG. Utilization review personnel are tasked with searching the medical record to determine whether Interqual's parameters for inpatient admission are satisfied. Interqual is more a reference than an automated tool; it is up to the user to apply the criteria to a patient's medical records and a make a determination whether the criteria are satisfied. Tr. 426:1-428:10 (Wilson); *see also* Tr. 419:10-21 (describing how MCG is used by utilization management nurses). While most hospitals use one of the two major commercial screening tools as part of their utilization review process, some hospitals use their own, home-grown criteria for determining whether inpatient admission is appropriate. Tr. 640:8-631:3 (Laucks).

55. If the case manager finds that the commercial screening tool's inpatient criteria are *not* met, the case is typically referred to a physician advisor for a second level of review. Tr. 420:2-11, 417:2-15 (Wilson); Tr. 644:21-25 (Laucks). Hospitals employ their own physician advisors, who are often members of the hospital's URC, hire third-party contractors to perform second-level reviews, or both. Tr. 645:11-19; 637:14-16 (Laucks).

56. If the physician advisor concludes that inpatient admission is not warranted, the treating physician is prompted to enter an observation order. Tr. 421:21-422:8, 432:1-5 (Wilson). A treating physician may take one of several courses of action in response to a request by the utilization review team to change a patient's status from inpatient to observation: (1) the physician can simply enter the requested observation order; (2) if the physician disagrees, the physician can contact the physician advisor to discuss the case; and (3) the physician can do nothing, leaving the inpatient admission order undisturbed. Tr. 435:21-436:25 (Wilson).

57. There was some evidence that the final decision whether to enter an observation order or leave the inpatient admission order undisturbed belongs to the treating physician, in that only a treating physician can enter an order, and a treating physician can, at least sometimes, decline to follow the recommendation of utilization review personnel, and in such a case the patient's status in the hospital's records will remain unchanged. *See, e.g.*, Tr. 130:4-7 (Kyle) (explaining that she did not face any negative consequences for declining to follow UR's recommendation, but noting that she was not directly employed by the hospital); Tr. 646:2-5 (Laucks)[34]; Tr. 1015:22-

[34] Ms. Laucks testified that, at John Dempsey Hospital, in the event of a disagreement between the treating physician and the UR physician advisor, "we would default to the [treating] physician." But when pressed to elaborate, her response suggested that the most common scenarios were that the treating physician would yield to the physician advisor's position or else provide additional documentation to support his or her position so that the physician advisor agreed with that position. Tr. 698:22-699:6. It was not clear that the treating physician in fact had the upper hand in cases of disagreement. Furthermore, John Dempsey Hospital's written guidelines suggest that treating physicians do not have the final say. *See* PX118 ("If two Physician Reviewers determine that no criteria are met, an internally generated denial letter may be created and sent to the attending physician and patient . . . .").

23 (Vedere) (whether to change an order is "finally the physician's decision")[35]. But if the utilization review team continues to disagree with the treating physician and believe that a claim is ineligible for Part A inpatient payment, the hospital cannot bill Medicare under Part A. Tr. 436:5-25 (Wilson).

58. On the other hand, some physicians believe that the utilization review team makes the final call as to patient status. Tr. 300:7-19 (Sheehy) (doctor's initial order is an "opinion" on what the status will be; it is reviewed by case managers and, if it is incorrect, the doctor will be asked to change it); Tr. 300:2-10 ("oftentimes" the utilization review team "makes the final call"); Tr. 127:21-24 (Kyle) ("[W]e're pretty much coached that you follow what [utilization review] tell[s] you."). And there was evidence that hospitals and physicians tell patients that the decision to place them on observation rather than admit them as inpatients is made by utilization review personnel and not the treating physician. *See, e.g.*, PX152 (Letter to Kanefsky: "During your January hospital visit, your case was reviewed by the Utilization Review to determine if your status could be changed from observation to inpatient. Ultimately, the reviewer determined that you still qualified for observation status and did not meet the requirement for inpatient status."); Tr. 66:17-67:7 (Lawson); PX028 at 1; *see also* Kanefsky Tr. 26:18-19 (Treating physician on Mr. Kanefsky's placement on observation: "I can't do anything about it.").[36]

59. Whether or not treating physicians make the final decision, the recommendation of the utilization review team is, at the least, highly influential. Thus, it is not surprising that the patients who testified at trial (either by themselves or through a family representative) all

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[35] Dr. Vedere also testified, however, that UR personnel "are trained and . . . have all the Medicare guidelines books" and "if we have any doubt, we always call the utilization review manager." Tr. 1011:21-1012:11.
[36] I consider Mr. Kanefsky's testimony about what his physician told him not for its truth, but for the fact that the physician said it to Mr. Kanefsky.

described experiences in which it appeared, at least from their perspective, that the utilization review team had overridden the judgment of the treating physician as to whether they should be inpatient or observation. For example, Plaintiff Ervin Kanefsky stayed at a hospital for five days after sustaining an evulsion fracture of the shoulder. ECF No. 394-10 at 25. Shortly before being discharged, Mr. Kanefsky was informed that "the powers that be changed you back from observation—from inpatient to observation so they're not going to pay for your rehab." ECF No. 394-10 at 26. According to Mr. Kanefsky, his treating physician, who was present at the time, was "aghast," and exclaimed "What? . . . I put this man as an inpatient." *Id.* When Mr. Kanefsky asked whether his treating physician could do anything about the status change, Dr. Glynn responded that he could not.[37] *Id.* As noted above, the letter he later received from the hospital informed him that although his "case was reviewed by the Utilization Review," the reviewer determined "that he still qualified for observation status." PX152.

60. Likewise, Plaintiff Andrew Roney was hospitalized for three nights. He was initially admitted as an inpatient, but prior to being discharged, his status was changed to observation. Tr. 80:2-81:25. He received a notice stating, "Your stay is being classified for billing purposes as 'Observation' stay, rather than as inpatient admission. . . . . Assigning a classification for billing purposes is required by your insurance. Please note, however, that the *quality of care* is exactly the same regardless of whether your stay is billed as observation or inpatient." PX218 at 51 (emphasis in original). The hospital later wrote to Mr. Roney that "we continually review each patient's clinical status during his or her stay," and that although he had been initially

[37] I do not consider these statements for their truth—except for the physician's exclamation, which is an excited utterance—but only for the fact that they were made to Mr. Kanefsky.

admitted as an inpatient, upon later review, his status was changed to observation. PX195 at 52.[38]

61. Similarly, Plaintiff Martha Leyanna was hospitalized for seven nights and, although she was initially admitted as an inpatient, she was subsequently placed on observation. Tr. 42:4-8; 58:5-7. The hospital told Ms. Leyanna's daughter and granddaughter, who were attempting to challenge her placement on observation, that the decision to change her status was made by the utilization review committee. Tr. 66:22-67:7.[39]

62. The decisive influence of the utilization review team in cases in which a patient's designation is changed from inpatient to observation stems from at least three factors. First, treating physicians often perceive utilization review personnel to be the experts regarding eligibility for Part A coverage for inpatient hospital services. Tr. 384:4-16; 394:13-19 (Sheehy) ("[D]octors generally defer to that team of experts who are charged—it's their job to review these orders. They have expertise in this order review. And we defer to them as far as the guidance on writing a compliant order with CMS regulations."); Tr. 1012:4-11 (Vedere) ("[I]f we have any doubt, you know, we always call the utilization review manager who's available 24/7"; utilization review personnel are "more trained in the Medicare guidelines"); Tr. 127 (Kyle) ("[W]e're pretty much coached that you follow what [URC staff] tell you.").

63. Second, treating physicians outside of dedicated observation units generally view the distinction between formal inpatient admission and designation as an outpatient receiving observation services as a billing distinction divorced from decisions regarding appropriate

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[38] I do not consider the statements in this letter for the truth of the matter asserted. As discussed above, however, other evidence at trial indicated that changing patient statuses as a result of continual utilization review is common practice.

[39] I consider this statement for the purpose of establishing Ms. Leyanna and her family's experience, and not for its truth.

medical care. Tr. 360:1-5 (Sheehy); 803:22-804:14 (Baugh). This view is supported by some statements by CMS, *see supra* ¶ 7; PX010 at 60 ("Observation/Outpatient Status is NOT a clinical concern . . . [s]ame patients, same services, same physicians, same rooms, same nurses . . . ."; "Observation/Outpatient Status IS a billing concern"), and communicated by hospitals to patients, PX218 at 51 ("Assigning a classification for billing purposes is required by your insurance . . . . [T]he quality of care is exactly the same regardless of whether your stay is billed as observation or inpatient. . . . You will have outpatient billing status, even though you are in a regular hospital bed and receive some of the same services as a patient with inpatient billing status."). So the treating physician is often not highly invested in what he or she regards as a billing designation. Further, in some cases, the treating physician who enters an observation order at the behest of utilization review personnel is not the same physician who entered the original inpatient order, depending on which physician is working when utilization review prompts the treating team for an order. *See, e.g.*, Tr. 434:6-435:20 (Wilson). Thus, even if one treating physician defies the utilization review team's recommendation, the physician on the next shift may not. *See, e.g.*, Tr. 1012:18-1013:20 (Vedere).[40]

64. Third, hospitals have more at stake with respect to the inpatient-observation distinction than treating physicians. If the treating physician maintains inpatient status while the physician

[40] The utilization review team may review observation orders as well as inpatient orders. Thus, if a treating physician initially enters an observation order and the utilization review team concludes that a patient qualifies for inpatient admission, the physician is similarly prompted for an inpatient order. *See, e.g.*, PX096 at 4; PX200 at 9. Dr. Baugh, who is an emergency department physician, credibly testified that, on occasion, a case manager recommends that a patient he has elected to manage in the observation unit would in fact qualify as an inpatient. Tr. 805:11-15 (Baugh). But this "doesn't change [his] plan," because he is "very comfortable knowing . . . what we can and can't do in that unit." Tr. 805:19-22. In other words, Dr. Baugh makes the decision to keep the patient in his observation unit, rather than recommending a transfer to an inpatient service where the patient might be formally admitted as an inpatient, based on whether his observation unit is clinically appropriate for the patient. As discussed above, his experience differs in important respects from the experience of many hospitalists. The Court heard no evidence on how physicians outside of EDOUs react to requests from the utilization review team to change an observation order to an inpatient order.

advisor continues to believe that Medicare's impatient criteria are not satisfied, the hospital cannot bill Medicare for inpatient services. Tr. 436:5-25 (Wilson). Nor can a hospital bill Medicare for observation services unless and until a treating physician enters an observation order. DX 548-020. Hospitals have an interest in maintaining compliance with CMS regulations and avoiding the administrative burden associated with the more intensive regulatory scrutiny that comes with persistent noncompliance. DX579-001; Tr. 177:13-179:12.

65. In light of all this, it is not surprising that the trial evidence showed that when an inpatient's status is changed to observation, this reclassification is invariably caused by utilization review personnel applying Medicare rules and guidance. As detailed above, the Court heard substantial evidence of the significant and continual involvement of utilization review personnel—and their decisive influence—in determining patient status. The Court also heard evidence of multiple instances where inpatient orders were changed to observation orders at the behest of utilization review staff. *See, e.g.*, Tr. 433:7-435:20 (Wilson) (inpatient order changed to observation at the behest of UR personnel); Tr. 127:15-24, 129:13-19 (Kyle) (inpatient order changed to observation at the behest of UR personnel before being changed back to inpatient on the initiative of the physician); PX152 (indicating that Mr. Kanefsky was placed on observation status based on a determination by utilization review). And the Court heard no evidence at all to suggest that treating physicians put patients on observation status on their own initiative after having admitted them as inpatients. There would be little reason for them to do so, since, as discussed above, such a reclassification constitutes little more than a change in billing status, and hospitals have dedicated utilization review personnel responsible for ensuring that hospital stays are billed appropriately. CMS has made clear, for example, that an inpatient should not be switched to observation status in response to clinical developments—such as an unexpected

recovery that changes the physician's earlier two-midnight expectation. *See* 78 Fed. Reg. 50496, 50946 (Aug. 19, 2013) ("[A] beneficiary who experiences an unexpected recovery during a medically necessary stay should not be converted to an outpatient but should remain an inpatient."). Rather, changes from inpatient to observation—and the initiation of Condition Code 44—are "specifically for the situation when the utilization review or management committee determines that the physician has not appropriately admitted a patient and the physician concurs that the status should be converted to outpatient prior to beneficiary discharge." *Id.* at 50496-97.[41]

66. In reviewing admission orders, utilization review personnel are applying criteria established by CMS, including the Two Midnight Rule, in largely the same manner it is applied by CMS contractors conducting short-stay reviews. *See, e.g.*, PX200 at 3 (Allina Health "System-wide Plan: Hospital Utilization Management" indicating that, like CMS contractors, Allina Health's utilization review process involved an initial screen using a commercial screening tool, which the plan refers to as "nationally accepted evidence-based criteria"); *id.* at 8 (flowchart documenting the review process at Allina captioned "Two Midnight Admission Review Workflow"); PX131 (summary of provider education call with QIO stating that QIO's goal "is to assist providers in reaching the 90% or greater compliance standard of the two midnight rule"); PX118 at 6 (John Dempsey Hospital Utilization Review Plan provides that admissions are reviewed to "determine if the patient meets CMS admission criteria"); PX256 at 11 (physician advisor explaining to QIO contractor that the hospital felt it was applying Two

[41] When a patient is changed from inpatient to observation and the entire stay is billed under Part B, the Claims Processing Manual provides that "the change must be fully documented in the medical record, complete with orders and notes that indicate why the change was made, the care that was furnished to the beneficiary, and the participants in making the decision to change the patient's status." Medicare Claims Processing Manual § 50.3.2. Thus, the URC's role in each status change is reflected in the medical record.

Midnight Rule "to a T"); Tr. 384:4-11 (Sheehy) (indicating that case managers are hired to review admission orders for compliance with Medicare regulations and hospitals and physicians rely on them for this purpose).

67. CMS in fact engages in significant efforts, often through its contractors, to educate hospital staff on the application of the Two Midnight Rule, including direct interactions with physician advisors regarding how to apply the Two Midnight Rule properly. *See, e.g.*, PX131; PX132; PX197 (transcripts of provider education calls); PX034 at 3 (describing planned efforts by CMS and its contractors "to provide guidance and education about the inpatient rule to ensure hospital understanding and compliance with the instructions"); PX034 at 9 (describing factors physicians should consider when making the admission decision); Tr. 958:5-18 (Duvall) (describing the Probe and Educate initiative, performed by CMS contractors at the behest of CMS); PX151 (QIO explaining to providers why certain claims were denied under the Two Midnight Rule). And the review and audit activities of CMS contractors, including QIOs and RACs, as well as as DOJ and HHS-OIG, described in Section III.B, *supra*, put substantial pressure on hospitals to apply CMS's inpatient admission criteria rigorously, uniformly, and in the same manner as CMS. In short, the evidence showed that when a patient's order was changed from inpatient to observation, it was done at the behest of URC staff, who were carrying out what they believed to be CMS's instructions.

D. The Stakes for Medicare Beneficiaries

68. When a beneficiary is placed on observation, rather than formally admitted as an inpatient, the beneficiary is effectively denied Part A coverage. This effective denial of Part A coverage can have significant negative consequences for beneficiaries, as CMS has acknowledged. PX007 at 1; PX049 at 7192-93 ("pressure number one" leading to the Two

Midnight Rule was "tremendous beneficiary concern regarding the growth and the duration" of observation care); PX031 at 45156 (trend of lengthy observation stays was concerning because of the "significant financial implications" for Medicare beneficiaries); PX043 at 2-3; Tr. 919:21-922:5 (Duvall).

1. Coverage for SNF Care

69. The most significant hardship caused by the Plaintiffs' placement on observation status is the loss of eligibility for Part A SNF coverage. Medicare will cover post-hospital SNF care only for those beneficiaries who spend three or more consecutive days in the hospital as an "inpatient," and time spent as an outpatient receiving observation services does not count towards the three-day requirement. 42 U.S.C. § 1395x(i); 42 C.F.R. § 409.30(a); PX007 at 1; PX095 at 6726-27; Tr. 319:18-320:17, 345:4-346:11 (Sheehy); Tr. 923:1-924:10 (Duvall); Tr. 858:5-859:10 (Baugh). When a beneficiary stays at the hospital for three or more consecutive days but is formally admitted as an inpatient for less than three days—spending one or more of those days on observation status—the beneficiary's placement on observation has the effect of depriving the beneficiary of SNF coverage.

70. Medicare beneficiaries who decide to receive post-hospital SNF care but who have not met the three-day inpatient requirement are forced to cover the costs of SNF care, which average over $10,000, out of their own pockets. PX043 at 2-3, 15 (according to an OIG study, the average out-of-pocket cost for SNF care not covered by Medicare was $10,503); PX024 at 11090 ($10,600 SNF bill for Martha Leyanna); PX025 at 11082 (explaining why Ms. Leyanna's SNF care was not covered by Medicare); Tr. 49:16-51:3 (Lawson) (indicating that Ms. Leyanna had to pay for her SNF care out of pocket); Tr. 354:10-19 (Sheehy); ECF No. 394-10:2-21 (indicating that Plaintiff Ervin Kanefsky paid "close to $10,000" for his non-covered stay at a skilled

nursing facility); PX124 (listing charges of $9,145 for room and board at PowerBack Rehabilitation for Mr. Kanefsky).

71. Medicare beneficiaries who run out of money to pay for SNF care out-of-pocket, but who have a continued need for care, may be forced to transfer to a nursing facility that cannot provide the rehabilitative care they need. Tr. 51:2-16, 70:18-72:2 (Lawson) (indicating that Ms. Leyanna ran out of money to pay for skilled nursing care, had to transfer to a facility providing a lower level of care, and never regained independent mobility). Other beneficiaries may be forced to forgo needed SNF care entirely because they cannot afford to cover the cost out-of-pocket. Tr. 121:3-17 (Kyle); Tr. 355:15-356:9 (Sheehy); Tr. 861:7-862:7 (Baugh).

72. According to a 2013 OIG report, during FY 2012, a total of 617,702 beneficiaries had hospital stays lasting at least three nights, fewer than three of which were inpatient nights. DX577-014. Of these, 4% obtained SNF services following their discharge from the hospital, even though they did not qualify for these services under Medicare.[42] DX577-015. However, the 4% figure does not include beneficiaries who were recommended for SNF care by their treating physician but did not receive it, due to concerns about the out-of-pocket costs they would incur or other circumstances. The data on this population are sparse, but one study indicated that five times as many patients are recommended for SNF care as actually receive it, which would mean that in FY2012 a total of around 20% of the 617,702 extended observation stay patients were recommended SNF care for which they did not qualify for Medicare coverage due to their designation as observation patients. Tr. 797:22-799:9, 802:3-14 (Baugh).

[42] According to the OIG Report, CMS in fact "inappropriately" paid for SNF services for the majority of these approximately 24,000 beneficiaries, but 2,097 beneficiaries were fully liable for their own SNF costs, which averaged $10,503. DX577-015.

73. Designation as an outpatient receiving observation services, with no ability to appeal the designation, and the attendant denial of SNF coverage, can also have negative emotional effects on beneficiaries and their families, as well as harmful effects on the doctor-patient relationship. Tr. 119:13-120:6, 121:3-17 (Kyle) (Upon learning that her placement on observation meant she was ineligible for SNF coverage, patient told her provider that if she couldn't get rehab and couldn't return home, it would bankrupt her family and that she would rather just die.); Tr. 354:20-355:6 (Sheehy); Tr. 419:8-12 (Lawson) (Plaintiff Martha Leyanna's granddaughter described losing trust in the system after all of her efforts to challenge her grandmother's placement on observation status, and the attendant denial of SNF care, proved futile.).

2. Hospital Costs for Those Lacking Part B or Private Coverage

74. When a beneficiary is placed on observation status, rather than formally admitted as an inpatient, the beneficiary is also, in effect, denied Part A coverage for the hospital stay. In such a case, the hospital stay may be covered by Medicare Part B or private insurance, if the beneficiary has chosen to pay the premiums to secure such coverage. If a beneficiary has no such coverage, the beneficiary is personally responsible for the full cost of the hospital stay, which constitutes a substantial financial burden. For example, one Medicare beneficiary, Andrew Roney, credibly testified that he did not have Part B coverage because he could not afford it. Tr. 74:22-23, 75:11-17. Part-way through his hospital stay, Mr. Roney's status was changed from inpatient to outpatient, making him ineligible for Part A coverage. As a result, he had to pay the cost of his hospital stay himself. PX218 at 1-4 (bill for $3,502 for Andrew Roney); Tr. 84:2-18 (Roney).

75. If a beneficiary has purchased Part B coverage, in most cases, the beneficiary's out-of-pocket costs for an observation stay covered under Part B are less than a comparable inpatient stay covered under Part A. PX149 at 13 (HHS OIG Report: In 2014, "[o]n average, beneficiaries

paid more for inpatient stays than for outpatient stays, but in some instances the reverse was the case."); DX577-002 (HHS OIG Report: In 2012, "[o]n average, short inpatient stays cost Medicare and beneficiaries more than observation stays.").[43] In some cases, however, the out-of-pocket cost of an observation stay covered under Part B is higher than a comparable inpatient stay. Prior to 2016, when a hospitalized Medicare beneficiary received observation services and was covered under Medicare Part B, the beneficiary was responsible for a 20 percent copayment for each individual service. DX575-010; PX149 at 13 ("Beneficiaries in outpatient stays generally pay 20 percent of Medicare's rate for each service, and there is no cap on the total amount they can be responsible for paying."). As a result, some beneficiaries have faced higher out-of-pocket costs for observation stays than they would have faced as an inpatient. For example, in 2012, for "6% of all observation stays, or 83,747 stays, beneficiaries paid more than the inpatient deductible," and "for 3,439 observation stays, beneficiaries paid more than two times the inpatient deductible." DX577-013; *see also* PX149 at 13 ("In FY 2014, beneficiaries in 352,940 outpatient stays paid more than the inpatient deductible.").

76. Starting in 2016, Medicare bundled most facility charges for observation services into a single payment, so beneficiaries receiving observation services subject to this bundling pay a single 20 percent copayment for all covered services during the stay. 80 Fed. Reg. at 70334; Tr. 788:4-8 (Baugh); DX561-018 to -20; DX575-010. In 2018, the bundled rate for observation services was $2,349.66, Tr. 791:24-25 (Baugh), resulting in a 20 percent copayment of $469.93. By comparison, the inpatient deductible in 2018 was $1,340. Beneficiaries designated as outpatients receiving observation services are still responsible, however, for the expense of self-

[43] Beneficiaries who have Part B coverage and who have stayed at the hospital less than three days or were inpatients for more than three days do not fall within the class definition.

administered medications, which are typically the beneficiary's home medications. Tr. 788:9-11 (Baugh). According to OIG, in 2014, the average charge for self-administered medication was $207. PX149 at 13. It is unclear how much such charges vary and how often the combination of the observation copayment and the cost of self-administered medications surpasses the inpatient deductible.

E. The Existing Procedures

77. Beneficiaries currently have no formal opportunity to challenge their placement on observation status, whether in the first instance by their treating physician or as the result of utilization review. They are not given a hearing prior to being placed on observation, at which they might argue that they meet the requirements for a payable inpatient admission under Medicare regulations, nor any later opportunity to challenge their placement on observation and the effective denial of Part A coverage that it entails. But while beneficiaries cannot appeal this critical determination, the parties did present evidence at trial of the existing procedures that allow hospitals to challenge denials of Part A claims by QIOs, as well as the existing procedures that allow beneficiaries to challenge, on an expedited basis, decisions to terminate Medicare benefits in the hospital context.

1. Standard Appeals

78. When a hospital's Part A claim is denied by a CMS contractor on the basis that the inpatient admission did not satisfy the Two Midnight Rule (or, before that, the 24-Hour Benchmark), the hospital may appeal the denial through the five-level, "standard appeals process." Tr. 975:5-13 (Duvall); Tr. 1081:10-20 (Ramirez). First, any party to an initial determination, such as a pre- or post-payment denial of Part A coverage by a CMS contractor, may ask for review of the initial determination by seeking a "redetermination" from the same contractor. 42 C.F.R. §§ 405.906(b), 405.940; Tr. 1081:10-20 (Ramirez); Tr. 1140:8-17 (Green);

Tr. 975:14-976:2, 994:15-995:24 (Duvall).[44] Second, if dissatisfied with the result of a redetermination, the party may seek "reconsideration" by a different contractor, called a Qualified Independent Contractor ("QIC"). 42 C.F.R. §§ 405.904(a)(2), (b), 405.960, 405.964; Tr. 1085:4-9 (Ramirez). Third, the QIC's decision may be appealed to an ALJ, provided a minimum amount in controversy is met. 42 C.F.R. §§ 405.904(a)(2), (b), 405.1002. Fourth, an ALJ's decision may, in some cases, be further appealed to the Medicare Appeals Council. *Id*. § 405.1102. Finally, judicial review may be available in U.S. District Court provided certain threshold requirements are met. *Id*. § 405.1136.

79. The standard appeals process offers no prospect of relief to the class members in this case, however, because it is not available unless a CMS contractor makes an initial determination denying a Part A claim. Consequently, a beneficiary has no right to access the standard appeals process when a treating physician declines to order inpatient admission in the first instance, when an earlier inpatient admission is overridden as the result of utilization review, or when a hospital declines to submit a Part A claim because utilization review personnel do not believe that a treating physician's inpatient order satisfies the Two Midnight Rule. In each of these circumstances, no Part A claim is submitted to CMS and thus no appeal can be brought by the Plaintiffs in this case.

[44] Under CMS rules, parties to an initial determination include the provider or supplier as well as the beneficiary. 42 C.F.R. § 405.906(a); Tr. 1143:18-1144:8 (Green); *see also* Tr. 1083:2-7 (Ramirez). Thus, the standard appeals process is technically available to both providers and beneficiaries. 42 C.F.R. § 405.906(a); Tr. 1143:18-24 (Green); Tr. 976:7-18 (Duvall). As a practical matter, however, a beneficiary generally has no incentive to appeal because neither inpatient status nor the beneficiary's eligibility for coverage is affected by the denial of an inpatient claim by a CMS contractor. *See* Tr. 996:10-21 (Duvall).

2. Expedited Appeals of Discharge Decisions

80. By way of illustrating the type of appeal rights they seek, the Plaintiffs also introduced evidence of an existing, expedited appeal scheme under Medicare that operates in the hospital context. A beneficiary classified as an inpatient under Medicare Part A currently has the right to appeal the termination of Medicare benefits, such as a planned discharge from a hospital, on an expedited basis. 42 C.F.R. §§ 405.1205-405.1206, 405.1204(c)(4)(iii); PX233 at § 7015; Tr. 337:12-21 (Sheehy); Tr. 480:10-481:5, 618:9-619:10 (Iwugo). This type of appeal is sometimes referred to as a "discharge" or "Weichardt" appeal. Tr. 716:5-9 (Iwugo).

81. Upon learning of a planned discharge, a beneficiary has the right to request an expedited determination by a QIO regarding whether Medicare will continue to cover care in the hospital setting, under Part A, beyond the planned date of discharge. 42 C.F.R. § 405.1206(a),(b)(1); Tr. 716:23-717:8. Hospitals are required to provide beneficiaries written notice of this right at or near admission, 42 C.F.R. § 1205, and follow-up notice "as far in advance of discharge as possible, but not more than 2 calendar days before discharge," 42 C.F.R. § 1205(c).

82. The QIO's determination in a discharge appeal is based on a review of the beneficiary's medical record and other written materials, 42 C.F.R. § 405.1206(b)-(e); PX233 at § 7015; Tr. 603:16-604:5, 618:9-619:10 (Iwugo), and the QIO must render a decision within 24 hours. 42 C.F.R. § 405.1206(d)(6)(i); PX233 at § 7015; Tr. 604:12-18, 737:16-738:12 (Iwugo). If the QIO renders an adverse determination, the beneficiary can request an expedited reconsideration with a separate QIO reviewer. 42 C.F.R. § 405.1206(g)(1); PX233 at §§ 7015 & 7040; Tr. 605:9-606:14 (Iwugo). If unsuccessful on reconsideration, a beneficiary may appeal through levels three, four, and five of the standard appeals process, involving appeal to an ALJ, the Medicare Appeals

Council, and a District Court, respectively. 42 C.F.R. §§ 405.1204(c)(4)(iii), 405.1200-405.1204; Tr. 600:23-601:5 (Iwugo).

83. In a discharge appeal, the QIO's inquiry is not whether the treating physician's plan to discharge the beneficiary is appropriate, but only whether Medicare would pay for the inpatient care beyond the planned date of discharge. Tr 603:4-9 (Iwugo). Thus, a favorable decision by the QIO does not guarantee a continued stay, nor does an unfavorable result guarantee that the beneficiary will be discharged.

F. The Additional Procedures Plaintiffs Seek

84. The Plaintiffs ask this Court to order the Secretary to "provide an opportunity for the named plaintiffs and class members to challenge their classification as observation status, and, if it is found that inpatient admission was appropriate, adjust the Medicare coverage for each beneficiary's hospitalization and post-hospital SNF care accordingly." ECF No. 123 at 29. The inquiry such an appeal would involve is the same one that RACs, QIOs, and ALJs already engage in for post-payment reviews and appeals therefrom—namely, whether the relevant standard for inpatient admission (currently the Two Midnight Rule) is satisfied. *See, e.g.*, Tr. 394:14-22 (Sheehy); DX579 (short-stay review guidelines followed by QIOs). While there may be some minor differences, depending on the contours of the Plaintiffs' due process rights, in the analysis that reviewers would need to perform under the procedures Plaintiffs seek versus the procedures currently employed, the similarities easily predominate over any differences. For example, where a treating physician ordered inpatient admission, but the beneficiary was subsequently changed to observation status because the utilization review team concluded that the inpatient admission did not satisfy the applicable CMS standard and thus did not qualify for Part A payment, the inquiry on appeal would be identical to existing reviews—whether the

original inpatient order was made pursuant to a reasonable two-midnight (or 24 hour) expectation. Thus, there are multiple entities involved in the administration of the Medicare program that already have the basic training and experience necessary to process the appeals the Plaintiffs seek.

85. The Plaintiffs seek both expedited and non-expedited appeals. ECF No. 123 at 28-29. CMS already has the procedural mechanisms in place to process both types of appeals—the five-step "standard appeals process" and the expedited "Weichardt" process. *See* Section III.E. Thus, just as CMS and its agents already conduct the very same inquiry that would be at issue in the appeals Plaintiffs seek, CMS also already has in place the relevant procedural mechanisms. In short, there is little substance to the Secretary's claim that the procedures sought by the Plaintiffs constitute "new kinds of reviews."

86. Nonetheless, in order to establish the procedures the Plaintiffs seek, the Secretary would have to undertake a number of administrative steps. These steps are likely to include drafting sub-regulatory guidance and may also include drafting regulatory language. Tr. 722:5-10, 724:21-725:9 (Iwugo). The latter, in particularly, would involve a substantial delay and some administrative burden. *See* Tr. 724:21-725:9 (Iwugo); Tr. 1100:5-1101:3 (Ramirez); Tr. 1163:24-1164:3. Nonetheless, while it seems likely that new regulatory language would be necessary, given the similarity of the procedures sought by the Plaintiffs to those already in place, any new regulations would largely involve an extension of existing procedures to a new context. The Secretary may also need to draft new contracts or modify existing contracts, Tr. 722:11-723:2, 727:7-21 (Iwugo); Tr. 1101:4-24 (Ramirez), develop appropriate educational and training materials, Tr. 1104:11-1105:2 (Ramirez); Tr. 1163:18–23 (Green), and secure a new appropriation from Congress to fund the additional reviews, Tr. 1103:6-19 (Ramirez). The

Secretary would also need to draft new or revised notices to beneficiaries concerning their appeal rights. The Secretary would be required to publish proposed changes to any notices in the Federal Register to allow the public to review and comment on the changes, respond to the comments, and republish the revised notices for a second round of review and comment. Tr. 1105:6-1106:18 (Ramirez). Each of these burdens, however, is limited by the great similarity between the existing procedures and those sought by the Plaintiffs. Moreover, these tasks are generally undertaken once and do not represent an ongoing administrative burden.[45]

87. In addition to the administrative burdens involved in initially establishing the procedures the Plaintiffs seek, processing these appeals would require an increase in contractor and agency staffing, *see, e.g.*, Tr. 728:17-729:5 (Iwugo), which would result in added expense. Resolving an appeal at the ALJ level, for example, costs roughly $1,000 per appeal, Tr. 1165:14-1166:1 (Green), and this cost increases if the ALJ needs to appoint an expert witness, Tr. 1166:20-1168:2 (Green). This estimate was "very crude," Tr. 1166:13-14 (Green), however, and did not take account of potential savings from economies of scale.

IV. CONCLUSIONS OF LAW

To state a due process claim, a plaintiff must show that (1) state action (2) deprived him or her of liberty or property (3) without due process of law. *See Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999).

[45] The Secretary may also face the additional burden of identifying the beneficiaries who fall within the class definition because they either (1) were designated as outpatients receiving observation services at their hospitals and lacked Part B coverage or (2) were designated as outpatients receiving observation services and spent at least three nights in the hospital but fewer than three nights as inpatients. Tr. 725:13-23 (Iwugo). It is unclear, however, why the Secretary must notify only these beneficiaries, instead of providing notice to some broader, more readily identifiable group, and simply noting the prerequisites to any right of appeal in the notice.

A. Deprivation of a Protected Property Interest

To establish entitlement to due process protection, the Plaintiffs must first demonstrate they possess a protected property interest. *Furlong v. Shalala*, 156 F.3d 384, 393 (2d Cir. 1998). In the context of government benefits, a "mere unilateral expectation of receiving a benefit" is not enough to create a property interest; rather, a property interest arises when state or federal law confers a "legitimate claim of entitlement" to the benefit. *Barrows*, 777 F.3d at 113. A benefits regime creates a "legitimate claim of entitlement" when the statutes and regulations governing the distribution of benefits "meaningfully channel official discretion by mandating a defined administrative outcome." *Barrows*, 777 F.3d at 113 (internal quotation marks and alterations omitted) (quoting *Kapps v. Wing*, 404 F.3d 105, 113 (2d Cir. 2005)).

The meaningful channeling standard involves two largely distinct inquiries: whether the relevant criteria governing eligibility "meaningfully channel official discretion" and whether conferral of the benefit becomes mandatory upon a finding that the relevant criteria are satisfied. A plaintiff must satisfy both inquiries to establish a property interest. *See Kentucky Dept. of Corrections v. Thompson*¸ 490 U.S. 454, 462 (1989) ("[T]he most common manner in which a state creates a liberty interest is by establishing substantive predicates to govern official decision making and, further, by mandating the outcome to be reached upon a finding that the relevant criteria have been met." (internal quotation marks and citation omitted)); *Wolff v. McDonnell*¸ 418 U.S. 539, 557 (1974) ("This analysis as to liberty parallels the accepted due process analysis as to property.").

Thus, if an administrative scheme "does not require a certain outcome, but merely authorizes particular actions and remedies, the scheme does not create 'entitlements' that receive constitutional protection." *Sealed v. Sealed*, 332 F.3d 51, 56 (2d Cir. 2003); *see also Thompson*,

490 U.S. at 463-64 (declining to recognize a liberty interest because, although the regulations and procedures at issue provided "substantive predicates" to guide the decisionmaker, the regulations lacked the "requisite relevant mandatory language"—that is, "they stop short of requiring that a particular result is to be reached upon a finding that the substantive predicates are met").

Likewise, if the criteria governing eligibility for a benefit are so subjective that they do not "meaningfully channel official discretion," no property interest is created. *See, e.g.*, *Colson on Behalf of Colson v. Sillman*, 35 F.3d 106, 109 (2d Cir. 1994) (statute providing that the state "shall" provide, "within the limits of the appropriations made thereof, such medical service for children with physical disabilities as in the judgment of the commissioner is needed" does not establish a property interest, notwithstanding its mandatory language, because, among other reasons, the standard "leaves the provision of medical services to the 'judgment' of state officials and provides neither direction nor constraint on that judgment"); *cf. Fittshur v. Village of Menomonee Falls*, 31 F.3d 1401 (7th Cir. 1994) (ordinance authorizing suspension or discharge of village employees "when necessary for the good of the Village service" does not create a property interest because it "does not restrict the village manager's discretion in any meaningful way"; "[a]lmost any discharge of a village employee can be described as 'necessary for the good of the Village service.'").

In analyzing whether the meaningful channeling requirement is satisfied in this case, both this Court and the Second Circuit have sometimes asked whether the relevant criteria are "fixed" and "objective."[46] Any such references must be read in light of the governing standard. The

[46] Whether Second Circuit precedent *requires* a standard to be "fixed" and "objective" to create a property interest is somewhat unclear. In *Kapps*—from which this language is drawn—the Court, after reciting the meaningful channeling standard, notes that "there has been no intimation in the course of this litigation that discretionary factors

plain language of the meaningful channeling standard makes clear that "official discretion" need not be eliminated entirely, but only "meaningfully channeled." The standard does not require, in other words, that the relevant criteria be so fixed and objective that they can be applied mechanically, without the application of any professional judgment. The relevant inquiry is thus better framed not in terms of whether the relevant criteria *are* "fixed" and "objective"—both of which are vague terms better understood in terms of a spectrum rather than a rigid dichotomy—but whether the criteria are *sufficiently* fixed and objective to "meaningfully channel official discretion."

Other Circuits have explicitly held that a standard that leaves room for judgment may still create a property interest. *See, e.g.*, *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."); *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

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enter into the [benefits determination]. On the contrary, it appears that all of the factors considered by the state in assessing . . . eligibility . . . are objective, and as such are ones over which . . . administrators have no discretionary control." *Kapps*, 404 F.3d at 114. *Kapps* makes no further mention of objectivity, and the above language is simply ambiguous as to whether objectivity is necessary to create a property interest, or merely a factor in the analysis. The latter is the more likely interpretation, since the language seems to equate "objectivity" with the absence of "discretionary control," while the meaningful channeling standard specifically contemplates the existence of residual "official discretion." Similarly, in *Barrows*, the Second Circuit, after also reciting the meaningful channeling standard, contrasts two scenarios—one in which "plaintiffs are able to prove their allegation that CMS 'meaningfully channels' the discretion of doctors by providing fixed or objective criteria for when patients should be admitted," in which case plaintiffs might have a property interest, and another in which "admission decisions are vested in the medical judgment of treating physicians," in which case plaintiffs would lack a property interest. *Barrows*, 777 F.3d at 115. But *Barrows* was decided on a motion to dismiss, and its analysis was of course addressed to the complaint. *Id.* at 114. The Court's ultimate holding was only that Plaintiffs' allegation that admissions decisions were made through "rote application of 'commercially available screening tools,' as directed by [CMS]," if proven, could plausibly support the existence of a property interest. *Barrows* is thus also ambiguous as to whether "fixed" and "objective" criteria are necessary to "meaningfully channel official discretion" and thus create a property interest, or whether they are merely a factor in the analysis. In any case, even if there is no independent requirement for "fixed" and "objective" criteria, fixity and objectivity are important considerations in the meaningful channeling inquiry. An entirely or even predominately subjective standard likely does not "meaningfully channel official discretion."

examining board exercised discretion in determining whether those criteria had been met); *see also Edison 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."). Similarly, in *Board of Pardons v. Allen*, the Supreme Court held that although a statute governing parole required the Board to make a decision that was "subjective and predictive," it nonetheless created a liberty interest because it "made release mandatory upon certain findings . . . ."[47] *Bd. of Pardons v. Allen*, 482 U.S. 369, 380-81 (1987). The Court explained that the fact that officials "must use judgment in applying" a standard—that the standard "cannot be applied mechanically"—does not preclude the existence of a protected interest. *Id.* at 375. Although *Allen* involved a liberty interest, *Fleury* and other cases have relied on it in assessing whether a legal standard creates a property interest, and the Supreme Court has described the due process analyses of liberty and property as "parallel." *Wolff*, 418 U.S. at 557. The Second Circuit has also relied on liberty interest cases in analyzing property interests, including in the case that first articulated the meaningful channeling standard. *See Sealed*, 332 F.3d at 56 (relying on the Supreme Court's decision in *Ky. Dep't of Corr. v. Thompson*, 490 U.S. 454, 462 (1989), which involved a liberty interest).

[47] The relevant statute provided that, subject to certain restrictions, "the board shall release on parole . . . any person confined in the Montana state prison or the women's correction center . . . when in its opinion there is reasonable probability that the prisoner can be released without detriment to the prisoner or to the community . . . ." *Id.* The statute further provides that "[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.*

Although property interests are most commonly created by statutes, regulations, or other formal policies, they may also "be established through such diverse sources as unwritten common law and informal institutional policies and practices." *Furlong v. Shalala*, 156 F.3d 384, 395 (2d Cir. 1998) (citing *Perry v. Sindermann*, 408 U.S. 593 at 602-03 (1972)). In either case, "[a]lthough the Constitution protects property interests, it does not create them." *Id.* at 393. Rather, property interests "are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law—rules or understandings that secure certain benefits and that support claims of entitlement to those benefits.'" *Id.* at 393 (quoting *Board of Regents v. Roth*, 408 U.S. 564, 577 (1972)).

Because the standards governing inpatient admission and Part A coverage have changed during this litigation, I examine below whether the Plaintiffs have proven a property interest during two periods spanned by this long-running lawsuit and by the class as currently defined: (1) the more recent Post–Two Midnight Rule Period and (2) the Pre–Two Midnight Rule Period. For the reasons that follow, I find that, for both periods, there is a property interest in Part A coverage, but no property interest in inpatient admission.

1. The Post–Two Midnight Rule Period

a. There Is No Property Interest in Inpatient Admission

i. The Language of the Rule, CMS's Sub-Regulatory Guidance, and CMS's Enforcement Practices

Neither the language of the Two Midnight Rule,[48] nor CMS's sub-regulatory guidance, nor CMS's enforcement practices establish a property interest in formal inpatient admission,

[48] Throughout this Ruling, I use "Two Midnight Rule" to refer to paragraph (d)(1) of 42 C.F.R. § 412.3, which provides that an inpatient admission is generally appropriate for payment when the admitting physician expects the patient to require a hospital stay that crosses two midnights. Section 412.3 also includes two other avenues for an

because CMS simply does not *require* treating physicians to order inpatient admission when a patient satisfies CMS's criteria. The currently operative language of the Two Midnight Rule, for example, is explicitly addressed to whether "an inpatient admission is generally appropriate for payment under Medicare Part A." 42 C.F.R. § 412.3(d)(1).[49] This language does not impose a mandate on treating physicians to enter inpatient orders upon developing a two-midnight expectation. Rather than setting forth what physicians must or even may do, the Rule purports to govern only whether an inpatient admission is eligible for Part A payment. Indeed, the opening clause of the Regulation in which the Rule appears begins, "For the purposes of payment under Medicare Part A . . . ." *Id.* § 412.3(a).

CMS's sub-regulatory guidance supports this interpretation of the Two Midnight Rule. For example, a list of frequently asked questions about the Two Midnight Rule, published by CMS, specifically addresses whether "the physician is required to admit the beneficiary as an inpatient once he or she develops the expectation that the beneficiary will require 2 or more midnights of medically necessary hospital care." PX034 at 16. CMS explains that "CMS does not require the treating physician to admit the beneficiary as an inpatient in these or any other

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inpatient admission to be eligible for payment—the inpatient only list, per (d)(2), and the case-by-case exception, per (d)(3)—as well as the inpatient order requirement, which is detailed in paragraphs (a), (b), and (c).

[49] The original language of the Two Midnight Rule—which was effective from October 1, 2013 until December 31, 2015—was somewhat more ambiguous. It stated that "[s]urgical 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." 42 C.F.R. 412.3(e)(1) (effective October 1, 2013 to December 31, 2014). But without more, this language does not make inpatient admission mandatory when a physician develops a two-midnight expectation. To say that a thing is "appropriate" under certain circumstances may mean that it is mandatory, but it may also mean that it is permissible or encouraged; and the use of "generally" further suggests something less than an obligation. Moreover, when the language was amended in 2015 to change "generally appropriate for inpatient admission and inpatient hospital payment under Medicare Part A" to "an inpatient admission is generally appropriate for payment under Medicare Part A," CMS characterized the change as being "for clarity," indicating that CMS did not understand the amendment to be a substantive change in the meaning of the regulation, much less the elimination of a mandate on a previously regulated party. 80 Fed. Reg. 70298, 70541 (Nov. 13, 2015). In short, even the earlier language of the rule is ambiguous at best. And, as discussed in more detail below, both CMS's sub-regulatory guidance and its enforcement practices make clear that the regulatory regime does not impose a mandate on physicians.

circumstances." *Id.* Rather, "where the treating physician expects a beneficiary to require medically necessary hospital care spanning 2 or more midnights, [CMS] encourage[s] the physician to consider ordering an inpatient admission, with the understanding that such a claim will not be denied by a Medicare review contractor for inappropriate status if all other requirements are met." *Id*. Similarly, in responses to comments published with the notice of final rulemaking for the Two Midnight Rule, CMS indicated that the Two Midnight Rule also does not prohibit treating physicians from ordering inpatient admission even when the Rule's requirements are not satisfied. In response to concerns that the Two Midnight Rule conflicts with some state laws requiring inpatient admission after 24 hours at a hospital, CMS explained that "[t]he 2-midnight benchmark does not prohibit physicians from ordering inpatient admission in accordance with state law; rather, this policy indicates when Medicare payment will be deemed appropriate." *See* 78 Fed. Reg. 50496, 50949 (Aug. 19, 2013).[50]

CMS's enforcement practice further bolsters this interpretation of the Two Midnight Rule. CMS's chief enforcement tool for the Two Midnight Rule since 2016 has been post-payment review of claims by QIO contractors. The CMS document governing these reviews describes their purpose as "determin[ing] the appropriateness of Part A payment," DX579-001, and the Two Midnight Rule as "guidance to Medicare review contractors to identify when an inpatient admission is generally appropriate for Medicare Part A payment," DX579-003. In short, the document makes clear that the Rule sets forth conditions for payment:

> When . . . the physician expects the beneficiary will require medically necessary hospital services for 2 or more midnights (including inpatient and pre-admission

[50] Plaintiffs' expert, Dr. Sheehy, testified that she was bound to order inpatient admission when the Two Midnight Rule is satisfied. *See* Tr. 324 ("[I]f a patient meets the two-midnight requirement, they are an inpatient. If they don't meet the two-midnight requirement, they are under observation. And I am bound to follow Medicare regulations."). But I find that the preponderance of the evidence admitted at trial, and discussed here, does not support that conclusion.

> outpatient time), and orders admission based upon that expectation, the services are generally appropriate for inpatient payment under Medicare Part A. QIOs will approve these cases so long as other requirements are met.

DX579-004 (emphasis in original). In addition to focusing the inquiry on appropriateness for payment, the language stating that the physician must have "order[ed] admission based upon that expectation," which is based on 42 C.F.R. § 412.3(a), suggests, again, that a treating physician may decide not to write an inpatient order even if she has a two-midnight expectation. Thus, CMS makes clear that inpatient admission by the treating physician is not a mandatory outcome of the Two Midnight Rule, but an independent prerequisite for Part A payment.

There was also no evidence that CMS has ever taken action against physicians for failing to admit patients when the Two Midnight Rule is satisfied. Dr. Baugh credibly testified, for example, that if he believes observation care in his EDOU is appropriate for a patient—on the basis of his clinical judgment and observation care protocols developed by him and his colleagues, and not on the basis of the Two Midnight Rule or any other government-specified criteria—he will order outpatient observation services (thus precluding inpatient admission). Dr. Baugh further testified that he maintains that order even if utilization review personnel contact him recommending inpatient admission on the basis of the Two Midnight Rule. *See supra* Part I: Findings of Fact ("Facts") ¶ 63 n.40. Neither the language of the Two Midnight Rule, nor any sub-regulatory guidance issued by CMS, nor CMS's enforcement practices suggest that this course of action violates the Two Midnight Rule or any other regulatory provision, and the Court is aware of no regulatory action taken against hospitals or treating physicians in these or similar circumstances. CMS's enforcement efforts run in one direction only—denying Part A inpatient claims where its reviewers find that the requirements of the Two Midnight Rule are not satisfied.

There was also no evidence that CMS has rejected Part B claims for observation services on the grounds that the treating physician improperly failed to order inpatient admission in a case in which, in CMS's estimation, the Two Midnight Rule was satisfied. Facts ¶ 30.

It is true that some of the language of the Two Midnight Rule appears to be addressed to physicians, rather than simply setting forth conditions for payment. For example, the Rule states that "[t]he 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" and that "[t]he 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)(i). But in light of the immediately preceding language, which states that "an 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," the most natural interpretation of the above language is that it limits the types of two-midnight expectations that qualify an inpatient admission for Part A payment to those that are based on "complex medical factors"[51] and adequately documented in the medical record.

Similarly, CMS expresses some of its sub-regulatory guidance regarding the Two Midnight Rule in terms of what physicians "should" and "should not" do. *See, e.g.*, 78 Fed. Reg. 50496, 50947 (Aug. 19, 2013) ("If the resultant length of medically necessary hospitalization is

[51] The requirement that eligible inpatient admissions be based on "complex medical factors"—and the inclusion of a non-exhaustive list of such factors, all of which are phrased in general terms—does little to cabin physician discretion, except perhaps to foreclose the consideration of non-medical factors, such as the convenience of the patient or the patient's family, *see, e.g.*, DX579-005 ("Without accompanying medical conditions, factors that would only cause the beneficiary inconvenience in terms of time and money needed to care for the beneficiary at home or for travel to a physician's office, or that may cause the beneficiary to worry, do not justify Part A payment for a continued hospital stay."). And the fact that the list of complex medical factors treating physicians "should" consider is non-exhaustive—as indicated by the inclusion of "such . . . as"—further reduces the force of the language.

expected to surpass 2 midnights, the physician should admit the patient as an inpatient."); *id.* at 50946 ("beneficiaries in medically necessary hospitalization should not pass a second midnight prior to the admission order being written"); DX540-005 (physicians "should order [inpatient] admission for patients who are expected to require a hospital stay that crosses two midnights and the medical record supports that reasonable expectation"). "Should" is not mandatory language, *see, e.g.*, *Geiser v. U.S.*, 2010 WL 3883433, at *4 (W.D. Pa. Sept. 28, 2010) ("[T]he use of the word 'should' is properly interpreted as suggestive language, rather than mandatory.") (citing cases), and in light of the preceding discussion, the more likely interpretation of this language is to inform treating physicians and hospitals what they "should" do to qualify for Part A payment, with the assumption that hospitals will generally follow this guidance given their financial incentive to do so. As noted above, hospitals are compensated more generously for inpatient claims paid under Part A than for observation claims paid under Part B.

Simply put, the Two Midnight Rule does not create a property interest in inpatient admission because it does not *require* physicians to order such admission when its criteria are satisfied, and thus does not "mandat[e] a defined administrative outcome." *Barrows*, 777 F.3d at 113.

ii. Physician Admission Practices

The evidence at trial did not suggest that the practices of physicians establish a property interest in inpatient admission either. It is true that property interests can be established not only by statute, regulation, or other formal policy, but also by "such diverse sources as unwritten common law and informal institutional policies and practices." *Furlong*, 156 F.3d at 395 (citing *Perry v. Sindermann*, 408 U.S. 593, 602-03 (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 . . . ." *Id.* (quoting *Sindermann*, 408 U.S. at 601). For example, in *Perry v. Sindermann*—the seminal case for informal property interests—the Supreme Court held that a college could create a tenure system "in practice" even though it had "no explicit tenure system." *Id*. at 602. The Court explained that just as there could be a "common law of a particular industry or of a particular plant that may supplement a collective-bargaining agreement, so there may be an unwritten common law in a particular university." *Id*. (internal citation and quotation marks omitted). And in *Furlong*, the Second Circuit held that a "constant, consistent pattern of ALJ decisions" was sufficient to create a property interest. *Id.* The Court noted that ALJs are "quasi-judicial officers" whose decisions are "persuasive authority" in interpreting Medicare law, and endorsed the view that "the consistent practice of a decisional body" could create a property interest. *Id.* at 395-96 ("It is possible, of course, for a legitimate expectation to arise based upon the consistent practice of a decisional body . . . ." (quoting *Tarpeh-Doe v. United States*, 904 F.2d 719, 724 (D.C. Cir. 1990))). *See also Ezekwo v. NYC Health & Hospital Corp.*, 940 F.2d 775 (2d Cir. 1991) (finding that a municipal hospital's established practice of giving each third-year resident the opportunity to serve as chief resident, coupled with the plaintiff's reasonable reliance thereon, created a property interest).

Here, the Court heard credible testimony from several treating physicians that they order inpatient admission when they expect a patient to require hospital care spanning two midnights, as well as credible testimony from Plaintiff's expert Dr. Sheehy that this practice is "typical" among hospitalists. Facts ¶ 45. This practice falls short, however, of creating a property interest. In both *Sindermann* and *Ezekwo*, there was direct evidence of a mutual understanding between the parties. In *Sindermann*, the plaintiff—an employee of the defendant public community

college—had alleged that his expectation of tenure stemmed from an "understanding fostered by the college administration," including provisions of the faculty guide, on which "he and others legitimately relied." *Sindermann*, 408 U.S. at 593. Similarly, in *Ezekwo*, the plaintiff, an employee of the defendant municipal hospital, relied on the defendant's established policy, which was expressly highlighted in informational documents and communicated directly to her. *Ezekwo*, 940 F.2d at 783. Both *Sindermann* and *Ezekwo* rely, at least in part, on the doctrine of implied contract. For example, the *Ezekwo* court characterizes *Sindermann* as follows:

> In *Sindermann*, the Supreme Court noted that principles of contract law recognize that not every term of a contract must be reduced to writing. Additional contractual provisions may be "implied" into a contract as a result of a course of dealing between the parties. The parties through their conduct and practice can create additional rights and duties. *Sindermann*, 408 U.S. at 602 (university's adherence to a particular pattern of conduct could create an expectation of continued employment in employees who lacked tenure).

Ezekwo, 940 F.2d at 782.

Here, by contrast, the Court heard no evidence of an informal, mutually explicit understanding between physicians and beneficiaries (let alone an implied contract) that would require treating physicians to order inpatient admission upon forming a two-midnight expectation. There is no evidence, for example, that treating physicians represent to patients that they must, or even always will, order inpatient admission upon forming a two-midnight expectation. Moreover, it is difficult to imagine such a mutually explicit understanding arising, given the absence of the type of ongoing relationship or course of dealing that might support such an understanding, such as an employment relationship. The relationship between a hospital patient and his or her treating hospitalist is generally limited to the duration of the patient's hospital stay, and a patient is often treated by more than one physician over the course of the stay.

Furlong also does not support the existence of a property interest in this case. The evidence does not support the conclusion that physician application of the Two Midnight Rule rises to the level of a "constant, consistent pattern of . . . decisions," as was the case in *Furlong*. For example, the Court heard credible testimony from the Secretary's expert Dr. Baugh that he and many other emergency department physicians order observation services—and thus preclude inpatient admission—on the basis of internally developed protocols unrelated to the Two Midnight Rule or any other government criteria. Facts ¶¶ 43-44. Moreover, the use of such observation care protocols is not limited to emergency departments with dedicated observation units, but also extends to at least some inpatient or hospitalist services. Facts ¶ 42 n. 24. Thus, physicians do not uniformly make admission decisions based on whether there is a two-midnight expectation.

Even if physician application of the Two Midnight Rule was "constant" and "consistent," *Furlong* is further distinguishable in that individual treating physicians are not "quasi-judicial officers" whose decisions are "persuasive authority in interpreting Medicare law." *See Furlong*, 156 F.3d at 395. It is one thing to say that a legitimate expectation, and hence a property interest, arises from the published decisions of Administrative Law Judges, who are agency officials "statutorily charged with interpreting Medicare law," *id.*, and who generally only act by interpreting and applying the law. It is quite another to draw the same conclusion on the basis of the practice of treating physicians, who generally act based on medical judgment, who have little training in Medicare law, whose interpretation of Medicare law has no authority, and who are not employees of the defendant.[52] While ALJs do not set agency policy, their decisions can

[52] The *Furlong* court also noted that the Secretary had "not only failed to issue a contradictory statement or exercise her authority to overturn the ALJ decisions, but, in fact, effectively endorsed those decisions by" regulation.

plausibly be viewed as authoritative statements of the law, and thus might create a legitimate expectation. The same cannot be said of the typical practice of treating physicians.

Finally, even if there were a "mutually explicit understanding," based on typical physician practice, requiring physicians to order inpatient admission upon forming a two-midnight expectation, any such rule would likely leave treating physicians with too much discretion to support the existence of a property interest. Such an informal rule would be derived from practice, and the evidence before the Court indicates that the practice of treating physicians applying the Two Midnight Rule is to apply individual medical judgment in a manner that is not otherwise "meaningfully channeled." Facts ¶ 46. As noted above, physicians generally make their two-midnight judgment based on an "overall assessment" of the patient, a practice consistent with regulatory language encouraging them to consider a non-exclusive list of broad, "complex medical factors." The evidence did not show that physicians themselves take into account the added objectivity of the reasonableness standard employed by CMS-contracted reviewers or other practices and policies of CMS aimed at making application of the Two Midnight Rule uniform. Treating physicians do not order inpatient admission when they determine that it would reasonable to expect a two-midnight stay; rather, the trial evidence showed that they rely on their own, individual expectation regarding the necessary duration of care in deciding whether to order inpatient admission.[53]

In sum, neither the regulatory scheme established by CMS, nor any mutually explicit understanding between physicians and patients, requires treating physicians to order inpatient

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Furlong, 156 F.3d at 395. By contrast, here, the statements and practice of the Secretary undermines the existence of a property right in inpatient admission. *See, e.g.*, PX034 at 16.

[53] Although there is evidence that treating physicians sometimes confer with utilization review personnel prior to making an initial decision whether to order inpatient admission, Facts ¶ 92, there is no evidence that this is universal, or even typical, practice.

admission upon developing a two-midnight expectation. Physicians act as "independent gatekeeper[s]," PX010 at 15, and although their decisions are not free from regulatory influence, they are nonetheless free from any regulatory mandate. Consequently, beneficiaries do not have a property interest in formal inpatient admission. To find otherwise would be to rewrite the regulatory scheme that is the purported basis of the property interest.[54]

b. There Is a Property Interest in Part A Hospital Coverage

The decision to provide Part A payment, and thus coverage, is governed by mandatory criteria that meaningfully channel official discretion; thus, while beneficiaries do not have a property interest in inpatient admission, they do have a protected property interest in Part A coverage.

As described above, a benefits regime creates a "legitimate claim of entitlement" when the statutes and regulations governing the distribution of benefits "meaningfully channel official discretion by mandating a defined administrative outcome." *Barrows*, 777 F.3d at 113 (internal quotation marks and alterations omitted) (quoting *Kapps*, 404 F.3d at 113). The Two Midnight Rule provides that "an inpatient admission is generally appropriate for payment under Medicare Part A when the physician expects the patient to require hospital care that crosses two

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[54] The Plaintiffs argue that their right to Part A coverage "does not depend upon whether a doctor initially designated a class member as inpatient . . . ." ECF No. 435 at 5. Plaintiffs argue that, as a factual matter, such a conclusion is inconsistent with the Secretary's role as the final decisionmaker as to whether a claim is payable. *Id.* (citing *State of N.Y. on Behalf ex rel. Bodnar v. Secretary of Health & Human Services*, 903 F.2d 122, 125-26 (2d Cir. 1990) (holding that an attending physician and URC's dual certification that a service was reasonable and medically necessary did not bind the Secretary to provide reimbursement)). But the *Bodnar* court's holding was that the dual certification was not *sufficient* to mandate payment, and the Secretary was thus free to disagree with the physician and URC's medical necessity and reasonableness determination. *Bodnar* does not preclude such a certification—or similar third-party determination—from serving as a prerequisite to payment. To the contrary, *Bodnar* suggests that this is precisely the role the dual certification requirement plays. *See id.* at 125 ("Nowhere does the language of the dual certification requirement provide that such certification is not just a prerequisite or condition *precedent* to payment, but also a condition sufficient that requires the Secretary to extend coverage, in derogation of his final authority pursuant to section 1395ff(a)." (emphasis original)). In the present case, a physician's inpatient admission order is unambiguously a necessary—but not sufficient—condition for Part A coverage and payment, as discussed above. Such a scheme is entirely consistent with the holding in *Bodnar*.

midnights." 42 C.F.R. § 412.3(d)(1). By itself, this language is ambiguous as to whether it *requires* payment, or merely authorizes it. But when the regulatory regime is viewed as a whole, including CMS's sub-regulatory guidance, its enforcement practice, and other statutory provisions, it is clear that the Two Midnight Rule does require CMS to cover inpatient admissions that satisfy the Rule.

CMS's review guidelines, for example, unambiguously require its contractors to approve claims that satisfy the Two Midnight Rule. *See, e.g.*, DX579-004 (If the Two Midnight Rule and the inpatient order requirements are satisfied, "the services are generally appropriate for inpatient payment under Medicare Part A. *QIOs will approve these cases so long as other requirements are met*." (emphasis added)); PX158 at 7 (If "it was reasonable for the admitting physician to expect the patient to require medically necessary hospital services for 2 Midnights or longer," then the "claim is payable under Part A (assuming all other requirements are met)."). Similarly, CMS's guidance to providers states that CMS "encourage[s] the physician to consider ordering an inpatient admission" when the Two Midnight Rule is satisfied, "with the understanding that *such a claim will not be denied* by a Medicare review contractor for inappropriate status if all other requirements are met." PX034 at 16 (italics added). There was no evidence that CMS has ever denied a claim satisfying the Two Midnight Rule on the basis of residual discretion, nor any evidence indicating that CMS believed itself to have such authority.[55]

This suggests that the language in the Two Midnight Rule stating that payment is "generally appropriate" is an allusion to other, independent requirements for payment, and not a

[55] Statutory provisions further support the mandatory nature of the payment regime. For example, the Medicare statute defines the overall "scope" of Part A benefits as the "*[e]ntitlement* to payment for inpatient hospital services, post-hospital extended care services, home health services, and hospice care." 42 U.S.C. § 1395d(a) (emphasis added).

grant of discretion allowing CMS to reject claims that otherwise satisfy the Rule. In fact, this was the interpretation proposed at trial by the CMS official responsible for overseeing QIOs. *See* Tr. 522:17-23 (The "generally appropriate" language indicates that "there are other things that could deem that stay not appropriate . . . such as other requirements that need to be included in the medical record.").

The Secretary argues that the Two Midnight Rule cannot be the basis for a protected property interest because it does not "set forth 'fixed' and 'objective' criteria," but instead calls for the exercise of discretion. ECF No. 430 at 46. The Secretary makes scant mention, however, of the well-established standard that ultimately determines the existence of a property right—whether the regulatory regime "meaningfully channels official discretion by mandating a defined administrative outcome." *See Sealed*, 332 F.3d at 56; *Kapps*, F.3d at 113; *Barrows*, 777 F.3d at 113; *Alexander v. Azar*, 370 F. Supp. 3d 302, 314 (D. Conn. 2019). The plain language of this standard explicitly contemplates the continued existence of "discretion." It makes clear that official discretion need not be eliminated, but only meaningfully channeled. In other words, Second Circuit precedent does not require that the relevant criteria be so fixed and objective that they can be applied mechanically, without the application of any professional judgment. As noted above, the inquiry is better framed not in terms of whether the relevant criteria *are* "fixed" and "objective," but whether the criteria are *sufficiently* fixed and objective to be capable of "meaningfully channeling official discretion."

Here, the Two Midnight Rule easily satisfies any requirement for "fixity." The Rule is codified in the Code of Federal Regulations and has undergone little change since it was first

promulgated in 2013. The Rule is in fact more "fixed" than the one at issue in *Kapps*, which the Court found to be fixed notwithstanding its being adjusted annually. *Kapps*, 404 F.3d at 114.[56]

Although it is a closer call, the Two Midnight Rule is also sufficiently "objective" to "meaningfully channel official discretion." First, while *physicians* order inpatient admission using a two-midnight expectation based on their own individual judgment and experience, CMS-contracted *reviewers* must apply a reasonableness standard. Facts ¶¶ 18, 22-24.[57] A reviewer applying the Rule to determine eligibility for coverage does not substitute his or her own individual judgment as to the expected length of necessary hospital care for the treating physician's; rather, the reviewer asks whether the treating physician's expectation was reasonable based on the documentation in the medical record. Facts ¶ 22. The latter represents a more objective inquiry, involving less individual discretion and aimed at producing a single correct answer.

Moreover, the reviewer's two-midnight inquiry is limited to the "documentation in the medical record," *see, e.g.*, DX579-004, which constitutes a closed universe of information. This allows for a more objective inquiry compared to a treating physician's development of an individual two-midnight expectation, which is an open-ended inquiry based on an "overall assessment" of the patient, Tr. 1015:18, and which is inevitably informed by subjective impressions formed in the course of treating the patient. *See, e.g.*, DX-511-004 (Dr. Handrigan

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[56] The substance of the fixity requirement—to the extent it is an independent requirement, *see supra* n.46—is somewhat unclear. For example, it is unclear why a standard that is frequently updated should be precluded from creating a property interest, and the Court is unaware of any cases that so hold. The requirement for fixity seems only to exclude those cases where the standard that applies to a given case is difficult or impossible to ascertain, or where the applicable standard is not prescribed by mutually explicit understanding but chosen by the decisionmaker on a discretionary basis. Because the Two Midnight Rule satisfies any plausible standard of fixity, the Court need not resolve this issue.

[57] While the text of the Two Midnight Rule itself does not mention a reasonableness standard, the Medicare statute includes a general reasonableness requirement that applies to all services. 42 U.S.C. § 1395y(a)(1)(A).

of CMS to QIOs: "The point here is not to look at the specific clinical issue, but to look at the record and whether what the physician decided to do was reasonable or unreasonable at that time.").

The use of commercial screening tools in reviewing inpatient admissions under the Two Midnight Rule provides further evidence of the objective nature of the inquiry. Commercial screening tools provide nurse reviewers with a set list of parameters for various conditions, the presence of which supports inpatient admission. These tools allow CMS contractors, as well as utilization review teams, to determine compliance with the Two Midnight Rule in a substantial number of cases without the involvement of a physician reviewer. Facts ¶¶ 36-38, 54. While it is true that commercial screening tools, like the Two Midnight Presumption, are meant to focus and support review efforts, and meeting screening tool criteria does not require a reviewer to conclude that the Two Midnight Rule has been satisfied, the widespread use of screening tools nonetheless indicates that the Rule is sufficiently objective to be automated to a significant degree.

Furthermore, CMS itself expects a great deal of consistency and accuracy in the application of the Two Midnight Rule, requiring, for example, that QIOs achieve a 95% "accuracy rate" in conducting reviews under the Rule. Facts ¶ 28; *see also* Tr. 305:20-22 (Sheehy) ("[T]here is a right and a wrong answer to the billing status of every patient, and CMS is the one that holds the right answer."). CMS instructs the QIOs to use a flowchart, which it has referred to as an "algorithm," when reviewing claims for compliance with Section 412.3, including the Two Midnight Rule. *See* PX207 at HHS18343-44; *see also* Tr. 742:14-17 (CMS official agreeing that the flowchart describes the steps through which a QIO determines whether

a claim is payable under Part A). It is difficult for CMS to argue that a standard it believed was capable of producing a 95% "accuracy rate" does not "meaningfully channel official discretion."

The fact that hospitals can appeal claim denials on the basis of the Two Midnight Rule to ALJs and even District Court Judges—who are generally lawyers rather than physicians, with no "medical judgment" to speak of—provides further evidence that the Two Midnight Rule "meaningfully channels" the judgment of reviewers. It would be impossible for ALJs and District Court judges to review these determinations if they were made on the basis of discretionary medical judgment not "meaningfully channeled" by regulatory rules.

To be sure, application of the Two Midnight Rule to determine whether coverage under Part A is warranted requires the application of a degree of judgment, and is not reduceable to the mechanical application of purely objective criteria. But as discussed above, the need for the application of judgment does not preclude a rule from creating an interest protected by the Due Process Clause. The relevant standard unambiguously permits the existence of "official discretion," requiring only that it be "meaningfully channeled." *See Barrows*, 777 F.3d at 113; *see also Fleury*, 847 F.2d at 1232 ("[T]he inclusion of elastic items in a list of criteria does not destroy a property interest."); *cf. Bd. of Pardons v. Allen*, 482 U.S. at 375 (The fact that a standard "cannot be applied mechanically" does not preclude the existence of a liberty interest.). Any requirement for "objective criteria" must be understood in light of the meaningful channeling standard, and thus should not be read to preclude a property interest simply because a determination requires the application of judgment. In short, while the application of the Two Midnight Rule requires a degree of judgment, it is nonetheless sufficiently objective to meaningfully channel official discretion.

Because the Two Midnight Rule is mandatory, in that it guarantees Part A coverage when its requirements are satisfied, and sufficiently fixed and objective to "meaningfully channel official discretion," beneficiaries have a property interest in Part A hospital coverage.

The Secretary argues that the Two Midnight Rule does not create a property interest in Part A coverage because it governs "payment" rather than coverage. ECF No. 436 at 9-10. It is true that the text of the rule refers to "payment," *see, e.g.*, 42 C.F.R. 412.3(d)(1) ("[A]n inpatient admission is generally appropriate for payment under Medicare Part A when . . . ."), and, in at least some circumstances, courts have recognized a distinction between payment and coverage, *see, e.g., Friedman v. Secretary of Dept. of Health and Human Services*, 819 F.2d 42, 44 (2d Cir. 1987) (agreeing with the Secretary that "coverage and payment are treated as two separate inquiries: first, the Secretary determines whether the individual and the services involved are covered by Medicare, and, second, if coverage exists, the Secretary determines whether the other requirements for payment to the provider have been met."). But the Secretary himself sometimes refers to the Two Midnight Rule as governing Part A coverage, including in the notice of final rulemaking for the Two Midnight Rule. *See* 78 Fed. Reg. 50496, 50947 (The Two Midnight Rule "provides guidance on when the hospitalized beneficiary is appropriate for coverage under Part A benefits as an inpatient . . . ."); *id.* at 50948 ("In addition, the use of 2 midnights is an easy concept for beneficiaries to understand in assessing the appropriateness of *their* assigned status, *associated coverage*, and impacts." (emphasis added)); *id.* at 50952 ("The 2-midnight benchmark represents guidance to admitting practitioners and reviewers to identify when an inpatient admission is generally appropriate for Medicare coverage and payment . . . ."). Moreover, unlike the requirement at issue in *Friedman*, the Two Midnight Rule is not a purely administrative requirement imposed on providers as a precondition to payment, with no effect on a

beneficiary's liability or interests. More generally, the Secretary has pointed to nothing in the Rule suggesting any practical distinction between payment by the Secretary for hospital services under Part A and coverage of the costs of a beneficiary's hospital stay under Part A. A rule that requires payment to a provider for an inpatient admission satisfying its criteria of course also entitles the beneficiary to coverage for the admission. To conclude otherwise would be to find that a beneficiary could still be liable to a provider even if the provider is paid by CMS for the same services. Thus, the Two Midnight Rule governs, not only payment to providers, but also coverage for beneficiaries, and creates a property interest that the latter may invoke.[58]

i. The Secretary's Procedural Argument

In his supplemental brief, the Secretary argues that no claim alleging the deprivation of a property interest in Part A hospital coverage is before me, and that it would be an abuse of discretion to rule on such an "unpleaded claim." ECF No. 436 at 3. The three operative complaints in this case make clear, however, that the gravamen of the Plaintiffs' complaint is precisely the deprivation of Part A coverage, and not simply the denial of inpatient admission in

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[58] Conversely, the requirement that a claim for payment be submitted to CMS in a timely fashion *is* a purely administrative precondition to payment, like the physician certification requirement at issue in *Friedman*. Thus, it does not affect a beneficiary's coverage. The same statutory section establishes both the claim submission requirement and the physician certification requirement. *See* 42 U.S.C. § 1395f(a)(1),(2). And the very same provision that the *Friedman* court relied on—apparently at the Secretary's own suggestion in that case—in concluding that the physician certification requirement governs payment to providers, and not coverage of beneficiaries, also provides that a beneficiary's coverage is unaffected by a provider's failure to submit an otherwise payable claim. *See Friedman*, 819 F.2d at 44 (citing 42 C.F.R. § 489.21(b)(1)); 42 C.F.R. § 489.21(b)(4). Thus, to the extent that the Secretary argues that Plaintiffs have no right to Part A coverage because no Part A claim has been submitted on their behalf, *see* ECF No. 436 at 10-11, the Secretary's argument is unavailing. Moreover, even if the submission of a claim were a prerequisite to Part A coverage, this would not affect the property interest analysis, because the property interest analysis "extends only to the consideration of whether—*were an applicant able to make out the requirements for . . . eligibility*—he or she would be entitled to benefits as a matter of law." *Kapps*, 404 F.3d at 117 (emphasis added); *see also id.* at 116 (the defendants' argument that the plaintiffs "cannot possess a due process protected interest in the receipt of benefits, because they have not yet been shown to fulfill the eligibility criteria," is "without merit"); *see also Roth*, 408 U.S. at 577 ("The recipients [in *Goldberg v. Kelly*] had not yet shown that they were, in fact, within the statutory terms of eligibility. But we held that they had a right to a hearing at which they might attempt to do so."). In other words, that a plaintiff might not—or even does not—satisfy one of the eligibility requirements for a public benefit simply does not preclude the existence of a protected property interest.

itself. *See Avant Petroleum, Inc. v. Banque Paribas*, 853 F.2d 140, 143 (2d Cir. 1988) ("The issues are defined by the pleadings of the parties before the court . . . ."); *Potenza v. City of New York, Dept. of Transp.*, 2009 WL 2156917 at *8 (E.D.N.Y. July 15, 2009) ("The Second Amended Complaint will define the issues to be tried.").

For example, in the very first paragraph of the original Complaint, filed on November 3, 2011, the Plaintiffs allege that they "were *deprived* of *Medicare Part A coverage* by being improperly classified as outpatients." ECF No. 1 at ¶ 1 (emphasis added). Several paragraphs later, after describing the Secretary's use of "observation status," the Plaintiffs explain that "[t]he impact of using observation status is to *deprive* Medicare beneficiaries of the *Medicare Part A coverage* to which they are entitled." *Id.* ¶ 6 (emphasis added). Similarly, in the portion of the Complaint describing the absence of procedural protections, the Plaintiffs allege that beneficiaries on observation status "are not informed that they have any appeal rights to challenge that placement and to contend that they should be formally admitted *and be covered under Part A*." *Id.* ¶ 43 (emphasis added). Finally, in the prayer for relief, the Plaintiffs ask that the Court prohibit the Secretary from "allowing Medicare beneficiaries to be placed on observation status and thus to deprive them of Medicare Part A coverage to which they are entitled"[59] and to "establish a procedure for administrative review of a decision to place a Medicare beneficiary on observation status, including the right to expedited review."[60] *Id.* at 29-30. These allegations do not—and need not—elaborate on the dimensions of the protected

[59] The original Complaint alleged that the placement of beneficiaries on observation was illegal in itself, regardless whether beneficiaries had the opportunity to appeal. While these claims have been dismissed, I include this excerpt because it describes the significance, as alleged by the Plaintiffs, of placement on observation status. These and other allegations in the Complaint make clear that the deprivation at issue is primarily a deprivation of Part A coverage, and not just a deprivation of inpatient admission.

[60] The First and Second Intervenor Complaints, ECF Nos. 53, 123, do not meaningfully differ from the original Complaint for present purposes.

property interest the Plaintiffs believed they were deprived of. *See Johnson v. City of Shelby, Miss.*, 574 U.S. 10, 11 (2014) ("Federal pleading rules . . . do not countenance dismissal of a complaint for imperfect statement of the legal theory supporting the claim asserted."). But the Complaint makes clear that the "depriv[ation]" the Plaintiffs allege they suffered when they were placed on observation status is ultimately a deprivation of "Part A coverage."

Moreover, this is not a case where a legal theory lay dormant in obscure passages of a complaint, only to be sprung upon an unsuspecting defendant at trial. The Plaintiffs have, throughout this case, consistently—indeed, almost exclusively—argued that they have a property interest in Part A coverage. At the motion to dismiss stage, the Plaintiffs filed supplemental briefing focused on the property interest issue. ECF No. 93. There, they characterized the relevant property interest as a "property interest in Part A coverage." *Id.* at 3. Similarly, the Plaintiffs began the introduction section of their brief in opposition to the Secretary's first motion for summary judgment by stating that the Secretary "moves for summary judgment on the question of whether plaintiffs have a protected property interest in Medicare coverage of their hospital stays as inpatients," ECF No. 165 at 5, and conclude the introduction by arguing that "[b]eneficiaries who have been determined to require care in a hospital thus have a protected property interest and an enforceable expectation to receive Part A inpatient coverage when their hospital stay meets the Secretary's definition." ECF No. 165 at 8. In the Plaintiffs' supplemental brief in opposition to the Secretary's second motion for summary judgment, which addressed the property interest issue under the Two Midnight Rule, the Plaintiffs again argued that they had a "protected property interest in Part A inpatient coverage." ECF No. 373 at 9. And during opening statements at trial, the Plaintiffs consistently stated that the property interest they intended to prove was an interest in Part A coverage. *See, e.g.*, ECF No. 419 at 26 ("That is

what the evidence will show . . . that class members have a protected property interest by being entitled to Part A benefits if they satisfy this criteria.").[61]

In arguing that no due process claim as to a protected property interest in Part A coverage is before me, the Secretary relies heavily on the Second Circuit's opinion, in which the Circuit held that the Plaintiffs had plausibly alleged a due process claim. There, the Second Circuit characterized the relevant property interest as "being admitted to their hospitals as 'inpatients.'" *Barrows*, 777 F.3d at 115-16. The Circuit held:

> If plaintiffs are able to 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. The Secretary's argument is unavailing for the simple reason that it is the pleadings—and not the Second Circuit (or this Court's) characterization of a possible legal theory on which the Plaintiffs might succeed—that define the contours of an undismissed claim. Moreover, elsewhere in its opinion the Second Circuit acknowledged that the Plaintiffs' complaint challenged the deprivation of Part A coverage, not merely the denial of inpatient admission. *Id.* at 110 ("On November 3, 2011, Plaintiffs filed this putative class action complaint, which asserts, *inter alia*, that the Secretary's use of 'observation status' deprived them of Part A coverage to which they were entitled."). And nowhere does the Second Circuit's opinion suggest that it intended to narrow the scope of the claim the Plaintiffs were alleging.

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[61] To be sure, the Secretary has consistently argued that the relevant inquiry is whether there is a protected property interest in being admitted as an inpatient. For example, during opening arguments, the Secretary was careful to point out that "'being admitted to their hospitals as inpatients,' that language is from the Second Circuit's decision. That is what the protected property interest question asserts." ECF No. 419 at 32. But the Secretary's assertions of course do not define the scope of the Plaintiffs' claim and are thus irrelevant to the present inquiry.

While it is true that the Second Circuit characterized the relevant property interest as "inpatient admission,"[62] the Circuit's task at that stage was simply to determine whether the Plaintiffs had alleged a plausible due perocess claim. Having identified a viable legal theory through which the Plaintiffs might prevail, this task was complete. Exhaustively detailing all of the legal theories through which the Plaintiff might ultimately prevail is decidedly not the task of a Court ruling on a motion to dismiss—nor is such a task feasible on the basis of allegations alone and prior to any discovery.

The Secretary's reliance on this Court's rulings on the two motions for summary judgments is likewise misplaced. It is true that I, like the Second Circuit, have often referred to a property interest in "being admitted as inpatients." *See, e.g.*¸ ECF No. 378 at 24 ("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 [t]he Plaintiffs have a protected property interest in being admitted as inpatients."). But I have also referred to a property interest in Part A coverage. *See, e.g.*, *id.* at 22 ("[The evidence] 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."). In any event, my characterization of the Plaintiffs' surviving claim is largely beside the point. On a motion for summary judgment, a court does not endeavor to exhaustively catalogue every genuine dispute of material fact. To do so would be a waste of

[62] It appears to have done so, at least in part, because I had framed the issue that way in my ruling dismissing the due process claim: "The District Court dismissed [the due process claim] on the sole ground that plaintiffs did not possess a property interest in being admitted to their hospitals as 'inpatients.' Because this determination relied on a factual finding that could not be made on a motion to dismiss, we vacate the District Court's dismissal of plaintiffs' due process claims and remand for limited discovery." *Barrows*, 777 F.3d at 106.

judicial resources. Once the Court has identified a path through which the non-movant might prevail, it can—and often does—deny the motion for summary judgment on that basis alone. This does not somehow "dismiss" or grant judgment with respect to all other legal theories, nor does it conclusively resolve all other genuine disputes of material fact. It is, again, the complaint, first and foremost, that defines the scope of a claim.

The Secretary's reliance on the Court's characterization of the property interest—rather than the Plaintiffs'—has not, in any case, prejudiced the Secretary. The Secretary claims that he "would have pursued different information in discovery," but he fails to identify a single alternative line of factual inquiry he would have pursued. After having presided over this case for almost a decade, I struggle to conceive what any such "roads not taken" might be. The law and the facts bearing on whether there is a property interest in inpatient admission or one in Part A coverage are, in this case at least, one and the same. Specifically, the regulatory provisions and enforcement practices that are the basis of the property interest in Part A coverage are the same ones that have been the main focus of this case from the beginning. Whether the property interest these regulations and practices create is best characterized as a property interest in "Part A coverage" or one in "inpatient admission," I fail to see—and the Secretary does not explain—how his litigation strategy would have meaningfully differed had he not assumed that the only possible property interest was in inpatient admission.

The line between "inpatient admission" and "Part A coverage" is, moreover, a thin one. The Plaintiffs have essentially taken the position that they are, in fact, one and the same[63]—that

[63] *See, e.g.*, ECF No. 322 at 18 n.11 ("Also, while the Secretary relies heavily on a claimed distinction between criteria 'for inpatient admission' versus criteria for Medicare Part A payment, this remains a distinction without a difference. In promulgating the Two-Midnight Rule, CMS itself has made the connection between payment and admission criteria explicit." (citations omitted)).

inpatient admission is a billing status, entirely divorced from decisions regarding patient care, and thus the decision whether to admit a patient as an inpatient functions as an initial determination as to eligibility for Part A coverage. While I do not endorse this theory in its entirety, there is much truth to the Plaintiffs' characterization. Inpatient status is indeed largely a billing status signifying eligibility for Part A coverage, particularly outside of emergency department observation units. Facts ¶¶ 7, 63. In any event, if the Secretary believed that the scope of discovery was preventing him from adequately defending a claim that the Plaintiffs had not only pled, but were actively pursuing, he should have requested additional discovery.[64] Thus, the Secretary has not been prejudiced by his decision to assume, and to argue, that the Court's characterization of the potential property interest on the basis of which the Plaintiffs might prevail represented the Plaintiffs' sole path to proving their surviving claim. This was a strategic decision by the Secretary. It simply does not define the scope of the Plaintiffs' due process claim.

In short, it is the complaint that defines the scope of a claim, and the three operative complaints plainly contemplate a property interest in Part A coverage. The Secretary's argument that the Plaintiffs failed to plead—and that the Court is prohibited from ruling on—a due process claim involving such a property interest is thus unavailing.[65]

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[64] The Second Circuit ordered an initial phase of discovery focused on the issue of "whether plaintiffs possessed a property interest in being admitted to their hospitals as 'inpatients.'" *Barrows*, 777 F.3d at 115. On remand, I issued a scheduling order permitting discovery on the "protected property interest issue." ECF No. 120 at 1. After I denied the Secretary's first motion for summary judgment, the parties were allowed an additional eight months for more fulsome discovery. *Id.*

[65] The Secretary argues that the focus on class members whose status has changed from inpatient to observation amounts to "an entirely different procedural due process claim" than the one Plaintiffs pled, which concerns the "placement [of Medicare beneficiaries] on observation status." ECF No. 436 at 4-5. This is incorrect. From the opening words of their original Complaint, the plaintiffs have been clear that a distinct sub-group of those "placed on observation status" includes Medicare beneficiaries who were initially admitted as inpatients. ECF No. 1 at ¶ 2 ("The Secretary has long had a policy under which Medicare beneficiaries in hospitals, instead of being formally admitted, are placed on what is commonly referred to as 'observation status' . . . . In some instances, beneficiaries who have been formally admitted have their status retroactively changed to observation."); *see also id.* at ¶ 13

2. The Pre–Two Midnight Rule Period

The class period preceding the promulgation of the Two Midnight Rule—January 1, 2009 until September 30, 2013—does not materially differ, for the purposes of the property interest analysis, from the post–Two Midnight Rule period. As an initial matter, the evidence showed that the promulgation of the Two Midnight Rule did not represent a fundamental change in the regulatory scheme. In its notice of final rulemaking, CMS repeatedly indicated that the Two Midnight Rule was not a substantial departure from its previous policy. *See, e.g.*, 78 Fed. Reg. 50496, 50945 (Aug. 19, 2013) ("Our previous guidance also provided for a 24-hour benchmark, instructing physicians that, in general, beneficiaries who need to stay at the hospital less than 24 hours should be treated as outpatients, while those requiring care greater than 24 hours may usually be treated as inpatients. Our proposed 2-midnight benchmark, which we now finalize, simply modifies our previous guidance to specify that the relevant 24 hours are those encompassed by 2 midnights."); *id.* at 50946 ("While previous guidance provided a 24-hour benchmark to be used in making inpatient admission decisions, we now specify that the 24 hours relevant to inpatient admission decisions are those encapsulated by 2 midnights."); *id.* at 50949 ("We proposed only a change in the inpatient admissions benchmark from an hourly expectation (24 hours) to a daily (2-midnights) expectation.").[66] Similarly, Dr. Duvall, the former Chief

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("Although [Plaintiff Lee Barrows] was hospitalized from July 3, to July 10, 2009 and although he was formally admitted before July 8, on July 8 his status was changed to observation status, retroactive to when he had been formally admitted"); *id.* at ¶ 44 ("Beneficiaries whose status as admitted patients is changed to observation status by the hospital's URC are supposed to receive written notification of the change in status. The notification does not inform them of any appeal rights to challenge that change and to contend that they should have remained as admitted inpatients and covered under Part A."); ECF No. 53 at ¶¶ 3, 16, 17, 45; ECF No. 123 at ¶¶ 3, 45, 77, 93. The Secretary also makes much of the Court's use of the term "outpatient" in its two-page order directing the parties to submit supplemental briefs, without limiting the term to include only those outpatients who are receiving observation services. *See* ECF No. 432. The Court did not intend to suggest that it was contemplating broadening the class to include all outpatients, and not just those who are receiving observation services.

[66] *But see* DX577 at 3 ("[I]n April 2013, CMS proposed policy changes through an NPRM that, if promulgated as proposed, would substantially affect how hospitals bill for observation stays and short inpatient stays.").

Medical Officer for the Center for Program Integrity at CMS, characterized the Two Midnight Rule as a "slight change from the earlier language. . . no different than its prior instructions in intent, slight difference in form and difference in where it's located." Tr. 956:8-15 (Duvall); *see also* Tr. 649 (Laucks) (indicating the utilization review process functioned in the same way following the promulgation of the Two Midnight Rule).

In light of these representations, it is not surprising that the relevant evidence for the pre–Two Midnight Rule period largely tracks the evidence for the post–Two Midnight Rule period and supports the same conclusions. First, the pre–Two Midnight Rule regulatory regime does not create a property interest in formal inpatient admission. Simply put, there is no evidence that the regulatory regime *requires* physicians or hospitals to formally admit a beneficiary as an inpatient when the requirements of the 24-Hour Benchmark are satisfied. The pre–Two Midnight Rule guidance to physicians, for example, uses non-mandatory language such as "should" and "recommended." *See, e.g.*, DX539-006 ("Physicians should use a 24-hour period as a benchmark, i.e., they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis."); *see also* PX243 at 6 ("Physicians are recommended to use a 24-hour period as a benchmark when making a determination on an inpatient admission."). Likewise, there was no evidence that CMS required physicians to order inpatient admission when the criteria of a commercial screening tool were satisfied. In fact, there was no evidence that treating physicians themselves rely on or even refer to commercial screening tools in making inpatient admission decisions at all.

Similarly, I cannot conclude based on the evidence presented at trial that informal understandings between beneficiaries and physicians created a property interest in inpatient admission prior to the promulgation of the Two Midnight Rule. The physicians who testified at

trial all focused on the post–Two Midnight Rule period. Thus, there is even less support for finding an informal property interest under *Sindermann* and its progeny for the pre–Two Midnight Rule period than for the post–Two Midnight Rule period.

As for the property interest in Part A coverage, however, the same features of the regulatory scheme that support such a property interest for the post–Two Midnight Rule period support a similar property interest for the pre–Two Midnight Rule period. First, the evidence showed that the inquiry under the 24-Hour Benchmark was nearly identical to the Two Midnight Rule inquiry. In both cases, the issue was whether the patient required hospital care spanning the relevant time period—24 hours or two midnights. Moreover, RACs reviewing claims under the 24-Hour Benchmark, like QIOs reviewing claims under the Two Midnight Rule, applied a reasonableness standard. *See, e.g.*, PX021 ("This audit examines the patient's condition and whether evaluation and treatment of that condition could be *reasonably* rendered safely within a 24-hour period versus the medical necessity of an inpatient admission by Medicare's criteria."); *see also* 42 U.S.C. § 1395y(a)(1)(A) (general reasonableness requirement for all services covered by Medicare). As discussed above, while such an inquiry requires the application of judgment, and cannot be applied mechanically, it is not so subjective that it does not meaningfully channel official discretion. Nor was there any evidence that CMS or its contractors had residual discretion to deny coverage for patients who satisfied the 24-Hour Benchmark. And, as under the post–Two Midnight Rule regime, providers had the right to appeal denials under the 24-Hour Benchmark to ALJs. According to one study, providers prevailed as to 71% of RAC denials that they appealed to the ALJ level. Tr. 398:11-25; 306:22-25 (Sheehy). The fact that denials under the 24-Hour Benchmark were appealed to—and often reversed by—administrative law judges, who are generally lawyers rather than doctors, suggests the existence of a right that is not

contingent on the favorable application of unchanneled discretionary judgment. In short, the evidence pertaining to the pre–Two Midnight Rule period did not differ materially from the post–Two Midnight Rule period and, consequently, supports finding a property interest in Part A coverage but no property interest in inpatient admission.

B. State Action

1. Applicable Law

"Because the United States Constitution regulates only the Government, not private parties, a litigant claiming that his constitutional rights have been violated must first establish that the challenged conduct constitutes state action." *Fabrikant v. French*, 691 F.3d 193, 206 (2d Cir. 2012) (citations and internal quotation marks omitted). To satisfy the "state action" prong of the due process analysis, the Plaintiffs must show that the challenged activity is "fairly attributable" to the state. *Brentwood Acad. v. Tennessee Secondary Sch. Athletic Ass'n*, 531 U.S. 288, 295 (2001). "Actions of a private entity are attributable to the State if there is a sufficiently close nexus between the State and the challenged action of the . . . entity so that the action of the latter may be fairly treated as that of the State itself." *Cooper v. U.S. Postal Service*, 577 F.3d 479, 491 (2d Cir. 2009). "The purpose of this requirement is to assure that constitutional standards are invoked only when it can be said that the State is responsible for the specific conduct of which the plaintiff complains." *Blum v. Yaretsky*, 457 U.S. 991, 1004 (1982) (emphasis in original).

There is "no single test to identify state actions and state actors. Rather, there are a host of factors that can bear on the fairness of an attribution of a challenged action to the State." *Fabrikant*, 691 F.3d at 207 (quoting *Cooper*, 577 F.3d at 491); *see also Brentwood*, 531 U.S. at 296 ("Our cases have identified a host of facts that can bear on the fairness of such an

attribution."). A sufficiently close nexus between a private entity and the state exists when "the state exercises coercive power, is entwined in the management or control of the private actor, or provides the private actor with significant encouragement, either overt or covert, or when the private actor operates as a willful participant in joint activity with the State or its agents, is controlled by an agency of the State, has been delegated a public function by the state, or is entwined with governmental policies." *Flagg v. Yonkers Sav. And Loan Ass'n, FA*, 396 F.3d 178, 187 (2d Cir. 2005) (internal quotation marks and citations omitted); *see also Brentwood*, 531 U.S. at 296 (listing the same factors). The Second Circuit has grouped these theories of state action into three "main tests":

> (1) [when] the entity acts pursuant to the coercive power of the state or is controlled by the state ("the compulsion test"); (2) when the state provides significant encouragement to the entity, the entity is a willful participant in joint activity with the state, or the entity's functions are entwined with state policies ("the joint action test" or "close nexus test"); or (3) when the entity has been delegated a public function by the state ("the public function test").

Fabrikant, 691 F.3d at 207. The determination of whether the specific conduct of which the plaintiff complains constitutes state action remains a "necessarily fact-bound inquiry," *Brentwood*, 531 U.S. at 298 (internal quotation marks omitted), and "the fundamental question under each test is whether the private entity's challenged actions are 'fairly attributable' to the state." *Fabrikant*, 691 F.3d at 207.

In the present case, the Plaintiffs complain that their placement on observation constitutes a deprivation of Part A coverage by the state. Both the Supreme Court and the Second Circuit have addressed the state action inquiry in similar contexts, and it is to these cases that I turn for guidance as to when government involvement in the activities of doctors and hospitals amounts to state action. In *Blum v. Yaretsky*, the Court found no state action in nursing homes' decisions

to discharge or transfer Medicaid beneficiaries that were not initiated by the URC.[67] 457 U.S. 991 (1982). The Court held that despite regulatory requirements that covered services be "medically necessary" and that physicians complete prescribed forms documenting the patient's mental and physical health, and despite the possibility of regulatory penalties for failing to discharge or transfer patients whose continued stay was inappropriate, the decision to discharge a particular patient did not constitute state action because it "ultimately turn[ed] on medical judgments made by private parties according to professional standards that are not established by the State." *Id.* at 1006-10. The Court noted, for example, that physicians retained the discretion to order admission to a nursing facility in spite of a "low" score on the prescribed form. *Id.* at 1006. The Court also found significant the fact that the plaintiffs were challenging not the adjustment of their benefits, but their actual discharge or transfer from the facility. *Id.* at 1005.

By contrast, in *Kraemer v. Heckler*, decided two years after *Blum*, the Second Circuit held that a decision by a hospital's URC that a patient's admission or continued stay was not medically necessary *could* constitute state action. 737 F.2d 214, 220 (2d Cir. 1984) ("If the facts prove to be as appellant contends, the government's use of [utilization review committee] determinations may well provide the state action that was missing in *Blum*."). The Court explained that, unlike in *Blum*, which concerned terminations originated by "the patients' own doctors or by hospital directors or nursing home administrators," the *Kraemer* case involved "only the determinations of utilization review committees." *Id.* at 219. *Blum* was thus not controlling. In concluding that there was a "far stronger basis for finding state action" than in

[67] Those discharges and transfers that *were* initiated by the URC were not at issue in the case, because the parties had already entered into a consent judgment establishing procedural rights for URC-initiated transfers to lower levels of care. *Blum*, 456 U.S. at 997. The only remaining issue was whether transfers and discharges initiated by other agents of the nursing home, such as the attending physician, constituted state action.

Blum, *id.* at 219, the Court noted that an unfavorable decision by the URC effectively terminated Medicare benefits and thus that, unlike the respondents in *Blum*, the *Kraemer* plaintiffs "*do* challenge the adjustment of benefits, [and] not simply the discharge or transfer of patients to lower levels of care or the finding that an admission or continued stay is not medically necessary," *id.* at 220. The Court further noted that the "URC decision-making process [appeared] to be governed largely by statute, regulation, HCFA[68] manuals, and transmittal letters," *id.* at 220, that "physician members [of the URC] must act in accordance with guidelines established by the Secretary to select or develop written criteria and standards for reviewing the necessity for admissions and continued stays . . . .," *id.*, and that the plaintiff class "may well be able to demonstrate that the Secretary's directives serve to pressure intermediaries and providers to cut back on benefits," *id.* at 221.

The Second Circuit revisited *Kraemer* and *Blum* a decade later, in *Catanzano by Catanzano v. Dowling*¸ and concluded that New York certified home health agencies ("CHHAs"), which were responsible for administering home health care services under Medicaid, were state actors when they made determinations as to eligibility for home health care. *Catanzano by Catanzano v. Dowling*, 60 F.3d 113, 119 (2d Cir. 1995). The Court relied on several features of the regulatory regime. First, the Court observed that CHHAs "are not simply regulated by the State; rather, they are deeply integrated into the regulatory scheme." *Id.* (citing, e.g., an administrative directive describing the "close collaborative relationship" between CHHAs and the Department of Social Services). Second, the Court noted that, as in *Kraemer*, and unlike in *Blum*, the decisions made by the CHHAs were not "purely medical judgments made according to professional standards," but involved the application of regulatory rules. *Id.*

[68] CMS was previously known as the Health Care Financing Administration (HCFA).

Third, the Court explained that, as in *Kraemer*, "the decisions of the CHHAs 'effectively' deny or reduce care. In this way, the state has delegated its power to deny services to the CHHAs . . . ." *Id.* Finally, the Court found evidence that CHHAs' decisions were influenced by the State's efforts to control costs, distinguishing them from the more independent decisions at issue in *Blum*. *Id.* The Court concluded that "the State 'has exercised coercive power [and] has provided such significant encouragement . . . that the [CHHA's determinations in step one and two] must in law be deemed th[ose] of the State,' *Blum*, 457 U.S. at 1004, 102 S.Ct. at 2785 and that the determinations thus trigger fair hearing rights." *Id.* (alterations in the original).

Catanzano and *Kraemer* were decided prior to the Second Circuit's grouping of the Supreme Court's theories of state action into "three main tests"—(1) the "compulsion" test, (2) the "joint action" or "close nexus" test, and (3) the "public function" test—which appears to have been first articulated in *Sybalski v. Independent Group Home Living Program, Inc.*, 546 F.3d 255, 257 (2d Cir. 2008). Thus, neither decision identifies which of the three tests it is applying. The *Catanzano* court's own summation of its holding, however,—that the state had exercised "coercive power" and provides "such significant encouragement" that a CHHA's determination "must in law be deemed th[at] of the state," 60 F.3d at 116—seems to point to "the compulsion test." Lower courts applying the compulsion test have relied on this same language, taken from *Blum*, to define the test. *See, e.g.*, *Caballero v. Shayna*, 2019 WL 2491717, at *4 (E.D.N.Y. June 14, 2019) ("Under the state compulsion test, 'a State normally can be held responsible for a private decision only when it has exercised coercive power or provided such significant encouragement, overt or covert, that the choice must in law be deemed to be that of the State.'" (quoting *Doe v. Harrison*, 254 F. Supp. 2d 338, 342 (S.D.N.Y. 2003) (quoting *Blum v. Yaretsky*, 457 U.S. 991, 1004 (1982)))); *D.W.M. Moore v. St. Mary School*, 2019 WL 4038410, at *9

(E.D.N.Y. Aug. 27, 2019) (using similar language); *Edwards v. Baptiste*, 2006 WL 3618021, at *2 (D. Conn. Dec. 11, 2006) (using similar language). On the other hand, the Second Circuit's descriptions of the three tests often splits up *Blum's* references to "coercion" and "significant encouragement" among two separate tests, assigning the "significant encouragement" language to the "joint action" or "close nexus" test and the "coercion" language to the "compulsion" test.[69] Because it is in any case clear that both "coercion" and sufficiently "significant encouragement" can support a finding of state action, because "the fundamental question under each test is whether the private entity's challenged actions are 'fairly attributable' to the state," *Fabrikant*, 691 F.3d at 207, and because the Second Circuit has directly addressed closely analogous issues in *Catanzano* and *Kraemer*, I need not determine precisely which test applies, and proceed instead by applying these bindings precedents to the facts in this case.

2. URC Determinations Constitute State Action

Many of the Plaintiffs, including all those who testified at trial, were initially admitted as inpatients by their treating physicians, but were subsequently placed on observation—and effectively deprived of their property interest in Part A coverage—as a result of a determination by the hospital's URC that they did not satisfy CMS's criteria for Part A coverage.[70] All of the

[69] For example, in *Fabrikant*, the Second Circuit articulated the three tests as follows: "(1) [when] the entity acts pursuant to the coercive power of the state or is controlled by the state ("the compulsion test"); (2) when the state provides significant encouragement to the entity, the entity is a willful participant in joint activity with the state, or the entity's functions are entwined with state policies ("the joint action test" or "close nexus test"); or (3) when the entity has been delegated a public function by the state ("the public function test")." 691 F.3d at 207.

[70] The Secretary argues that when a patient's status is changed from inpatient to observation, there is no deprivation of Part A coverage because it is still possible that the patient will subsequently be readmitted as an inpatient and the entire stay covered under Part A. While this sequence of events is possible, the Secretary has pointed to no evidence that it occurs with any regularity (or even that it occurs at all). In any case, the relevant unit of analysis under the Two Midnight Rule is an "inpatient admission," and not a beneficiary's entire hospital stay. *See, e.g.*, 42 C.F.R. § 412.3(d)(1) ("[A]n *inpatient admission* is generally appropriate for payment under Medicare Part A . . . ." (emphasis added). The fact that a subsequent inpatient admission might be covered under Part A does not mean that Part A coverage for the instant inpatient admission has not been effectively denied when utilization review results in the beneficiary's placement on observation.

factors that led the *Catanzano* court to conclude that CHHA determinations constituted state action, and the *Kraemer* court to conclude that URC medical necessity determinations "may well" be state action, also militate in favor of finding state action in URC determinations that an inpatient does not qualify for Part A coverage and should thus be placed on observation.[71]

The utilization review team's patient status determinations are not only "influenced" by the government's desire to reduce overpayments and control costs, as in *Catanzano*, 60 F.3d at 119—they are largely a consequence of these efforts. As the Second Circuit noted in *Kraemer*, hospitals are required by statute to implement a UR plan providing for review by the URC of the medical necessity of hospital admissions, the duration of stays, and the professional services furnished to each patient. 42 C.F.R. § 482.30(c). CMS enforces this mandate with respect to inpatient admissions by putting significant pressure on hospitals to submit only payable inpatient admission claims for Part A payment. While the form this pressure has taken has varied over the course of the class period, it has nonetheless remained a constant presence. Prior to the promulgation of the Two Midnight Rule, for example, CMS directed RACs to audit hospital inpatient admissions for compliance with CMS's inpatient criteria. These audits resulted in the denial of a substantial number of claims and imposed significant administrative burdens on hospitals. Facts ¶ 30. Although RAC audits have since been limited to hospitals referred for "persistent noncompliance," and, as of the time of trial, there had not been any such referrals, Facts ¶¶ 31-32, the prospect of a RAC audit nonetheless continues to loom, and the absence of any such audits as likely indicates CMS's success in influencing hospital behavior as it does a

[71] The evidence at trial indicated that the utilization review process did not materially differ, for the purposes of the state action analysis, in the periods before and after the promulgation of the Two Midnight Rule. *See, e.g.*, Tr. 649 (Laucks) (indicating the utilization review process functioned in the same way before and after the promulgation of the Two Midnight Rule). Thus, I analyze the state action issue for both periods together.

reduction in pressure. *See also* Tr. 342:3-6 (Sheehy) ("[T]he hospitals are trying to avoid the risk of the RAC . . . . I think that's pretty well known around the country.").[72]

RAC audits, in any case, represent just one of the instruments through which CMS puts pressure on hospitals. CMS contractors such as QIOs continue to conduct post-payment reviews of a sample of each hospital's inpatient claims and conduct one-on-one calls with providers to educate them on the proper application of CMS's inpatient criteria. Facts ¶¶ 20, 66-67. And there is no doubt that the "education" of providers by QIOs, who also determine whether the providers' claims will be paid, leads hospitals to conform the practices of their URCs to CMS policy. *See, e.g.*, PX131 at 6 (during "education" meeting with QIO, "[t]he provider says it seems they should change how they approach their team and how to educate their physicians."). As a result, URCs tend to apply the Two Midnight Rule in much the same way CMS contractors do. Facts ¶ 66. For example, like CMS contractors, URCs typically perform an initial screen using one of the major commercial screening tools, followed by more detailed review by a physician depending on the result produced by the screening tool. Facts ¶¶ 53-56, 66.

Moreover, until 2013, CMS's rebilling policy, which permits hospitals to re-submit claims under Part B when a Part A claim is denied by a CMS contractor, greatly limited the services for which a hospital could re-bill under Part B. This raised the prospect that a hospital's unsuccessful submission of a claim under Part A would result in its not being reimbursed for many of its services, and created a financial incentive to classify more patients as outpatients receiving observation services as a "safe harbor." CMS eventually "acknowledged concerns that

[72] *See also* Tr. 344:9-15 (Sheehy) ("[I] believe that the pressure from the auditors has certainly forced hospitals to take this observation safe harbor. When you have a hospital that cannot either have the infrastructure to appeal or cannot have their dollars tied up for four and a half years, they're forced to take observation as a safe harbor, as a risk over strategy, to get paid something for . . . that care.")

hospitals appear to be responding to the financial risk of admitting Medicare beneficiaries for inpatient stays that might later be denied upon contractor review by electing to treat beneficiaries as outpatients receiving observation services, rather than admitting them as inpatients." 78 Fed. Reg. 50496, 50922 (Aug. 19, 2013).[73]

Hospitals are also subject to audit by HHS-OIG for compliance with CMS criteria. For example, Christiana Hospital, where one of the named plaintiffs was treated, was audited by OIG in 2012 as part of a "hospital compliance initiative." PX029 at 1. OIG identified significant billing errors, including improper inpatient admissions, and attributed these errors to "weaknesses in the patient admission and admission screening processes." *Id.* at 14. The report recommended that Christiana "strengthen controls to ensure full compliance with Medicare requirements." *Id.* at 9. Christiana responded to the report in a letter signed by its Chief Compliance Officer in which it described the ways in which it was working to improve its utilization review process with respect to inpatient admissions. Christiana noted, for example, that the utilization review team now received "daily reports from its consultants regarding the appropriate level of care. This information is communicated to our ordering physicians when a

[73] In 2013, CMS began permitting hospitals to re-bill for most services provided to a beneficiary during a hospital stay under Part B on an individual basis. But hospitals are still not permitted to rebill using the billing code for *bundled* "observation services." Facts ¶ 13 n.15. Because there was no evidence regarding the financial impact of this distinction at trial, the degree to which hospitals continue to face financial risk from erroneous inpatient admissions is unclear. *See, e.g.*, Medicare Claims Processing Manual, ch. 1, § 50.3 ("While hospitals may not report observation services under HCPCS code G0378 for the time period during the hospital encounter prior to a physician's order for observation services, in Condition Code 44 situations, as for all other hospital outpatient encounters, hospitals may include charges on the outpatient claim for the costs of all hospital resources utilized in the care of the patient during the entire encounter."); DX577 003-04 ("[I]n March 2013, CMS implemented a ruling regarding payments for inpatient services when a CMS contractor or a hospital determines that an inpatient admission was not reasonable and necessary. Specifically, CMS revised its Part B inpatient billing policy to allow payment for all hospital services that were provided and would have been reasonable and necessary if the beneficiary had been treated as an outpatient. This revision substantially reduces hospitals' financial risk when admitting beneficiaries if CMS contractors later deny or recoup payments for inpatient claims. Prior to this ruling, if an inpatient claim was denied, hospitals received payment for only a limited set of services even if all the services provided would have been reasonable and necessary in the outpatient setting.").

determination has been made that the documentation does not support an admission order." *Id.* at 20-21.

CMS not only places significant pressure on hospitals to, in effect, deny improper inpatient admissions before they are even submitted as claims to CMS, but also channels hospitals' responses to this pressure by requiring hospitals to act through their URCs when changing patient statuses.[74] As noted above, hospitals are compelled by statute to have both a utilization review committee as well as a utilization review plan that provides, *inter alia*, for review of inpatient admissions and the duration of stays for medical necessity. Facts ¶ 52. Further, CMS requires that a hospital act through its utilization review process when it changes a patient's status for billing purposes. CMS's "Claims Processing Manual" includes a section titled "When an Inpatient Admission May Be Changed to Outpatient Status," which sets forth the procedure a hospital must follow to change, for billing purposes, an inpatient admission to outpatient status. Medicare Claims Processing Manual, ch. 1, § 50.3, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf. The Manual provides:

> In cases where a hospital . . . UR committee determines that an inpatient admission does not meet the hospital's inpatient criteria, the hospital . . . may change the beneficiary's status from inpatient to outpatient and submit an outpatient claim (bill type 13x or 85x) for medically necessary Medicare Part B services that were furnished to the beneficiary, provided all of the following conditions are met: . . . .

[74] While the URC is formally responsible for conducting utilization review, URC-initiated changes to patient statuses can be effected by a single physician member of the URC, Claims Processing Manual § 50.3.22, and CMS "encourages and expects hospitals to employ case management staff to facilitate the application of hospital admission protocols and criteria, to facilitate communication between practitioners and the UR committee or [QIO], and to assist the UR committee in the decision-making process," Medicare Claims Processing Manual, ch. 1, § 50.3.1. Thus, in practice, utilization review is often conducted not by the URC as a formal body, but by the utilization review team, which includes individual members of the URC as well as other utilization review personnel.

Id. When all of the requirements set forth in the manual are met, hospitals are permitted to bill for the entire patient encounter under Part B by using "Condition Code 44." There is no indication in the Manual that a hospital may choose to bypass the UR committee in changing patient statuses pursuant to internal review, and when commenters "stated that hospitals conduct internal reviews other than utilization review, and asked if the inpatient stay could be rebilled if the error is discovered as part of another type of review," CMS responded that it "did not propose and [was] not finalizing a policy that would allow hospitals to bill Part B following an inpatient reasonable and necessary self-audit determination that does not conform to the requirements for utilization review under the [Conditions of Participation]." 78 Fed. Reg. 50496, 50914 (Aug. 19, 2013). Thus, the only path CMS permits hospitals to take in response to the significant pressure CMS puts on hospitals to prevent the submission of improper inpatient claims is utilization review. It is therefore not surprising that every hospital about which the Court heard testimony had a utilization review process in place through which it reviewed inpatient admissions for compliance with CMS's inpatient criteria, often resulting in URC-initiated changes to a patient's status.

This case also mirrors *Catanzano* in several other important respects. As in *Catanzano*—and unlike in *Blum*—URC determinations are "not purely medical judgments made according to professional standards," *Catanzano*, 60 F.3d at 119, but involve the application of a standard prescribed by CMS. Facts ¶¶ 53, 66-67.[75] Moreover, as previously discussed, CMS directly

[75] The Secretary points out that some of the language in the Medicare Claims Processing Manual seems to suggest that URCs apply hospitals' own criteria—rather than CMS's—in reviewing inpatient admissions. *See* ECF No. 436 at 14 n.2 ("CMS's guidance with respect to the use of Condition Code 44 applies when a URC, with a treating physician's concurrence, 'determines that an inpatient admission does not meet the hospital's inpatient criteria,' Medicare Claims Processing Manual, Ch. 1, § 50.3.2."). But the Court heard substantial evidence with respect to the practices of hospital URCs, and the evidence unambiguously showed that patient status changes are initiated by URCs applying CMS's criteria, and not some alternative set of criteria developed by the hospital on its own without regard to CMS policy. *See, e.g.*, PX118 at 6 (John Dempsey Hospital Utilization Review Plan, providing for the

educates URCs on the application of the prescribed standard, and URCs apply the standard in largely the same manner as CMS reviewers. *Id.* While this standard leaves some room for professional judgment, it is designed to closely circumscribe this judgment, and CMS expects it to be applied with a high degree of consistency. There is also, as in *Catanzano*, close collaboration, 60 F.3d at 119, between CMS's agents and utilization review teams, such as conference calls in which CMS contractors educate utilization review staff on the proper application of CMS criteria by, for example, working through detailed case studies. Facts ¶ 67. And, as in *Kraemer* and *Catanzano*, the UR team's determination effectively denies the beneficiary Part A coverage. If the UR team causes the beneficiary's status to be changed to observation on the grounds that CMS's criteria are not satisfied and initiates Condition Code 44, the patient is precluded from obtaining Part A coverage for the admission. Even if the treating physician refuses to comply with the UR team's request to change the patient's status, once the UR team has determined that an inpatient admission does not satisfy CMS's requirements, the hospital cannot bill Medicare under Part A. Facts ¶ 57. But a URC's determination does not itself constitute—and generally does not even lead to—a change in the provision of care, such as a discharge or transfer, distinguishing this case from *Blum*, where patients sought to appeal not the adjustment of their benefits, but their discharge or transfer from an SNF.

In short, to prevent overpayments and reduce costs, rather than review every inpatient admission for compliance with its coverage criteria, CMS imposes pressure on hospitals to prevent improper claims for inpatient admissions from being submitted in the first place by ensuring that statutorily mandated URCs review inpatient admissions for compliance with CMS

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review of every admission by case management "within the first day of admission" to "determine if the patient meets CMS criteria"); *see also* Facts ¶¶ 53, 66-67. This is unsurprising, in light of the substantial pressure that CMS places on hospitals to ensure compliance with CMS's inpatient criteria.

criteria and change the status of patients believed to be ineligible for Part A payment. UR personnel apply CMS criteria in reviewing inpatient admissions, and CMS directly educates UR personnel on their application. CMS thus not only causes URCs to engage in the practice of changing patient statuses from inpatient to observation in order to deny coverage for admissions thought to be ineligible, but also largely determines the outcome of decisions in particular cases by establishing the relevant criteria and educating URCs on their application. Thus, when a hospital URC causes a patient's status to be changed to observation, CMS has provided "such significant encouragement" that the URC's conduct is "fairly attributable to the state" and therefore constitutes "state action."

3. Initial Placements on Observation Are Not State Action

While some class members were initially designated as inpatients by their treating physicians, and were only placed on observation status pursuant to a determination by the hospital's URC, other class members were placed on observation status at the outset. These initial decisions to order observation—which also have the effect of denying the beneficiary Part A coverage—are not fairly attributable to the state on a class-wide basis, and thus do not constitute state action. These decisions differ in several important respects from the decisions to place previously admitted patients on observation. First, the evidence showed that the initial decision to place a patient on observation is made by the treating physician, with only limited evidence of involvement by utilization review personnel. While there was some evidence that treating physicians consult utilization review personnel prior to making the initial status determination, Facts ¶ 92, there is no evidence that this represents universal, or even typical, practice. Dr. Baugh, for example, testified that the utilization review team is not involved in his decisions to place patients on observation. Facts ¶ 43. By contrast, the evidence showed that

decisions to change a patient's status from inpatient to observation were invariably driven by statutorily mandated and heavily regulated URCs.

Second, initial placements on observation by treating physicians are influenced by the government's desire to reduce overpayments and control costs to a significantly lesser degree than the URC-driven decisions to change a beneficiary from inpatient to observation. Although treating physicians are indirectly influenced by the government's desire to control costs through the cumulative effect of ongoing utilization review, the pressure from CMS and its agents is directed at hospitals and utilization review personnel, as detailed above, and not at treating physicians. Similarly, there was no evidence of "close collaboration" between treating physicians and CMS. For example, utilization review staff, rather than treating physicians, participate in the one-on-one calls with QIOs. Facts ¶¶ 66-67. CMS's largely "hands-off" approach with respect to treating physicians is not surprising, in light of the long-standing policy prohibiting CMS from interfering with the "practice of medicine." 42 U.S.C. § 1395.

Third, unlike URC determinations, which always involve the application of government-specified criteria, initial decisions to place a beneficiary on observation status are sometimes made following observation care protocols developed by the hospital's physicians. Facts ¶¶ 42-43.[76] And even when these decisions are made by applying the relevant CMS-specified benchmark, a greater degree of medical judgment is brought to bear compared to the more objective process employed by CMS reviewers and utilization review personnel, which includes a reasonableness standard, is limited to a review of the medical record, and incorporates the use of commercial screening tools. While there is some evidence that physicians in at least some hospitals, particularly outside of EDOUs, are asked to check a box on every admission indicating

[76] The use of these protocols is most common in EDOUs, but also occurs in other settings. Facts ¶ 42 n.24.

whether they have a two-midnight expectation, Facts ¶ 49, and physicians do recognize that the decision they are making about the two-midnight expectation is one that stems from Medicare requirements, *see, e.g.*, Tr. 1021:2-16 (Vedere), this is not enough to make them state actors. *See Blum v. Yaretsky*, 457 U.S. 991, 1006-07 (1982) ("We cannot say that the State, by requiring completion of a form, is responsible for the physician's decision."). In short, initial placements on observation status by physicians differ in significant ways from the URC-driven decisions to change a patient's status from inpatient to observation, such that the former, unlike the latter, cannot fairly be attributed to the state under Second Circuit precedent.

C. The Process Due

I have found that, when a hospital URC causes a beneficiary's status to be changed from inpatient to observation, the beneficiary is deprived of her property interest in Part A coverage by state action—thus satisfying the first two prongs of the due process analysis. To determine whether such a deprivation is also made without due process of law, *Mathews v. Eldridge* requires the Court to look to 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.

424 U.S. 319, 335 (1976).

As an initial matter, it is unquestionable that the Plaintiffs' private interest is weighty. This interest differs somewhat between the two portions of the class: (a) those who were not enrolled in Part B coverage at the time of their hospitalization ("the Part A only portion of the class") and (b) those who stayed at the hospital for three or more consecutive days but were designated as inpatients for fewer than three days ("the three-day portion of the class"). For the

three-day portion of the class, when a hospital URC deprives the class member of Part A hospital coverage by causing their status to be changed to outpatient, a direct collateral consequence of this deprivation is the loss of Part A SNF coverage. This loss of coverage has serious consequences for beneficiaries. First, a beneficiary must cover the cost of any post-hospitalization SNF care they receive out-of-pocket. According to an OIG report, the cost of such care averages over $10,000. Facts ¶ 70.[77] This constitutes a significant financial burden, particularly for those who are on a fixed income. In *Kraemer v. Heckler*, which also involved Medicare coverage of SNF benefits, the Second Circuit noted that "the private interest at stake should be weighed more heavily than in *Eldridge* because of the astronomical nature of medical costs." 737 F.2d at 222. The cost of SNF care, the Circuit noted, "can financially cripple all but the very wealthy." *Id.* But, perhaps more importantly, many Medicare beneficiaries simply cannot afford to pay for SNF care out of pocket or may only be able to afford a shorter period of SNF care than they need. Such patients may be forced to forgo needed rehabilitative care, which can have serious negative consequences for their health.[78] *See id.* (noting that an adverse decision by a URC "diminishes the probability that a patient could choose to continue receiving medical care"). Moreover, the loss of SNF coverage can have severe emotional and psychological consequences for beneficiaries. One physician described an experience where a patient, upon learning that her placement on observation meant she would lose SNF coverage, told the physician that the care would bankrupt her family and that she just wanted to die. Facts ¶ 73.

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[77] This estimate is confirmed by the experiences of some of the named Plaintiffs. For example, Plaintiff Martha Leyanna was billed for $10,600 for her SNF care, and Plaintiff Erwin Kanefsky was billed $9,145. Facts ¶ 70.
[78] The granddaughter of Plaintiff Martha Leyanna testified that her grandmother had to move from an SNF to a facility providing a lower level of care because she could no longer afford to pay for SNF care. This facility was unable to provide the rehabilitative care she needed and she never regained independent mobility. Facts ¶ 71.

The Secretary points out that the majority of class members will not require SNF care upon discharge. ECF No. 430 at 51. While this appears to be true, the percentage of class members requiring post-hospitalization SNF care is nonetheless substantial According to an OIG report, of the 617,702 beneficiaries who had hospital stays lasting at least three nights, fewer than three of which were inpatient nights—a category which is nearly identical to the three-day portion of the class—4% received SNF services following their discharge from the hospital, even though they did not qualify for Medicare coverage of these services. But many more of these patients were recommended for SNF care by their physician—five times as many, according to the only data presented at trial. Facts ¶ 72. Thus, the evidence suggests that SNF care was recommended for approximately 20% of the three-day portion of the class. These class members faced, and continue to face, the difficult choice of whether to pay thousands of dollars for SNF care out of pocket—a sum many Medicare beneficiaries likely cannot afford—or to forgo necessary medical care recommended by their physicians. Moreover, the outcome of the *Mathews* balancing test is not highly sensitive to the proportion of class members that need SNF care, because this figure directly impacts not only the weight of the private interest, but also the burden on the government. If they do not require SNF care, members of the three-day portion of the class would have no incentive to appeal their placement on observation status. Thus, it is unlikely that the government will be burdened by having to process appeals for these class members.

Class members who have only Part A coverage, for their part, stand to lose all Medicare coverage for their hospital stay and thus incur thousands of dollars in out-of-pocket medical costs. For example, Plaintiff Andrew Roney, who could not afford to pay the monthly premium

for Medicare Part B, received a bill for $3,502 after he was changed from inpatient to observation part-way through his hospital stay. Facts ¶ 75.

The second *Mathews* factor—"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"—also militates in the Plaintiffs' favor. As an initial matter, at present, the Plaintiffs are currently entitled to no procedural safeguards whatsoever. Thus, a Medicare beneficiary like Plaintiff Ervin Kanefsky can simply be informed, shortly prior to discharge, that "the powers that be changed you back . . . from inpatient to observation so they're not going to pay for your rehab." Facts ¶ 59. Such a beneficiary has no mechanism through which to challenge or appeal this determination.

The evidence suggests, moreover, that there is a significant risk of error in the URC determinations that lead to changing a patient's status from inpatient to observation based on a judgment that the physician's inpatient admission did not satisfy the Two Midnight Rule or the 24-Hour Benchmark. As noted, these URC reviews mimic the nearly identical reviews conducted by CMS contractors. The trial evidence showed that providers, who can appeal determinations by CMS contractors, have a high rate of success in obtaining a reversal, indicating that it is not uncommon for such determinations to be erroneous.[79] According to one study, providers prevailed as to 71% of RAC denials that they appealed to the ALJ level. Tr. 398:11-25; 306:22-25 (Sheehy).[80] Moreover, the Secretary himself acknowledged the difficulty

[79] As noted above, these provider appeals do not provide any relief to the Plaintiffs in this case because providers do not submit Part A claims for patients they have placed on observation, and thus no CMS contractor issues a Part A coverage determination from which a provider or a beneficiary might appeal.

[80] Courts sometimes rely on reversal rates to demonstrate a risk of erroneous deprivation. *See, e.g.*, *Fox v. Bowen*, 656 F. Supp. 1236, 1250 (D. Conn. 1986) ("The risk that plaintiffs will erroneously be deprived of their Medicare benefits is great indeed, as is demonstrated by the high percentage of decisions denying physical therapy coverage that are reversed on appeal."). A high reversal rate also speaks to the added value of additional safeguards.

of maintaining consistency in eligibility determinations under the Two Midnight Rule when he temporarily suspended QIO short-stay reviews for retraining "to ensure accuracy and consistency" in the QIOs' application of the Rule. Facts ¶ 20 n.18. And there are only two QIOs nationwide. By contrast, there are thousands of URCs across the country making virtually the same determinations. It is difficult to imagine that URCs are not less consistent—and less accurate—in performing this task than the QIOs. Thus, it is not surprising that a 2013 OIG report found that "hospitals varied widely in their use of observation stays and long outpatient stays," DX577-011, as well as in their use of "short inpatient stays," DX577-013. In short, it is clear that there is a high risk of erroneous deprivation. And the high reversal rate that providers already achieve in nearly identical appeals also indicates that the additional procedural safeguards sought by the Plaintiffs would significantly improve the accuracy and consistency of these determinations.

Under *Mathews*, the Plaintiffs' weighty private interest, the high risk of erroneous deprivation, and the evident value of additional safeguards must be weighed against the "fiscal and administrative burdens that the additional or substitute procedural requirement would entail." The Secretary has pointed to several administrative steps that would need to be taken in order to establish the procedures the Plaintiffs seek, including the promulgation of new regulatory and sub-regulatory guidance, drafting new or modifying existing contracts, developing appropriate educational and training materials, securing appropriations from Congress, and drafting and approving a new notice to beneficiaries. *See generally* Facts ¶¶ 84-87. Contrary to the Secretary's assertions, however, the procedures the Plaintiffs seek do not constitute an entirely new type of appeal, but are largely similar—both substantively and procedurally—to the existing

appeals processes available to providers. Thus, while some of the burdens the Secretary cites may well materialize, those that do will be significantly less onerous than the Secretary suggests.

The Secretary also cites the added financial burden of actually processing the new appeals. These costs, unlike those associated with establishing the procedural protections sought by the Plaintiffs, are not defrayed by the appeals' similarity to existing procedures.

"The fundamental prerequisite of due process of law is the opportunity to be heard, . . . at a meaningful time and in a meaningful manner." *Goldberg v. Kelly*, 397 U.S. 254, 267 (1970). Here the Plaintiffs have no opportunity whatsoever to challenge the deprivation of their Part A coverage when a statutorily mandated URC—responding to substantial pressure from CMS—finds that a physician's inpatient admission does not satisfy CMS's criteria. I conclude that, in light of the Plaintiffs' weighty pecuniary, physical, and psychological interests, the significant risk of erroneous deprivation, and the evident value of additional procedural safeguards, the *Mathews* scale tips decidedly in the Plaintiffs' favor. This is true with respect to the Plaintiffs' general request for an opportunity to challenge their placement on observation status, but it is also true of their further request for an expedited appeal process. One of the chief injuries Plaintiffs face as the result of an erroneous deprivation—having to forgo needed medical care due to an apparent lack of coverage—can only be remedied by an expedited procedure. While the administrative and fiscal burdens cited by the Secretary are not insignificant, they must nonetheless yield in this case to the Plaintiffs' substantial due process interests.

D. Class Definition

"[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) (citing

Richardson v. Byrd, 709 F.2d 1016, 1019 (5th Cir. 1983) ("The district judge must define, redefine, subclass, and decertify as appropriate in response to the progression of the case from assertion to facts.")); *see also Vogt v. State Farm Life Insurance Co.*, 2018 WL 4937069, at *2 (W.D. Mo. Oct. 11, 2018) ("Federal Rule of Civil Procedure 23(c)(1)(C) permits the court to modify the class definition before the entry of a final judgment and that includes after a trial on the merits."); *Garcia v. Tyson Foods, Inc.*, 890 F. Supp. 2d 1273, 1297 (D. Kan. 2012) (collecting cases and authorities). 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).

The current class definition is as follows:

> 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.

See ECF No. 378 at 41. I conclude above, based on the evidence presented at trial, that only those class members who were formally admitted as inpatients have proven that their deprivation of Part A coverage results from state action. Moreover, beneficiaries whose injury in fact stems from the denial of coverage for SNF care or, alternatively, having to forgo SNF care for lack of coverage, do not have standing if more than 30 days has passed since their hospital stay without their having been admitted to an SNF. These beneficiaries' injury cannot be redressed by an injunction directing the Secretary to provide the procedural protections mandated by the Due Process Clause. CMS of course cannot provide coverage for services that were never rendered, and CMS only covers post-hospital SNF care if a beneficiary is admitted to the SNF within 30

days of the date of discharge, Facts ¶ 11. And there is no evidence that such beneficiaries have any continued need for SNF services. I therefore adopt the following modified class definition:

> All Medicare beneficiaries who, on or after January 1, 2009: (1) have been or will have been formally admitted as a hospital inpatient, (2) have been or will have been subsequently reclassified as an outpatient receiving "observation services"; (3) 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 (4) 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, unless more than 30 days has passed after the hospital stay without the beneficiary's having been admitted to a skilled nursing facility. 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.[81]

V. RELIEF

For the reasons set forth above, I find that the Secretary is violating the Due Process Clause of the Fifth Amendment by denying the members of the modified class the right to challenge the denial of their Part A coverage. Accordingly, the Secretary is ENJOINED as follows:

1. The Secretary shall permit all members of the modified class to appeal the denial of their Part A coverage.

2. For class members who have stayed, or will have stayed, at the hospital for three or more consecutive days, but who were designated as inpatients for fewer than three days, the Secretary shall permit appeals through an expedited appeal process substantially similar to the existing expedited process for challenging hospital discharges.

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[81] To be a member of the class, a beneficiary need not show that the beneficiary's status change was caused by the hospital's URC, because the evidence before the Court indicates that such changes are invariably the result of the utilization review process. Facts ¶ 65.

3. In the appeals to be established under this order, the Secretary shall permit class members to argue that their inpatient admission satisfied the relevant criteria for Part A coverage—for example, that the medical record supported a reasonable expectation of a medically necessary two-midnight stay at the time of the physician's initial inpatient order, in the case of a post–Two Midnight Rule hospital stay—and that the URC's determination to the contrary was therefore erroneous. If the class member prevails, the Secretary shall disregard, for the purposes of determining Part A benefits, including both Part A hospital coverage and Part A SNF coverage, the beneficiary's reclassification as an outpatient that resulted from the URC's erroneous determination.

4. The Secretary shall provide class members with timely notice of the procedural rights described above.

5. For those class members whose due process rights were violated, or will have been violated, prior to the availability of the procedural protections set forth above, the Secretary shall provide a meaningful opportunity to appeal the denial of their Part A coverage, as well as effective notice of this right.

6. The Secretary may provide greater procedural protections than the ones described above, and may provide these protections to a broader class of beneficiaries, provided that the due process rights of the class members are fully protected as set forth above.

IT IS SO ORDERED.

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

Dated: Hartford, Connecticut
March 24, 2020