UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

CHRISTINA ALEXANDER, *et al.*,

Plaintiffs,

v.

NORRIS COCHRAN, Acting Secretary of Health and Human Services,

Defendant.

No. 3:11-cv-1703 (MPS)

MEMORANDUM OF DECISION

I. INTRODUCTION

This putative class action concerns the rights of Medicare beneficiaries placed on "observation status" rather than being admitted as "inpatients" while receiving treatment in a hospital. For the plaintiffs and other Medicare beneficiaries they seek to represent, the distinction is a significant one. Identical services provided to patients on observation status are covered under Medicare Part B, instead of Part A, and are therefore reimbursed at a lower rate. Allegedly, the plaintiffs lost thousands of dollars in coverage—of both hospital services and subsequent skilled nursing care—as a result of being placed on observation status during their hospital stays.

According to the plaintiffs, while official Medicare policy leaves the inpatient vs. observation decision to the discretion of individual doctors, in practice, hospitals apply fixed criteria set by Defendant Secretary of the Department of Health and Human Services (the "Secretary") through the Centers for Medicaid and Medicare Services ("CMS"). The plaintiffs claim that CMS pressures hospitals to place more patients in observation status and to make their patient status determinations using computer algorithms known as "commercial screening tools."

They also claim that once a Medicare beneficiary is placed in observation status, the beneficiary does not receive sufficient notice and does not have an opportunity to seek review of the decision.

The case is before this Court for a second time. The Court of Appeals reversed in part the Court's earlier dismissal of the multi-count complaint, and remanded the case for further consideration as to the due process claims only. *Barrows v. Burwell*, 777 F.3d 106 (2d Cir. 2015). A claim under the Due Process Clause of the Fifth Amendment has three elements: "a plaintiff must show that: (1) state action (2) deprived him or her of liberty or property (3) without due process of law." *Id.* at 113 (citing *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999)). As for the second element, the Court of Appeals held that the plaintiffs had sufficiently alleged a property interest in being admitted as inpatients and directed the District Court to oversee a limited period of discovery on that issue and then address summary judgment. *Id.* at 115-16. On the first and third elements, the Court of Appeals directed the Court to consider whether dismissal would be appropriate based on the allegations in the complaint. *Id.* Accordingly, the parties conducted limited discovery and the Secretary filed a motion for summary judgment with a renewed motion to dismiss. Plaintiffs filed a cross-motion for summary judgment.

For the reasons detailed below, the Court DENIES the Secretary's Motion for Summary Judgment (ECF No. 160), DENIES Plaintiffs' Motion for Summary Judgment (ECF No. 166), and GRANTS in part and DENIES in part the Secretary's Motion to Dismiss (ECF No. 160). As a preliminary matter, all plaintiffs have standing and the case is not moot. Significant factual disputes preclude summary judgment on the property interest question, in particular about how the final inpatient status determination is made within hospitals, and to what extent CMS influences hospital decision-making. As for the motion to dismiss, the plaintiffs have sufficiently alleged state action in the form of encouragement by the Secretary, through CMS. They have also plausibly

alleged that the existing process is inadequate, because, though their claim for expedited notice is moot, no administrative appeals process exists.

II. PROCEDURAL HISTORY

On November 3, 2011, seven plaintiffs filed this class action complaint against the Secretary, claiming violations of the Medicare Act, the Administrative Procedure Act, the Freedom of Information Act, and the Due Process Clause of the U.S. Constitution. (ECF No. 1.) Seven additional intervenor-plaintiffs joined the case on April 9, 2012. (ECF No. 53.) On September 23, 2013, this Court granted the Secretary's motion to dismiss as to all nine causes of action, and denied the motion for class certification as moot. *Bagnall v. Sebelius*, 2013 WL 5346659 (D. Conn. Sept. 23, 2013).

On appeal, plaintiffs challenged only the dismissal of their claims (Counts Six and Seven) that the Secretary had failed to provide expedited notice and administrative review for patients placed on observation status, in violation of the Medicare Act and the Due Process Clause. The Court of Appeals, while affirming the dismissal of the Medicare Act claims, reversed as to the due process claims on January 22, 2015. *Barrows*, 777 F.3d 106. The Court of Appeals held that at the motion to dismiss stage, plaintiffs had alleged a property interest sufficient to state a due process claim, explaining:

> [T]he complaint alleges that the decision to admit a patient to a hospital is—in practice—made through rote application of "commercially available screening tools," as directed by the centers for Medicare and Medicaid Services ("CMS"), which substitutes for the medical judgment of treating physicians. Plaintiffs also allege that CMS exerts pressure on hospitals through its billing policies and through its retroactive "Recovery Audit Contractor" reviews, which give hospitals the incentive—as a cost-saving or compliance measure—to place more Medicare beneficiaries into "observation status" for longer periods of time. Therefore, drawing all reasonable inferences in favor of plaintiffs, these allegations show that the Secretary—acting through CMS—has effectively established fixed and objective criteria for when to admit Medicare beneficiaries as "inpatients," and that, notwithstanding

> the Medicare Policy Manual's guidance, hospitals apply these criteria when making admissions decisions, rather than relying on the judgment of their treating physicians.
>
> 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 114–15 (footnotes omitted). The Court of Appeals took "no position regarding whether plaintiffs have pleaded facts sufficient to establish the other two prongs of the due process analysis… *i.e.,* that the 'inpatient' decision constituted state action, and that the process provided to challenge the 'inpatient' decision was inadequate." *Id.* at 115.

The Court of Appeals directed this Court to supervise limited discovery and then consider the remaining issues:

> This discovery period will be focused on the sole issue of whether plaintiffs possessed a property interest in being admitted to their hospitals as "inpatients" …. If, after this period of discovery, the District Court grants summary judgment to the Secretary on the ground that the evidence *fails* to establish a property interest, an appeal will then be authorized in the normal course. However, if the District Court concludes that the evidence establishes that plaintiffs do have a property interest, or that there are material issues of fact that preclude summary judgment as to that issue, it is directed to analyze whether the complaint is properly dismissed on the other two prongs of the due process analysis—*i.e.*, "state action" and "due process."

Id. at 115–16 (footnote omitted, emphasis in original).

After remand, on May 11, 2015, a final intervenor plaintiff, Dorothy Goodman, joined the case. (ECF No. 123.) There are now fourteen plaintiffs,[1] all Medicare beneficiaries or

---

[1] One of the intervenor-plaintiffs, Frederick Ruschmann, died and was substituted by Jessie Ruschmann, the personal representative of his estate. (ECF No. 101.) When Ms. Ruschmann subsequently died without substitution, she was terminated as a party. (ECF No. 189.)

representatives of their estates:[2] Christina Alexander (executrix of Bernice Morse's estate), Lee Barrows (executrix of Lawrence Barrows' estate), Irma Becker,[3] Shirley Burton (executrix of Nettie Jean Sapp's estate), Louis Dziadzia,[4] Dorothy Goodman,[5] Charles Holt, Loretta Jackson, Sarah Mulcahy, Ann Pelow (executor of Richard Bagnall's estate), George Renshaw (executor of Charles Renshaw's estate), Denise Rugman (executrix of Florence Coffey's estate), Michael Savage (executor of Mildred Savage's estate), and Mary Smith (personal representative of Martha Leyanna's estate). (ECF Nos. 1 ¶¶ 11-17; 53 ¶¶ 12-18; 86; 105; 123 ¶ 12; 152.) Plaintiffs have not yet filed a renewed motion for class certification.

As directed by the Court of Appeals, the parties engaged in discovery limited to the issue of whether plaintiffs had a property interest in being admitted to the hospital as inpatients. Plaintiffs submitted interrogatories and requests for production to the Secretary. (ECF No. 166-1 at 9.) Plaintiffs also conducted depositions of: (1) four hospitals that treated six of the named Medicare beneficiaries: William W. Backus ("Backus") Hospital, University of Connecticut John Dempsey ("Dempsey") Hospital, Christiana Care ("Christiana") Hospital, and Clearwater Valley ("Clearwater") Hospital; (2) four Medicare contractors with different roles: Performant Recovery (a Recovery Audit Contractor, or "RAC"), CGI Federal, Inc. (also a RAC), National Government

---

[2] For simplicity, the Court refers to the Medicare beneficiaries by their own names throughout this opinion, even if they are deceased and the estate representative is the relevant plaintiff.

[3] Plaintiffs' counsel represented that Ms. Becker passed away and that they expect an estate representative to file a motion for substitution. (ECF Nos. 192; 195.)

[4] Plaintiffs' counsel represented that Mr. Dziadzia passed away and that they expect an estate representative to file a motion for substitution. (ECF Nos. 192; 195.)

[5] Plaintiffs' counsel represented that Ms. Goodman passed away and that they are in the process of determining whether an estate representative will substitute. (ECF No. 195.)

Services, Inc. (a Medicare Administrative Contractor, or "MAC"), and Qualis (a Quality Improvement Organization, or "QIO"); and (3) witnesses from the Department of Health and Human Services ("HHS"). (*Id.*)

The parties then filed cross-motions for summary judgment on the property interest question and the Secretary filed a renewed motion to dismiss, arguing that hospitals' decisions to place patients on observation status does not constitute state action, Plaintiffs' claim for expedited notice is moot, and the existing appeal procedures are adequate. (ECF Nos. 160; 166.) The parties presented oral argument on the pending motions at a hearing on December 15, 2016, and submitted supplemental briefing focused on standing and mootness issues on January 17, 2017. (ECF Nos. 193; 194.)

III. SUBJECT MATTER JURISDICTION

Before turning to the cross-motions for summary judgment and the motion to dismiss, the Court must address *sua sponte* issues that go to its subject matter jurisdiction, including standing and mootness under Article III of the U.S. Constitution. *See Cent. States Se. & Sw. Areas Health & Welfare Fund v. Merck-Medco Managed Care, L.L.C.*, 433 F.3d 181, 198 (2d Cir. 2005). Accordingly, the Court asked the parties to brief standing and mootness issues with regard to Medicare beneficiaries who have died and/or received a full refund for Medicare coverage. Standing and mootness issues specific to the claim of insufficient notice are addressed separately in Section V.C.2.

A. Relevant Facts

Since the litigation commenced, five of the fourteen Medicare beneficiaries or their estates in this case have received full refunds for the services that were not initially covered by Medicare: Lawrence Barrows, Dorothy Goodman, Bernice Morse, Charles Renshaw, and Mildred Savage.

(ECF Nos. 22-1; 62-1; 65-3; 68-1; 83-2; 166.) Of those five, three—Lawrence Barrows, Charles Renshaw, and Mildred Savage—died before this case was filed, and two—Dorothy Goodman and Bernice Morse—have since passed away. (ECF Nos. 1 ¶¶ 11-17; 105; 195.) Two other beneficiaries, Florence Coffey and Nettie Jean Sapp, died before the case was filed, but their estates have not received refunds. (ECF No. 1 ¶¶ 11-17.) Four beneficiaries, Richard Bagnall, Irma Becker, Louis Dziadzia, and Martha Leyanna, have died since the case began, and again their estates have not received refunds. (ECF Nos. 86; 152; 192.) The three remaining Medicare beneficiaries named in this case, Charles Holt, Loretta Jackson, Sarah Mulcahy, are, to the best of the Court's knowledge, still alive and have not received refunds. (ECF No. 192.)

B. Legal Standard

Article III of the U.S. Constitution restricts the power of federal courts to "Cases" and "Controversies." U.S. Const. Art. III. For a plaintiff to have standing under Article III's case-or-controversy requirement, the plaintiff must have suffered an "injury in fact" that is "fairly traceable to the challenged action of the defendant" and "it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan v. Defs. of Wildlife,* 504 U.S. 555, 560–61 (1992) (citations, quotation marks, and alterations omitted). Standing is assessed at the time the suit is commenced. *Id.* at 570, n.5. In addition, it is "not enough that a dispute was very much alive when suit was filed; the parties must continue to have a personal stake in the ultimate disposition of the lawsuit." *Chafin v. Chafin*, 133 S. Ct. 1017, 1023 (2013) (citation and quotation marks omitted). A claim generally becomes moot when subsequent events eliminate the controversy between the parties: "when the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome." *Id.* (citation and quotation marks omitted).

C. Discussion

First, for the Medicare beneficiaries who had passed away before the litigation began and have not received refunds, their estate representatives have standing to pursue claims for damages and prospective relief. To establish Article III standing for a claim of prospective relief, the "threatened injury must be certainly impending… allegations of possible future injury are not sufficient." *Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1147 (2013) (citation, quotation marks, and alterations omitted). The Secretary argues that these plaintiffs do not have standing because it is too speculative to imagine that they will be hospitalized or placed incorrectly on observation status in the future. However, this argument misunderstands the nature of the case. Plaintiffs are seeking not a change in how hospitals make admission decisions, but rather an administrative process to appeal those decisions. (*See, e.g.* ECF No. 1 at 28-29 (prayer for relief seeking, among other things, an injunction "ordering defendant… to establish a procedure for administrative review of a decision to place a Medicare beneficiary on observation status, including the right to expedited review").) The Medicare beneficiaries' estate representatives are injured by the continuing lack of such an appeals process, which, to this day, is preventing them from requesting and receiving monetary refunds for care that was not covered.

Second, for the Medicare beneficiaries who have passed away since the case began, have been substituted by estate representatives, and have not received refunds, their claims for damages and prospective relief are not moot for much the same reasons. It is generally true that if "the plaintiff dies or ceases to be subject to the condition that caused his deprivation before his request for prospective injunctive relief is resolved, his claims may in some circumstances become moot." *ABN Amro Verzekeringen BV v. Geologistics Americas, Inc.,* 485 F.3d 85, 94 (2d Cir. 2007).

However, here, the estate representatives continue to lack administrative appeal rights, depriving them of their ability to seek a monetary refund.

Finally, while the Medicare beneficiaries who received full refunds may no longer have individual claims in the case, they can still act as putative class representatives. A putative class action does not necessarily become moot when the named plaintiff's personal stake expires, even though the class has not yet been certified or class certification has been denied. *U.S. Parole Comm'n v. Geraghty*, 445 U.S. 388 (1980). For example, the "exception to the mootness doctrine for 'inherently transitory' claims asserted by the named plaintiff(s) in a class action allows such claims to 'relate back' to the time of the filing of the complaint with class allegations." *Salazar v. King*, 822 F.3d 61, 73 (2d Cir. 2016). The inherently transitory exception applies to putative class actions if "(1) it is uncertain that a claim will remain live for any individual who could be named as a plaintiff long enough for a court to certify the class; and (2) there will be a constant class of persons suffering the deprivation complained of in the complaint." *Id.* (citation and quotation marks omitted). "Whether claims are inherently transitory is an inquiry that must be made with reference to the claims of the class as a whole as opposed to any one individual claim for relief." *Amador v. Andrews*, 655 F.3d 89, 100 (2d Cir. 2011).

In *Salazar*, students brought a class action to challenge the Department of Education's refusal to suspend collection of student loans fraudulently incurred on their behalf. Before the class was certified, however, the plaintiffs received loan discharges from the Department of Education. The Second Circuit held that the inherently transitory exception to the mootness doctrine applied because (1) it was uncertain that the court could address the class certification motion before the Department of Education processed the administrative applications, and (2) there were a large number of potential class members who had received the allegedly fraudulent loans. *Salazar*, 822

F.3d at 74. The Second Circuit specifically noted that mootness doctrine "does not require a plaintiff to forgo [administrative] remedies to which she is entitled in order to seek broader remedies" in federal court and that to hold otherwise would cause the court to "acquiesce" in the Department of Education's refusal to suspend collection activities on loans it knows to be fraudulent. *Id.* at 75.

In this case, just as in *Salazar*, the named plaintiffs pursued monetary relief through an administrative process while at the same time pursing this broader action. Just as in *Salazar*, it is uncertain with respect to the "claims of the class as a whole," *Amador*, 655 F.3d at 100, whether Medicare beneficiaries who are placed on observation status will receive refunds from the Secretary before a class is certified. And there is a constant class of Medicare beneficiaries across the country being placed on observation status. Therefore, the inherently transitory exception applies and the named plaintiffs' claims are preserved for purposes of the putative class action.

D. Conclusion

All named plaintiffs had standing at the time the complaint was filed, and no named plaintiff need be terminated due to mootness. The case may proceed on the merits.

IV. CROSS-MOTIONS FOR SUMMARY JUDGMENT

The parties have filed cross-motions for summary judgment on the second prong of the due process analysis: whether Medicare beneficiaries have a protected property interest in inpatient status.

A. Undisputed Facts

The following undisputed facts are taken from the parties' Local Rule 56(a) Statements and the documents cited therein, including statutes and CMS's Medicare Benefit Policy Manual ("Policy Manual"). *See* Defendant's Local Rule 56(a)(1) Statement, ECF No. 160-2; Plaintiffs'

Local Rule 56(a)(2) Statement, ECF No. 163-1; Plaintiffs' Local Rule 56(a)(1) Statement, ECF No. 164-1; Defendant's Local Rule 56(a)(2) Statement, ECF No. 176-1. Disputed facts are discussed in Section IV.C where relevant.

1. Official Policy on Inpatient vs. Observation Status

When Medicare beneficiaries are admitted to a hospital as "inpatients," they are eligible for coverage under Medicare Part A. 42 U.S.C. § 1395d. When they are placed in "observation status," however, they are considered to be "outpatients," and their care is covered under Medicare Part B. 42 U.S.C. § 1395k; Policy Manual, Ch. 6 § 20.6(B). Medicare beneficiaries placed in observation and covered under Part B pay more out of pocket for equivalent hospital services than those admitted as inpatients and covered under Part A. 42 U.S.C. §§ 1395e, 1395cc(a)(2)(A). Also, Medicare covers the cost of post-hospital care at a skilled nursing facility only if the individual was classified as an inpatient at the hospital for at least three consecutive days. *Id.* §§ 1395d(a)(2), 1395x(i). In other words, the decision to place on observation status rather than admit as an inpatient has significant financial consequences for the patient. But that decision does *not* affect what treatment or medical services the hospital can provide. (ECF Nos. 164-1 ¶ 6; 176-1 ¶ 6.)

According to the Policy Manual, the decision whether to admit a Medicare beneficiary as an inpatient belongs to the "physician or other practitioner responsible for a patient's care at the hospital" and "the decision to admit a patient is a complex medical judgment." Policy Manual, Ch. 1 § 10.

By contrast, CMS considers the determination as to whether services are properly *billed and paid* as inpatient or outpatient to be a regulatory matter, under the authority of the Secretary. (ECF Nos. 164-1 ¶ 12; 176-1 ¶ 12.) The Policy Manual defines inpatient as "a person who has been admitted to hospital for bed occupancy for purposes of receiving inpatient hospital services."

Policy Manual, Ch. 1 § 10. It defines observation services as "a well-defined set of 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." *Id.*, Ch. 6 § 20.6(A). In October 2013, CMS adopted the Two-Midnight Rule to address "high rates of error for hospital services rendered in a medically-unnecessary setting (*i.e.* inpatient rather than outpatient)." (ECF Nos. 164-1 ¶ 7; 176-1 ¶ 7 (quoting CMS Fact Sheet dated June 7, 2015, ECF No. 164-10 at 2).) The Two-Midnight Rule instructs 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." 42 C.F.R. § 412.3(d)(1). CMS provides an exception to the Two-Midnight Rule for certain medical procedures listed in an annual "inpatient only list." (ECF Nos. 164-1 ¶¶ 14-15; 176-1 ¶¶ 14-15.) Those procedures qualify for Medicare Part A coverage regardless of the expected length of stay. (*Id.* ¶ 15.)

2. Government Review Processes

After hospitals have admitted a Medicare beneficiary as inpatient or placed her on observation status, they submit claims for reimbursement under the Medicare program. (ECF Nos. 160-2 ¶ 11; 163-1 ¶ 11.) Those claims are reviewed by different government contractors and entities, at least some of which use computer programs known as commercial screening tools. (ECF Nos. 164-1 ¶ 22; 176-1 ¶ 22.) The two nationally available commercial screening tools, InterQual and Milliman, analyze patient status using an algorithm that processes objective information from the medical record. (ECF Nos. 164-1 ¶¶ 16, 18; 176-1 ¶¶ 16, 18.) If the government disagrees with the hospitals' decision to admit someone as an inpatient, during either pre- or post-payment review, it does not affect the original patient directly—instead, the hospitals

are left to cover the financial difference. Plaintiffs claim (and the Secretary disputes) that these government review processes pressure hospitals to use commercial screening tools in their own patient status determinations by creating financial incentives to shape those determinations around the same criteria used by the governmental claims reviewers.

The first level of review is done by Medicare Administrative Contractors ("MACs"), which are engaged by CMS to process and pay claims submitted by hospitals for Medicare reimbursement. (ECF Nos. 160-2 ¶ 11; 163-1 ¶ 11.) Both before and after payment, the MACs review hospitals' inpatient claims to evaluate whether they meet Medicare's standards. (ECF Nos. 164-1 ¶¶ 26, 28; 176-1 ¶¶ 26, 28.) MACs use commercial screening tools in their reviews, but cannot reject claims solely on the basis of screening tool results; instead, MAC reviewers must apply their own clinical judgment. (ECF Nos. 160-2 ¶¶ 17-18, 20; 163-1 ¶¶ 17-18, 20; 164-1 ¶¶ 14, 22; 176-1 ¶¶ 14, 22.). In practice, all MACs use either InterQual or Milliman, or both. (ECF Nos. 164-1 ¶ 22; 176-1 ¶ 22.) The treating physician's order plays a "role" in the review, but is not dispositive or even presumed to be correct. (*Id.* ¶ 66.) MACs also work to educate hospital staff on the process for making inpatient vs. observation determinations, including through web postings, "exit conferences" after a post-payment audit, an online program called "Medicare University," and telephone calls, which at least occasionally reference the use of commercial screening tools. (*Id.* ¶¶ 27, 29, 33, 34, 37.)

Second, CMS engages Recovery Audit Contractors ("RACs") to provide another level of review, performing targeted post-payment audits of the payments that MACs make to hospitals. (ECF Nos. 160-2 ¶ 19; 163-1 ¶ 19.) In fiscal year 2014, RACs "recouped" from hospitals $1.2 billion in improper inpatient claims. (ECF No. 164-21 at 9.) RACs do not, however, review *outpatient* claims to determine whether they should have been paid as inpatient. (ECF Nos. 164-1

¶ 42; 176-1 ¶ 42.) Similar to the MACs, during the time period covered by this litigation, all RACs used either InterQual or Milliman, or both, in their reviews of inpatient hospital claims. (*Id.* ¶ 22.) CMS requires RACs to "use screening tools and disclose their use to the provider community consistent with the requirements in their statements of work." (*Id.* ¶ 21, quoting Medicare Program Integrity Manual, ECF No. 164-19 at 4.) The deposed RACs explained that they use the commercial screening tools to maintain consistency and uniformity of decisions on patient status. (ECF Nos. 164-1 ¶ 24; 176-1 ¶ 24.) One RAC, Performant, stated that if the patient status decision meets the "screening tool's requirements," then inpatient status is appropriate so long as the hospital physician had issued a technically valid order. (*Id.* ¶¶ 49-50.) In other words, Performant did not review the medical record further when claims passed InterQual or Milliman. (ECF Nos. 164-1 ¶ 52; 176-1 ¶ 52.) Another RAC, CGI Federal, Inc., referenced the failure to pass InterQual criteria in letters to hospitals denying their inpatient claims. (*Id.* ¶ 59; ECF No. 164-38.)

Third, the HHS Office of Inspector General audits inpatient hospital claims. (ECF Nos. 164-1 ¶ 123; 176-1 ¶ 123.) The Office of Inspector General, like the RACs, only examines whether inpatient claims should have been outpatient, not vice-versa. (*Id.* ¶ 126.)

3. Hospital Practices

In practice, at the four hospitals deposed in this case, physicians make the initial decision about whether to admit a patient as an inpatient, on the basis of their clinical judgment. (ECF Nos. 160-2 ¶¶ 5-6; 163-1 ¶¶ 5-6.)

That decision is then subject to additional review. As a condition of participating in Medicare, CMS requires hospitals to maintain a "Utilization Review" plan to evaluate the medical necessity of admission decisions. (ECF Nos. 164-1 ¶ 67; 176-1 ¶ 67.) All four hospitals use InterQual in their utilization review process. (*Id.* ¶ 71.) When a treating physician decides to admit

a patient as an inpatient, a nurse then screens the decision using InterQual. (*Id.* ¶ 72.) Backus, Christiana, and Clearwater Hospitals outsource that screening to a private company called Executive Health Resources ("EHR") (*Id.* ¶ 69.) At all four hospitals, if the treating physician has admitted the person as an inpatient and InterQual's "objective inpatient criteria" are met, the doctor's initial decision is "left unchallenged." (*Id.* ¶ 73.) If the criteria are *not* met, the treating physician's initial decision undergoes further review by a separate, non-treating physician. (ECF Nos. 160-2 ¶ 8; 163-1 ¶ 8; 164-1 ¶¶ 73-74; 176-1 ¶¶ 73-74.) The four hospitals also follow a similar process for reviewing the treating physician's decision to place on observation status: InterQual screening, followed, if necessary, by further physician review. (ECF Nos. 164-16 at 5; 164-41 at 3-4, 6-7; 164-42 at 5; 164-43 at 5; 164-44 at 4.)

The parties generally dispute the extent to which the commercial screening tools influence the outcome of the utilization review process, and how the ultimate patient status decision is made when the reviewer and the treating physician disagree. However, it is undisputed that at Christiana Hospital, when the treating physician and the reviewer from EHR disagree about whether a Medicare beneficiary should be admitted as an inpatient, a Medicare contractor called a Quality Improvement Organization ("QIO") makes the final binding determination. (ECF Nos. 164-1 ¶ 76; 176-1 ¶ 76.) The QIO deposed in this case relied in part on InterQual to review hospital inpatient decisions. (*Id.* ¶ 116; ECF Nos. 160-2 ¶ 32; 163-1 ¶ 32.)

4. Individual Plaintiffs' Experiences

As discussed above, the parties have presented evidence about the general practices at four hospitals that treated six of the Medicare beneficiaries in this case: Backus Hospital, which treated Charles Renshaw and Mildred Savage; Christiana Hospital, which treated Martha Leyanna; Clearwater Hospital, which treated Dorothy Goodman; and Dempsey Hospital, which treated

Richard Bagnall and Lawrence Barrows. Plaintiffs have also provided evidence about how this process specifically functioned for three of those individual Medicare beneficiaries: Ms. Goodman, Ms. Leyanna, and Ms. Savage.

Backus Hospital admitted Ms. Savage as an inpatient on September 11, 2011. (ECF Nos. 164-1 ¶ 108; 176-1 ¶ 108.) On September 12, 2011, EHR stated that observation status was appropriate after review by InterQual, and Ms. Savage was changed to observation status. (*Id.*)

Clearwater Hospital admitted Ms. Goodman as an inpatient on January 31, 2014. (*Id.* ¶ 88.) Her treating physician wrote, "I believe this patient does qualify for an inpatient stay. She will be here clearly at least 2 or 3 days as she is slowly mobilized." (*Id.* ¶¶ 89-90; ECF No. 164-50 at 3.) The same day, a physician reviewer from EHR reviewed Ms. Goodman's medical information and stated that Ms. Goodman was appropriate for observation services. (ECF Nos. 164-1 ¶ 91; 176-1 ¶ 91.) Also the same day, an "InterQual Review Summary" was issued, reading: "Patient Name/ID GOODMAN, DOROTHY… Review Status Pending Secondary-Medical… Criteria Status CRITERIA NOT MET." (*Id.* ¶ 96; ECF No. 164-56 at 2.) After further EHR review, on February 2, 2014, Ms. Goodman was changed to observation status. (ECF Nos. 164-1 ¶¶ 94-96; 164-53; 164-56; 176-1 ¶¶ 94-96.)

Christiana Hospital admitted Ms. Leyanna as an inpatient on November 15, 2011. (ECF Nos. 164-1 ¶ 104; 176-1 ¶ 104.) She was changed to observation status after a physician order stated, "I concur with the Utilization Review Committee's determination that this patient's inpatient admission does not meet the hospital's inpatient criteria and agree to change the patient's status to outpatient." (*Id.* ¶ 105; ECF No. 164-60 at 3.) The hospital then discharged Ms. Leyanna and sent her home, but she quickly came back to the hospital. (ECF Nos. 164-1 ¶ 104; 176-1 ¶ 104.) On November 17, 2011, she was re-admitted as an inpatient. (*Id.*) On November 18, 2011,

Ms. Leyanna's daughter called the hospital and an employee noted in the medical record: "Medicare regs explained to her and the possibility of pt being observation. Explained we are awaiting EHR determination at SLR [second-level review]." (*Id.* ¶ 106; ECF No. 164-62 at 7.) Ms. Leyanna was again changed to observation status after the entry of an identical physician order ("I concur with the Utilization Review Committee's determination…."). (ECF Nos. 164-1 ¶ 105; 176-1 ¶ 105; 164-62 at 5.)

Neither the plaintiffs nor the Secretary have provided any evidence specific to the remaining Medicare beneficiaries or the hospitals where they were treated: Irma Becker (Mercy Hospital), Florence Coffey (South Shore Hospital), Louis Dziadzia (Hospital of Saint Rafael), Charles Holt (Milford Memorial Hospital), Loretta Jackson (Santa Rosa Memorial Hospital), Bernice Morse (Middlesex Hospital), Sarah Mulcahy (Manchester Memorial Hospital), and Nettie Jean Sapp (Scott and White Hospital).

B. Legal Standard

Summary judgment is appropriate only when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The "party seeking summary judgment bears the burden of establishing that no genuine issue of material fact exists." *Goenaga v. Mar. of Dimes Birth Defects Found.*, 51 F.3d 14, 18 (2d Cir. 1995). "In moving for summary judgment against a party who will bear the ultimate burden of proof at trial, the movant's burden will be satisfied if he can point to an absence of evidence to support an essential element of the nonmoving party's claim." *Id.* If the moving party carries its burden, "the opposing party must come forward with specific evidence demonstrating the existence of a genuine dispute of material fact." *Brown v. Eli Lilly & Co.*, 654 F.3d 347, 358 (2d Cir. 2011) (citation omitted).

An issue of fact is "material" if "it might affect the outcome of the suit under the governing law." *Konikoff v. Prudential Ins. Co. of America*, 234 F.3d 92, 97 (2d Cir. 2000) (citation and quotation marks omitted). "A dispute regarding a material fact is genuine if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Williams v. Utica Coll. of Syracuse Univ.*, 453 F.3d 112, 116 (2d Cir. 2006) (citation and quotation marks omitted). On summary judgment, a court must "construe the facts in the light most favorable to the nonmoving party and must resolve all ambiguities and draw all reasonable inferences against the movant." *Caronia v. Philip Morris USA, Inc.*, 715 F.3d 417, 427 (2d Cir. 2013) (citation and quotation marks omitted). In this case, both parties have moved for summary judgment.

C. Discussion

Recipients of government benefits, including Medicare, may possess a property interest that is protected by the Due Process Clause of the Fifth Amendment. *See, e.g. Kraemer v. Heckler*, 737 F.2d 214 (2d Cir. 1984) (due process claim based on termination of Medicare benefits). A "mere 'unilateral expectation' of receiving a benefit, however, is not enough; a property interest arises only where one has a 'legitimate claim of entitlement' to the benefit." *Kapps v. Wing*, 404 F.3d 105, 113 (2d Cir. 2015) (quoting *Bd. Of Regents of State Colleges v. Roth*, 408 U.S. 564, 577 (1972)). A legitimate claim of entitlement is created by "placing substantive limitations on official discretion," *Ky. Dep't of Corr. v. Thompson*, 490 U.S. 454, 462 (1989) (citation and quotation marks omitted), or "meaningfully channel[ing] official discretion by mandating a defined administrative outcome." *Sealed v. Sealed*, 332 F.3d 51, 56 (2d Cir. 2003).

Although property interests are most commonly created by statutes, regulations, or other formal policy, they may also "be established through such diverse sources as unwritten common law and informal institutional policies and practices." *Furlong v. Shalala*, 156 F.3d 384, 395 (2d

Cir. 1998). "A person's interest in a benefit is a 'property' interest for due process purposes if there are such rules or mutually explicit understandings that support his claim of entitlement to the benefit and that he may invoke at a hearing." *Perry v. Sindermann*, 408 U.S. 593, 601 (1972). For example, the Supreme Court in *Perry* 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).

In this case, the Court of Appeals held that the plaintiffs could establish a protected property interest if they proved their allegation "that the Secretary—acting through CMS—has effectively established fixed and objective criteria for when to admit Medicare beneficiaries as 'inpatients,' and that, notwithstanding the Medicare Policy Manual's guidance, hospitals apply these criteria when making admissions decisions, rather than relying on the judgment of their treating physicians." *Barrows*, 777 F.3d at 115. On the other hand, "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.*

The Secretary argues that the undisputed fact that a physician makes the initial patient status determination on the basis of clinical judgment is enough to demonstrate that there is no due process property interest at stake. Plaintiffs contend that the collected evidence shows that the *final* patient status determination is made by the hospital using objective criteria, i.e., commercial screening tools, that CMS has effectively set those criteria through various forms of pressure, and that therefore they do have a property interest. The Court disagrees with both positions. The numerous facts that remain in dispute, taken together, are material to the question of whether

"CMS 'meaningfully channels' the discretion of doctors by providing fixed or objective criteria for when patients should be admitted." *Id*. Summary judgment is therefore inappropriate.

1. Role of Commercial Screening Tools at the Hospitals

There is a genuine dispute of material fact about the extent to which Backus, Christiana, Clearwater, and Dempsey hospitals rely on commercial screening tools in their patient status decisions. The parties agree that treating physicians make the *initial* decision about whether to admit someone as an inpatient or place on observation status based on their clinical judgment. (ECF Nos. 160-2 ¶¶ 5-6; 163-1 ¶¶ 5-6.) However, they have widely divergent views of how the ultimate decisions are made—in particular, whether "fixed and objective" criteria in the form of commercial screening tools effectively override the treating physicians' medical judgment.

There is evidence that objective criteria in the form of commercial screening tools are automatically applied to all Medicare beneficiaries who receive hospital treatment, regardless of whether they were initially placed on observation status or admitted as inpatients. For example, a representative of Backus Hospital explained, "once the patient is admitted or placed in observation, that triggers us to do the review. We try to do it as soon as possible no later than 24 hours after the order is placed either to admit or to place in observation. And then the nurse case manager… applies InterQual." (ECF No. 164-16 at 4.) The Backus representative also noted, "we use InterQual… so that we can actually make an objective assessment as to whether or not the patient meets inpatient criteria or not." (*Id.* at 3.) A representative of Dempsey Hospital explained that it uses InterQual whenever someone enters the hospital and conducts periodic reviews throughout the stay, "whether that's inpatient or observation." (ECF No. 160-6 at 13.) Clearwater Hospital's protocol similarly suggests that all patients admitted as inpatients and those placed on observation status are automatically run through InterQual. (ECF No. 164-47 at 2.)

Plaintiffs have also provided evidence that failing InterQual played a substantial, perhaps dispositive, role in the ultimate decision to change a patient's status from inpatient to observation—or at least that the treating physician's judgment was easily set aside. In Ms. Goodman's case, for example, after the treating physician at Clearwater Hospital admitted her as an inpatient, she failed InterQual multiple times. (ECF No. 164-56.) An EHR reviewer stated, "[t]he recommendation for this patient is Outpatient. Although the documentation in the medical record supports a clinical recommendation for inpatient or observation services, *all regulatory requirements have not been met* for this patient." (ECF No. 164-55 at 2-3 (emphasis added).) The treating physician who admitted Ms. Goodman disagreed with the observation status recommendation, but her status was nevertheless changed by a different doctor after she failed InterQual. (ECF No. 164-52.) Conversely, for patients who are initially admitted and then *pass* InterQual, the treating physician's inpatient decision is left in place without any further review. (ECF Nos. 164-1 ¶ 73; 164-40 at 6; 164-47 at 2.) A reasonable factfinder could conclude from this evidence that the commercial screening tool was dispositive: had Ms. Goodman passed InterQual, she would have remained an inpatient; because she failed InterQual, she was changed to observation status. By the same token, the evidence is not so one-sided that a reasonable fact-finder would be compelled to reach this conclusion.

Even for the Medicare beneficiaries initially placed on observation status by their treating physicians, the evidence permits an inference that they *would have been changed to inpatient* had they passed screening tool criteria, possibly without any further review or consultation. Clearwater Hospital's protocol states that "[i]f EHR recommends that a patient be acute (inpatient), not observation, notify the doctor, receive an order to change the patient to acute from observation. Write the order, notify the unit secretary, she will close out the observation chart and admit the

patient to acute from the time the order is written." (ECF No. 164-47 at 2.) At Christiana Hospital, all Medicare patients' information is put into a portal "[w]hen there is a decision to place the patient into observation status or inpatient status" and then EHR conducts a first level review "where the documentation and the record is screened for the appropriateness of that status." (ECF No. 164-41 at 4, 6.)

Finally, plaintiffs have submitted evidence that treating physicians do not typically challenge changing a patient's status from inpatient to observation. Backus and Clearwater hospitals described the utilization review process recommendation, through EHR, as usually followed in practice. (ECF Nos. 164-16 at 10; 164-40 at 20.) As noted, part of that process includes "run[ning] the patient through InterQual." (ECF No. 164-47 at 2.) Clearwater Hospital's protocol instructs nurses to simply call the patient's physician and "*get the ok* to write an order for the change to observation." (*Id.* (emphasis added).) A Backus Hospital representative explained that when Ms. Savage was switched from inpatient to observation, it was likely because a nurse ran her case through InterQual, she didn't meet the criteria, and the nurse "confirmed" with the doctor to change to observation. (ECF No. 164-16 at 17.) When Christiana Hospital twice switched Ms. Leyanna from inpatient to observation status, the physician order used identical language both times—the hospital representative termed this a "standard concurrence." (ECF Nos. 164-41 at 20; 164-60 at 3; 164-62 at 5.)

On the other hand, the Secretary has presented evidence that in cases when a Medicare beneficiary does not meet InterQual criteria, the final decision about whether to change to observation status is still made by a physician on the basis of clinical judgment. For example, a representative of Dempsey Hospital stated that if a patient who is initially admitted as an inpatient does not meet InterQual criteria, "it really falls back to the physician determination," and if the

treating physician still disagrees after further review, the hospital "would defer to the treating physician's determination." (ECF No. 160-6 at 13, 17.) A representative of Clearwater Hospital, when asked whether the hospital would ever submit claims to CMS that EHR did not agree with, responded, "Yes. I don't know that it's ever happened, but, yes, I mean, because our doctors have the final say." (ECF No. 160-9 at 9.) A representative of Backus Hospital stated that the physician advisors from EHR who review cases that fail InterQual, "don't necessarily use criteria, because, again, it's physician judgment." (ECF No. 164-16 at 9; *see also* ECF No. 164-47 at 2 (Clearwater protocol, noting that doctors at EHR "have different criteria [from the InterQual criteria] to use to see if they can qualify the patient for In-patient (acute) or Observation.").) The Backus representative also explained that some treating physicians do disagree with utilization review recommendations: "a lot of the times we find it with our oncology population who tend to, there's a lot of emotion associated with the case… and we have one particular provider who will always disagree." (ECF No. 164-16 at 11.)

2. CMS Influence on Hospital Decision-Making

There is also a genuine dispute of material fact regarding the extent to which CMS actions and policies have shaped hospital decision-making about inpatient admissions. In particular, the parties dispute whether CMS pressures hospitals to apply commercial screening tools and place more patients on observation status.

Plaintiffs have provided evidence that CMS directs its contractors to use commercial screening tools in their reviews and audits. According to CMS's Medicare Program Integrity Manual, "[i]n an effort to identify the claims most likely to contain improper billing, MACs are encouraged to use prepayment and postpayment screening tools or natural language coding software…. MACs have the discretion to post the screening tools in use to their Web site or

otherwise disclose to the provider community." (ECF No. 164-19 at 4.) For certain acute claims, CMS requires MACs to use a screening tool. (ECF No. 164-20 at 3 ("The reviewer shall use a screening tool as part of their medical review of acute IPPS and LTCH claims.").) CMS also reviews samples of MAC determinations "to determine whether or not indeed [the MAC's] determinations were in sync with CMS' guidelines." (ECF No. 164-14 at 29-30.) As for RACs, the Medicare Program Integrity Manual provides that "Recovery Auditors shall use screening tools and disclose their use to the provider community consistent with the requirements in their statements of work." (ECF No. 164-19 at 4.) RACs are required to submit proposed medical review guidelines to CMS for approval. (ECF Nos. 164-1 ¶ 48; 176-1 ¶ 48.) All twelve MACs and RACs engaged by CMS since 2009 use either InterQual or Milliman in their CMS-approved reviews. (ECF No. 164-21 at 3-7.)

Plaintiffs have also provided evidence that government-directed reviews and audits meaningfully channel hospital behavior—even though they do not directly affect Medicare beneficiaries. For example, Christiana Hospital changed its patient admission practices—including by contracting with EHR to review patient admissions—in reaction to RAC denials of their inpatient claims, an Office of Inspector General audit, and changes in the regulatory world. (ECF No. 164-39 at 5-7.) According to a Christiana Hospital representative, the RAC denied their claims because it felt that, "patients really didn't meet inpatient criteria [in "[t]he screening tool and the CMS guideline"] and the care could have been provided in observation status." (*Id.* at 5, 12-15.) The representative estimated that 80% of the denied inpatient claims were based on InterQual. (*Id.*) Christiana Hospital appealed thousands of RAC denials, a "very expensive" process requiring 75% of eight to ten nurses' time. (*Id.* at 14-17.) According to the Christiana Hospital

representative, the message they took from the government reviews was clear—the inpatient vs. observation decision should be based on screening tool criteria, not left to physician discretion:

> Q. What were these weaknesses in the patient admission and admission screening processes?
> ....
> A. The fact that it was at that time considered to be the physician's call on how ill their patient was and what care they needed; not necessarily a screening tool.
> Q. And was that impression mistaken?
> A. Well, not according to us, but according to the reviewers; yes.
> Q. What did the reviewers think?
> A. They felt that there wasn't enough documentation in the chart to qualify the patient for inpatient versus observation.
> Q. Now, you mentioned a screening tool. What did the reviewers say specifically with respect to the screening tool?
> A. If the MAC and the RAC is looking at it as far as reviewers, they basically would look at it that the patient didn't meet all of the criteria that was offered in that tool.
> Q. Any by "tool" you mean the screening guide, like an InterQual or Milliman?
> A. Yes.

(*Id.* at 3-4.) As part of the changes made in response to these reviews, Christiana Hospital tried to "review more of the cases," either through EHR or its own case management group, both of which used InterQual. (*Id.* at 6-8.)

Medicare contractors communicate their use of commercial screening tools to hospitals. Five of the eight MACs engaged by CMS since 2009 disclosed their use of specific screening tools to hospitals, including through one-on-one conversations, webinars, educational events, and on their websites. (ECF No. 164-21 at 3-6.) All RACs engaged by CMS in the same time period also shared their use of commercial screening tools on their websites, through provider outreach, and in review results letters. (*Id.* at 6-7.) One RAC confirmed that it has communicated the importance of commercial screening tools to hospitals. (ECF No. 164-32 at 5.) During "outreach," the RAC tells hospitals that if they submit inpatient claims, and those claims pass an initial screening tool, they will not be subject to further review—in other words, the claims will pass the audit. (*Id.*)

There is also evidence that at least some hospitals believe that screening tools are required for Medicare compliance. According to a Dempsey Hospital representative, "CMS… requires us to use some type of screening. They don't require a particular proprietary type, but they require that we use some type of screening mechanism." (ECF No. 160-6 at 11.) A Clearwater Hospital representative stated, "InterQual is a specific algorithm… it's been approved to meet Medicare and private pay or insurances, their criteria. And so if a patient meets InterQual, it's essentially meeting Blue Cross, Blue Shield, Medicare, their criteria for inpatient." (ECF No. 164-40 at 5.) A Christiana Hospital representative explained that they use InterQual because "it is industry-accepted standards," and when asked, "Why is it important to use an industry-accepted standard when screening patient status determinations?" responded, "You need to have some standard in which to screen that documentation and it is a requirement by Medicare." (ECF No. 160-7 at 5-6.) The MAC deposed in the case agreed that, "Providers' understanding very often was that if a claim met InterQual or Milliman standards, it was automatically considered as compliant with Medicare standards," but noted that this understanding was incorrect. (ECF No. 164-14 at 18.)

CMS's own educational presentation further supports the inference that CMS considers the inpatient vs. outpatient decision to be based on fixed criteria. The presentation explains, "[t]he decision to keep or send home is a clinical decision" whereas "[t]he decision to keep as inpatient or keep as outpatient is a regulatory decision." (ECF No. 164-15 at 13.) Consequently, whereas the first type of decision is "more intuitive, more physician deference," the second (inpatient vs. observation) decision is "[r]elatively prescribed, less physician deference." (*Id.* at 14-15.)

However, there is also evidence that CMS prohibits its contractors from relying exclusively on commercial screening tools (ECF Nos. 160-10 ¶ 7; 160-11 ¶ 5) and that the contractors have similarly cautioned hospitals not to rely on the tools. According to a MAC representative, MACs

actually deny some claims despite their meeting InterQual criteria. (ECF No. 164-14 at 29.) In training sessions, when hospitals asked why this was, the MAC representative "explain[ed] consistently that although that tool was available to them and available to us, it was not a true measurement of whether or not the claim would be paid. It was simply a reference." (*Id.*) Similarly, a MAC "Medicare University" presentation slide read: "CMS recommends the use and application of tools to assist the physician in decision-making; however these programs are tools and the final decision must be based on patient-specific presentation." (ECF No. 164-26 at 4.)

D. Conclusion

These factual disputes, taken together, go to the heart of whether CMS has established objective criteria that hospitals apply in making their inpatient vs. observation status determinations. Thus they "might affect the outcome of the suit under the governing law," *Konikoff*, 234 F.3d at 97 (citation and quotation marks omitted). The cross-motions for summary judgment are therefore denied.

V. MOTION TO DISMISS

The Secretary has filed a motion to dismiss on the first and third prongs of the due process analysis: whether the plaintiffs have plausibly alleged state action, and whether the existing notice and review procedures already provide constitutionally adequate process.

A. Factual Allegations

The allegations in the initial complaint and the first intervenor complaint are set forth fully in this Court's earlier ruling, *Bagnall*, 2013 WL 5346659 at *2-5, described in the Court of Appeals decision, *Barrows*, 777 F.3d at 110-11, and discussed in Section V.C where relevant.

In addition, it is worth summarizing the allegations of the final intervenor plaintiff, Dorothy Goodman, who joined the case after the Court's earlier ruling.[6] Ms. Goodman was 91 years old when she fell, fractured her pelvis, and was hospitalized. (ECF No. 123 ¶¶ 64-65.) On January 31, 2014, an emergency room doctor admitted her as an inpatient, noting "[s]he will be here clearly at least 2 or 3 days as she is slowly mobilized." (*Id.* ¶¶ 65-66.) However, on February 2, 2014, she was changed to observation status. (*Id.* ¶ 77.) This change was allegedly in response to the hospital's utilization review process, namely the recommendation of EHR, where multiple employees, some using the commercial screening tool InterQual, concluded that inpatient admission was not appropriate. (*Id.* ¶¶ 69-77, 93.)

Ms. Goodman received no notification of the switch to observation status while she was in the hospital, and on February 3, 2014, she was transferred to a skilled nursing facility for rehabilitation. (*Id.* ¶¶ 78, 82.) Unbeknownst to Ms. Goodman, because she had been classified as an inpatient for two days and observation status for one day, she did not have the requisite three day inpatient hospital stay to be eligible for Medicare coverage of the skilled nursing care. (*Id.* ¶ 84.) The skilled nursing care cost her $20,000. (*Id.)*

After learning of the lack of coverage, Ms. Goodman's son attempted to challenge the hospital's decision by communicating with the hospital, asking the nursing facility to demand payment from Medicare, speaking to his congressman, complaining to a QIO, and consulting with a CMS regional office and a state Medicare counseling office. (*Id.* ¶¶ 85-94.) These attempts were unsuccessful. (*Id.*) The QIO, for example, stated that it had "no authority" to address the hospital classification, and that its decision was not reviewable. (*Id.* ¶¶ 89, 92.) The CMS and state office

---

[6] Evidence about Ms. Goodman's case is discussed *supra*, Section IV.A, but the Court considers only the allegations in the complaint for purposes of the motion to dismiss.

did not provide Mr. Goodman with any method to challenge the classification. (*Id.* ¶ 94.) Ultimately, he submitted appeals to Medicare using a "Medicare Redetermination Request Form" suggested by his congressman. (*Id.* ¶ 95.) The redetermination was rejected, and Mr. Goodman appealed.[7] (*Id.* ¶ 96-98.)

B. Legal Standard

In the motion to dismiss portion of this ruling, the Court takes the plaintiffs' factual allegations in the complaint "to be true and [draws] all reasonable inferences in" their favor. *Harris v. Mills*, 572 F.3d 66, 71 (2d Cir. 2009). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation and quotation marks omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* A court need not accept legal conclusions as true and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.*

C. Discussion

1. State Action

The Secretary argues that the plaintiffs have failed to plausibly allege state action and therefore have not stated a claim for relief under the Due Process Clause. The Court disagrees.

[7] At the time of the intervenor complaint, the appeal was pending. But according to plaintiffs, Ms. Goodman ultimately did receive a refund for the skilled nursing care, in what they term an "anomalous" decision by an Administrative Law Judge who concluded that because the hospital did not provide notice of the switch to observation, the hospitalization should be considered a qualifying inpatient stay for purposes of coverage of the skilled nursing care. (ECF No. 166 at 4, n.1.)

To satisfy the first prong of the Due Process Clause, plaintiffs must show the challenged activity is "fairly attributable" to the state. *Brentwood Acad. v. Tennessee Secondary Sch. Athletic Ass'n*, 531 U.S. 288, 295 (2001). The Supreme Court has acknowledged that determining state action "is a matter of normative judgment, and the criteria lack rigid simplicity." *Id.* An activity of an ostensibly private individual or organization may be treated as state action when, for example, "it results from the State's exercise of coercive power, when the State provides significant encouragement, either overt or covert, or when a private actor operates as a willful participant in joint activity with the State or its agents." *Id.* at 296 (internal citations and quotation marks omitted). State action also exists when the private entity "is controlled by an agency of the State, when it has been delegated a public function by the State, when it is entwined with governmental policies, or when government is entwined in its management or control." *Id.* (internal citations, quotation marks, and alteration omitted).

To determine state action in the context of government-provided health insurance, the Court must reconcile two controlling decisions. First, in 1982, the Supreme Court held that nursing homes' decisions to discharge or transfer Medicaid beneficiaries did not constitute state action. *Blum v. Yaretsky*, 457 U.S. 991 (1982). At the time of the case, federal regulations required nursing homes to have utilization review committees. *Id.* at 994-95. If a utilization review committee "determine[d] that the patient should be discharged or transferred to a different level of care, either more or less intensive, it [needed to] notify the state agency responsible for administering Medicaid assistance," which then prepared to reduce or terminate payments. *Id.* at 995. The nursing homes were "required to complete patient care assessment forms designed by the State" but the "regulations [did] not require the nursing homes to rely on the forms in making discharge or transfer decisions," which instead were made by private parties on the basis of their medical

judgment. *Id.* at 1008. The government also imposed a range of financial and other penalties on nursing homes that failed "to discharge or transfer patients whose continued stay is inappropriate." *Id.* at 1009. In light of those facts, the Supreme Court held that the nursing homes' transfer and discharge decisions were *not* state action (the utilization review committees' decisions were not at issue at that stage of the case). The Supreme Court reasoned that those nursing home decisions were *not* influenced by the State's obligation to adjust benefits, the State's form-completion requirement, or the State's penalties, which "themselves do not dictate the decision to discharge or transfer." *Id.* at 1005-1010.

Second, in 1984, the Second Circuit *did* find possible state action in utilization review committee decisions that Medicare beneficiaries' admission or continued stay was not medically necessary. *Kraemer*, 737 F.2d at 220 ("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 Second Circuit distinguished *Blum* by explaining that "the only issue remaining before the Supreme Court involved whether there was state action and due process rights with respect to patient transfers *initiated by the health-care facility and its agents*, not those resulting from decisions of [utilization review committees]." *Id.* at 219 (emphasis in original). *Kraemer*, on the other hand, involved "only the determinations of utilization review committees," not "terminations originated by the patients' own doctors or by hospital directors or nursing home administrators." *Id.* Although utilization review committee decisions were not technically made by the Secretary, the Secretary did direct the medical providers to accept adverse utilization review committee decisions unless there was "a clear deficiency" or "fail[ure] to follow the procedures." *Id.* at 220.

Also, "unlike the respondents in *Blum*, the plaintiffs [in *Kraemer*] [*did*] challenge the adjustment of benefits, 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. And unlike in *Blum* (as interpreted by the Second Circuit), there was an issue of material fact as to whether the government had pressured medical providers into terminating Medicare coverage prematurely. *Id.* at 220-21. Specifically, "[s]everal medical providers testified… that administrators, directors of nurses, and utilization review committees are pressured in decisionmaking by the fact that the hospital or nursing home may be held liable for the costs of care retroactively denied coverage." *Id.* at 220.

Putting aside considerations of how the Medicaid and Medicare programs at issue in *Blum* and *Kraemer* actually operated, this Court is bound by *Kraemer*'s interpretation of *Blum* and this case would appear to fall between the scenarios set forth in the two decisions. In this case, plaintiffs allege that *both* the observation status decisions "originated by the patients' own doctors," *see id.* at 219, and the decisions made later, through the utilization review process, constitute state action. *See, e.g.,* ECF No. 1 ¶ 41 (alleging that a "patient who has formally been admitted may be reclassified, while still in the hospital, as an outpatient on observation status by the hospital's utilization review committee"). This case is closer to *Kraemer* than *Blum*, however, in that the plaintiffs are challenging the benefits they receive that flow from the admissions decision, rather than a discharge/transfer order. And most importantly, as the Court of Appeals already discussed, the complaint alleges "that CMS exerts pressure on hospitals through its billing policies and through its retroactive… reviews, which give hospitals the incentive—as a cost-saving or compliance measure—to place more Medicare beneficiaries into 'observation status' for longer periods of time." *Barrows,* 777 F.3d at 114. This is similar to the financial "pressure" from

retroactive coverage denials discussed in *Kraemer*, 737 F.2d at 220, and in contrast to *Blum*, where there was "no suggestion that those decisions were influenced in any degree" by the government. 457 U.S. at 1005.

Drawing reasonable inferences in favor of the plaintiffs, the Court finds that the complaint has plausibly alleged that the inpatient admission decision is the result of "significant encouragement" from the Secretary, through CMS. The Court therefore denies the motion to dismiss on state action grounds.

2. Notice

The parties also dispute whether the existing procedures are constitutionally adequate, beginning with the notice provided. Notice, "like the right to a fair hearing, is a basic requirement of procedural due process…. in the absence of effective notice, the other due process rights afforded a benefits claimant—such as the right to a timely hearing—are rendered fundamentally hollow." *Kapps*, 404 F.3d at 124. The Secretary argues, and the Court agrees, that (1) the plaintiffs lack standing to challenge the content of the notices and (2) their challenge to the timing of the notices is moot because of the NOTICE Act, 42 U.S.C. § 1395cc(a)(1)(Y).

In their initial complaint, the plaintiffs maintained that the Secretary violated the Due Process Clause by failing to provide written notification to Medicare beneficiaries while they are in the hospital "of their placement on observation status, of the consequences of that placement for their Medicare coverage, and of their right to challenge that placement." (ECF No. 1 ¶ 104 (Count Six).) They alleged that "[b]eneficiaries who are placed in observation status do not receive written notification of that status or of the significance of that status while they are in the hospital," and even when they do later receive notice of their status, they are still not informed that they have appeal rights. (*Id.* ¶¶ 42-43.)

First, this Court and the Court of Appeals have previously indicated that the plaintiffs lack standing to challenge the content of the notices. As this Court explained:

> Standing requires that Plaintiffs have suffered an "injury in fact" that is "fairly traceable to the challenged action of the defendant."… Plaintiffs' injuries were not caused by their inability to appeal their initial determinations of benefits. Despite the alleged inadequacy of the notices, each Plaintiff *did* appeal his or her initial determination. Because the conduct complained of—i.e., the alleged inadequacy of the notices—did not cause Plaintiff's injuries, they lack standing to challenge the content of the notices.

Bagnall, 2013 WL 5346659 at *18 (citing *Lujan*, 504 U.S. at 560). The Court of Appeals affirmed this determination, holding that "plaintiffs lack standing to challenge the adequacy of the notices they received." *Barrows*, 777 F.3d at 112. Although these statements were made in the context of the now-dismissed Medicare Act claims,[8] the same logic applies in the due process context. *See also United States v. Quintieri*, 306 F.3d 1217, 1225 (2d Cir. 2002) ("when a court has ruled on an issue, that decision should generally be adhered to by that court in subsequent stages in the same case, unless cogent and compelling reasons militate otherwise." (internal citations and quotation marks omitted)).

Second, the NOTICE Act moots the plaintiffs' claims with regard to expedited notice. In a case for declaratory and injunctive relief, the "voluntary cessation of allegedly illegal activities will usually render a case moot if the defendant can demonstrate that (1) there is no reasonable expectation that the alleged violation will recur and (2) interim relief or events have completely

---

[8] Both this Court and the Court of Appeals proceeded, appropriately, to the merits of the Medicare Act claims regarding the *timing* of the notices. Plaintiffs did have standing to challenge notice timing, as their injuries were "fairly traceable" to the lack of expedited notice of observation status (and the subsequent ability to timely challenge that status). For example, the complaint alleged that Ms. Sapp's family paid $9,200 for skilled nursing facility care not covered by Medicare for nearly two months. (ECF No. 1 ¶ 87.) When her family could no longer afford that care, they moved her to an assisted living facility. (*Id.*) It was not until months later that Ms. Sapp's sister received information from Medicare about how to appeal. (*Id.* ¶ 88.) Ms. Sapp died in the assisted living facility. (*Id.* ¶ 87.)

and irrevocably eradicated the effects of the alleged violation." *Lamar Advert. of Penn, LLC v. Town of Orchard Park*, *N.Y.*, 356 F.3d 365, 375 (2d Cir. 2004) (citation and quotation marks omitted). "[C]onstitutional challenges to statutes are routinely found moot when a statute is amended." *Id.* at 376 (citation and quotation marks omitted).

In this case, the statute and regulations have been amended. The NOTICE Act, effective August 2016, requires hospitals to provide written and oral notice to patients receiving observation services in a hospital for more than 24 hours. 42 U.S.C. § 1395cc(a)(1)(Y). Under the NOTICE Act, written notice must be provided within 36 hours and must explain, "the status of the individual as an outpatient receiving observation services and not as an inpatient of the hospital… the reasons for such status… the implications of such status on services furnished by the hospital… such as implications for cost-sharing requirements under this subchapter and for subsequent eligibility for coverage under this subchapter for services furnished by a skilled nursing facility." *Id.* The final CMS rule became effective on October 1, 2016, and hospitals must begin providing the standardized notice no later than March 8, 2017. The standardized notice has space for an explanation of the observation status placement ("You're a hospital outpatient receiving observation services. You are not an inpatient because:") and includes information on the consequences of observation status for Medicare coverage. 81 Fed. Reg. 57038 (Aug. 22, 2016); *see also* standardized notice, available at Centers for Medicare & Medicaid Services, "Beneficiary Notice Initiative (BNI)," www.cms.gov/Medicare/Medicare-General-Information/BNI (last accessed January 18, 2017).

These changes remedy the lack of expedited notice identified by the plaintiffs in their complaint. Specifically, hospitals must now provide expedited notice of the observation status placement, the reasons for the placement, and its consequences for the Medicare beneficiary.

While the NOTICE Act still does not require hospitals to provide expedited notice of the right to *challenge* the placement, the Secretary correctly notes the standardized notice could not describe appeal rights because no such rights exist. (ECF No. 194 at 5.)

3. Opportunity for Review

Finally, the plaintiffs claim that "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." (ECF No. 1 ¶ 105 (Count Seven).) The Secretary argues that the review procedures already in place are constitutionally adequate to protect any property interests the plaintiffs may have. However, the Court finds this argument far-fetched, as the parties agree there are *no* administrative review procedures for Medicare beneficiaries who seek to challenge their placement on observation status.

Under the *Mathews v. Eldridge* balancing test, to determine the amount of process due, the Court must consider: (1) "the private interest that will be affected by the official action"; (2) "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 (3) "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).

At oral argument, the Secretary conceded that no administrative review process exists for Medicare beneficiaries who seek to challenge their placement on observation status, let alone an expedited process. In addition to the Secretary's own concession, the Court notes that CMS Ruling 1455-R, promulgated in 2013, and the Medicare Appeals Council decisions interpreting that Ruling, stated that Medicare beneficiaries may not appeal their placement on observation status. 78 Fed. Reg. 16632; ECF Nos. 102-1; 164-75. For example, in the case of Louis Dziadzia, the

Medicare Appeals Council held, "[i]n applying the reasoning of CMS Ruling 1455-R, the Council finds that the beneficiary's contention that the hospital should have billed the services provided to him under Medicare Part A is not an appealable issue *by the beneficiary*, as there was never a Part A claim submitted by the hospital." (ECF No. 102-1 at 5 (emphasis in original).) The allegations related to Ms. Goodman, accepted as true, also reflect the lack of a clear existing process. Ms. Goodman's son unsuccessfully attempted to challenge the observation placement by communicating with the hospital and nursing facility, consulting with a CMS regional office and state Medicare counseling office, and complaining to a Medicare contractor. (ECF No. 123 ¶¶ 85-94.) Not until he contacted his congressperson was Ms. Goodman's son able to find an audience for his appeal. (*Id.* ¶¶ 95-98.)

The Secretary argues that the existing process is nevertheless sufficient because "[h]ospitals have the incentive to file such claims, to ensure they are paid for services that they provided to patients. There is no reason to think that a patient's financial interests are not sufficiently protected by a hospital's ability to file a claim for Part B service rendered to the patient." (ECF No. 179 at 19-21.) This contention is not plausible, especially once reasonable inferences are drawn in the plaintiffs' favor.

D. Conclusion

Plaintiffs' notice claim (Count Six) is dismissed on standing and mootness grounds. But Plaintiffs' claim for adequate administrative review procedures (Count Seven) survives, as they have plausibly alleged state action and there is no existing opportunity for review. The Secretary's motion to dismiss is therefore granted in part and denied in part.

VI. CONCLUSION

For the foregoing reasons, the Court DENIES the Secretary's Motion for Summary Judgment (ECF No. 160), DENIES Plaintiffs' Motion for Summary Judgment (ECF No. 166), and GRANTS in part and DENIES in part the Secretary's Motion to Dismiss (ECF No. 160). The parties shall confer and submit a revised Rule 26(f) report within 14 days, including a timeline for completing any further discovery and for any further proceedings.

IT IS SO ORDERED.

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

Dated: Hartford, Connecticut
February 8, 2017