UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CLARIAN HEALTH WEST, LLC, Plaintiff, v. SYLVIA MATHEWS BURWELL, Defendant.	)	Civil Action No. 14-cv-0339 (KBJ)

MEMORANDUM OPINION

The Centers for Medicare and Medicaid Services ("CMS") is the sub-agency within the Department of Health and Human Services ("HHS") that administers the federal health insurance program known as Medicare. In 2012, an agent of CMS informed Plaintiff Clarian Health West, LLC ("Clarian"), an Indiana hospital, that it needed to repay more than $2 million in Medicare reimbursement funds that the hospital had received under the Medicare program, due to a reconciliation process that CMS had performed with respect to certain Medicare payments. Clarian objected to CMS's repayment demand, and filed the instant action against Sylvia Mathews Burwell, the Secretary of HHS, to contest the agency's contentions. Clarian's one-count complaint cites the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–706, and the Medicare statute's review provisions, 42 U.S.C. § 1395oo(f)(1), and asserts that the agency lacks the statutory and regulatory authority to make Clarian repay the money because the regulation that authorizes the reconciliation process ("the 2003 Rule") and the guidelines that implement that rule ("the 2010 guidelines" or "the 2010 manual")

were improperly promulgated and are contrary to the terms of the Medicare statute.

Before this Court at present are the parties' cross-motions for summary judgment. (Pl.'s Mot. for Summ. J. ("Pl.'s Mot."), ECF No. 13; Def.'s Mot. for Summ. J. ("Def.'s Mot."), ECF No. 14.) In its motion, Clarian contends, among other things, that CMS's decision to recoup the $2 million was procedurally defective because the agency failed to employ required notice-and-comment procedures prior to adopting the guidelines that establish the criteria for identifying which hospitals should be subjected to the reconciliation process. (*See* Pl.'s Mem. in Supp. of Pl.'s Mot. ("Pl.'s Mem."), ECF No. 13-1, at 29–36.)[1] The Secretary's cross-motion argues that there is nothing procedurally or substantively improper about the rule that relates to the reconciliation process or its implementation. (*See* Def.'s Mem. in Supp. of Def.'s Mot. ("Def.'s Mem."), ECF No. 14-1, at 24–49.)

Upon consideration of the parties' arguments, this Court agrees with Clarian that the qualifying criteria contained in the implementing manual were the sort of substantive rule that must go through notice-and-comment rulemaking, and on that ground alone, Clarian's motion for summary judgment will be **GRANTED**, and the Secretary's motion for summary judgment will be **DENIED**. A separate order consistent with this opinion will follow.

I. BACKGROUND

A. The Applicable Statutory And Regulatory Framework

The Medicare program "was established in 1965 and provides health care

[1] Page numbers herein refer to those that the Court's electronic case filing system automatically assigns.

coverage for persons age 65 and older, disabled persons, and persons with end stage renal disease who meet certain eligibility requirements." *Allina Health Servs. v. Burwell*, No. 14-cv-1415, 2016 WL 4409181, at *1 (D.D.C. Aug. 17, 2016) (citing 42 U.S.C. §§ 426, 426a). Medicare reimbursements are governed by federal law, and the obtuse text of the Medicare statute has produced much inspired grappling among judges, many of whom have described the legal provisions that govern the Medicare system as a "maze[,]" *Hall v. Sebelius*, 667 F.3d 1293, 1301 n.9 (D.C. Cir. 2012) (Henderson, J., dissenting), a "legislative and regulatory thicket[,]" *Adirondack Med. Ctr. v. Sebelius*, 29 F. Supp. 3d 25, 28 (D.D.C. 2014), *aff'd sub nom. Adirondack Med. Ctr. v. Burwell*, 782 F.3d 707 (D.C. Cir. 2015), and a "labyrinth[,]" *Biloxi Reg'l Med. Ctr. v. Bowen*, 835 F.2d 345, 349 (D.C. Cir. 1987), among other things.[2] The instant lawsuit centers on the government's reimbursement of inpatient hospital care under Medicare Part A, pursuant to which the federal government provides direct reimbursements to healthcare providers to cover the bulk of the expenses that a patient with Medicare insurance (called a "beneficiary") incurs for inpatient hospital care. *See* 42 U.S.C. § 1395d; *see also* Ctrs. for Medicare & Medicaid Servs., Pub. No. 100-01, Medicare General Information, Eligibility, and Entitlement Manual, Ch. 3 §§ 10.2–10.3.

1. Medicare's Prospective Payment System

The complexity of the Medicare scheme is partly due to the intricacies of the prospective payment system that Congress has adopted with respect to Part A

[2] *See also Rehab. Ass'n of Va. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994) (calling the Medicare statute "among the most completely impenetrable texts within human experience"); *Catholic Health Initiatives-Iowa, Corp. v. Sebelius*, 841 F. Supp. 2d 270, 271 (D.D.C. 2012) (inviting the reader to "[p]icture a law written by James Joyce and edited by E.E. Cummings[,]" and remarking that "[s]uch is the Medicare statute"), *rev'd*, 718 F.3d 914 (D.C. Cir. 2013).

reimbursements—a payment system that Congress developed in reaction to the failures of the cost-based payment system that was used when Medicare was first enacted. *See Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 49 (D.C. Cir. 2015). Under the prior regime, hospitals and other health care providers were reimbursed for all "reasonable costs" that the provider incurred in treating beneficiaries, *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 405 (1993), but that cost-based system "deteriorated over time . . . because it provided little incentive for hospitals to keep costs down, as the more they spent, the more they were reimbursed[,]" *Dist. Hosp. Partners*, 786 F.3d at 49 (internal quotation marks and citation omitted); *see also* H.R. Rep. No. 98-25, at 132 (1983), *reprinted in* 1983 U.S.C.C.A.N. 219, 351 (asserting that the cost-based payment system "lack[ed] incentives for efficiency" because the federal government would "simply respond[] to hospital cost increases by providing increased reimbursement"). In 1983, Congress replaced Medicare's cost-based payment system with the prospective payment scheme that has given rise to many legal disputes and that is at the heart of the present action. *See* Social Security Amendments of 1983, Pub. L. No. 98-21, § 601, 97 Stat. 65, 149-63.

Under the prospective payment system, in contrast to the cost-based system, the federal government pays the hospital a set reimbursement amount that is established in advance of the hospital's expenditures and that is generally based upon the government's *ex ante* assessment of what it costs to care for an individual with the Medicare beneficiary's specific diagnosis, regardless of how much the hospital actually spends to care for a beneficiary. *See Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 205 (D.C. Cir. 2011); *see also Dist. Hosp. Partners*, 786 F.3d at 49 (explaining that

prospective payments incentivize hospitals to reduce the cost of inpatient care because any reduction in cost directly profits the hospitals, while increases in the cost of care beyond the predetermined amount are borne by the hospitals rather than the federal government). The prospective payments that hospitals receive for treating Medicare patients are calculated by private health care insurers known as Medicare Administrative Contractors ("MACs") pursuant to a multifactor formula that begins with a "standardized amount," which generally "reflects the average cost incurred by hospitals nationwide for each patient they treat and then discharge." *Cape Cod Hosp.*, 630 F.3d at 205.[3]

In order to ensure that the prospective payment system fairly approximates the actual cost of the care provided, the MACs adjust the standardized amount to account for various factors, including the relative cost of the care associated with different patient diagnoses. *See Dist. Hosp. Partners*, 786 F.3d at 49; *Cape Cod Hosp.*, 630 F.3d at 205. Per the Medicare statute, HHS has classified the care that can be afforded to every type of hospital patient into Diagnosis Related Groups ("DRGs"), *see* 42 U.S.C. § 1395ww(d)(4)(A), and each DRG is weighted in accordance with "the estimated relative cost of hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups[,]" 42 C.F.R. § 412.60(b).[4] This means, for example, that the DRG classification that includes a heart transplant

[3] The standardized amount was initially determined as of 1984, after the prospective payment system came into being; this baseline has been adjusted for inflation each year subsequently. *See Cape Cod Hosp.*, 630 F.3d at 205.

[4] There are other factors that contribute to the calculation of the DRG weight, *see, e.g.*, *Adirondack Med. Ctr. v. Sebelius*, 935 F. Supp. 2d 121, 123–24 (D.D.C. 2013) (describing the need for a budget neutrality adjustment), but these details are not relevant to this case.

will be weighted more heavily than one for a non-invasive procedure—i.e., the "DRG weight" will be greater—because heart surgery uses more resources and imposes higher costs on the hospital. *Cty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1008 (D.C. Cir. 1999). And the greater the DRG weight, the higher the rate of reimbursement; indeed, the DRG weight adjustment is such an important factor in determining the rate of reimbursement under the prospective payment system that the Medicare statute itself refers to reimbursements as the "DRG prospective payment rate." *See, e.g.*, 42 U.S.C. § 1395ww(d)(5)(A)(ii).

Significantly for present purposes, Medicare's prospective payment system not only seems to provide incentives for hospitals to control costs while accounting for the variable care costs that are associated with different patient diagnoses, it also recognizes that the costs of healthcare can sometimes be unpredictable, and that a purely prospective system would unfairly omit reimbursements for the high costs a hospital can incur when a particular beneficiary's care ends up being unduly expensive through no fault of the hospital, as sometimes happens. *See Cty. of Los Angeles*, 192 F.3d at 1009 ("Despite the anticipated virtues of [the prospective payment system], Congress recognized that health-care providers would inevitably care for some patients whose hospitalization would be extraordinarily costly or lengthy."). To prevent hospitals from facing significant losses for providing care to patients in such "outlier" cases—i.e., situations in which the cost of the care provided to a Medicare beneficiary far exceeds the prospective reimbursement rate for a particular diagnosis—Congress authorized HHS to reimburse hospitals for these costs through a system of "outlier payments." *See* 42 U.S.C. § 1395ww(d)(5)(A); H.R. Rep. No. 98-25, at 154, *reprinted*

in 1983 U.S.C.C.A.N. 219, 373. It is the manner in which CMS calculates, assesses, and retroactively reconciles such outlier payments that is at issue in this case.

2. Outlier-Payment Calculations

Section 1395ww(d)(5)(A)(ii) of Title 42 of the U.S. Code permits a hospital to "request additional payments" (above and beyond the standardized payments that are provided pursuant to the prospective payment system) in certain instances, and the statute identifies the particular circumstances under which such a request is warranted. Specifically, per the statute, "[a] hospital is eligible for an outlier payment 'in any case where charges, adjusted to cost, exceed . . . the sum of the applicable DRG prospective payment rate . . . plus a fixed dollar amount determined by the Secretary.'" *Dist. Hosp. Partners*, 786 F.3d at 49 (alterations in original) (quoting 42 U.S.C. § 1395ww(d)(5)(A)(ii)); *see also* 42 U.S.C. § 1395ww(d)(5)(A)(iii) (stating that the amount of the outlier payment "shall be determined by the Secretary and shall . . . approximate the marginal cost of care beyond" the otherwise applicable "cutoff point"). In practice, this statutory command has spawned an "elaborate process" for calculating outlier payments, which involves the intersection of three distinct concepts: (1) charges, adjusted to cost, (2) the outlier threshold, and (3) the marginal cost factor. *Dist. Hosp. Partners*, 786 F.3d at 49.

The "charges, adjusted to cost" figure ensures that the outlier payment reflects the actual cost of the care provided to a beneficiary, and that the government "does not simply reimburse a hospital for the charges reflected on a patient's invoice[.]" *Dist. Hosp. Partners*, 786 F.3d at 50. It is calculated by multiplying two different numbers: the first is the amount that the hospital charged for the service provided to the beneficiary, and the second is the "cost-to-charge ratio," which is "a fraction that

represents the estimated amount that [a hospital] incurs in costs for every dollar that it bills in charges." (Def.'s Mem. at 13.) In other words, the cost-to-charge ratio is "a number representing a hospital's average markup[.]" *Appalachian Reg'l Healthcare, Inc. v. Shalala*, 131 F.3d 1050, 1052 (D.C. Cir. 1997).

The outlier threshold is also a combination of numbers, but the numbers are added rather than multiplied.[5] The first figure is "the applicable DRG prospective payment rate[,]" 42 U.S.C. § 1395ww(d)(5)(A)(ii), which is the payment that the hospital would ordinarily receive under Medicare's reimbursement process for a non-outlier case. The second number is the "fixed loss threshold," which is a fixed amount that the Secretary sets anew each year. *Dist. Hosp. Partners*, 786 F.3d at 50.[6] The fixed loss threshold essentially "acts like an insurance deductible[,]" *id.* (quoting *Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp.*, 582 F.3d 1227, 1229 (11th Cir. 2009)) (internal quotation mark omitted), in that it reflects an amount that the hospital simply has to bear in order to receive any outlier payments.

The final component that factors into the calculation of an outlier payment is the marginal cost factor. This factor represents the "marginal cost" of offering extra care to outlier patients, 42 U.S.C. § 1395ww(d)(5)(A)(iii), and by regulation, this factor is set at 80%, *see* 42 C.F.R. § 412.84(k).

[5] The outlier threshold can include a number of other factors beyond the two discussed here, such as when a hospital has a disproportionate share of low-income patients, *see* 42 U.S.C. § 1395ww(d)(5)(F), or is a teaching hospital, *see id.* § 1395ww(d)(5)(B). Because none of these additional factors are implicated by the present case, discussion of them has been omitted.

[6] The fixed loss threshold is calculated such that outlier payments for the following year will amount to between 5% and 6% of the Medicare system's total aggregate reimbursement. *See* 42 U.S.C. § 1395ww(d)(5)(iv).

Putting these all together, the amount of an outlier payment is determined by taking the cost-adjusted charges (which are determined by multiplying the charge for the outlier treatment by the hospital's cost-to-charge ratio), subtracting the outlier threshold (which is determined by adding the standard reimbursement payment for the services provided and the fixed loss threshold), and multiplying that number by the marginal cost factor (which is always 80%).[7] In a recent opinion, the D.C. Circuit provided a helpful example that explains how this formula works in practice, and also illustrates the fact that outlier payments cover some, but not all, of the costs associated with treating outlier cases:

> Assume that the Secretary sets the fixed loss threshold at $10,000. Assume also that a hospital treats a Medicare patient for a broken bone and that the DRG rate for the treatment is $3,000. The Medicare patient required unusually extensive treatment which caused the hospital to impose $23,000 in cost-adjusted charges. If no other statutory factor is triggered, . . . the hospital is eligible for an outlier payment of $8,000, which is 80% of the difference between its cost-adjusted charges ($23,000) and the outlier threshold ($13,000).

Dist. Hosp. Partners, 786 F.3d at 50–51.

B. The 2003 Rule And The 2010 Implementation

1. The Road To Reconciliation Of Past Outlier Payments

In the early 2000s, many hospitals were attempting to game the outlier-payment process through a sophisticated form of overbilling known as "turbocharging." *See Banner Health v. Burwell*, 126 F. Supp. 3d 28, 48 (D.D.C. 2015). Through the practice of turbocharging, which exploits a tension that arises when the cost-adjusted charges

[7] The following formula generally captures the interaction between these various concepts:

Outlier Payment = (Cost-Adjusted Charges – Outlier Threshold) x Marginal Cost Factor

are calculated, a hospital can generate outlier payments that are significantly greater than would otherwise be expected under the formula discussed above. This can happen because, as explained, the cost-adjusted charges are determined by multiplying the amount the hospital actually charged for a particular type of care by the hospital's cost-to-charge ratio. However, there can be a temporal disconnect between these two numbers, given that the amount charged for a type of care is determined as of the time that the care is provided, while the cost-to-charge ratio is based on the most recently settled cost report, and cost reports can take several years to settle. *See Dist. Hosp. Partners, L.P. v. Sebelius*, 973 F. Supp. 2d 1, 14 (D.D.C. 2014), *aff'd in part, rev'd in part sub nom. Dist. Hosp. Partners*, 786 F.3d 46. Thus, the cost-to-charge ratio that is used for purposes of calculating outlier payments in any given year is based on data that lags behind the hospital's actual cost-to-charge ratio for that year, *see id.*, and a hospital can manipulate the cost-adjusted charge factor in the outlier-payment calculation by drastically increasing the amount that it charges for inpatient care, out of all proportion to the actual increase in costs associated with that care. In other words, when current (heavily inflated) charges are multiplied by an out-of-date (relatively deflated) cost-to-charge ratio, the hospital's cost-adjusted charges figure increases, and the hospital ends up being reimbursed for outlier payments at ever higher rates despite no obvious increase in the quality or cost of care. (*See* Pl.'s Mem. at 15–17.) *See also* Elizabeth A. Weeks, *Gauging the Cost of Loopholes: Health Care Pricing and Medicare Regulation in the Post-Enron Era*, 40 Wake Forest L. Rev. 1215, 1248–50 (2005) (describing this process).[8]

[8] Notably, the outlier-payment system is uniquely susceptible to this kind of manipulation because, as explained above, outlier payments are partially cost-based—i.e., outlier payments reference the amount

By 2003, HHS had discovered that turbocharging practices were widespread among hospitals, and issued a proposed rule regarding a change in the methodology for determining outlier payments partly to address the turbocharging problem. *See* Medicare Program; Proposed Change in Methodology for Determining Payment for Extraordinarily High-Cost Cases (Cost Outlier) Under the Acute Care Hospital Inpatient Prospective Payment System, 68 Fed. Reg. 10,420 (March 5, 2003). The agency received notice and comment, and promulgated the final rule—referred to herein as the "2003 Rule"—on June 9, 2003. *See* Medicare Program; Change in Methodology for Determining Payment for Extraordinarily High-Cost Cases (Cost Outliers) Under the Acute Care Hospital Inpatient and Long-Term Care Hospital Prospective Payment Systems, 68 Fed. Reg. 34,494 (June 9, 2003).

The 2003 Rule revised "the methodology for determining payments for extraordinarily high-cost cases (cost outliers) . . . under the . . . prospective payment system[.]" *Id.* at 34,494. Notably, the 2003 Rule did not alter the underlying formula for calculating outlier payments, but it did include a host of measures designed to combat turbocharging. For example, instead of relying on the most recent settled cost report, the rule provided that a MAC can consider "the most recent *tentative* settled cost report" when determining the applicable cost-to-charge ratio for the following year. *See id.* at 34,499 (emphasis added); *see also* 42 C.F.R. § 412.84.[9] Furthermore, and

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that a hospital *actually* charges for patient care rather than by a predetermined, standardized amount—and cost-based repayment systems tend to incentivize providers to increase the cost of care, unmoored from any improvements in the quality of care being offered. *Cf.* Alice G. Gosfield, Medicare and Medicaid Fraud and Abuse § 1:7 (2014) (describing various types of Medicare fraud and abuse in the context of physician reimbursement, which is governed by a cost-based reimbursement system).

[9] Using the most recent tentative report results in less of a lag time between the cost-to-charge ratio applied to a provider and that provider's actual cost-to-charge ratio.

most relevant to the present case, the 2003 Rule provided for the "reconciliation" of outlier payments after the cost report for the relevant period has been finalized. *See* Change in Methodology, 68 Fed. Reg. at 34,501 ("[W]e proposed to add a provision to our regulations to provide that outlier payments would become subject to reconciliation when hospitals' cost reports are settled."); 42 C.F.R. § 412.84(i)(4) ("[A]ny reconciliation of outlier payments will be based on operating and capital cost-to-charge ratios calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled."). Pursuant to this new reconciliation process, MACs were authorized to revisit outlier payments once a hospital's actual cost-to-charge ratio for a particular year had been determined—despite the fact that the necessary data for making that determination is ordinarily not available until years after the pertinent outlier payments have been disbursed—and to revise outlier payments retroactively.

2. The 2010 CMS Manual And The Qualifying Criteria For Being Subjected To The Outlier Payment Reconciliation Process

The core of Clarian's complaint revolves around the fact that the 2003 Rule only generally authorized the reconciliation process and specified that any reconciliation would be based on the cost and charge data contained in the hospital's final settled cost report, and did *not* proceed to detail how the reconciliation process would operate in practice. *See* 42 C.F.R. § 412.84(i)(4). In fact, in response to a number of comments that asked the agency to set certain "parameters" in order to guide the implementation of the newly authorized reconciliation process, the Secretary expressly acknowledged that the agency would not be addressing the specific circumstances under which reconciliation would be appropriate at the time the rule was promulgated. *See* Change

in Methodology, 68 Fed. Reg. at 34,503. The Secretary made crystal clear that the agency's plan was to issue implementation guidelines at some later point in time, *id.* (stating that HHS "intend[s] to issue a program instruction in the near future . . . [containing] thresholds for fiscal intermediates to reconcile outlier payments for other hospitals during FY 2003") and, in the context of the 2003 Rule, the Secretary's preamble merely mentioned that the agency was "considering" certain thresholds for "cost reporting periods beginning during FY 2004[,]" *id.*

In December of 2010—more than seven years after the 2003 Rule took effect—the HHS finally provided specific standards for MACs to use when administering the reconciliation process: it published instructions for reconciliation in a CMS manual governing Medicare claims processing. *See* Ctrs. for Medicare & Medicaid Servs., Pub. No. 100-04, Medicare Claims Processing Manual, Ch. 3 § 20.1.2.5. Importantly, according to this 2010 manual, a hospital's outlier payments are potentially subject to reconciliation if two criteria are met:

> (1) the provider's "actual operating [cost-to-charge ratio] is found to be plus or minus 10 percentage points from the [cost-to-charge ratio] used [to calculate a provider's] outlier payments," and
>
> (2) the provider's "[t]otal outlier payments in that cost reporting period exceed $500,000."

Id. § 20.1.2.5(A). The manual instructs that a MAC must follow a step-by-step procedure for initiating reconciliation if these two criteria are satisfied. *See id.* ("If the criteria for reconciliation are met, Medicare contractors shall follow the instructions below in § 20.1.2.7."); *see also id.* § 20.1.2.7 (detailing the 14-step reconciliation process). And as part of that process, the MAC must alert the CMS Central Office that the offending hospital has met the reconciliation criteria and provide a bevy of

information about the hospital. *See id.* § 20.1.2.7. If CMS gives the go-ahead, the MAC must then calculate the difference between the original and revised outlier payments, finalize the hospital's cost report, issue a Notice of Program Reimbursement, and "make the necessary adjustment from or to the provider." *Id.* The manual is less clear about what happens if a hospital does *not* meet the reconciliation criteria after the cost report for a given year settles: on the one hand, it suggests that no reconciliation will occur because "the cost report shall be finalized[;]" on the other hand, it notes that "[e]ven if a hospital does not meet the criteria for reconciliation . . . the Medicare contractor has the discretion to request that a hospital's outlier payments . . . be reconciled if the hospital's most recent cost and charge data indicate that the outlier payments to the hospital were significantly inaccurate." *Id.* § 20.1.2.5(A).

Notably, as mentioned, the Secretary's statement in the preamble to the 2003 Rule hinted at the possibility that the agency might eventually adopt these two qualifying criteria for initiating reconciliation, *see* Change in Methodology, 68 Fed. Reg. at 34,503, but these reconciliation standards did not become official agency policy until the 2010 claims processing manual was published. It is undisputed that the 2010 manual was produced without notice or an opportunity for the public to comment on the selected standards, and the manual contains no statement from the agency that sets forth any justification for these particular criteria. The only record evidence regarding the agency's reasoning appears in the preamble to the 2003 Rule, which notes the agency's general view that these thresholds "would appropriately capture those hospitals whose outlier payments will be substantially inaccurate when using the ratio from the contemporaneous cost reporting period." Change in Methodology, 68 Fed. Reg. at

34,503.

C. Instant Facts And Procedural History[10]

Clarian West Medical Center is a 127-bed hospital that is located in Avon, Indiana. (*See* Compl., ECF No. 1, ¶ 8.) Clarian began operating in December of 2004 (*see id.* ¶ 48), and according to the complaint, in its relatively brief existence, Clarian has already been subjected to the whims of the outlier-payment reconciliation process *twice*. The first instance (which Clarian is not challenging in the instant lawsuit) purportedly occurred in 2005; Clarian maintains that its outlier payments for that year should have been—but were not—reconciled, and as a result, the hospital lost out on $1 million in outlier payments. (*See* Compl. ¶¶ 48–49; Pl.'s Mem. at 23–24.)[11] It is the second instance of alleged unfairness with respect to the outlier-payment reconciliation process that is the subject of the instant dispute; specifically, Clarian insists that the agency has improperly identified it as a turbocharger under the criteria laid out in the 2010 manual, and then subjected its outlier payments for the year 2007 to reconciliation, which has wrongly resulted in a recoupment demand of more than $2 million. (*See id.* at 24–25.)

The problem, according to Clarian, was the agency's alleged failure to recognize that the cost-to-charge ratio for new hospitals starts high and inevitably decreases in the

[10] The Secretary has not disputed any of the factual allegations contained in Clarian's complaint and this Court therefore accepts these facts as true for purposes of analyzing the cross-motions for summary judgment. *See Lee v. United States*, 570 F. Supp. 2d 142, 152 (D.D.C. 2008).

[11] Under the 2003 Rule, outlier payments for new hospitals (like Clarian) are calculated according to the statewide average cost-to-charge ratio, rather than the hospital's actual cost-to-charge ratio, because, by its very nature, a brand new hospital has not submitted any cost reports from which a genuine cost-to-charge ratio can be predicted. *See* 42 C.F.R. § 412.84(i)(3). Clarian asserts that if its actual cost-to-charge ratio in 2005 had been considered, then the reconciliation criteria would have been met, and it would have netted an extra $1 million worth of outlier payments for that year as a result of the reconciliation process. (*See* Compl. ¶ 49.)

first few years of operation, not because of turbocharging but because initial hospital operations are inherently costly when evaluated on a per-patient basis. (*See* Compl. ¶ 50.)[12] Per standard practice, the cost-to-charge ratio that was used to calculate Clarian's outlier payments for 2007 was based on Clarian's cost reports from 2005 and 2006; those cost reports necessarily generated a higher cost-to-charge ratio than Clarian's actual (decreased) cost-to-charge ratio for 2007. (*See* Pl.'s Mem. at 24.) Consequently, the MAC that undertook the retrospective evaluation of Clarian's 2007 outlier payment once the cost reports for that year had settled determined that the two qualifying criteria for reconciliation were met, and on March 30, 2012, the MAC informed Clarian that its outlier payments from 2007 were being revised downward to reflect updated information regarding Clarian's actual cost-to-charge ratio for that year. (*See* Compl. ¶ 52.) The upshot of Clarian's claim is that, due to the reconciliation process, the agency demanded that Clarian pay back more than $2.4 million worth of outlier payments that it had received during the period at issue, when, according to Clarian, reconciliation should not have been undertaken in the first place. (*See id.* ¶ 53.)

To challenge the agency's recoupment demand, Clarian appealed the repayment decision to the Provider Reimbursement Review Board ("PRRB"), which is the administrative tribunal that Congress has authorized to review cost-report disputes between MACs and service providers. *See* 42 U.S.C. § 1395oo; 42 C.F.R.

[12] This is apparently because new hospitals see a sharp increase in the "patient utilization rate" in the first few years, which decreases their "per-unit costs[.]" (Compl. ¶ 50; *see* Pl.'s Mem. at 24, 38.) Put another way, all other things being equal, a new hospital with few patients has higher costs per patient than a more established hospital with more patients, and as a hospital gains patients, its average costs decrease even as the amount it charges stays constant, which results in a decrease in its cost-to-charge ratio. (*See* Compl. ¶ 50.)

§§ 405.1835–77. Clarian requested expedited judicial review of the dispute pursuant to 42 U.S.C. § 1395oo(f)(1) (*see* Pl.'s Mem. at 25), and on January 3, 2014, the PRRB permitted expedited judicial review of some of Clarian's arguments, paving the way for the instant action (*see id.*).[13]

Clarian's one-count complaint, which was filed in this Court on March 3, 2014, asserts that "the Secretary's 2012 [reconciliation] determination, and the agency rules governing that determination, are invalid and should be set aside" because they violate the Administrative Procedure Act and the Medicare statute. (Compl. ¶ 58; *see id.* ¶ 60.) Thus, Clarian challenges not only the $2.4 million recoupment demand but also the administrative acts that form the backbone of that repayment determination: the 2003 Rule that authorizes reconciliation and the 2010 guidelines that implement that rule. And Clarian's memorandum of law in support of its motion for summary judgment, which was filed October 10, 2014, clarifies that it seeks to attack these regulatory enactments on three fronts.

First, Clarian argues that the Secretary failed to adhere to the Medicare statute's notice-and-comment rulemaking requirements when the agency adopted the standards

[13] Expedited judicial review permits the PRRB to grant an appellant access to federal court when the PRRB has jurisdiction over an appeal but lacks the authority to decide the controlling question of law. *See* 42 U.S.C. § 1395oo(f)(1); *Three Lower Ctys. Cmty. Health Servs., Inc. v. U.S. Dep't of Health & Human Servs.*, 517 F. Supp. 2d 431, 435 n.4 (D.D.C. 2007), *aff'd*, 317 F. App'x 1 (D.C. Cir. 2009). In this instance, the PRRB decided that it lacked jurisdiction over three of Clarian's claims; as to the other three, including the key claim that the governing reconciliation standards "were not adopted in accordance with the notice and comment rulemaking requirements mandated by the [APA] and Medicare Act" (Administrative Record ("AR"), ECF No. 19, at 10), the PRRB concluded that it possessed jurisdiction but lacked the authority to decide the question of law, and granted Plaintiff's request for expedited judicial review. (*See id.* at 11–12.) When a party challenges the PRRB's determination that it lacks jurisdiction over an issue, the Court "must limit its review to the PRRB's jurisdiction determination" and not reach the merits of the claim. *Eagle Healthcare, Inc. v. Sebelius*, 969 F. Supp. 2d 38, 45 (D.D.C. 2013). However, in this case, the Court addresses only the merits of the claims over which the PRRB granted expedited judicial review, and addressing these claims is sufficient to resolve the case. Therefore, there is no need for this Court to assess whether the PRRB was correct in its determination that it lacked jurisdiction over some of Clarian's claims.

for reconciliation that appear in the 2010 manual. (Pl.'s Mem. at 29–30, 32–33.)[14] Second, Clarian argues that the Secretary's decision to authorize reconciliation for outlier payments in the 2003 Rule was not the product of reasoned decision making, because the Secretary improperly failed to consider a host of factors, including the effect of reconciliation on new hospitals (*id.* at 37–40); the procedures for implementing the reconciliation rules (*id.* at 40–43); and whether the retrospective reconciliation process was justified, given the broader prospective payment scheme (*id.* at 43–45). (*See also id.* at 47–49 (arguing that the Secretary did not have sufficient evidence from which to conclude that retroactively correcting cost-to-charge ratios through reconciliation would actually lead to more accurate outlier payments).) Third, and finally, Clarian argues that, to the extent that the 2003 Rule and the 2010 implementing guidelines permit MACs to recover interest on payments owed as a result of the reconciliation process (*see id.* at 50–53) and transgress certain statute of limitations and beneficiary notification requirements (*see id.* at 33–36), these agency pronouncements are inconsistent with the Medicare statute.

The Secretary filed a cross-motion for summary judgment on October 10, 2014. In that motion, the Secretary argues that the agency fully complied with the procedural requirements of the Medicare statute's notice-and-comment rulemaking provision when it promulgated the 2003 Rule and undertook the 2010 implementation. (*See* Def.'s

[14] Clarian specifically objects to the two qualifying criteria for initiating the reconciliation process that the agency adopted in the 2010 manual (*see* Pl.'s Mem. at 29–35), and it also challenges the Secretary's decision "to use an 'offline' process 'to reprice outlier claims' [and thereby] make[] hospitals subject to retroactive outlier adjustments to prior outlier-payment determinations even after expiration of the four-year reopening period for those determinations" (*id.* at 33). Clarian's attack is procedural in nature, because it maintains that these guidelines for the implementation of the authorized reconciliation process are substantive rules and thus the agency should only have adopted them after undertaking adequate notice-and-comment procedures. (*See id.* at 29–30.)

Mem. at 26–34.) The Secretary further argues that the substance of the 2003 Rule is entirely consistent with the terms of the Medicare statute. In particular, the Secretary contends that there is nothing improper about using an "offline" process for reconciling outlier payments (*id.* at 35–37), or in requiring that interest be paid on all reconciled outlier payments (*id.* at 46–49). Finally, the Secretary defends the 2003 Rule's emphasis on revising bloated cost-to-charge ratios without altering other elements of the outlier-payment formula, and also the fact that it does not exempt new hospitals from the outlier-payment reconciliation process. (*Id.* at 37–42, 44–46.)

This Court held oral argument on the parties' cross-motions for summary judgment on February 10, 2015, and it took the motions under advisement at that time. On March 9, 2015, the Court ordered the parties to submit supplemental briefs on significant questions of law regarding the Medicare statute and the agency conduct at issue here. (*See* Order, ECF No. 20.) Those supplemental briefs became ripe on May 1, 2015. (*See* Pl.'s Supplemental Brief ("Pl.'s Suppl. Br."), ECF No. 21; Def.'s Supplemental Brief ("Def.'s Suppl. Br."), ECF No. 22.)

II. LEGAL STANDARDS

A. Motions For Summary Judgment In APA Cases

"Summary judgment is the proper mechanism for deciding, as a matter of law, whether an agency action is supported by the administrative record and consistent with the APA standard of review." *Hill Dermaceuticals, Inc. v. FDA*, No. 11-cv-1950, 2012 WL 5914516, at *7 (D.D.C. May 18, 2012) (citing *Richard v. INS*, 554 F.2d 1173, 1177 & n.28 (D.C. Cir. 1977)); *see also Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083–84 (D.C. Cir. 2001) (collecting cases). Although, in general, a court will grant

summary judgment "if 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), due to the limited role a court plays in reviewing the administrative record, the typical summary judgment standards set forth in Rule 56(c) are not applicable in APA cases, *see Stuttering Found. of Am. v. Springer*, 498 F. Supp. 2d 203, 207 (D.D.C. 2007). Rather, "[u]nder the APA, it is the role of the agency to resolve factual issues to arrive at a decision that is supported by the administrative record, whereas 'the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.'" *Id.* (quoting *Occidental Eng'g Co. v. INS*, 753 F.2d 766, 769 (9th Cir. 1985)). In other words, "when a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal[,]" and "[t]he 'entire case' on review is a question of law." *Am. Bioscience*, 269 F.3d at 1083 (footnote and citations omitted); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (explaining that a reviewing court cannot "substitute its judgment for that of the agency").

This Court's review of the Secretary's interpretation of the Medicare Act is governed by the familiar two-step test that the Supreme Court adopted in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843–44 (1984). Under that test, a court first determines "whether Congress has directly spoken to the precise question at issue[,]" *id.* at 842; and if not, the court defers to the agency's interpretation so long as it is permissible and reasonable, *see id.* at 843–44. However, when the question posed is whether or not a particular agency enactment should have been subjected to notice-and-comment rulemaking or is exempted from that

requirement, no deference is owed to an agency's characterization of its own rule. *See Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1056 (D.C. Cir. 1987) ("[W]e are not compelled to defer to agency characterizations of rules as [being exempt from notice and comment.]"); *Citizens to Save Spencer Cty. v. U.S. Envtl. Prot. Agency*, 600 F.2d 844, 879 n.171 (D.C. Cir. 1979) ("The . . . characterizations of these rules as interpretive by EPA counsel are of no avail. . . . The label that the particular agency puts upon its given exercise of administrative power is not, for our purposes, conclusive; rather it is what the agency does in fact." (internal quotation marks and citation omitted)).

B. Medicare's Notice-and-Comment Requirements

In the APA, Congress requires that agency policymaking be subjected to notice-and-comment procedures (unless an exemption applies) in order "to reintroduce public participation" and "assure[] that the agency will have before it the facts and information relevant to a particular administrative problem, as well as suggestions for alternative solutions." *Am. Hosp. Ass'n*, 834 F.2d at 1044 (internal quotation marks and citations omitted); *see also id.* (explaining that notice-and-comment requirements instantiate "policy goals of maximum participation and full information"). In the Medicare context, the HHS generally must proceed by notice-and-comment rulemaking, but the notice-and-comment mandate emerges from the Medicare statute itself rather than the APA.[15] Section 1395hh(a)(1) of the Medicare statute authorizes the Secretary to "prescribe such regulations as may be necessary to carry out the administration" of the

[15] Medicare is, in fact, statutorily exempt from the APA's notice-and-comment requirements because those requirements do not apply to "matter[s] relating to . . . benefits[.]" 5 U.S.C. § 553.

Medicare statute, 42 U.S.C. § 1395hh(a)(1), and Section 1395hh(b)(1) states that, "[e]xcept as [otherwise] provided . . . , before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment therein[,]" *id.* § 1395hh(b)(1). The Secretary's rulemaking power encompasses any "rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits[,]" *id.* § 1395hh(a)(2)—a Medicare-related policy pronouncement that falls within this definition and that is not subject to an exemption in the Medicare statute is considered to be a "substantive" rule with respect to which the HHS must provide notice and an opportunity for comment prior to its adoption. *See Allina Health*, 2016 WL 4409181, at *8.

As a general matter, courts use the APA's standards for determining whether or not a particular Medicare rule is a "substantive" one for notice-and-comment purposes. *See Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 814 (D.C. Cir. 2001); *Adirondack Med. Ctr. v. Sebelius*, 935 F. Supp. 2d 121, 130 (D.D.C. 2013). This is because the Medicare statute's notice-and-comment rulemaking requirements are substantially similar to those of the APA; however, the two statutes' notice-and-comment provisions do differ in certain respects, most notably with respect to the recognized exemptions. The APA provides four exemptions to notice-and-comment rulemaking: three under Section 553(b)(A) of Title 5 of the U.S. Code and one under Section 553(b)(B). *See* 5 U.S.C. § 553(b). The three exemptions under Section 553(b)(A) are for interpretive

rules, policy statements, and procedural rules. *See id.* § 553(b)(A).[16] And the APA exemption in Section 553(b)(B) is for situations in which a federal agency finds that notice-and-comment rulemaking would be "impracticable, unnecessary, or contrary to the public interest." *Id.* § 553(b)(B). The D.C. Circuit has cautioned that "Congress intended the exceptions to § 553's notice and comment requirements to be narrow ones[,]" *Am. Hosp. Ass'n*, 834 F.2d at 1044; therefore, rules that do not fit into any one of these four categories are typically deemed "substantive" rules and, as such, must be subjected to notice-and-comment procedures, *see U.S. Telecom Ass'n v. FCC*, 400 F.3d 29, 34 (D.C. Cir. 2005).

The Medicare statute expressly exempts the HHS from notice-and-comment rulemaking in three circumstances: (1) when a statutory provision permits an interim regulation to be issued, *see* 42 U.S.C. § 1395hh(b)(2)(A); (2) when a statutory provision requires that a rule be promulgated within 150 days of the passage of that provision, *see id.* § 1395hh(b)(2)(B); and (3) when the rule at issue would be exempt under the APA's Section 553(b)(B) exemption, *see id.* § 1395hh(b)(2)(C). The Medicare statute thus expressly incorporates only the APA's exemption for situations where notice and comment would be impracticable, unnecessary, or contrary to the public interest, but it does not contain any provision that expressly contains or references the APA's exemptions for interpretive rules, policy statements, and procedural rules. Nevertheless, courts have interpreted the Medicare statute to import the APA's

[16] Although courts sometimes use the term "interpretive rules" as a catchall term to encompass all three exceptions contained in 5 U.S.C. § 553(b)(A), *see, e.g.*, *Cent. Tex. Tel. Co-op., Inc. v. FCC*, 402 F.3d 205, 210 (D.C. Cir. 2005), the instant Memorandum Opinion differentiates between these three different exemptions; the opinion's references to "interpretive rules" are intended to address that exemption alone.

exemption for interpretive rules because one of the Medicare statute's provisions requires that the Secretary publish certain material in the Federal Register and indicates that "manual instructions, *interpretative rules*, statements of policy, and guidelines of general applicability," 42 U.S.C. § 1395hh(c)(1) (emphasis added), may not fit the definition of a "regulation" under Section 1395hh(a)(1). *See Monmouth Med. Ctr.*, 257 F.3d at 814 n.2 ("Although no explicit exception to those requirements is made for 'interpretive rules,' an exception is implicit in the provision for periodic publication for such rules, *see* 42 U.S.C. § 1395hh(c), and courts generally have assumed the exception."). Thus, while the Medicare Act has been interpreted to incorporate the APA's distinction between substantive and interpretive rules, this Court is not aware of any case that squarely holds that the Medicare statute should be read to incorporate the *other* exemptions contained in APA Section 553(b)(A)—i.e., policy statements and procedural rules.

III. ANALYSIS

By pressing a bevy of legal arguments about the agency's reconciliation process and the rules that undergird it, Clarian seeks to challenge the Secretary's decision to recoup from Clarian the $2.4 million that the agency previously provided to the hospital for outlier payments under Medicare's prospective payment system. As explained above, Clarian's opening salvo is its contention that the agency guidelines that establish the criteria for eligibility for reconciliation and other specifics regarding the mechanics of the reconciliation process constitute a substantive rule, and as such, can only be valid if promulgated through notice-and-comment rulemaking, which indisputably did not occur when the Secretary adopted those guidelines in 2010. (*See* Pl.'s Mem. at 29–32.)

If Clarian is right about this threshold issue, then there is no need for this Court to proceed to consider the merits of Clarian's myriad contentions regarding the unlawful and/or improper substance of the guidelines; it can vacate the agency's recoupment decision and remand this matter to the agency simply and solely because of the agency's failure to comply with required notice-and-comment procedures. *See, e.g.*, *Catholic Health Initiatives v. Sebelius*, 617 F.3d 490, 497 (D.C. Cir. 2010); *United Steel, Paper & Forestry, Rubber, Mfg., Energy, Allied Indus. & Serv. Workers Int'l Union v. Fed. Highway Admin.*, 151 F. Supp. 3d 76, 89, 91–92, 94 (D.D.C. 2015). Consequently, the parties have devoted a considerable amount of time and effort to the notice-and-comment inquiry—and have even engaged in a round of supplemental briefing—in an attempt to persuade this Court that the qualifying criteria and other standards regarding the reconciliation process that the Secretary adopted long after promulgating the reconciliation rule are substantive provisions that required notice-and-comment procedures (Clarian's argument), or, alternatively, are the types of enactments that the Medicare statute exempts from notice-and-comment rulemaking (the Secretary's position).[17]

This Court has evaluated the legal standards for characterizing agency guidelines such as those at issue here, and, in particular, the requirement that notice-and-comment

[17] Prior to oral argument on the cross-motions for summary judgment, the Secretary had argued only that the 2010 guidelines qualify as an interpretive rule, and as a result, that it was proper for the agency to adopt them without notice and comment. (*See* Def.'s Mem. at 30–34.) Following oral argument, it became clear that it might also be feasible to consider the 2010 guidelines exempt from notice-and-comment rulemaking as a so-called procedural rule, but only if the Medicare statute, like the APA, contains an exemption for procedural rules. On March 9, 2015, this Court ordered the parties to submit supplemental briefing on two questions related to the applicability of the procedural-rule exemption: first, whether the guidelines for reconciliation established in the 2010 manual fall within the procedural-rule exemption as contained in the APA, and if so, second, whether the procedural-rule exemption is available under the Medicare statute's notice-and-comment provision.

procedures be afforded unless the agency's pronouncement is interpretive, procedural, or otherwise fits into one of the statutory exemptions from notice-and-comment rulemaking. For the reasons explained below, the Court concludes that the qualifying criteria for being subjected to the outlier-payment reconciliation process that the agency adopted in the 2010 manual and applied to Clarian do not qualify as an interpretive rule or a procedural rule (even assuming that there is a procedural-rule exemption in the Medicare statute), and thus, must be deemed a substantive rule that should have been promulgated through notice-and-comment rulemaking. Accordingly, and without characterizing the *other* reconciliation standards that Clarian challenges or reaching the merits of Clarian's arguments regarding the propriety of the policies that the guidelines embody, this Court will grant Clarian's motion for summary judgment and remand this matter to the agency for proceedings consistent with the findings in this opinion.[18]

A. The Qualifying Criteria For Reconciliation That CMS Established In The 2010 Guidelines Are Not Interpretive Rules

1. Interpretive Rules Must Relate To Specific Text In A Statute Or A Regulation

As noted, this Court's determination regarding whether or not the qualifying criteria in the 2010 manual are "substantive" rules involves eliminating the possibility

[18] To be clear, Clarian's notice and comment–based challenge is broader than the Court's holding in this case: Clarian challenges not only the two criteria governing the determination of which hospitals undergo reconciliation but also the rules governing retroactive adjustments to payments following reconciliation (including the use of a so-called "offline" re-pricing process), on the ground that the guidelines did not undergo notice and comment. (*See* Pl.'s Mem. at 32–36.) The Court addresses only the validity of the qualifying criteria, which alone is sufficient to merit judgment for the Plaintiff. *See Catholic Health Initiatives*, 617 F.3d at 494 (declining to reach a plaintiff's various other challenges to an agency's policy where the court determined, as an "antecedent" matter, that the rule was substantive yet did not undergo notice and comment); *cf. PDK Labs. Inc. v. DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004) (Roberts, J., concurring) (stating where there "is a sufficient ground for deciding th[e] case," the "cardinal principle of judicial restraint—if it is not necessary to decide more, it is necessary not to decide more—counsels [the Court] to go no further").

that these guidelines are the type of pronouncement that is exempted from notice-and-comment procedures by statute, because a substantive rule is defined in opposition to the various exemptions. *Cf. Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014) (defining substantive rules as "the category of rules to which the notice and comment requirements do apply"); *U.S. Telecom Ass'n*, 400 F.3d at 34 (same). Put another way, a substantive rule is any rule that is *not* interpretive, procedural, or otherwise subject to an exemption, and because the statutory exemptions represent a departure from the default notice-and-comment requirement, the D.C. Circuit has instructed that "the various exceptions . . . will be narrowly construed and only reluctantly countenanced." *N.J., Dep't of Envtl. Prot. v. U.S. Envtl. Prot. Agency*, 626 F.2d 1038, 1045 (D.C. Cir. 1980).

Beginning with the Court's consideration of whether the qualifying criteria are interpretive in nature, the Court notes that agency rules are deemed interpretive when the particular promulgation "clarif[ies] a statutory or regulatory term, remind[s] parties of existing statutory or regulatory duties, or merely track[s] preexisting requirements and explain[s] something the statute or regulation already required." *Mendoza*, 754 F.3d at 1021 (internal quotation marks and citation omitted). "To fall within the category of interpretive, the rule must derive a proposition from an existing document whose meaning compels or logically justifies the proposition[,]" and "[t]he substance of the derived proposition must flow fairly from the substance of the existing document." *Catholic Health Initiatives*, 617 F.3d at 494 (internal quotation marks and citation omitted). Courts have warned that "the spectrum between a clearly interpretive rule and a clearly substantive one is a hazy continuum," *Am. Hosp. Ass'n*, 834 F.2d at 1045;

consequently, any analysis that seeks to categorize agency action as interpretive or substantive is necessarily "an extraordinarily case-specific endeavor[,]" *id.* There are some guideposts, however; for example, an interpretive rule must be grounded in the specific text of a statute or a regulation. *See Catholic Health Initiatives*, 617 F.3d at 494 ("If the rule cannot fairly be seen as interpreting a statute or a regulation, and if (as here) it is enforced, the rule is not an interpretive rule exempt from notice-and-comment rulemaking." (internal quotation marks and citation omitted)); *Cent. Tex. Tel. Co-op., Inc. v. FCC*, 402 F.3d 205, 212 (D.C. Cir. 2005) ("If, despite an agency's claim, a rule cannot fairly be viewed as interpreting—even incorrectly—a statute or a regulation, the rule is not an interpretive rule exempt from notice-and-comment rulemaking."). Failure to meet this requirement is fatal to the contention that the 2010 guidelines constitute an interpretive rule.

2. The Purported Textual Basis For The Qualifying Criteria Is Too Broad And Attenuated To Render These Guidelines Merely Interpretive

The Secretary's cross-motion for summary judgment suggests only one textual reference point that potentially could support the agency's contention that the qualifying criteria for reconciliation that were adopted in the 2010 manual are interpretive rules: the statement in Section 1395ww(d)(5)(A)(iii) that outlier payments must "'approximate the marginal cost of care beyond' the fixed-loss threshold." (Def.'s Mem. at 30 (quoting 42 U.S.C. § 1395ww(d)(5)(A)(iii)). But under binding precedent, this statutory language is too broad to support the invocation of the interpretive-rule exemption to Medicare's notice-and-comment requirements, and the link between it and the technical details of a reconciliation program is too attenuated. *See Catholic Health*

Initiatives, 617 F.3d at 496; *United Steel, Paper & Forestry, Rubber, Mfg., Energy, Allied Indus. & Serv. Workers Int'l Union*, 151 F. Supp. 3d at 89.

The D.C. Circuit's opinion in *Catholic Health Initiatives v. Sebelius*, 617 F.3d 490 (D.C. Cir. 2010), requires this conclusion. That case involved an agency manual that provided for the reimbursement of a hospital's insurance costs, *see id.* at 491–92, but the relevant statutory and regulatory language said only that the government would reimburse a hospital's "reasonable costs" and left the determination of what costs are "reasonable" to the Secretary, *id.* at 491. The Secretary subsequently determined that insurance costs were in the realm of reasonable costs, and also permitted reimbursement of insurance costs even where those costs were paid to so-called "captive" insurers—i.e., insurers that were actually a wholly owned subsidiary of the hospital—but the agency expressly differentiated between "domestic" captives and "offshore" captives, with insurance costs paid to offshore captives being reimbursable only if those captives satisfied a series of requirements not imposed on domestic captives. *See id.* at 492 (noting that, unlike domestic captives, a covered offshore captive could not invest more than ten percent of its assets in equity securities). Significantly for present purposes, when setting out the additional coverage requirements for offshore captives, the Secretary did not use notice-and-comment rulemaking, *see id.* at 493, and the D.C. Circuit held that the requirements that the agency imposed on offshore captives had to be promulgated through notice-and-comment rulemaking because the requirements were substantive and not interpretive, *see id.* at 497.

Two principles undergirded the Circuit's conclusion in *Catholic Health Initiatives* and are instructive here. First, the panel reasoned that, if the statutory or

regulatory language that is purportedly being interpreted is sufficiently broad, then any attempt by the agency to implement that language would necessarily involve making substantive policy judgments that require notice-and-comment rulemaking. *See id.* at 494–95. In the context of the *Catholic Health Initiatives* case, the Circuit concluded that the statutory term "reasonable cost" was so broad that "the sort of detailed—and rigid—investment code" that the agency imposed when it determined which offshore captives would be covered could not have been derived from an act of interpretation. *Id.* at 496. Second, the *Catholic Health Initiatives* Court noted that, if an interpretive rule imposes "arbitrary" numeric criteria, then it likely reflects a substantive, rather than interpretive, policy judgment. *See id.* at 495-96. By "arbitrary," the Circuit meant numeric criteria that represented just one "choice among [many] methods of implementation[,]" *id.* at 495 (quoting *Hoctor v. U.S. Dep't of Agric.*, 82 F.3d 165, 170 (7th Cir. 1996)) (internal quotation marks omitted), and the panel viewed the manual's requirement that equity securities not exceed ten percent of an offshore captive's assets as precisely the sort of numeric requirement that reflects an agency's substantive policy determination rather than mere interpretation of statutory provisions, *see id.* at 496.

Applying these two principles to the circumstances at issue in the instant case, this Court concludes that the qualifying criteria for the outlier-payment reconciliation process that the agency adopted in the 2010 manual are not merely interpretive of Congress's command that outlier payments must "approximate the marginal cost of care beyond" the fixed-loss threshold. 42 U.S.C. § 1395ww(d)(5)(A)(iii). This is so because the statutory phrase "marginal cost of care"—much like "reasonable cost"—is quite broad and does not, on its own, suggest any particular application. Furthermore,

as the complicated nature of the outlier-payment formula demonstrates, giving effect to that term requires a series of interlocking policy and technical considerations, *see Dist. Hosp. Partners*, 786 F.3d at 49–51, which means that the Secretary's identification and adoption of the two qualifying criteria inherently involved the sort of "reasonable but arbitrary . . . choice among methods" that the D.C. Circuit found to be substantive in *Catholic Health Initiatives*. 617 F.3d at 495 (quoting *Hoctor*, 82 F.3d at 170). The numeric thresholds that the agency has selected also plainly reflect an arbitrary policy determination, because nothing in the language of "marginal cost of care" suggests that a ten percent change in cost-to-charge ratios should trigger the reconciliation process, as opposed to a five percent or fifteen percent change. And however solid the Secretary's reasons for adopting those specific numeric requirements might have been, the fact that the agency's policy choice is supported and justified does not make its decision merely interpretive (i.e., less substantive).

The Secretary objects to this conclusion on a number of grounds, none of which succeeds. Starting with the most sweeping contention, the agency argues that the qualifying criteria must be deemed interpretive rules simply and solely because they are set forth in CMS instruction manuals. (*See* Def.'s Reply, ECF No. 18, at 12–13 ("Courts construing [Medicare Provider Reimbursement Manual] provisions have concluded that they are interpretive rules and do not require notice and comment rulemaking." (internal quotation marks and citation omitted).) The D.C. Circuit's *Catholic Health Initiatives* case belies this contention; the provisions under review in that case were contained in a CMS manual and were nevertheless found to be substantive, not interpretive. *See Catholic Health Initiatives*, 617 F.3d at 497.

Undaunted, the Secretary further insists that the qualifying criteria and other, similar manual instructions provide "technical details of issues such as calculation methodologies" in order "to help intermediaries and providers better understand the regulations" and are exempt from Medicare's notice-and-comment requirements on *that* basis as well. (Def.'s Mem. at 31 (internal quotation marks and citations omitted)). Even if this is an accurate statement regarding the agency's intentions, it does not help the Secretary, because the particular criteria that Clarian challenges are much more than mere "technical details"—they reflect substantive policy decisions, as explained further below. *See infra* Part III.C. Moreover, as discussed above, the two qualifying criteria are not sufficiently grounded in the statutory phrase "marginal cost of care" for them to amount to an implementation of that language, and their seeming consistency with Medicare's outlier-payment provisions and/or the text of the 2003 Rule (*see* Def.'s Mem. at 32–33) is beside the point; it is well established that an agency's well-intentioned efforts to adopt provisions that are consistent with the text of a statute or regulation is not a reason to sidestep Medicare's notice-and-comment requirements if the rule that emerges "is simply too attenuated to represent an interpretation of those terms[,]" *Catholic Health Initiatives*, 617 F.3d at 496.

Finally, the Secretary argues that the qualifying criteria are distinguishable from the reimbursement instructions at issue in *Catholic Health Initiatives* because the investment instructions in *Catholic Health Initiatives* were mandatory whereas the qualifying criteria for the outlier-payment reconciliation process do not necessarily result in reconciliation—in this regard, the agency emphasizes that the CMS manual builds in an extra layer of discretion whereby CMS must approve reconciliation once a

hospital has been shortlisted. (*See* Def.'s Mem. at 33–34.) *See also* Ctrs. for Medicare & Medicaid Servs., Pub. No. 100-04, Medicare Claims Processing Manual, Ch. 3 § 20.1.2.5 (providing that reconciliation of any hospitals that satisfy the qualifying criteria will be "[s]ubject to the approval of the CMS Central Office"). However, the mandatory-versus-discretionary distinction between the investment instructions in *Catholic Health Initiatives* and the qualifying criteria for outlier-payment reconciliation does not bear on the fundamental question of whether the challenged provisions are tied to any reasonably specific statutory or regulatory language, or whether those provisions reflect a substantive policy judgment. In other words, when a rule is plainly not interpretive in light of the ordinary criteria for making this designation, its mandatory or voluntary nature is of no moment. *Cf. Catholic Health Initiatives*, 617 F.3d at 494–97 (holding that the agency instruction is a substantive rule without reference to its mandatory nature). Thus, in this Court's view, the difference between the qualifying criteria and the agency instructions in *Catholic Health Initiatives* that the Secretary has identified is not a meaningful one for the purpose of determining whether the former are interpretive rules, and the D.C. Circuit's analysis compels the conclusion that the qualifying criteria cannot be labeled as such.

B. The Medicare Statute Does Not Provide For A Procedural-Rule Exemption And, In Any Event, The Qualifying Criteria Are Not A Procedural Rule

1. There Is No Express Exemption For Procedural Rules In The Medicare Statute And One Cannot Reasonably Be Inferred

Procedural rules are agency provisions that are "primarily directed toward improving the efficient and effective operations of an agency, not toward a determination of the rights [or] interests of affected parties." *Mendoza*, 754 F.3d at

1023 (quoting *Batterton v. Marshall*, 648 F.2d 694, 702 n.34 (D.C. Cir. 1980)) (alteration in original, internal quotation marks omitted). According to the D.C. Circuit, a "prototypical procedural rule" is an agency's determination that it will not search for documents produced after the date of a requester's letter when responding to a FOIA request, *Pub. Citizen v. Dep't of State*, 276 F.3d 634, 641 (D.C. Cir. 2002); but "the distinction between substantive and procedural rules" is not always that clear, *Elec. Privacy Info. Ctr. v. U.S. Dep't of Homeland Sec.*, 653 F.3d 1, 5 (D.C. Cir. 2011), and the difference can be "one of degree depending upon whether the substantive effect is sufficiently grave so that notice and comment are needed to safeguard the policies underlying the APA[,]" *id.* at 5–6 (internal quotation marks and citation omitted). Generally speaking, to determine whether or not a rule qualifies as procedural, courts often inquire into "whether the agency action . . . encodes a substantive value judgment or puts a stamp of approval or disapproval on a given type of behavior." *Am. Hosp. Ass'n*, 834 F.2d at 1047.

As mentioned, the Medicare statute does not contain any express exemption from notice-and-comment rulemaking for procedural rules, unlike the APA. *See* 42 U.S.C. § 1395hh(b)(2). That fact would ordinarily be sufficient to dispose of the issue of the applicability of the procedural-rule exemption to the qualifying criteria for the outlier-payment reconciliation process, but it is at least theoretically possible that an exemption for procedural rules could be read into the Medicare statute just as the exemption for interpretive rules has been. *Cf. Monmouth Med. Ctr.*, 257 F.3d at 814 n.2 (holding that the interpretive-rule exemption exists in the Medicare Act despite its absence from the Act's express exemptions). This Court has reviewed the parties' submissions regarding

this possibility (*see* Order, ECF No. 20; *see also* Pl.'s Suppl. Br., ECF No. 21; Def.'s Suppl. Br., ECF No. 22), and concludes that the language and structure of Medicare's notice-and-comment requirements foreclose any such reading, for several reasons.

First of all, given that the Medicare statute expressly provides for some of the exemptions contained in the APA but not the exemption for procedural rules, *see* 42 U.S.C. § 1395hh(b)(2)(C), the canon *expressio unius est exclusio alterius*—"the expression of one is the exclusion of others[,]" *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 696 (D.C. Cir. 2014)—strongly suggests this Court should treat the exclusion of procedural rules from the list of exemptions to Medicare's notice-and-comment requirement as an intentional policy choice, *see United States v. Vonn*, 535 U.S. 55, 65 (2002) (explaining that, under this canon of interpretation, the legislature's "expressi[ion of] one item of a commonly associated group or series" is considered the intentional "exclu[sion of] another left unmentioned"). Of course, this canon applies only where "it is fair to suppose that Congress considered the unnamed possibility and meant to say no to it[.]" *Marx v. Gen. Revenue Corp.*, 133 S. Ct. 1166, 1175 (2013) (internal quotation marks and citation omitted). And so it is here, because Congress has expressly incorporated into the Medicare statute one of the four express APA exemptions, *see* 42 U.S.C. § 1395hh(b)(2)(C), which makes it entirely plausible that Congress actually considered—and rejected—the possibility of incorporating the APA's *other* exemptions, including the one for procedural rules. *Cf. Council for Urological Interests v. Burwell*, 790 F.3d 212, 221 (D.C. Cir. 2015) ("Congress knew how to permit per-click payments explicitly, suggesting that the omission in this particular context was deliberate."). In addition, the exemptions that Congress expressly included

in Section 1395hh(b)(2) of the Medicare statute are all of a common type—that is, exemptions to notice-and-comment rulemaking—and the procedural-rules exemption is also of that type, which makes application of the *expressio unius* canon even more reasonable. *See Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168 (2003) (asserting that the *expressio unius* canon "has force only when the items expressed are members of an 'associated group or series,' justifying the inference that items not mentioned were excluded by deliberate choice, not inadvertence").

To be sure, the D.C. Circuit has indicated that the *expressio unius* canon has limited utility in the administrative law context. *See Adirondack Med. Ctr.*, 740 F.3d at 697. But it can still be relevant where there are no other reasonable explanations for the exclusion, *see Indep. Ins. Agents of Am., Inc. v. Hawke*, 211 F.3d 638, 644 (D.C. Cir. 2000), and, here, the Secretary has offered none (*see* Def.'s Suppl. Br. at 20–22 (arguing that the procedural-rule exemption should be read into the Medicare statute without providing any rationale for importing this exemption)). Thus, the *expressio unius* canon provides a clear and compelling reason to find that the Medicare statute does not incorporate the APA's procedural-rule exemption.

The text and structure of the Medicare statute also supports the conclusion that there is no procedural-rule exemption in the Medicare context. First, and foremost, Medicare's notice-and-comment provisions are plainly distinguishable from those that appear in the APA, which means that exemption conformity cannot be assumed. *See Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1109 (D.C. Cir. 2014) (noting that the fact "that the Medicare statute is similar to the APA hardly means it is identical"). Moreover, Section 1395hh(b) proceeds in definitive terms, and those terms provide no

indication that any exemptions beyond the three specified in that section are applicable. *See* 42 U.S.C. § 1395hh(b)(1) (stating that notice-and-comment rulemaking shall apply "[e]xcept as provided" by the three enumerated exemptions). And Congress's silence regarding procedural rules is especially telling in light of the fact that the Medicare statute expressly cross-references one of the APA's exemptions, *see* 42 U.S.C. § 1395hh(b)(2)(C); that is, Congress has specified in the clearest possible terms that the APA exemption contained in 5 U.S.C. § 553(b)(B) applies, but says nothing of the exemptions contained in 5 U.S.C. § 553(b)(A). Couple this with the fact that the Medicare statute expressly recognizes that "statements of policy" may not constitute regulations subject to Medicare's notice-and-comment procedures, *see* 42 U.S.C. § 1395hh(c)(1), but makes no such references to the types of non-policy procedural pronouncements that are sometimes needed in order to effectuate the agency's policy statements, and one is left with the distinct impression that the exemptions in Medicare's notice-and-comment procedures were not intended to incorporate procedural rules.

The Secretary is certainly correct to point out that courts have found that certain APA exemptions have been *implicitly* incorporated into the Medicare statute under similar circumstances (*see* Def.'s Suppl. Br. at 21), as this Court acknowledges above. *See, e.g.*, *Vencor Nursing Centers, L.P. v. Shalala*, 63 F. Supp. 2d 1, 11 (D.D.C. 1999) ("The court treats the Medicare Act's exemption for interpretive rules as identical to the APA's."). However, courts have made this finding based on a separate subsection of the Medicare statute that expressly references "*interpretative rules*[.]" 42 U.S.C. § 1395hh(c)(1) (emphasis added); *see Monmouth Med. Ctr.*, 257 F.3d at 814 ("[I]t seems

fair to infer that, as the Medicare Act was drafted after the APA, § 1385hh(c)'s reference to 'interpretive rules' without any further definition adopted an exemption at least similar in scope to that of the APA."); *see also id.* at 814 n.2 ("Although no explicit exception to those requirements is made for 'interpretive rules,' an exception is implicit in the provision for periodic publication for such rules . . . ."). The Secretary has not demonstrated that *procedural* rules are likewise specifically referenced in another provision of the Medicare statute; therefore, this Court doubts that the reasoning that has compelled several courts to infer an exemption for interpretive rules actually supports the conclusion that the Medicare statute has, *sub silentio*, adopted an additional exemption for procedural rules.

The Secretary's suggestion that this Court should infer that a procedural-rule exemption exists in the Medicare context nevertheless, because the D.C. Circuit appears to have done so in *American Hospital Association v. Bowen*, 834 F.2d 1037 (D.C. Cir. 1987), is also unavailing, and it fails for one simple reason: the challenged agency action in the *American Hospital Association* case occurred *before* the passage of the Medicare statute's notice-and-comment provision—at a time when the Secretary had voluntarily adopted the APA's notice-and-comment requirements, including the APA's exemptions. *See* 36 Fed. Reg. 2532 (Feb. 5, 1971) (directing agencies "to utilize the public participation procedures of the APA, 5 U.S.C. 553"); *see also* Timothy Stoltzfus Jost, *Governing Medicare*, 51 Admin. L. Rev. 39, 88 & n.272 (1999). Thus, while it was entirely appropriate for the D.C. Circuit to apply a procedural-rule exemption in the *American Hospital Association* case, that case says nothing about the applicability of a procedural-rule exemption to Medicare's current notice-and-comment provisions.

Nor is this Court persuaded by fact that more recent decisions from this district have relied upon a procedural-rule exemption in the Medicare context. (*See* Def.'s Suppl. Br. at 22 (citing *Sierra-Nevada Mem'l-Miners Hosp., Inc. v. Shalala*, No. 91-cv-2198, 1994 WL 675720, at *4–6 (D.D.C. Nov. 21, 1994); *Beverly Health & Rehab. Servs. v. Thompson*, 223 F. Supp. 2d 73, 99–101 (D.D.C. 2002); and *Gentiva Healthcare Corp. v. Sebelius*, 857 F. Supp. 2d 1, 13 (D.D.C. 2012)).) "[A] decision from another Judge in this District is not controlling authority on this [Court.]" *Carik v. U.S. Dep't of Health & Human Servs.*, 4 F. Supp. 3d 41, 54 n.8 (D.D.C. 2013) (internal quotation marks and citation omitted); *see also Cmty. Health Sys., Inc. v. Burwell*, No. 14-cv-1432, 2015 WL 4104644, at *20 n.22 (D.D.C. July 7, 2015) (noting that, "[w]hile potentially persuasive," other District Court "decisions are not binding"). And it appears that the opinions on which the Secretary relies merely *assumed* the applicability of a procedural-rule exemption to Medicare's notice-and-comment requirement, without specifically analyzing the issue. *See Sierra-Nevada Mem'l-Miners Hosp.*, 1994 WL 675720 at *4; *Beverly Health & Rehab. Servs.*, 223 F. Supp. 2d at 99; *Gentiva Healthcare Corp.*, 857 F. Supp. 2d at 13.

Finally, this Court rejects the Secretary's suggestion that a procedural-rule exemption must necessarily be implied because an agency's ability to develop procedural rules is a "basic tenet of administrative law[.]" (Def.'s Suppl. Br. at 20 (quoting *Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1207 (2015)) (internal quotation marks omitted).) It is no doubt true that an agency must have the capacity to provide for the implementation of the policies it adopts, especially in the APA context, *see* 5 U.S.C. § 553(b)(A), but that is beside the point; what matters for present purposes

is whether Congress intended to excuse the agency from its duty to provide the public with notice of any such procedural command, and an opportunity to comment on it, prior to its adoption. And the fact that a rule is procedural in nature (and thus important to the agency's function) does not, in itself, establish that Congress implicitly desired to permit the agency to forgo the public vetting that it has otherwise prescribed.

2. Even If The Medicare Statute Could Be Read To Contain A Procedural-Rule Exemption, The Qualifying Criteria For Reconciliation Are Not Procedural Rules

The two qualifying criteria for the initiation of the reconciliation process that the Secretary adopted in the 2010 manual—(1) that a hospital's actual cost-to-charge ratio for a given year is "plus or minus 10 percentage points" from the cost-to-charge ratio that was used to calculate the hospital's outlier payments for that year, and (2) that the hospital's "[t]otal outlier payments in that cost reporting period exceed[ed] $500,000[,]" Ctrs. for Medicare & Medicaid Servs., Pub. No. 100-04, Medicare Claims Processing Manual, Ch. 3 § 20.1.2.5(A)—unquestionably "encode[] a substantive value judgment" about the hospital's charges and cost reporting for Medicare reimbursements and "put[] a stamp of . . . disapproval" on the hospitals that are singled out by the rule. *Am. Hosp. Ass'n*, 834 F.2d at 1047. Indeed, according to the Secretary, the entire purpose of the reconciliation process was to prevent the manipulation of outlier payments by nefarious turbochargers, *see* 68 Fed. Reg. at 34,5001 (claiming that reconciliation process was needed to "completely eliminate" the ability of "hospitals to manipulate the system to maximize outlier payments"), and the selected criteria purportedly reflect the agency's substantive judgment regarding how best to "appropriately capture those hospitals whose outlier payments will be substantially inaccurate when using the ratio from the contemporaneous cost reporting period." *Id.* at

34,503. In other words, because the qualifying criteria are the mechanism by which the agency identifies those hospitals that it has deemed potentially worthy of this metaphorical "stamp of . . . disapproval[,]" *Am. Hosp. Ass'n*, 834 F.2d at 1047, the Secretary is hard-pressed to make a convincing argument that the qualifying criteria fall within the category of agency actions that properly can be deemed mere "procedural" rules.

In its supplemental briefing, the agency makes a valiant effort, nevertheless. The Secretary contends, in essence, that the qualifying criteria are procedural for two reasons: first, because they are a "type[] of agency guidance" that merely "provide[s] details as to the operational aspects of reconciliation" (Def.'s Suppl. Br. at 17), and second, because the qualifying criteria are not the final say in determining whether a hospital's outlier payments are reconciled because reconciliation is still subject to the approval of CMS (*see id.* at 16–17). The first argument is belied by the analysis above, and in particular, by this Court's finding that the qualifying criteria initiate the process pursuant to which the agency disgorges prior Medicare payments and thereby visits opprobrium upon a hospital, and insofar as the criteria speak to *which* hospitals may be subjected to this treatment, they represent substantive policy choices on the part of the agency. The Secretary's second contention fails because it is the flip-side of the (misguided) argument that the mandatory nature of a rule makes it less non-substantive, which is an assertion that this Court has already rejected. *See supra* Part III.A.2.

What is more, the D.C. Circuit has already held that agency discretion does not, alone, transform an otherwise substantive rule into a procedural one. In *Electronic Privacy Information Center v. U.S. Dep't of Homeland Sec.*, 653 F.3d 1 (D.C. Cir. 2011), the government sought to defend the introduction of a new type of security-screening machine

at airports without going through notice-and-comment rulemaking, on the ground that "there are no [machines] at some airports and the agency retains the discretion to stop using the scanners where they are in place." *Id*. at 7.[19] The D.C. Circuit rejected this argument, noting that, although the government retained discretion to use the machines or not, "[m]ore clearly significant is that a passenger is bound to comply with whatever screening procedure the TSA is using on the date he is to fly at the airport from which his flight departs." *Id.* In other words, the D.C. Circuit has made clear that the existence of agency discretion to adopt a rule that mandates certain procedures (or not) does not ameliorate the fact that the rule has consequences for those subject to its terms, and this Court finds that principle fully applicable here. That is, although CMS may, in its discretion, decide not to reconcile a hospital's outlier payments despite the fact that the qualifying criteria are satisfied, those criteria have a very real effect on those hospitals that do not receive the benefit of the agency's discretionary determination that reconciliation is not warranted, and thus, the discretionary nature of the challenged criteria is of no moment with respect to the characterization of those agency pronouncements as of the type that requires notice-and-comment rulemaking.

C. The Qualifying Criteria Have The Typical Characteristics Of A Substantive Rule Because They Govern The Scope Of Benefits

Having determined that the qualifying criteria for reconciliation of outlier payments that the Secretary adopted in the 2010 manual are neither interpretive nor procedural as the Secretary claims, and seeing no other exemption in the Medicare statute under which these

[19] The discretion argument that was addressed in the *EPIC* case arose in the context of a dispute about whether the introduction of the screening machine fell within the APA's policy statement exemption, but the circuit panel also addressed the government's attempt to rely on the procedural-rule exemption. *See Elec. Privacy Info. Ctr.*, 653 F.3d at 5–6. Thus, the fact that the rule contemplated agency discretion did not transform it into a procedural rule.

guidelines might fit, this Court has already effectively deemed those criteria substantive. *See Mendoza*, 754 F.3d at 1021; *U.S. Telecom Ass'n*, 400 F.3d at 34. Because courts have also articulated a number of positive characteristics that tend to indicate that a rule is substantive rather than interpretive or procedural, *see, e.g.*, *Mendoza*, 754 F.3d at 1021 (explaining that a rule is likely substantive if it "supplements a statute, adopts a new position inconsistent with existing regulations, or otherwise effects a substantive change in existing law or policy"); *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 95 (D.C. Cir. 1997) (noting that a substantive rule "modifies or adds to a legal norm based on the agency's own authority"), this Court observes additionally that the qualifying criteria in the instant case have at least two quintessential "substantive rule" characteristics.

First, the qualifying criteria for reconciliation of outlier payments clearly effect a change in agency policy. In the Secretary's notice of proposed rulemaking for the 2003 Rule, the Secretary stated that reconciliation was adopted for a singular purpose: "to correct those situations in which hospitals would otherwise receive overpayments for outlier cases due to excessive charge increases." Proposed Change in Methodology, 68 Fed. Reg. at 10,421. The Secretary emphasized the agency's findings regarding the substantial number of hospitals that it deemed guilty of engaging in the practice of drastically increasing charges for care provided to beneficiaries in order to decrease the cost-to-charge ratio, and explained the agency's view that combatting such turbocharging justified the new reconciliation process. *See id.* at 10,428 ("[W]e have identified 123 hospitals that appear to have been most aggressively gaming the current policy."). But the qualifying criteria that the agency subsequently adopted do not plainly distinguish between turbocharging hospitals and those hospitals that experience a significant change in their cost-to-charge ratio for different reasons, as Clarian

asserts. Indeed, the qualifying criteria are such that hospitals whose cost-to-charge ratio *increases* (i.e., the opposite of turbocharging) by 10 percentage points or more, as well as hospitals whose cost-to-charge ratio decreases by that much because of a decrease in costs rather than an increase in charges, are also implicated. The qualifying criteria thus broaden the applicability of the outlier-payment reconciliation process beyond the specific problem of turbocharging, and while that approach may well be justified for reasons of policy and practicality, it clearly represents a substantive departure from the purposes of the reconciliation process that were identified when the 2003 Rule was proposed.

The qualifying criteria also plainly "implicate the policy interests animating notice-and-comment rulemaking." *Elec. Privacy Info. Ctr.*, 653 F.3d at 6. The purpose of notice-and-comment rulemaking is "(1) to reintroduce public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies; and (2) to assure that the agency will have before it the facts and information relevant to a particular administrative problem." *MCI Telecomm. Corp. v. FCC*, 57 F.3d 1136, 1141 (D.C. Cir. 1995) (internal quotation marks and citation omitted); *accord Am. Hosp. Ass'n*, 834 F.2d at 1044. There were a number of public comments that addressed how the reconciliation process would be applied during the 2003 Rule's notice-and-comment period, despite the fact that the notice of proposed rulemaking did not discuss how the reconciliation process would be implemented. *See* Change in Methodology, 68 Fed. Reg. at 34,503 ("Some commenters suggested that we clarify how reconciliation will be implemented and only reconcile outlier payments to those providers whose cost-to-charge ratios increased or decreased outside of certain

parameters."). And not only was there a desire among members of the public to comment on the specific criteria that would subject a hospital to reconciliation, there is also reason to think that subjecting those criteria to notice and comment may have led the agency to a different result. For example, and as noted above, the current qualifying criteria do not take into account fluctuations in the cost-to-charge ratio that are caused by decreasing costs rather than increases in the amount that a hospital charges beneficiaries. According to Clarian, this scenario is common among new hospitals in particular (*see* Pl.'s Mem. at 37–40), and notice-and-comment rulemaking would have allowed the Secretary to respond to these concerns and/or develop a rule that accounted for this circumstance.

Thus, in addition to the fact that the qualifying criteria are neither interpretive nor procedural—which is sufficient to trigger the requirement of notice-and-comment rulemaking standing alone—this Court finds that the criteria also share at least two of the characteristics that courts have established as being indicative of a substantive rule.

IV. CONCLUSION

Clarian has sustained its contention that the qualifying criteria CMS issued to MACs in the 2010 manual, which were used to identify Clarian as a candidate for the outlier-payment reconciliation process, needed to be subjected to notice-and-comment rulemaking prior to their adoption. This is because, for the reasons explained above, the criteria are not sufficiently grounded in any statutory or regulatory text to fall within the interpretive-rule exemption, and the qualifying criteria cannot be construed as a procedural rule, even assuming that the procedural-rule exemption applies in the Medicare context. (The Court concludes herein that it does not.) The inapplicability of

these exemptions means that the qualifying criteria count as a substantive rule, and the fact that the criteria also exhibit the characteristics of substantive rules further reinforces that conclusion.

Accordingly, and as set forth in the accompanying order, Clarian's motion for summary judgment will be **GRANTED**, the Secretary's motion for summary judgment will be **DENIED**, the matter will be **REMANDED** to the Secretary for further proceedings consistent with this opinion.

DATE: August 26, 2016

Ketanji Brown Jackson

KETANJI BROWN JACKSON
United States District Judge