

I. STATUTORY AND REGULATORY BACKGROUND

A. Medicare Payment, Cost Reporting, and Appeals Process

The Medicare program was established to provide health insurance to the elderly and disabled. *See* 42 U.S.C. §§ 1395–1395hh. The Centers for Medicare and Medicaid Services (“CMS”) is the operating component of the Department of Health and Human Services (“HHS”) charged with administering the Medicare program. Part A of Medicare, at issue here, “provides basic protection against the costs of hospital, related post-hospital, home health services, and hospice care” for the elderly. 42 U.S.C. § 1395c.

Hospitals participate in the Medicare program by, among other things, entering into written agreements with the Secretary of HHS to provide hospital services to eligible individuals. 42 U.S.C. § 1395cc. CMS, through a fiscal intermediary or Medicare Administrative Contractor (“Intermediary”), pays hospitals participating in the Medicare program. *See* 42 U.S.C. § 1395ww. A hospital’s claimed costs for services furnished to Medicare beneficiaries are reviewed and subject to audit by the Intermediary acting as an agent of the Secretary. *See* 42 U.S.C. § 1395h. At the end of the fiscal year, the hospital must submit a cost report that indicates the appropriate portion of its operating and capital-related costs that should be allocated to Medicare. *See* 42 C.F.R. § 413.24. This report is then reviewed and is subject to audit by the Intermediary. *See id.* To preserve its appeal rights, a Medicare provider has the right to file its cost report “under protest” when it believes that it is entitled to an amount of Medicare reimbursement that the Intermediary will deny under an interpretation of regulation or policy. *See* 42 C.F.R. § 405.1835(a)(1)(ii); *see also Bethesda Hosp. Ass’n v. Bowen*, 485 U.S. 399, 408 (1988); Medicare Provider Reimbursement Manual (CMS Pub. 15-2) § 115. This requires the Medicare provider to “self-disallow” or “self-adjust” the amounts at issue.

After completion of the Intermediary’s audit, the Intermediary issues a Notice of Program Reimbursement (“NPR”), which informs the hospital of the final determination of its Medicare reimbursement for the cost reporting period—including any positive or negative adjustments—pursuant to the Medicare Act and regulations. *See* 42 C.F.R. § 413.20. If a hospital “is dissatisfied with a final determination of the organization serving as its fiscal intermediary . . . as to the amount of total program reimbursement due the provider for the items and services furnished to individuals for which payment may be made under this title for the period covered by such report,” the hospital has a right to obtain a hearing before the Provider Reimbursement Review Board (“PRRB”) by filing an appeal within 180 days of receiving its NPR. 42 U.S.C. § 1395oo(a)(1)(A)(i). A group of commonly owned hospitals may appeal the same issue to the PRRB as a group appeal. The Secretary, through the Administrator of CMS (“Administrator”), may elect to reverse, affirm, or modify the PRRB’s decision. *See* 42 U.S.C. § 1395oo(f).

Providers “have the right to obtain judicial review of any final decision of the PRRB, or of any reversal, affirmance, or modification by the Secretary, by a civil action commenced within 60 days of the date on which notice of any final decision by the PRRB or of any reversal, affirmance, or modification of the Secretary is received.” 42 U.S.C. § 1395oo(f). If the Administrator declines to review the PRRB’s decision, the providers are entitled to judicial review of the PRRB’s decision. 42 C.F.R. § 405.1877(b)(2).

A provider may seek expedited judicial review—that is, judicial review without a hearing before the PRRB or a decision of the Administrator—if the following three requirements are satisfied: First, the provider must be eligible for a PRRB hearing, meaning that the provider meets the applicable amount-in-controversy and timeliness requirements. Second, there must be no factual issues in dispute. Third, the case must turn on an issue that the PRRB lacks authority

to decide, such as an interpretation of CMS policy. *See* 42 C.F.R. § 405.1842.; *Hunterdon/Somerset 2001 Wage Index Group v. Riverbend Gov't Benefits Adm'r*, PRRB Hearing Dec. No. 2004-D13, Case No. 01-0881GE (Apr. 14, 2004).

B. Acute Care Hospital Prospective Payment System

Since 1983, under 42 U.S.C. § 1395ww(d) the Medicare program has paid for an acute care hospital's operating costs in furnishing inpatient services to Medicare beneficiaries under a prospective payment system ("Inpatient PPS" or "IPPS"), in which payment is made at a predetermined, specific rate for each discharge. *See Washington Hosp. Ctr. v. Bowen*, 795 F.2d 139, 142 (D.C. Cir. 1986). The average stay of all Medicare patients in a general acute care hospital is approximately six days, so the prospective payment system for general acute care hospitals is not designed to reimburse hospitals on a regular basis for long-term hospital care.

C. Long Term Care Hospitals and Hospitals within Hospitals

In contrast to acute care hospitals, in order to qualify as a long term care hospital ("LTCH") for Medicare payment purposes, a hospital must "have an average length of stay of greater than 25 days." 42 C.F.R. § 412.23(e). Medicare reimbursement to LTCHs is based on a prospective payment system ("LTCH PPS"). *See* 42 C.F.R. § 412.500; 42 C.F.R. § 412.1(a)(4). The LTCH PPS system uses diagnosis-related groups ("DRGs") "to classify patient discharges from a long-term care hospital based on clinical characteristics and average resource use, for prospective payment purposes" 42 C.F.R. § 412.503.

LTCHs may operate as hospitals within hospitals ("HwHs"), which are defined as hospitals that occupy space in a building also used by another hospital, or in one or more separate buildings located on the same campus as buildings used by another hospital. 42 C.F.R. § 412.22(e). LTCHs may also operate satellite facilities, which are defined as a part of a hospital

that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital. *See id.* § 412.22(h). A general acute care hospital located in the same building or on the same campus as an LTCH is often referred to as the “host” or “co-located” hospital. *See id.* § 412.22(e).

The co-location of an HwH and its host hospital creates the possibility of inappropriate financial incentives, so CMS requires that an HwH be organizationally and financially independent from its host, as the HwH is not a unit of the host hospital. *See id.* In addition, CMS imposes certain payment limitations on HwHs intended to “diminish the possibility of [an HwH] actually functioning as a unit of an acute care hospital and at the same time generating unwarranted payments” under the more lucrative LTCH PPS system, a situation precluded by statute. 69 Fed. Reg. 48916, 49194 (Aug. 11, 2004); *see also* 42 U.S.C. § 1395ww(d)(1)(B); 69 Fed. Reg. at 49191.

D. May 2004 Proposed Rule and the 25 Percent Policy

Until 2004, CMS had required that HwHs meet at least one of three criteria regarding the performance of basic hospital functions in order to be excluded from IPPS. *See* 42 C.F.R. § 412.22(e)(5) (2004). One of the three criteria directed that at least 75 percent of the admissions to an HwH be referred from a source other than the host hospital. *Id.* at § 412.22(e)(5)(iii). CMS subsequently determined that hospitals were almost never electing to meet the 75 percent requirement of section 412.22(e)(5)(iii), choosing instead to meet one of two other criteria in the regulation. *See* 69 Fed. Reg. at 49192. In doing so, CMS perceived that entities were using “complex arrangements” to subvert the policy intent of the criteria they used, thereby enabling the use of an HwH as simply another unit of its co-located hospital while simultaneously

obtaining Medicare reimbursement under the LTCH PPS system as if the HwH functioned independently. *Id.* at 49193.

Therefore, on May 18, 2004 CMS issued a notice of proposed rulemaking, explaining that it had identified a problem with respect to “incentives to prematurely discharge patients to a postacute care setting in spite of the fact that the acute care hospital could continue to provide the appropriate level of care” and that there existed “significant inducements for patients to be moved to the provider setting that generates the highest Medicare payments.” 69 Fed. Reg. 28196, 28325 (May 18, 2004). More specifically, CMS outlined the policy behind the proposed rule:

[A]n acute care hospital that consistently discharges a higher cost patient to a postacute care setting for the purpose of lowering its costs undercuts the foundation of the IPPS DRG system, which is based on averages. In this circumstance, the hospital would recoup larger payments from the Medicare system than is intended under the DRG system because the course of acute treatment has not been completed. At the same time, the patient, still under active treatment for an acute illness, will be admitted to a LTCH, thereby generating a second admission and Medicare payment that would not have taken place but for the fact of co-location.

Id.

Accordingly, CMS solicited comments on three proposed options, each of which provided that the HwH meet the requirement under § 412.22(e)(5)(iii) that at least 75 percent of its admissions be from a source other than the host hospital, meaning that its admissions from the host could equal no more than 25 percent of its discharges for the cost year. *Id.* at 28326–27. This policy came to be known as the “25 percent policy.” In the proposed rule, CMS stated that it believed any of the three proposed options “would diminish the possibility of a hospital-within-a-hospital actually functioning as a unit of an acute care hospital and at the same time generating unwarranted payments under the more costly LTCH PPS.” *Id.* at 28326. CMS also indicated in the proposed rule that it was

further seeking comments on the options presented if the hospital-within-a-hospital fails to meet the 75-percent criterion that would either require that all of the hospital's Medicare payment would be made under the IPPS or, alternatively, to allow a hospital-within-a-hospital to still be paid as an excluded hospital for its admissions from onsite providers while applying specific payment adjustments for patients admitted from the host hospital.

Id.

E. August 2004 Final Rule

After a comment period, on August 11, 2004, CMS published the final rule adopting the 25 percent policy at 42 C.F.R. § 412.534. CMS explained in the preamble to the final rule that under the new regulation,

if a LTCH HwH or LTCH satellite's admissions from its host hospital exceed 25 percent (or the applicable percentage) of its discharges for the LTCH HwH or LTCH satellite's cost reporting period, an adjusted payment will be made at the lesser of the otherwise payable amount under the LTCH PPS or the amount that would be equivalent to what Medicare would otherwise pay under the IPPS.

69 Fed. Reg. at 49196. In response to comments that CMS had received regarding the proposed rule, the preamble explained that the final rule provided a four-year transition period for existing LTCH HwHs or LTCH satellites to adapt to the requirements of the new policy. *See id.* The preamble stated that for cost reporting periods from October 1, 2004 through September 30, 2005, these hospitals would be "grandfathered, with the first year as a 'hold harmless'" under which grandfathered LTCH HwHs or LTCH satellites would only need to continue to meet the existing separateness criteria at § 412.22(e). *Id.* The agency noted that it was

requiring that even for grandfathered facilities, in the first cost reporting period, the percentage of discharges admitted from the host hospital may not exceed the percentage of discharges admitted from the host hospital in its FY 2004 cost reporting period. Therefore, while we are grandfathering existing LTCH HwHs and allowing for a 4-year transition, beginning on or after October 1, 2004 and before October 1, 2005 (FY 2005), those hospitals may not increase the percentage of discharges admitted from the host in excess of the percentage that they had admitted in FY 2004.

Id. This requirement was articulated two more times in the preamble to the final rule in CMS's response to comments that it had received during the comment period. *See id.* at 49206 (“[W]e are requiring that even for grandfathered facilities, in the first cost reporting period, the percentage of discharges admitted from the host hospital may not exceed the percentage of discharges admitted from the host hospital in its FY 2004 cost reporting period.”); *id.* at 49213 (“We are requiring that even for grandfathered facilities, for cost reporting periods beginning on or after October 1, 2004 and before October 1, 2005, the percentage of discharges admitted from the host hospital may not exceed the percentage of discharges admitted from the host hospital in its FY 2004 cost reporting period.”).

The preamble went on to describe the language of the regulation establishing the three-year transition of the percentage threshold for the payment adjustment that would occur after the “hold harmless” year in FY 2005. In the second year, FY 2006, the percentage of discharges admitted from the host hospital would be the lesser of the percentage admitted in FY 2004 or 75 percent; in the third year, FY 2007, the percentage of discharges admitted from the host hospital would be the lesser of the percentage admitted in FY 2004 or 50 percent; and in the fourth year, FY 2008, the percentage of discharges admitted from the host hospital would be the lesser of that admitted in FY 2004 or 25 percent. *See* 69 Fed. Reg. 48916, 49213–14.

Despite the preamble's clear articulation of the final rule's transition period for implementing the 25 percent policy, the language of the final rule published in the Code of Federal Regulations was inconsistent with the language of the preamble published in the Federal Register. The final rule language regarding the first “hold harmless” year of the transition period for implementing the 25 percent policy merely stated that “[f]or each discharge during the first cost reporting period beginning on or after October 1, 2004 and before October 1, 2005 the

amount paid is the amount payable under this subpart with no adjustment under this § 412.534.”
42 C.F.R. § 412.534 (2004).

F. Correcting Amendment

Four months after the final rule was published, on December 30, 2004 CMS issued a correcting amendment to correct errors in the final rule. 69 Fed. Reg. 78526 (Dec. 30, 2004). In the correcting amendment, CMS stated that although the preamble to the final rule had indicated that the rule would not allow the percentage of discharges admitted by grandfathered facilities from the host hospital to exceed the percentage of discharges that had been admitted from the host hospital in their FY 2004 cost reporting periods, the language of the final rule did not explicitly state this. The agency went on to explain that one of the reasons for issuing the correcting amendment was because CMS

inadvertently omitted from this regulation text that these facilities are required to not exceed the percentage of discharges admitted from the host hospital in its FY 2004 cost reporting period as was indicated in the preamble of the FY 2005 final rule on pages 49213 and 49196. We are revising the wording in paragraph (f)(1) [of 42 C.F.R § 412.534] to include this requirement and thus precisely reflect the policy stated in the preamble by adding “but the hospital may not exceed the percentage of patients admitted from the host during its FY 2004 cost reporting period” to the end of that paragraph.

69 Fed. Reg. at 78527. The text of 42 C.F.R. § 412.534(f)(1) was revised accordingly, and CMS made the amendment effective as of October 1, 2004 “as if [it] had been included correctly in the FY 2005 final rule.” 69 Fed. Reg. at 78526. The public was not offered an opportunity to comment on the language of the correcting amendment.

II. PROCEDURAL HISTORY

Plaintiffs are all Medicare-certified LTCHs that operate as HwHs. *See* Admin. R. [12] at 13. When preparing their fiscal year 2005 cost reports for submission to the Intermediary, each plaintiff self-disallowed the amounts of Medicare reimbursement at issue in their fiscal year

2005 Medicare cost reports to reduce the payment rate from LTCH PPS rates to IPPS rates for each discharge from plaintiffs' LTCHs that were admitted from the host hospital in excess of the percentage of Medicare patients admitted from the host during its fiscal year 2004 cost reporting period. Admin. R. at 22. Plaintiffs filed their cost reports under protest in order to preserve the issue for appeal. *Id.* According to plaintiffs, they were collectively entitled to additional Medicare reimbursement of \$507,401. *See* Admin. R. at 60.

Upon completing its review of plaintiffs' fiscal year 2005 cost reports, the Intermediary finalized the self-disallowances without adjustment and without reimbursing plaintiffs for the amounts in dispute. *Id.* at 22–23. The Intermediary issued NPRs on behalf of CMS to plaintiffs, confirming that no Medicare reimbursement would be made for the disputed amounts. *Id.* at 60. This triggered plaintiffs' right to appeal these protested amounts under 42 C.F.R. § 405.1835.

Plaintiffs then appealed the fiscal year 2005 NPRs to the PRRB. *See* Admin. R. at 308. The issue before the PRRB was whether plaintiffs—LTCHs operating as HwHs or satellite facilities—were subject to a payment adjustment under § 412.534 if their percentage of patients admitted from the host hospitals during the fiscal year 2005 cost reporting period exceeded the percentage of patients admitted from the host hospital during the fiscal year 2004 cost reporting period. Because this issue requires a determination of the validity of an amended regulation, which the PRRB lacks authority to decide pursuant to § 405.1842(f), plaintiffs requested and were granted expedited judicial review. Following the PRRB's grant of expedited judicial review, plaintiffs appealed the disputed Medicare reimbursement amounts by filing a complaint with this Court on June 4, 2010.

III. LEGAL STANDARD

Under Federal Rule of Civil Procedure 56(c), summary judgment is appropriate when the moving party demonstrates that “there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). However, in a case involving review of a final agency action under the Administrative Procedure Act, 5 U.S.C. § 706, the standard set forth in Rule 56(c) does not apply because of the limited role of a court in reviewing the administrative record. *See AFL-CIO v. Chao*, 496 F. Supp. 2d 76, 81 (D.D.C. 2007); *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 89–90 (D.D.C. 2006). Under the APA, the agency’s role is to resolve factual issues to arrive at a decision that is supported by the administrative record, whereas the district court’s function “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.” *Occidental Eng’g Co. v. INS*, 753 F.2d 766, 769–70 (9th Cir. 1985). Summary judgment thus serves as a mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and is otherwise consistent with the APA standard of review. *See Richard v. INS*, 554 F.2d 1173, 1177 & n.28 (D.C. Cir. 1977).

IV. ANALYSIS

Plaintiffs move for summary judgment on their claims that: (1) the correcting amendment violates 5 U.S.C. § 553; (2) the correcting amendment violates the Medicare Act; (3) CMS’s adoption of the correcting amendment is arbitrary, capricious, an abuse of discretion, and not in accordance with law pursuant to 5 U.S.C. § 706(2)(A); and (4) CMS’s decision to amend the final rule is unsupported by substantial evidence pursuant to 5 U.S.C. § 706(2)(E).

Defendants move for summary judgment on the basis of two arguments: (1) CMS’s promulgation of the correcting amendment without another round of notice and comment

rulemaking did not violate 5 U.S.C. § 553 because the particular provision at issue had previously been the subject of notice and comment rulemaking; and (2) the preamble to the final rule that was published in the Federal Register regarding the exception to the grandfather clause during the first year of the transition period to the 25 percent policy was sufficient to bind plaintiffs.

A. CMS did not violate the Notice and Comment Rulemaking Requirements of 5 U.S.C. § 553 and the Medicare Act

Plaintiffs argue that they are entitled to summary judgment on their first and second claims for relief because CMS’s correcting amendment constituted substantive rulemaking without notice and an opportunity for public comment, and thus violated § 553 of the APA and the Medicare Act. Defendant claims that it is entitled to summary judgment on this matter because the provision added to the final rule by the correcting amendment had already been the subject of notice and comment rulemaking.

Under the APA, an agency undergoing informal rulemaking—defined as “agency process for formulating, amending, or repealing a rule”—must first publish notice of the proposed rulemaking in the Federal Register, including a “statement of the time, place, and nature of public rule making proceedings,” a reference to the “legal authority under which the rule is proposed,” and “either the terms or substance of the proposed rule or a description of the subjects and issues involved.” 5 U.S.C. §§ 551(5), 553(b)(1)–(3). After giving the appropriate notice, the agency must give “interested persons” an opportunity to comment on the proposed rule. 5 U.S.C. § 553(c). Then, “[a]fter consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose.” *Id.* Notice and comment is not required when the agency is promulgating “interpretive rules, general

statements of policy, or rules of agency organization, procedure, or practice.” 5 U.S.C. § 553(b)(A). Notice and comment is also not required “when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 553(b)(B).

The Medicare Act places notice and comment requirements on the Secretary’s substantive rulemaking similar to those created by the APA. *See* 42 U.S.C. § 1395hh(b); 5 U.S.C. § 553(b); *Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 814 (D.C. Cir. 2001). In particular, the Medicare Act requires the Secretary to provide notice of a proposed regulation in the Federal Register and a period of at least 60 days for public comment on the proposed regulation before issuing that regulation in final form. 42 U.S.C. § 1395hh(b)(1). That 60 day public comment period is not required where 5 U.S.C. § 553(b)(B) carves out an exception to the notice and comment requirement—that is, “when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 553(b)(B); *see* 42 U.S.C. § 1395hh(b)(2)(C).

CMS does not argue that any of the exceptions to notice and comment rulemaking laid out in 5 U.S.C. § 553(b)(A) and (B) apply here, and in fact explicitly concedes that it did not invoke any of these exceptions when it issued the correcting amendment. Def.’s Reply [26] at 9. Therefore, the question of whether CMS violated the APA and the Medicare Act turns whether the public had sufficient opportunity to comment on the substance of the correcting amendment during the initial comment period before the final rule was promulgated.¹

¹ Plaintiffs cite *Paralyzed Veterans of Am. v. DC Arena LP*, 117F.3d 579, 586 (D.C. Cir. 1997), for the proposition that an agency can only change its interpretation of a regulation through notice and comment rulemaking. *See* Pls.’

A final rule, to be considered validly promulgated, must be a “logical outgrowth” of the proposed rule on which the public had the opportunity to comment. *Health Ins. Ass’n of Am., Inc. v. Shalala*, 23 F.3d 412, 421 (D.C. Cir. 1994). However, it is well established that a final rule need not be identical to the proposed rule. *See Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 546 (D.C. Cir. 1983). “The whole rationale of notice and comment rests on the expectation that the final rules will be somewhat different—and improved—from the rules originally proposed by the agency.” *Trans-Pac. Freight Conf. v. Fed. Mar. Comm’n*, 650 F.2d 1235, 1249 (D.C. Cir. 1980). There is no requirement that an agency “select a final rule from among the precise proposals under consideration during the comment period.” *Sierra Club v. Costle*, 657 F.2d 298, 352 (D.C. Cir. 1981). Nor is it uncommon for a final rule to contain new provisions that are “substantially different” from those in the proposed rule. *See Health Ins. Ass’n of Am.*, 23 F.3d at 421. A standard that required otherwise would obligate an agency to engage in successive rounds of notice and comment any time a final rule differs from what it proposed, greatly impeding and delaying an agency’s ability to address a problem. *See AMA v. United States*, 887 F.2d 760, 768 (7th Cir. 1989).

CMS began the rulemaking process on May 18, 2004 when it published a proposed rule in the Federal Register where it presented for public comment three payment options intended to “diminish the possibility of a hospital-within-a-hospital actually functioning as a unit of an acute care hospital.” 69 Fed. Reg. 28326 (May 18, 2004). Each of the three options provided that the regulation “retain as the only qualifying criterion that the hospital-within-a-hospital have at least 75 percent of its admissions from a source other than the host hospital,” meaning that its

Reply [23] at 8. Defendant disputes plaintiffs’ reading of that case, arguing that it actually expresses the idea that APA rulemaking is required when an agency interpretation of a regulation adopts a new position inconsistent with existing regulations. *See* Def.’s Reply [26] at 10. Regardless of which reading of the case the Court accepts, the question of the process that an agency must undergo to change its interpretation of a regulation is irrelevant here. CMS did not promulgate a new agency interpretation of the final rule in its correcting amendment; rather, it modified the language of the final rule that was originally published in the Code of Federal Regulations.

admissions from the host could equal no more than 25 percent of its discharges for the cost year. *Id.* at 28326–27. Following publication of the proposed rule, the public offered comments on various aspects of the three options until the close of the comment period on July 12, 2004. CMS then published the final rule on August 11, 2004. *See* 69 Fed. Reg. 48196 (Aug. 11, 2004).

In the preamble to the final rule, CMS noted that it had “received several comments urging us not to adopt any of the proposed payment policies; that they were arbitrary and unprecedented and would result in lesser payments to the LTCH HwH or satellite based upon the source of patients.” *Id.* at 49204. However, the agency explained that “after further analysis and consideration of the commenter’s concerns, we have made various changes” to the 25 percent policy. *Id.* at 49196. CMS then outlined a four-year transition period in the final rule to implement the 25 percent policy, repeatedly articulating that in the first “hold harmless” year of this transition period, even grandfathered facilities would not be allowed to exceed the percentage of discharges admitted from their host hospitals in the fiscal year 2004 cost reporting period. *See id.* at 49196; *id.* at 49206; *id.* at 49213. The preamble expressed that this transition period was the direct result of commenters’ suggestions. *See, e.g., id.* at 49196. However, the final rule language published in the Code of Federal Regulations, while setting out the four-year transition period, omitted the limitation that grandfathered facilities in the first year of the transition period would not be allowed to exceed the percentage of patients admitted from the host during the fiscal year 2004 cost reporting period. Without issuing notice or allowing for another opportunity for public comment, on December 30, 2004 CMS published a correcting amendment to add a clause into the language of the final rule that would reflect the policy expressed in the preamble. *See* 69 Fed. Reg. 78526 (Dec. 30, 2004).

Although the transition period articulated in the preamble and the correcting amendment to the final rule was not specifically articulated in the notice of proposed rulemaking, it was merely a mechanism that the agency decided after public comment to use to implement the 25 percent policy—a component of the final rule that *was* subject to extensive public comment before the final rule was promulgated. “[F]ailure to provide notice-and-comment rulemaking will usually mean that affected parties have had no prior formal opportunity to present their contentions.” *Am. Mining Congress v. Mine Safety & Health Admin.*, 995, F.2d 1106, 1111(D.C. Cir. 1993). However, both the proposed rule and the preamble to the final rule addressing commenters’ concerns demonstrate that the public had an opportunity during the comment period to present to the agency its contentions to the proposed rule. Moreover, as the transition period was merely an implementing mechanism for the 25 percent rule—already the subject of extensive public comment after CMS issued the notice of proposed rulemaking—an additional notice and comment period before the correcting amendment was issued “would not provide commentators with their first occasion to offer new and different criticisms which the agency might find convincing.” *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1311 (D.C. Cir. 1991). Therefore, CMS did not violate the notice and comment requirements of the APA and the Medicare Act when it published the correcting amendment to the final rule without an additional notice and comment period because as indicated by the preamble to the final rule, the contents of the correcting amendment were the logical outgrowth of previous public comments. *See id.*

B. The Agency Action at Issue was Not Arbitrary and Capricious, and the Preamble to the Final Rule was Sufficient to Bind Plaintiffs

Plaintiffs argue that they are entitled to summary judgment on their third claim for relief because CMS’s promulgation of the correcting amendment to the final rule was arbitrary and

capricious, an abuse of discretion, and contrary to law. Specifically, plaintiffs argue that the agency's actions made a substantive change to an existing rule without prior notice and an opportunity for public comment and imposed a retroactive change to the Medicare payment rules which significantly decreased the Medicare payments owed to plaintiffs in return for the services provided to Medicare beneficiaries. Defendant argues that it is entitled to summary judgment because the preamble to the final rule was sufficient to bind plaintiffs to the limitation that even in the first hold-harmless year, a HwH may not exceed the percentage of patients admitted from the host hospital during its fiscal year 2004 cost reporting period.

Under the APA, the Court must “hold unlawful and set aside agency action, findings, and conclusions” that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). The “scope of review under the ‘arbitrary and capricious’ standard is narrow and a court is not to substitute its judgment for that of the agency.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Under that standard, the agency is required to “examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’” *Id.* (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)). The agency “must cogently explain why it has exercised its discretion in a given manner,” and that explanation must be sufficient to enable the Court “to conclude that the agency’s action was the product of reasoned decisionmaking.” *State Farm*, 463 U.S. at 48, 52. The agency’s decisions are entitled to a “presumption of regularity,” and although “inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one.” *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415, 416 (1971).

The Court’s review of agency action is “confined to the administrative record.” *Sierra Club v. Mainella*, 459 F. Supp. 2d at 90 (citing *Camp v. Pitts*, 411 U.S. 138, 142 (1973)).

An agency has an inherent power to correct errors in an adjudication. *See Am. Trucking Ass’ns v. Frisco Transp. Co.*, 358 U.S. 133 (1958); *Utility Solid Waste Activities Group v. EPA*, 236 F.3d 749, 753 (D.C. Cir. 2001); *Howard Sober, Inc. v. ICC*, 628 F.2d 36, 41–42 (D.C. Cir. 1980). However, the D.C. Circuit has declined to extend such an inherent power to the rulemaking context. *See Utility Solid Waste Activities Group*, 236 F.3d at 752. An agency wishing to correct a mistake in a rule must therefore either undergo the notice and comment process spelled out in § 553 of the APA or invoke an exception thereto. *See id.*

As the Court previously noted, CMS does not assert that an exception applies to the notice and opportunity for public comment required by the APA. Rather, CMS argues that it was merely correcting a ministerial error in the final rule to make it consistent with the policy expressed in the preamble to that rule. Language in the preamble of a regulation is not controlling over the language of the regulation itself. *Jurgensen v. Fairfax County, Va.*, 745 F.2d 868, 885 (4th Cir. 1984). However, the D.C. Circuit has “often recognized that the preamble to a regulation is evidence of an agency’s contemporaneous understanding of its proposed rules.” *Wyoming Outdoor Council v. U.S. Forest Service*, 165 F.3d 43, 53 (D.C. Cir. 1999); *see, e.g., Chem. Mfrs. Ass’n v. DOT*, 105 F.3d 702, 708 (D.C. Cir. 1997); *Booker v. Edwards*, 99 F.3d 1165, 1168 (D.C. Cir. 1996). “Although the preamble does not control the meaning of the regulation, it may serve as a source of evidence concerning contemporaneous agency intent.” *Wyoming Outdoor Council*, 165 F.3d at 53. Even though the language of the final rule published in the Code of Federal Regulations did not contain a limitation on Medicare reimbursement for grandfathered LTCHs in the first year of the transition period, the preamble language published

in the Federal Register was an unequivocal expression of the agency's intended meaning of the final rule and the policy underlying that rule. Taken together, the preamble language serves as evidence of CMS's contemporaneous understanding of the final rule, even if technical inconsistencies existed between the final rule language and the preamble language before the correcting amendment was issued. CMS's decision to rely on the preamble as contemporaneous evidence of its intended meaning of the final rule language is entitled to a "presumption of regularity" by the Court. *Citizens to Preserve Overton Park*, 401 U.S. at 415. The preamble language regarding the limitation on reimbursement of grandfathered LTCHs during the first year of the transition period to the 25 percent policy was therefore sufficient to bind plaintiffs.

Furthermore, CMS offered a logical explanation for issuing the correcting amendment in the manner that it did, and plaintiffs have made no argument to refute this explanation. In the correcting amendment, CMS states that it "inadvertently omitted" from the regulation text that grandfathered facilities "are required to not exceed the percentage of discharges admitted from the host hospital in its FY 2004 cost reporting period as was indicated in the preamble of the FY 2005 final rule on pages 49213 and 49196." 69 Fed. Reg. 78526, 78527. Plaintiffs argue that the Court should ignore this explanation, but offer no alternative explanation as to why the Court should completely disregard the agency's assertion that it inadvertently left language out of the final rule consistent with the repeated expressions of agency intent articulated in the preamble. When it issued the correcting amendment, CMS "cogently explain[ed] why it has exercised its discretion in a given manner," giving the Court reason "to conclude that the agency's action was the product of reasoned decisionmaking." *State Farm*, 463 U.S. at 48, 52. CMS therefore did not act in an arbitrary and capricious manner when it issued the correcting amendment without an additional notice and comment period.

Plaintiffs also argue that because the correcting amendment was promulgated after fiscal year 2005 had begun and modified the reimbursement amounts for that year, the amendment was retroactive in nature, caused harm to plaintiffs, and was therefore arbitrary and capricious. To determine whether a rule is impermissibly retroactive, the Court “first look[s] to see whether it effects a substantive change from the agency’s prior regulation or practice.” *Nat’l Mining Ass’n v. Dep’t of Labor*, 292 F.3d 849, 860 (D.C. Cir. 2002). Then, the Court “examines its impact, if any, on the legal consequences of prior conduct.” *Northeast Hosp. Corp. v. Sebelius*, 2011 WL 4036318, at *12 (D.C. Cir. 2011). A rule that “alter[s] the *past* legal consequences of past actions” is retroactive, whereas a rule that alters only the “future effect” of past actions is not. *Mobile Relay Assocs. v. FCC*, 457 F.3d 11, 11 (D.C. Cir. 2006). As the Court already found, the effect of the correcting amendment was not to substantively change the final rule, but rather to correct the language of the final rule so that it was consistent with the agency’s intent as expressed in the preamble to the rule. The correcting amendment only clarified the amount that CMS would give to plaintiffs as reimbursement at the end of fiscal year 2005 and had no effect on the legal consequences of the hospitals’ past actions, only a future effect on the amount of money plaintiffs would receive as reimbursement at the end of the year. Moreover, plaintiffs did not suffer any monetary harm when the agency issued the correcting amendment because plaintiffs had not yet received any reimbursement from CMS for fiscal year 2005 at that point. Even though the correcting amendment was promulgated four months after the start of fiscal year 2005, plaintiffs would not be reimbursed by CMS until the end of fiscal year 2005. As the correcting amendment was not issued retroactively, nor did plaintiffs suffer any harm as a result of its issuance, CMS did not act in an arbitrary and capricious manner when it issued the correcting amendment.

C. The Substantial Evidence Standard is Inapplicable

Plaintiffs argue that they are entitled to summary judgment on their fourth claim for relief because CMS's conclusions that (1) rulemaking procedures in accordance with APA § 553 were not required for CMS to issue the correcting amendment, and (2) the amount of Medicare reimbursement owed to plaintiffs for fiscal year 2005 was capped at the percentage of patients admitted from the host hospital during its FY 2004 cost reporting period, were not supported by substantial evidence. The substantial evidence standard, however, does not apply in the rulemaking context. Section 706 of the APA says that a reviewing court "shall hold unlawful and set aside agency action, findings, and conclusions found to be . . . unsupported by substantial evidence in a case subject to sections 556 and 557 of [the APA] or otherwise reviewed on the record of an agency hearing provided by statute." 5 U.S.C. § 706(2)(E). Sections 556 and 557 of the APA govern agency hearings at which evidence is taken. *See* 5 U.S.C. §§ 556, 557. In other words, the substantial evidence standard applies only to agency findings of fact made after a hearing, rather than the rulemaking process that is at issue in this case.² The Court therefore cannot find that CMS's conclusions were not supported by substantial evidence because the substantial evidence standard does not apply in this case.

V. CONCLUSION

For the foregoing reasons, the Court finds that no genuine issue of material fact remains and that the evidence in the administrative record permitted the agency to issue the correcting amendment without another round of notice and comment. The Court will therefore DENY plaintiffs' motion for summary judgment and GRANT defendant's cross-motion for summary judgment.

² That is not to say, of course, that agency rulemaking goes unreviewed. Instead, as explained herein by the Court, the agency's conclusions in rulemaking cannot be arbitrary and capricious. *See* 5 U.S.C. §706(2)(A).

Signed by Royce C. Lamberth, Chief Judge, on October 25, 2011.