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23 January 2014

Department of Health and Human Services, Provider Reimbursement Review Board
2520 Lord Baltimore Drive, Suite L
Baltimore, MD 21244-2670

Re: **Individual Hearing Request and Request for Expedited Judicial Review**
[redacted] Hospital
FYE: Fiscal Years Ending on December 31, 2013 and December 31, 2014[1]
Provider No. [redacted]
Case No: Unassigned

Dear Sir or Madam:

[redacted] Hospital (Provider No. [redacted]) hereby requests an individual hearing regarding the 0.2 percent payment reduction that the Centers for Medicare & Medicaid Services (CMS) adopted in its Medicare hospital inpatient prospective payment system (IPPS) final rule for federal fiscal year (FFY) 2014. [redacted] and its fiscal intermediary are listed in the attached Model Form A Individual Appeal Request. Hospital

This appeal is timely filed within 180 days of the Secretary's final determination to apply a 0.2 percent reduction to the standardized amounts and hospital-specific rates used to calculate the IPPS payment rates for discharges in the FFY 2014, which was published in the Federal Register on August 19, 2013, 78 Fed. Reg. 50,496. The fiscal period at issue for the appeal is FFY 2014. The estimated reimbursement effect of the issue in this appeal exceeds $10,000, as shown in the attached Model Form A and supporting documentation.

The only issue raised in this individual appeal is a pure question of law regarding the validity of the 0.2 percent reduction. Specifically [redacted] contends that CMS's 0.2 percent payment reduction is invalid for at least three reasons. First, it relies on assumptions that appear to be indefensible, and that in any event, CMS did not explain. Second, the 0.2 percent payment reduction is procedurally invalid because CMS failed to comply with the notice and comment requirements of the Administrative Procedure Act by refusing to provide sufficient information about its calculations to give providers a meaningful opportunity to comment. Third, the 0.2 percent reduction is invalid because CMS did not codify it in the Code of Federal Regulations, as required by the Medicare statute. As a result, [redacted] requests a revision of the standardized amounts and hospital-specific rates for FFY 2014 and additional reimbursement for the flow-through effects of eliminating the 0.2 percent reduction (e.g., additional indirect medical education payments) for Medicare discharges occurring on or after October 1, 2013.

1 The relevant time period for this appeal is the federal fiscal year (FFY) rather than the hospital's fiscal year. The federal fiscal year ends on September 30, 2014. The federal fiscal year crosses parts of two provider fiscal years, but this appeal is based upon a single final determination: the Secretary's promulgation of the FFY 2014 IPPS final rule.

[redacted] also requests expedited judicial review (EJR) of the issue raised in this appeal. [redacted] believes EJR is appropriate because the Board has jurisdiction over this appeal, but the only issue raised in the appeal is a pure question of law regarding the substantive and procedural validity of the 0.2 percent reduction, which the Board lacks the authority to decide. *See* Social Security Act § 1878(f)(1); 42 C.F.R. § 405.1842(f)(1). And [redacted] seeks a remedy that the Board lacks the power to grant: reversal of the 0.2 percent reduction, revision of the IPPS payment rates for FFY 2014, and additional reimbursement under Medicare Part A for the Medicare discharges occurring on or after October 1, 2013. *See* 42 C.F.R. § 405.1867; *Hunterdon/Somerset 2001 Wage Index Group v. Riverbend Gov't Benefits Adm'r,* Board Hearing Dec. No. 2004-D13, Case No. 01-0881GE (Apr. 14, 2004) (granting EJR after concluding that the Board "has no authority to dictate or fashion CMS policy or to retroactively apply policy changes" and therefore could not grant the requested change to the Secretary's policies used to calculate wage indices). Therefore, [redacted] requests that the Board grant EJR of this appeal.

Enclosed are the following documents for [redacted] in the above-named individual appeal:

1. Request for Individual Hearing and supporting documentation, including a designation of representative letter

Copies of the enclosures, including the request for EJR, have been sent to the Intermediary, National Government Services, on this date.

[redacted] has appointed me to serve as its authorized representative in this FFY 2014 appeal. Please direct all correspondence regarding this matter to my attention at the address listed below.

Sincerely,

[redacted]

Sheree R. Kanner

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Enclosures

cc: National Government Services, Appeals Department

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PROVIDER REIMBURSEMENT REVIEW BOARD

[redacted] Hospital
Provider No. [redacted]
Audit Adjustment No.: N/A
Board Case No: Unassigned
FYE: Fiscal Years Ending December 31, 2013 and December 31, 2014[1]
Intermediary: National Government Services (NGS)

Provider's Request for A Hearing

[redacted] Hospital (the "Provider") requests a hearing by the Provider Reimbursement Review Board ("the Board") of the issue in this case. The Provider also requests, under separate cover, that the Board grant expedited judicial review ("EJR") of the issue in this case pursuant to Section 1878(f)(1) of the Social Security Act ("SSA") and 42 C.F.R. § 405.1842.

The Provider challenges the validity of the Secretary of Health & Human Services' 0.2 percent reduction to the standardized amounts, the hospital-specific rates, and the Puerto-Rico-specific standardized amounts used to calculate the rates paid under the prospective payment system for inpatient hospital services ("IPPS") ("the 0.2 percent payment cut"). The Secretary, acting through the Centers for Medicare & Medicaid Services ("CMS"), issued a final determination regarding the 0.2 percent payment cut by publishing it in the Federal Register as part of the hospital inpatient prospective payment system final rule for FFY 2014 (the "IPPS Final Rule") on August 19, 2013. As stated in the Provider's initial hearing request (attached hereto), and as discussed below, the Provider maintains that this 0.2 percent payment cut is unlawful and must be set aside for a host of reasons. Chief among these are: (1) the reduction is

[1] The relevant time period for this appeal is federal fiscal year ("FFY") 2014, rather than the hospital's fiscal year. FFY 2014 ends on September 30, 2014 and crosses parts of two of the Provider's fiscal years, the fiscal years ending on December 31, 2013 and December 31, 2014.

arbitrary and capricious because CMS relied on indefensible assumptions and offered no reasoned explanation for those assumptions; (2) the reduction is invalid because CMS failed to comply with notice and comment procedures required by the Administrative Procedure Act ("APA"); and (3) the reduction is invalid because CMS failed to codify it in the Code of Federal Regulations, as required by statute and APA. The Provider seeks judicial review of pure questions of law regarding the substantive and procedural validity of the 0.2 percent reduction, and a court order declaring that the 0.2 percent payment cut must be set aside and the Provider reimbursed for the reduced payments it received for hospital discharges on or after October 1, 2013. Because the Board lacks the power to grant the Provider's requested relief, it should grant EJR.

Statement of the Issue

There is only one issue in this case: the legality of the 0.2 percent reduction in IPPS payment rates for discharges occurring on or after October 1, 2013. The Provider challenges the 0.2 percent payment cut as invalid for at least three reasons. First, the 0.2 percent reduction is unlawfully arbitrary and capricious because CMS relied on indefensible assumptions in adopting the policy and in any event did not explain those assumptions. Second, the 0.2 percent payment cut is invalid because CMS failed to comply with the notice and comment procedures required by the APA. Third, the 0.2 percent reduction is invalid because CMS failed to codify it in the Code of Federal Regulations, as required by the plain language of the Medicare statute and the APA. Accordingly, the Provider is entitled to a revision of the standardized amounts for FFY 2014 and additional reimbursement under Medicare Part A for the discharges of Medicare patients occurring on or after October 1, 2013.

Background

The Provider

[redacted]Hospital is a[redacted]

IPPS Payment Rates

The Provider is reimbursed on a prospective basis for the inpatient care it provides to Medicare beneficiaries. Specifically, the Provider is paid a predetermined amount for each discharge based on the Medicare Severity Diagnosis-Related Group ("MS-DRG") that corresponds to the beneficiary's clinical condition and treatment provided. *See* SSA § 1886(d); 42 C.F.R. §§ 412.60, 412.64, 412.100-.374. The MS-DRG payment amount is based on two national base payment rates or "standardized amounts," one providing for operating expenses and one for capital expenses, that are adjusted to account for the beneficiary's clinical condition and market conditions in the hospital's location. *See* 42 C.F.R. §§ 412.60, 412.64(c).

Additional amounts are added to the MS-DRG payment amount to reflect the higher indirect patient care costs associated with teaching medical residents ("indirect medical education" or "IME" payments), *id.* § 412.105, and the costs associated with treating a disproportionate share of low-income patients ("disproportionate share hospital" or "DSH"

[redacted]

payments), *id.* § 412.106.[3] The IME payment and DSH payment amounts are calculated by multiplying an adjustment factor by the standardized amounts. *Id.* §§ 412.64, 412.105, 412.106, 412.312, 412.320, 412.322.

The IPPS Proposed and Final Rule

CMS published its proposed rule governing Medicare payment policy under IPPS for FFY 2014 on May 10, 2013. 78 Fed. Reg. 27,486. Included among its proposals were several policies intended "[t]o reduce uncertainty regarding the requirements for payments to hospitals and [critical access hospitals] under Medicare Part A related to when a Medicare beneficiary should be admitted as an inpatient." Specifically, CMS proposed to:

- instruct physicians that they "should order admission if [they] expect[ ] that the beneficiary's length of stay will exceed a 2-midnight threshold or if the beneficiary requires a procedure specified as inpatient-only under 42 C.F.R. 419.22";
- establish a time-based presumption to be applied during medical review of inpatient claims that "inpatient admissions spanning 2 midnights in the hospital would generally qualify as appropriate for payment under Medicare Part A";
- establish as a rule that hospitals cannot obtain payment under Part A unless the patient's record contains a physician's order admitting the patient as an inpatient; and
- "use [its] exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the [Social Security] Act to offset the additional expenditures under this proposal by reducing the standardized amount, the hospital-specific amount, and the Puerto-Rico-specific standardized amount by 0.2 percent."

78 Fed. Reg. at 27,496, 27,497–98; *id.* at 27,644–50 (May 10, 2013).

CMS published the IPPS Final Rule in the Federal Register on August 19, 2013. 78 Fed. Reg. 50,496. Among other things, the IPPS Final Rule adopted, with few changes, the proposed policies enumerated above, including the 0.2 percent payment cut. *Id.* at 50,508. CMS wrote

[3] There are a number of other adjustments made to the per-discharge reimbursement amount, such as adjustments based on hospital performance in the Hospital Readmissions Reduction Program or Value-Based Purchasing Program, *see generally* 42 C.F.R. §§ 412.152–.154, 412.160–.167, or adjustments for certain high-cost outlier discharges, *id.* § 412.80, but the impact of the 0.2 percent reduction on the amount of those adjustments is much less significant.

that as a result of its changes in hospital admissions policies, CMS's actuaries estimated that expenditures under IPPS would increase by approximately $220 million due to an expected net increase in hospital inpatient encounters. *Id.* at 50,952. Specifically, CMS's actuaries examined FY 2009 through FY 2011 Medicare claims data and estimated that approximately 400,000 encounters would shift from outpatient to inpatient and approximately 360,000 encounters would shift from inpatient to outpatient, causing a net shift of 40,000 encounters. *Id.*

In the preamble to the IPPS Final Rule, CMS for the first time identified—but did not explain—two major limitations on its actuarial analysis. First, in estimating the number of encounters that would shift from outpatient to inpatient, CMS's actuaries examined only "outpatient claims for observation or a major procedure. Claims not containing observation or a major procedure were excluded." *Id.* at 50,953. Second, in estimating the number of claims that would shift from inpatient to outpatient, CMS wrote that its actuaries examined only "claims containing a surgical MS-DRG. Claims containing medical MS-DRGs were excluded." *Id.*

Based on the 40,000-encounter shift and the relative difference in expenditures between the shifting outpatient and inpatient encounters, CMS concluded that IPPS expenditures would increase by some $220 million. *Id.* CMS stated that "[i]n light of the widespread impact of the proposed 2-midnight policy on the IPPS and the systemic nature of the issue of inpatient status and improper payments under Medicare Part A for short-stay inpatient claims . . . it is appropriate to use our exceptions and adjustments authority under section 1886(d)(4)(I)(i) of the Act to propose to offset the estimated $220 million in additional IPPS expenditures associated with the proposed policy." *Id.* It accordingly reduced the IPPS payment rate by 0.2 percent for FFY 2014 by reducing the standardized amount, the hospital-specific rates, and the Puerto-Rico-

specific standardized amount by 0.2 percent for discharges occurring on or after October 1, 2013. *Id.* at 50,954.

Discussion

A. The Board Has Jurisdiction Over This Appeal.

A provider is entitled to a Board hearing if the provider is "dissatisfied with a final determination of the Secretary as to the amount of the payment under subsection (b) or (d) of section 1886," the "amount in controversy is $10,000 or more," and the provider files a request for a hearing within 180 days after notice of the Secretary's "final determination." SSA § 1878(a); 42 C.F.R. §§ 405.1835, 405.1839. Those requirements are easily satisfied here and the Board has jurisdiction over this case.

First, it is well-established that publication in the Federal Register of a general notice regarding an adjustment to IPPS payment rates is a "final determination of the Secretary as to the amount of payment under [IPPS]" that may be reviewed by the Board. *See District of Columbia Hospital Association Wage Index Group Appeal*, (HCFA Adm. Dec. Jan. 15, 1993), *Medicare & Medicaid Guide* ¶ 41,025 (publication of wage index in Federal Register is a final determination which can be appealed to the Board). Publication of the 0.2 percent reduction in the Federal Register on August 19, 2013 therefore is a "final determination of the Secretary" as to the amount of payment under IPPS and the Provider is entitled to seek Board review.

Second, the amount in controversy is well over $10,000 for each of the cost reporting periods affected by the FFY 2014 0.2 percent payment cut [redacted]

Finally, the Provider's appeal is timely because it was received by the Board before February 14, 2014, which is within 180 days after the Secretary's publication of the IPPS Final Rule in the Federal Register on August 19, 2013. *See* 78 Fed. Reg. at 50,496. Therefore, the Board has jurisdiction over the Provider's appeal and the first criterion for EJR is met.

B. The Provider Challenges the Validity of the 0.2 Percent Payment Cut.

The Provider challenges the 0.2 percent payment cut as invalid for at least three reasons. First, it relies on assumptions that appear indefensible and that in any event CMS did not bother to explain. Second, CMS failed to provide enough information about its calculations to give hospitals a meaningful opportunity to comment. Third, the adjustment is invalid under the plain terms of the Medicare statute because CMS did not codify it in the Code of Federal Regulations.

1. *Indefensible, Unexplained Assumptions.*

First, the 0.2 percent payment cut relies on assumptions that appear indefensible and that CMS did not bother to explain. That is unlawful.

The Administrative Procedure Act provides that courts "shall hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A), (C). Applying that test, the D.C. Circuit has held that data-driven rules are unlawful when the agency relies on assumptions that appear arbitrary or flawed on their face and which the agency has failed to justify.

In *West Virginia v. EPA*, 362 F.3d 861 (D.C. Cir. 2004), for example, the D.C. Circuit explained that it vacates rules when the agency leaves important assumptions "completely unexplained" or fails to "explain why results that appear arbitrary on their face are, in fact, reasonable." *Id.* at 866 (citation omitted). Likewise, in *Appalachian Power Co. v. EPA*, 251 F.3d 1026 (D.C. Cir. 2001), the court wrote that agencies have "undoubted power to use

predictive models," but they must "explain the assumptions and methodology used in preparing the model and provide a complete analytic defense should the model be challenged." *Id.* at 1035 (citation omitted). It vacated the agency rule at issue because the agency had "adopted a particular methodology . . . that generated seemingly implausible results," and it had done so "without offering any reasoned explanation for its choice." *Id.* And in *Advanced Micro Devices v. C.A.B.*, 742 F.2d 1520 (D.C. Cir. 1984), the court rejected an agency rate-approval order because the data the agency had used to evaluate the rate "were wholly inadequate to the task, and they were presented without explanation or shred of analysis." *Id.* at 1543. The court noted that the rule's challengers had been "unable to replicate the [agency's] figures" and that this was "a cause for some concern." *Id.* It explained: "[I]t was error for the Board not to advert to the data and methods of calculation it used in such a way as to allow rate opponents and reviewing courts to understand how the Board reached its conclusions." *Id.*

CMS's 0.2 percent payment cut cannot stand under these precedents because it relies on several assumptions that appear indefensible on their face, and the agency failed to explain those assumptions at all—much less to "provide a complete analytic defense"—once "the model [was] challenged." *Appalachian Power*, 251 F.3d at 1035.

CMS's calculation of inpatient-to-outpatient shifts provides the most telling example. When CMS's actuaries estimated how many encounters would shift from inpatient to outpatient, they examined only "claims containing a surgical MS-DRG. Claims containing medical MS-DRGs were excluded." 78 Fed. Reg. at 50,953. In other words, CMS's calculations ignored an *entire category of cases*—medical cases that do not involve a surgery.

That makes no sense. Perhaps CMS assumed that surgical cases and medical cases will behave the same way under its new policies in terms of the percentage that will shift. But if that

is CMS's logic, it does not hold; there is no reason to assume the two kinds of cases will behave the same way, and good reason to think they will not. After all, in surgical cases it often is easier for doctors to predict how long a patient will be hospitalized, and therefore to meet the new CMS criterion that physicians may "order admission if [they] expect[ ] that the beneficiary's length of stay will exceed a 2-midnight threshold[.]" 78 Fed. Reg. at 27,496. In medical cases, by contrast, the patient is often hospitalized with symptoms that have not yet been diagnosed; in such cases it often will be more difficult for a physician to definitively predict how long the patient needs to be hospitalized. Simple logic therefore suggests that medical cases are *more* likely to shift from inpatient to outpatient—and that CMS undercounted the shifts in that direction by considering only surgical cases in its modeling. [redacted]

But there is an even bigger problem with CMS's analytical approach: It did not impose a similar surgical-cases-only limitation when it counted how many encounters would shift in the other direction, from outpatient to inpatient. Instead, CMS examined "outpatient claims for observation or a major procedure." 78 Fed. Reg. at 50,953. That approach does not track on the approach CMS used in counting inpatient-to-outpatient shifts because it includes *observation* cases—cases that were categorically excluded from the inpatient-to-outpatient count. And that disconnect is critical. After all, CMS's decision to impose a 0.2 percent reduction turns *entirely* on its conclusion that more encounters would shift from outpatient to inpatient than vice versa. *See id.* If CMS used a smaller bucket of cases when it counted the subset shifting one way than

it did the subset shifting the other, then the underpinnings supporting the payment reduction simply collapse.

There are other indicators, too, that CMS undercounted the cases shifting from inpatient to outpatient. For example, CMS concluded that 360,000 cases would shift in that direction under its new "2-midnights" policies. *See* 78 Fed. Reg. at 50,953. But there are about one million zero- or one-midnight stay inpatient cases each year,[4] and CMS elsewhere has stated its expectation that a "*majority* of short (total of zero or one midnight) Medicare hospital stays will be provided as outpatient services."[5] Taking CMS at its word, that should mean at least 500,000 short-stay cases, and perhaps more, will shift to outpatient. If so, CMS should have increased IPPS rates, not decreased them.

For these and other reasons, CMS's modeling and assumptions "appear arbitrary on their face," *West Virginia*, 362 F.3d at 866, and "generated seemingly implausible results," *Appalachian Power*, 251 F.3d at 1035. But even if those assumptions and results could be explained, that makes no difference because the agency in fact did *not* explain them. Numerous commenters during the rulemaking complained that "CMS actuaries' estimated increase in IPPS expenditures of $220 million was unsupported[.]" 78 Fed. Reg. at 50,953. And yet even in the final rule CMS did not explain its assumptions. That failure violates the well-established APA principle that agencies must "explain the assumptions and methodology used in preparing the model and provide a complete analytic defense should the model be challenged." *Appalachian Power*, 251 F.3d at 1035; *accord Advanced Micro Devices*, 742 F.2d at 1543.

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[4] CMS, FY 2014 Final Rule Data Files, AOR/BOR File, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2014-IPPS-Final-Rule-Home-Page.html (click on "FY 2014 Data Files and download the "AOR/BOR File").

[5] CMS, *FREQUENTLY ASKED QUESTIONS 2 Midnight Inpatient Admission Guidance & Patient Status Reviews for Admissions on or after October 1, 2013, Question 13* (emphasis added), *available at* http://cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/Downloads/QAsforWebsitePosting_110413-v2-CLEAN.pdf.

2. *Failure to Comply With Notice-and-Comment Requirements*

The 0.2 percent payment cut also is invalid for a separate, though related, reason: The agency violated notice-and-comment procedures when it refused to reveal its data, or even explain its calculations, in sufficient detail for commenters to join issue with them.

It is black-letter law that "an agency cannot rest a rule on data 'that, [in] critical degree, is known only to the agency.' " *Time Warner Entertainment Co., L.P. v. FCC*, 240 F.3d 1126, 1140 (D.C. Cir. 2001) (quoting *Community Nutrition Inst. v. Block*, 749 F.2d 50, 57 (D.C. Cir. 1984)); *accord American Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 237 (D.C. Cir. 2008); *Wisconsin Power & Light Co. v. F.E.R.C.*, 363 F.3d 453, 463 (D.C. Cir. 2004). In *American Radio*, for example, the FCC refused to reveal, either in its notice of proposed rulemaking or its final rule, "five scientific studies consisting of empirical data gathered from field tests" on which it relied in arriving at its policy. 524 F.3d at 237. The D.C. Circuit invalidated the rule. It wrote that "[u]nder APA notice and comment requirements, '[a]mong the information that must be revealed for public evaluation are the 'technical studies and data' upon which the agency relies [in its rulemaking].'" *Id.* at 235 (alteration in original) (citation omitted). "By requiring the most critical factual material used by the agency be subjected to informed comment," the court explained, "the APA provides a procedural device to ensure that agency regulations are tested through exposure to public comment, to afford affected parties an opportunity to present comment and evidence to support their positions, and thereby to enhance the quality of judicial review." *Id.* at 236. It concluded: "It would appear to be a fairly obvious proposition that *studies upon which an agency relies in promulgating a rule must be made available during the rulemaking in order to afford interested persons meaningful notice and an opportunity for comment.*" *Id.* at 237 (emphasis added). *Accord Solite Corp. v. EPA*, 952 F.3d 473 (D.C. Cir.

1991) ("Integral to the notice requirement is the agency's duty 'to identify and make available technical studies and data that it has employed in reaching the decisions to proposed particular rules'") (citation omitted).

CMS's failure even to explain its actuaries' assumptions—much less the bases for those assumptions—plainly violates that rule. Absent that information, hospitals could not meaningfully critique the actuaries' estimates that the 2-midnights policies will cause a net shift of 40,000 patient encounters from outpatient to inpatient, and would in turn result in an estimated $220 million increase in IPPS expenditures. 78 Fed. Reg. at 27,649.

3. *Failure to Codify the Adjustment*

Finally, the 0.2 percent payment cut is invalid under the plain terms of the Medicare statute because CMS did not codify it in the Code of Federal Regulations.

That relevant statutory provision states that the Secretary "shall provide" for exceptions and adjustments "*by regulation.*" SSA § 1886(a)(1)(A)(i) (emphasis added). The 0.2 percent reduction has not been provided "by regulation," because CMS did not codify it in the Code of Federal Regulations. *Cf. Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 538-39 (D.C. Cir. 1986) (explaining that "*[p]ublication* in the Federal Register does *not* suggest that the matter published *was* meant to be a regulation," and noting that "[t]he real dividing point between regulations and general statements of policy is publication in the Code of Federal Regulations" because "the statute authorizes [it] to contain only documents 'having general applicability *and legal effect,*' and which the governing regulations provide shall contain only 'each Federal *regulation* of general applicability and current or future effect.'"). Instead, CMS discussed the reduction only in the *preamble* to the IPPS Final Rule. *See* 78 Fed. Reg. at 50,953-54. And it is well-established that preambles are not part of the statutes or regulations that follow them. *See,*

e.g., *Hawaii v. Office of Hawaiian Affairs*, 556 U.S. 163, 175 (2009) (stating that "the preamble is no part of the act"); *International Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 68 Fed. Appx. 205, 206 (D.C. Cir. 2003) (unpublished; per curiam) ("it is well-settled that preambles, though undoubtedly 'contribut[ing] to a general understanding' of statutes and regulations, are not 'operative part[s]' of statutes and regulations." (quoting *Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 569-70 (D.C. Cir. 2002))); *Utah Power & Light Co. v. Secretary of Labor*, 897 F.2d 447, 450 (10th Cir. 1990) ("preamble to the regulations . . . is not part of the regulations as published in the Code of Federal Regulations."). CMS accordingly failed to provide for the 0.2 percent reduction in the only manner approved by statute. That renders the reduction invalid. For the same reason, the reduction is invalid under the APA. *See Nat'l Res. Def. Council v. E.P.A.*, 559 F.3d 561, 565 (D.C. Cir. 2009) ("Agency statements 'having general applicability and legal effect' are to be published in the Code of Federal Regulations.").

C. The Board Should Grant EJR.

As discussed in the Provider's request for EJR, each of these arguments presents a legal question that the Board does not have the authority to decide. *See* SSA § 1878(f)(1); 42 C.F.R. § 405.1842(f). The Board "must grant EJR for a legal question" if it determines that it has jurisdiction and yet it "lacks the authority to decide a specific legal question relevant to the specific matter at issue because the legal question is a challenge to . . . the substantive or procedural validity of a regulation or CMS Ruling." 42 C.F.R. § 405.1842(f)(1). That is this case. There are no material facts in dispute. The Provider's challenge turns on pure "questions of law" regarding the validity of the 0.2 percent reduction, as set forth above. And the Provider seeks a remedy that the Board lacks the power to grant: reversal of the 0.2 percent reduction. Because the Board is bound to apply the 0.2 percent reduction contained in the IPPS Final Rule,

it does not have the authority to give the Provider the relief it seeks. *See* 42 C.F.R. § 405.1867; *Hunterdon/Somerset 2001 Wage Index Group v. Riverbend Gov't Benefits Adm'r,* Board Hearing Dec. No. 2004-D13, Case No. 01-0881GE (Apr. 14, 2004) (granting EJR after concluding that the Board "has no authority to dictate or fashion CMS policy or to retroactively apply policy changes" and therefore could not grant the requested change to the Secretary's policies used to calculate wage indices). The Board should grant EJR of the issue in this appeal.

Respectfully submitted,

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PROVIDER REIMBURSEMENT REVIEW BOARD

[redacted] Hospital
Provider No. [redacted]
Audit Adjustment No.: N/A
Board Case No: Unassigned
FYE: Fiscal Years Ending December 31, 2013 and December 31, 2014[1]
Intermediary: National Government Services (NGS)

Provider's Request for Expedited Judicial Review

[redacted] Hospital (the "Provider") in the above-captioned appeal requests that the Provider Reimbursement Review Board ("the Board") grant expedited judicial review ("EJR") of the issue in this case pursuant to Section 1878(f)(1) of the Social Security Act ("SSA") and 42 C.F.R. § 405.1842.

The Provider challenges the validity of the Secretary of Health & Human Services' 0.2 percent reduction to the standardized amounts, the hospital-specific rates, and the Puerto-Rico-specific standardized amounts used to calculate the rates paid under the prospective payment system for inpatient hospital services ("IPPS") ("the 0.2 percent payment cut"). The Secretary, acting through the Centers for Medicare & Medicaid Services ("CMS"), issued a final determination regarding the 0.2 percent payment cut by publishing it in the Federal Register as part of the hospital inpatient prospective payment system final rule for FFY 2014 (the "IPPS Final Rule") on August 19, 2013. As stated in the Provider's initial hearing request (attached hereto), and as discussed below, the Provider maintains that this 0.2 percent payment cut is unlawful and must be set aside for a host of reasons. Chief among these are: (1) the reduction is arbitrary and capricious because CMS relied on indefensible assumptions and offered no

[1] The relevant time period for this appeal is federal fiscal year ("FFY") 2014, rather than the hospital's fiscal year. FFY 2014 ends on September 30, 2014 and crosses parts of two of the Provider's fiscal years, the fiscal years ending on December 31, 2013 and December 31, 2014.

reasoned explanation for those assumptions; (2) the reduction is invalid because CMS failed to comply with notice and comment procedures required by the Administrative Procedure Act ("APA"); and (3) the reduction is invalid because CMS failed to codify it in the Code of Federal Regulations, as required by statute and APA. The Provider seeks judicial review of pure questions of law regarding the substantive and procedural validity of the 0.2 percent reduction, and a court order declaring that the 0.2 percent payment cut must be set aside and the Provider reimbursed for the reduced payments it received for hospital discharges on or after October 1, 2013. Because the Board lacks the power to grant the Provider's requested relief, it should grant EJR.

Statement of the Issue

There is only one issue in this case: the legality of the 0.2 percent reduction in IPPS payment rates for discharges occurring on or after October 1, 2013. The Provider challenges the 0.2 percent payment cut as invalid for at least three reasons. First, the 0.2 percent reduction is unlawfully arbitrary and capricious because CMS relied on indefensible assumptions in adopting the policy and in any event did not explain those assumptions. Second, the 0.2 percent payment cut is invalid because CMS failed to comply with the notice and comment procedures required by the APA. Third, the 0.2 percent reduction is invalid because CMS failed to codify it in the Code of Federal Regulations, as required by the plain language of the Medicare statute and the APA. Accordingly, the Provider is entitled to a revision of the standardized amounts for FFY 2014 and additional reimbursement under Medicare Part A for the discharges of Medicare patients occurring on or after October 1, 2013.

Background

The Provider

[redacted] Hospital is a [redacted]

IPPS Payment Rates

The Provider is reimbursed on a prospective basis for the inpatient care it provides to Medicare beneficiaries. Specifically, the Provider is paid a predetermined amount for each discharge based on the Medicare Severity Diagnosis-Related Group ("MS-DRG") that corresponds to the beneficiary's clinical condition and treatment provided. *See* SSA § 1886(d); 42 C.F.R. §§ 412.60, 412.64, 412.100-.374. The MS-DRG payment amount is based on two national base payment rates or "standardized amounts," one providing for operating expenses and one for capital expenses, that are adjusted to account for the beneficiary's clinical condition and market conditions in the hospital's location. *See* 42 C.F.R. §§ 412.60, 412.64(c).

Additional amounts are added to the MS-DRG payment amount to reflect the higher indirect patient care costs associated with teaching medical residents ("indirect medical education" or "IME" payments), *id.* § 412.105, and the costs associated with treating a disproportionate share of low-income patients ("disproportionate share hospital" or "DSH"

[redacted]

payments), *id.* § 412.106.[3] The IME payment and DSH payment amounts are calculated by multiplying an adjustment factor by the standardized amounts. *Id.* §§ 412.64, 412.105, 412.106, 412.312, 412.320, 412.322.

The IPPS Proposed and Final Rule

CMS published its proposed rule governing Medicare payment policy under IPPS for FFY 2014 on May 10, 2013. 78 Fed. Reg. 27,486. Included among its proposals were several policies intended "[t]o reduce uncertainty regarding the requirements for payments to hospitals and [critical access hospitals] under Medicare Part A related to when a Medicare beneficiary should be admitted as an inpatient." Specifically, CMS proposed to:

- instruct physicians that they "should order admission if [they] expect[ ] that the beneficiary's length of stay will exceed a 2-midnight threshold or if the beneficiary requires a procedure specified as inpatient-only under 42 C.F.R. 419.22";
- establish a time-based presumption to be applied during medical review of inpatient claims that "inpatient admissions spanning 2 midnights in the hospital would generally qualify as appropriate for payment under Medicare Part A";
- establish as a rule that hospitals cannot obtain payment under Part A unless the patient's record contains a physician's order admitting the patient as an inpatient; and
- "use [its] exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the [Social Security] Act to offset the additional expenditures under this proposal by reducing the standardized amount, the hospital-specific amount, and the Puerto-Rico-specific standardized amount by 0.2 percent."

78 Fed. Reg. at 27,496, 27,497–98; *id.* at 27,644–50 (May 10, 2013).

CMS published the IPPS Final Rule in the Federal Register on August 19, 2013. 78 Fed. Reg. 50,496. Among other things, the IPPS Final Rule adopted, with few changes, the proposed policies enumerated above, including the 0.2 percent payment cut. *Id.* at 50,508. CMS wrote

[3] There are a number of other adjustments made to the per-discharge reimbursement amount, such as adjustments based on hospital performance in the Hospital Readmissions Reduction Program or Value-Based Purchasing Program, *see generally* 42 C.F.R. §§ 412.152–.154, 412.160–.167, or adjustments for certain high-cost outlier discharges, *id.* § 412.80, but the impact of the 0.2 percent reduction on the amount of those adjustments is much less significant.

that as a result of its changes in hospital admissions policies, CMS's actuaries estimated that expenditures under IPPS would increase by approximately $220 million due to an expected net increase in hospital inpatient encounters. *Id.* at 50,952. Specifically, CMS's actuaries examined FY 2009 through FY 2011 Medicare claims data and estimated that approximately 400,000 encounters would shift from outpatient to inpatient and approximately 360,000 encounters would shift from inpatient to outpatient, causing a net shift of 40,000 encounters. *Id.*

In the preamble to the IPPS Final Rule, CMS for the first time identified—but did not explain—two major limitations on its actuarial analysis. First, in estimating the number of encounters that would shift from outpatient to inpatient, CMS's actuaries examined only "outpatient claims for observation or a major procedure. Claims not containing observation or a major procedure were excluded." *Id.* at 50,953. Second, in estimating the number of claims that would shift from inpatient to outpatient, CMS wrote that its actuaries examined only "claims containing a surgical MS-DRG. Claims containing medical MS-DRGs were excluded." *Id.*

Based on the 40,000-encounter shift and the relative difference in expenditures between the shifting outpatient and inpatient encounters, CMS concluded that IPPS expenditures would increase by some $220 million. *Id.* CMS stated that "[i]n light of the widespread impact of the proposed 2-midnight policy on the IPPS and the systemic nature of the issue of inpatient status and improper payments under Medicare Part A for short-stay inpatient claims . . . it is appropriate to use our exceptions and adjustments authority under section 1886(d)(4)(I)(i) of the Act to propose to offset the estimated $220 million in additional IPPS expenditures associated with the proposed policy." *Id.* It accordingly reduced the IPPS payment rate by 0.2 percent for FFY 2014 by reducing the standardized amount, the hospital-specific rates, and the Puerto-Rico-

specific standardized amount by 0.2 percent for discharges occurring on or after October 1, 2013. *Id.* at 50,954.

Discussion

Section 1878 of the Act provides that EJR is appropriate when the Board has jurisdiction to conduct a hearing but the challenged agency action "involves a question of law or regulations relevant to the matters in controversy whenever the Board determines . . . that it is without authority to decide the question." SSA § 1878(f)(1); 42 C.F.R. § 405.1842(a),(d). The regulations implementing Section 1878 state that the Board "must grant EJR for a legal question" if the Board determines that it has jurisdiction and "[t]he Board lacks the authority to decide a specific legal question relevant to the specific matter at issue because the legal question is a challenge to . . . the substantive or procedural validity of a regulation or CMS Ruling." 42 C.F.R. § 405.1842(f)(1) (emphasis added). The Board must issue its decision on a request for EJR within thirty days of receipt of the request. SSA § 1878(f)(1); 42 C.F.R. § 405.1842(e).

This appeal meets the legal test for EJR. The Board has jurisdiction over the appeal. Because the only legal questions in the case involve challenges to the substantive and procedural validity of the 0.2 percent reduction, however, the Board does not have the authority to decide those questions. EJR accordingly should be granted.

A. The Board Has Jurisdiction Over This Appeal.

A provider is entitled to a Board hearing if the provider is "dissatisfied with a final determination of the Secretary as to the amount of the payment under subsection (b) or (d) of section 1886," the "amount in controversy is $10,000 or more," and the provider files a request for a hearing within 180 days after notice of the Secretary's "final determination." SSA

§ 1878(a); 42 C.F.R. §§ 405.1835, 405.1839. Those requirements are easily satisfied here and the Board has jurisdiction over this case.

First, it is well-established that publication in the Federal Register of a general notice regarding an adjustment to IPPS payment rates is a "final determination of the Secretary as to the amount of payment under [IPPS]" that may be reviewed by the Board. *See District of Columbia Hospital Association Wage Index Group Appeal*, (HCFA Adm. Dec. Jan. 15, 1993), *Medicare & Medicaid Guide* ¶ 41,025 (publication of wage index in Federal Register is a final determination which can be appealed to the Board). Publication of the 0.2 percent reduction in the Federal Register on August 19, 2013 therefore is a "final determination of the Secretary" as to the amount of payment under IPPS and the Provider is entitled to seek Board review.

Second, the amount in controversy is well over $10,000 for each of the cost reporting periods affected by the FFY 2014 0.2 percent payment cut. [redacted]

Finally, the Provider's appeal is timely because it was received by the Board before February 14, 2014, which is within 180 days after the Secretary's publication of the IPPS Final Rule in the Federal Register on August 19, 2013. *See* 78 Fed. Reg. at 50,496. Therefore, the Board has jurisdiction over the Provider's appeal and the first criterion for EJR is met.

B. The Board Lacks Authority to Decide The Legal Questions Presented.

The Board does not, however, have the authority to decide the issues raised in the appeal. *See* SSA § 1878(f)(1); 42 C.F.R. § 405.1842(f). The second criterion for EJR thus is met as well.

1. The EJR Test

The Board "must grant EJR for a legal question" if it determines that it has jurisdiction and yet it "lacks the authority to decide a specific legal question relevant to the specific matter at issue because the legal question is a challenge to . . . the substantive or procedural validity of a regulation or CMS Ruling." 42 C.F.R. § 405.1842(f)(1). That is this case. There are no material facts in dispute. The Provider's challenge turns on pure "questions of law" regarding the validity of the 0.2 percent reduction, as set forth below. And the Provider seeks a remedy that the Board lacks the power to grant: reversal of the 0.2 percent reduction. Because the Board is bound to apply the 0.2 percent reduction contained in the IPPS Final Rule, it does not have the authority to give the Provider the relief it seeks. *See* 42 C.F.R. § 405.1867; *Hunterdon/Somerset 2001 Wage Index Group v. Riverbend Gov't Benefits Adm'r,* Board Hearing Dec. No. 2004-D13, Case No. 01-0881GE (Apr. 14, 2004) (granting EJR after concluding that the Board "has no authority to dictate or fashion CMS policy or to retroactively apply policy changes" and therefore could not grant the requested change to the Secretary's policies used to calculate wage indices).

2. The Provider's Legal Challenges

The Provider challenges the 0.2 percent payment cut as invalid for at least three reasons. First, it relies on assumptions that appear indefensible and that in any event CMS did not bother to explain. Second, CMS failed to provide enough information about its calculations to give hospitals a meaningful opportunity to comment. Third, the adjustment is invalid under the plain terms of the Medicare statute because CMS did not codify it in the Code of Federal Regulations.

a. *Indefensible, Unexplained Assumptions.*

First, the 0.2 percent payment cut relies on assumptions that appear indefensible and that CMS did not bother to explain. That is unlawful.

The Administrative Procedure Act provides that courts "shall hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A), (C). Applying that test, the D.C. Circuit has held that data-driven rules are unlawful when the agency relies on assumptions that appear arbitrary or flawed on their face and which the agency has failed to justify.

In *West Virginia v. EPA*, 362 F.3d 861 (D.C. Cir. 2004), for example, the D.C. Circuit explained that it vacates rules when the agency leaves important assumptions "completely unexplained" or fails to "explain why results that appear arbitrary on their face are, in fact, reasonable." *Id.* at 866 (citation omitted). Likewise, in *Appalachian Power Co. v. EPA*, 251 F.3d 1026 (D.C. Cir. 2001), the court wrote that agencies have "undoubted power to use predictive models," but they must "explain the assumptions and methodology used in preparing the model and provide a complete analytic defense should the model be challenged." *Id.* at 1035 (citation omitted). It vacated the agency rule at issue because the agency had "adopted a particular methodology . . . that generated seemingly implausible results," and it had done so "without offering any reasoned explanation for its choice." *Id.* And in *Advanced Micro Devices v. C.A.B.*, 742 F.2d 1520 (D.C. Cir. 1984), the court rejected an agency rate-approval order because the data the agency had used to evaluate the rate "were wholly inadequate to the task, and they were presented without explanation or shred of analysis." *Id.* at 1543. The court noted that the rule's challengers had been "unable to replicate the [agency's] figures" and that this was "a cause for some concern." *Id.* It explained: "[I]t was error for the Board not to advert to the data and methods of calculation it used in such a way as to allow rate opponents and reviewing courts to understand how the Board reached its conclusions." *Id.*

CMS's 0.2 percent payment cut cannot stand under these precedents because it relies on several assumptions that appear indefensible on their face, and the agency failed to explain those assumptions at all—much less to "provide a complete analytic defense"—once "the model [was] challenged." *Appalachian Power*, 251 F.3d at 1035.

CMS's calculation of inpatient-to-outpatient shifts provides the most telling example. When CMS's actuaries estimated how many encounters would shift from inpatient to outpatient, they examined only "claims containing a surgical MS-DRG. Claims containing medical MS-DRGs were excluded." 78 Fed. Reg. at 50,953. In other words, CMS's calculations ignored an *entire category of cases*—medical cases that do not involve a surgery.

That makes no sense. Perhaps CMS assumed that surgical cases and medical cases will behave the same way under its new policies in terms of the percentage that will shift. But if that is CMS's logic, it does not hold; there is no reason to assume the two kinds of cases will behave the same way, and good reason to think they will not. After all, in surgical cases it often is easier for doctors to predict how long a patient will be hospitalized, and therefore to meet the new CMS criterion that physicians may "order admission if [they] expect[ ] that the beneficiary's length of stay will exceed a 2-midnight threshold[.]" 78 Fed. Reg. at 27,496. In medical cases, by contrast, the patient is often hospitalized with symptoms that have not yet been diagnosed; in such cases it often will be more difficult for a physician to definitively predict how long the patient needs to be hospitalized. Simple logic therefore suggests that medical cases are *more* likely to shift from inpatient to outpatient—and that CMS undercounted the shifts in that direction by considering only surgical cases in its modeling. [redacted]

[redacted]

But there is an even bigger problem with CMS's analytical approach: It did not impose a similar surgical-cases-only limitation when it counted how many encounters would shift in the other direction, from outpatient to inpatient. Instead, CMS examined "outpatient claims for observation or a major procedure." 78 Fed. Reg. at 50,953. That approach does not track on the approach CMS used in counting inpatient-to-outpatient shifts because it includes *observation* cases—cases that were categorically excluded from the inpatient-to-outpatient count. And that disconnect is critical. After all, CMS's decision to impose a 0.2 percent reduction turns *entirely* on its conclusion that more encounters would shift from outpatient to inpatient than vice versa. *See id.* If CMS used a smaller bucket of cases when it counted the subset shifting one way than it did the subset shifting the other, then the underpinnings supporting the payment reduction simply collapse.

There are other indicators, too, that CMS undercounted the cases shifting from inpatient to outpatient. For example, CMS concluded that 360,000 cases would shift in that direction under its new "2-midnights" policies. *See* 78 Fed. Reg. at 50,953. But there are about one million zero- or one-midnight stay inpatient cases each year,[4] and CMS elsewhere has stated its expectation that a "*majority* of short (total of zero or one midnight) Medicare hospital stays will be provided as outpatient services."[5] Taking CMS at its word, that should mean at least 500,000

[4] CMS, FY 2014 Final Rule Data Files, AOR/BOR File, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2014-IPPS-Final-Rule-Home-Page.html (click on "FY 2014 Data Files and download the "AOR/BOR File").

[5] CMS, *FREQUENTLY ASKED QUESTIONS 2 Midnight Inpatient Admission Guidance & Patient Status Reviews for Admissions on or after October 1, 2013, Question 13* (emphasis added), *available at* http://cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/Downloads/QAsforWebsitePosting_110413-v2-CLEAN.pdf.

short-stay cases, and perhaps more, will shift to outpatient. If so, CMS should have increased IPPS rates, not decreased them.

For these and other reasons, CMS's modeling and assumptions "appear arbitrary on their face," *West Virginia*, 362 F.3d at 866, and "generated seemingly implausible results," *Appalachian Power*, 251 F.3d at 1035. But even if those assumptions and results could be explained, that makes no difference because the agency in fact did *not* explain them. Numerous commenters during the rulemaking complained that "CMS actuaries' estimated increase in IPPS expenditures of $220 million was unsupported[.]" 78 Fed. Reg. at 50,953. And yet even in the final rule CMS did not explain its assumptions. That failure violates the well-established APA principle that agencies must "explain the assumptions and methodology used in preparing the model and provide a complete analytic defense should the model be challenged." *Appalachian Power*, 251 F.3d at 1035; *accord Advanced Micro Devices*, 742 F.2d at 1543.

b. *Failure to Comply With Notice-and-Comment Requirements*

The 0.2 percent payment cut also is invalid for a separate, though related, reason: The agency violated notice-and-comment procedures when it refused to reveal its data, or even explain its calculations, in sufficient detail for commenters to join issue with them.

It is black-letter law that "an agency cannot rest a rule on data 'that, [in] critical degree, is known only to the agency.' " *Time Warner Entertainment Co., L.P. v. FCC*, 240 F.3d 1126, 1140 (D.C. Cir. 2001) (quoting *Community Nutrition Inst. v. Block*, 749 F.2d 50, 57 (D.C. Cir. 1984)); *accord American Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 237 (D.C. Cir. 2008); *Wisconsin Power & Light Co. v. F.E.R.C.*, 363 F.3d 453, 463 (D.C. Cir. 2004). In *American Radio*, for example, the FCC refused to reveal, either in its notice of proposed rulemaking or its final rule, "five scientific studies consisting of empirical data gathered from field tests" on which

it relied in arriving at its policy. 524 F.3d at 237. The D.C. Circuit invalidated the rule. It wrote that "[u]nder APA notice and comment requirements, '[a]mong the information that must be revealed for public evaluation are the 'technical studies and data' upon which the agency relies [in its rulemaking].'" *Id.* at 235 (alteration in original) (citation omitted). "By requiring the most critical factual material used by the agency be subjected to informed comment," the court explained, "the APA provides a procedural device to ensure that agency regulations are tested through exposure to public comment, to afford affected parties an opportunity to present comment and evidence to support their positions, and thereby to enhance the quality of judicial review." *Id.* at 236. It concluded: "It would appear to be a fairly obvious proposition that *studies upon which an agency relies in promulgating a rule must be made available during the rulemaking in order to afford interested persons meaningful notice and an opportunity for comment.*" *Id.* at 237 (emphasis added). *Accord Solite Corp. v. EPA*, 952 F.3d 473 (D.C. Cir. 1991) ("Integral to the notice requirement is the agency's duty 'to identify and make available technical studies and data that it has employed in reaching the decisions to proposed particular rules'") (citation omitted).

CMS's failure even to explain its actuaries' assumptions—much less the bases for those assumptions—plainly violates that rule. Absent that information, hospitals could not meaningfully critique the actuaries' estimates that the 2-midnights policies will cause a net shift of 40,000 patient encounters from outpatient to inpatient, and would in turn result in an estimated $220 million increase in IPPS expenditures. 78 Fed. Reg. at 27,649.

c. *Failure to Codify the Adjustment*

Finally, the 0.2 percent payment cut is invalid under the plain terms of the Medicare statute because CMS did not codify it in the Code of Federal Regulations.

That relevant statutory provision states that the Secretary "shall provide" for exceptions and adjustments "*by regulation.*" SSA § 1886(a)(1)(A)(i) (emphasis added). The 0.2 percent reduction has not been provided "by regulation," because CMS did not codify it in the Code of Federal Regulations. *Cf. Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 538-39 (D.C. Cir. 1986) (explaining that "*[p]ublication* in the Federal Register does *not* suggest that the matter published *was* meant to be a regulation," and noting that "[t]he real dividing point between regulations and general statements of policy is publication in the Code of Federal Regulations" because "the statute authorizes [it] to contain only documents 'having general applicability *and legal effect,*' and which the governing regulations provide shall contain only 'each Federal *regulation* of general applicability and current or future effect.'"). Instead, CMS discussed the reduction only in the *preamble* to the IPPS Final Rule. *See* 78 Fed. Reg. at 50,953-54. And it is well-established that preambles are not part of the statutes or regulations that follow them. *See, e.g., Hawaii v. Office of Hawaiian Affairs*, 556 U.S. 163, 175 (2009) (stating that "the preamble is no part of the act"); *International Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 68 Fed. Appx. 205, 206 (D.C. Cir. 2003) (unpublished; per curiam) ("it is well-settled that preambles, though undoubtedly 'contribut[ing] to a general understanding' of statutes and regulations, are not 'operative part[s]' of statutes and regulations." (quoting *Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 569-70 (D.C. Cir. 2002))); *Utah Power & Light Co. v. Secretary of Labor*, 897 F.2d 447, 450 (10th Cir. 1990) ("preamble to the regulations . . . is not part of the regulations as published in the Code of Federal Regulations."). CMS accordingly failed to provide for the 0.2 percent reduction in the only manner approved by statute. That renders the reduction invalid. For the same reason, the reduction is invalid under the APA. *See Nat'l Res. Def. Council v.*

E.P.A., 559 F.3d 561, 565 (D.C. Cir. 2009) ("Agency statements 'having general applicability and legal effect' are to be published in the Code of Federal Regulations.").

Each of these arguments presents a "legal question" that is "a challenge to . . . the substantive or procedural validity of a regulation or CMS Ruling." 42 C.F.R. § 405.1842(f)(1). The Board lacks authority to adjudicate such a challenge. The second criterion for EJR accordingly is met as well.

Conclusion

EJR should be granted.

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