UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

KAWEAH DELTA HEALTH CARE DISTRICT d/b/a KAWEAH DELTA MEDICAL CENTER *et al*.,

Plaintiffs,

v.

XAVIER BECERRA, Acting Secretary, United States Department of Health and Human Services, in his official capacity,

Defendant.

Case No.: CV 20-6564-CBM-SP(x)

ORDER RE: PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT

The matters before the Court are (1) Plaintiffs' Motion for Summary Judgment (Dkt. No. 28); and (2) Defendant's Cross-Motion for Summary Judgment (Dkt. No. 34). The matters are fully briefed.[1] (Dkt. Nos. 35, 36, 37.)[2]

I. BACKGROUND

"Under the Medicare Prospective Payment System,[3] hospitals are

[1] Defendant filed a consolidated opposition to Plaintiffs' summary judgment motion and cross-motion for summary judgment.

[2] After the matters were fully briefed, Plaintiffs filed a notice of supplemental authority re: *Bridgeport Hosp. v. Becerra*, 2022 WL 612658 (D.D.C. Mar. 2, 2022), which the Court has considered in ruling on the motions.

[3] The system is also sometimes referred to as the Hospital Inpatient Prospective Payment System.

reimbursed for inpatient operating costs primarily on the basis of diagnostic related groups. For each diagnostic related group assigned to a discharged Medicare patient, Medicare pays the hospital a prospectively determined amount. The diagnostic related group payment under this Prospective Payment System is determined by the standardized rate and the wage index, both of which are based on the hospital's geographic location." *Skagit Cnty. Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379, 381 (9th Cir. 1996). "The wage index measures the ratio of the average hourly wage (AHW) of hospitals in a given geographic area with the nationally calculated AHW." *Id*. (citing 42 U.S.C. § 1395ww(d)(3)(E)). "Each hospital is assigned to a particular geographic area, and an area wage rate is computed for all participating hospitals in that area. The wage index is used to adjust Prospective Payment System rates to reflect local variations in labor costs." *Id*. Therefore, "the wage index in a specific locality affects the amount of Medicare reimbursements." *Id*. at 382.

This is an action for declaratory and injunctive relief and for "sums due" under the Medicare Act brought by 53 "general acute-care hospitals) (hereinafter, "Plaintiffs" or "Hospitals") against the Defendant Alex M. Azar II ("Defendant" or "Secretary"), in his official capacity as Secretary of the Department of Health and Human Services ("HHS"). This action challenges the federal fiscal year ("FFY") 2020 Hospital Inpatient Prospective Payment System ("IPPS") Final Rule, 84 Fed. Reg. 42,044-01, adopted on August 16, 2019 through which the Secretary increased the wage index values for the bottom quartile of Medicare-participating acute care hospitals with the lowest wage index nationwide (the "Low Wage Index Redistribution") and reduced Medicare inpatient hospital payments of all hospitals for FFY 2020 (the "Payment Reduction") in order to fund the Low Wage Index Redistribution without increasing overall Medicare spending. Plaintiffs assert the Secretary's reduction of Medicare inpatient hospital payments for FFY 2020 through the Payment Reduction policy to fund the

Secretary's Low Wage Index Redistribution was unlawful, and contend as a result of the Secretary's unlawful actions Medicare payments to Plaintiffs (who own 53 California hospitals) for FFY 2020 were "cut by approximately $3.8 million." Plaintiffs each filed appeals of the Low Wage Index Redistribution in the FFY 2020 IPPS Final Rule with the Provider Reimbursement Review Board ("PRRB"), and requested that the PRRB grant an expedited judicial review ("EJR") of the appeals. (*Id*. ¶¶ 19-20.) The PRRB granted Plaintiffs' EJR requests in a letter dated May 27, 2020 (*id*. ¶ 21), and Plaintiffs then filed this action on July 23, 2020 (Dkt. No. 1).[4]

The Complaint asserts the following causes of action: 1) "Violation of the APA [Administrative Procedures Act] and the Medicare Act – The Low Wage Index Redistribution is Contrary to Wage Index Law"); and 2) "Violation of the APA and Medicare Act – The Low Wage Index Redistribution is Unlawful Under 42 U.S.C. § 1395ww(d)(5)(I)"; 3) "Violation of the APA and the Medicare Act - The Low Wage Index Redistribution is Arbitrary and Capricious"; 4) "Violation of the APA and the Medicare Act - The Secretary's Actions Under 42 U.S.C. § 1395ww(d)(5)(I) are Unlawful Because the Secretary Failed to Observe the Procedure Required by Law"; 5) "Violation of the APA - The Low Wage Index Redistribution is Unsupported by the Evidence in the Record"; 6) Mandamus; and 7) All Writs Act. On February 18, 2021, the parties filed a stipulation wherein they stipulated this is an administrative record review case and the action "can be resolved on the basis of cross-motions for summary judgment," and waived any right to pretrial proceedings and trial in this action. (Dkt. No. 23.)

[4] "A hospital may appeal a final determination as to the amount of payment due to a hospital under the Prospective Payment System to the Provider Reimbursement Review Board (PRRB or Reimbursement Board)" and "can seek judicial review of that administrative decision." *Skagit*, 80 F.3d at 382 (citing 42 U.S.C. § 1395oo(a); *id*. § 1395oo(f)(1)). A hospital may seek expedited judicial review regarding a matter that "involves a question of law or regulations relevant to the matters in controversy[, and] the [Board] determines . . . that it is without authority to decide the question." 42 U.S.C. § 1395oo(f)(1).

Given the extensive administrative record filed, the Court set a status conference in this case and inquired whether the parties expected the Court to review the entire administrative record for purposes of ruling on the summary judgment motions. In response to the Court's inquiry, the parties filed a joint stipulation wherein they "designate[d] portions of the administrative record to be reviewed by the Court in connection with the motions for summary judgment" and "agree[d] that the Court should review those portions that are cited or otherwise relied upon by one or more parties concerning the summary judgment motions" as identified in the Appendix to the stipulation. (Dkt. Nos. 45, 46.)

II. STATEMENT OF THE LAW

Under the APA, a court may set aside an agency's action if the action is:

1) "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law";
2) "contrary to constitutional right, power, privilege, or immunity;"
3) "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;"
4) "without observance of procedure required by law;"
5) "unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute;" or
6) "unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court."

5 U.S.C. § 706(2). A motion for summary judgment is the proper mechanism for the district court to review the agency's action under the APA. *Nw. Motorcycle Ass'n v. U.S. Dep't of Agric.*, 18 F.3d 1468, 1471-72 (9th Cir. 1994). However, the Rule 56 standard for summary judgment motions does not apply to cases involving judicial review under the APA because the Court is not required to

resolve any facts in review of an administrative proceeding. *Id.* at 1472 (for cases "involv[ing] review of a final agency determination under the [APA], ... resolution of this matter does not require fact finding on behalf of this court" because "the court's review is limited to the administrative record"). Rather, in APA cases, "the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *City & Cty. of San Francisco v. United States*, 130 F.3d 873, 877 (9th Cir. 1997) (quoting *Occidental Eng'g Co.*, 753 F.2d at 769). "[W]hile formal findings are not required, the record must be sufficient to support the agency action, show that the agency has considered the relevant factors, and enable the court to review the agency's decision." *Beno v. Shalala*, 30 F.3d 1057, 1074 (9th Cir. 1994). The scope of review is typically limited to "the administrative record in existence at the time of the [agency] decision and [not some new] record that is made initially in the reviewing court." *Lands Council v. Powell*, 395 F.3d 1019, 1030 (9th Cir. 2005) (citation omitted).

III. DISCUSSION

A. Writ Mandamus and All Writs Act

Plaintiffs' sixth cause of action entitled "Mandamus" seeks a writ of mandamus "requiring the Secretary to order the Hospitals' MACs [Medicare Administrative Contractors] to make new determinations for FFY 2020 to reverse the effect of applying the 0.2016% payment reduction [i.e. the Payment Reduction], and pay appropriate underpayment interest thereon pursuant to 42 U.S.C. §§ 1395oo(f)(2), 1395g(d) and/or 1395l(j), and 42 C.F.R. § 405.378." (Compl. ¶ 86.) Plaintiff's seventh cause of action entitled "All Writs Act" seeks "issuance of an order" under the All Writs Act, 28 U.S.C. § 1651, "requiring the Secretary to order the Hospitals' MACs to make new determinations for FFY 2020 to reverse the effect of applying the 0.2016% payment reduction [the Payment Reduction], and pay appropriate underpayment interest thereon under 42

U.S.C. §§ 1395oo(f)(2), 1395g(d) and/or 1395l(j), and 42 C.F.R. § 405.378." (*Id.* ¶ 88.) Plaintiffs state they are "not pursuing these counts" for Mandamus and under the All Writs Act and therefore "do not address them further" in their opposition to Defendant's summary judgment motion or Plaintiffs' motion for summary judgment. (Plaintiffs' Opp. at 44 n.22.) Moreover, Plaintiffs stated at the hearing that these claims are being withdrawn and may be dismissed by the Court.

Accordingly, Plaintiffs' sixth cause of action for Writ of Mandamus and seventh cause of action under the All Writs Act are dismissed without prejudice.

B. Standing

As an initial matter, Defendant argues "it is not clear that Plaintiffs have standing to challenge the wage indexes assigned to hospitals in the lowest quartile" through the Low Wage Index Redistribution because "Plaintiffs are not among the hospitals in the lowest quartile" and "thus they are not directly affected by the Secretary's low wage index hospital policy." (Defendant's Motion at 16.) Defendant contends Plaintiffs' alleged injury was caused by the Secretary's separate budget neutrality Payment Reduction policy, and not caused by the Low Wage Index Redistribution policy, and therefore Plaintiffs lack standing to challenge the Low Wage Index Redistribution policy.

Here, the Low Wage Index Redistribution policy and the "budget neutral" Payment Reduction policy are inextricably related. As explained by the Secretary in the Final Rule, "we are finalizing a budget neutrality adjustment to the national standardized amount for all hospitals so that the increase in the wage index for low wage index hospitals, as finalized in this rule, is implemented in a budget neutral manner," "given that budget neutrality is required under section 1886(d)(3)(E) of the Act. (R.R. 00069.) Furthermore, as the Secretary acknowledges in its Motion, "the Secretary adjusted the national standardized amount for all hospitals so that the low wage index hospital policy's increase in the wage indexes for low wage

index hospitals would be implemented in a budget neutral manner." (Defendant's Motion at 21.) Thus, the Secretary adopted the budget neutral Payment Reduction because he believed the Low Wage Index Redistribution policy could not be implemented otherwise unless all the wage index amounts for all hospitals were adjusted (*see* R.R. 00069). Therefore, based on the Secretary's explanation as set forth in the Final Rule, the Payment Reduction policy would not have been necessary absent the Low Wage Index Redistribution policy. Accordingly, treating the Low Wage Index Redistribution policy and the Payment Reduction policy as separate for purposes of challenging Plaintiffs' standing in this action is inappropriate. *See, e.g., Bridgeport Hosp. v. Becerra*, 2022 WL 612658, at *5 (D.D.C. Mar. 2, 2022) (plaintiff hospitals alleging the Secretary reduced the standardized amount to which they are otherwise entitled in order to adopt the Low Wage Index Redistribution policy had Article III standing).

Moreover, since the Secretary articulated in the Final Rule that the reason for the Payment Reduction policy was so that the increase in the wage index for low wage index hospitals pursuant to the Low Wage Index Redistribution policy could be implemented in a budget neutral manner (i.e., without increasing the Medicare budget), the Secretary is barred from arguing for purposes of this litigation that the policies are separate and distinct. *See Independence Mining Co., Inc. v. Babbitt,* 105 F.3d 502, 511 (9th Cir. 1997) ("The rule barring consideration of post hoc agency rationalizations operates where an agency has provided a particular justification for a determination at the time the determination is made, but provides a different justification for that same determination when it is later reviewed by another body."); *Am. Fed'n of Lab. v. Chertoff*, 552 F. Supp. 2d 999, 1012 (N.D. Cal. 2007) (noting "it is unlikely that this Court will even be able to consider DHS's most recent rationale" which was a post hoc rationalization offered for purposes of litigation different from the reason provided by DHS when it promulgated the rule being challenged).

Here, since Plaintiffs allege "the Secretary elected to fund the inflation of wage index values (i.e., Low Wage Index Redistribution) for hospitals in markets with the lowest hospital wage levels in a budget neutral manner by decreasing by 0.2016% the IPPS payments to all Medicare-participating hospitals (i.e., Payment Reduction), which caused Plaintiffs to receive an expected FFY 2020 reduction in IPPS payment of approximately $3.8 million" (Compl. ¶ 2), Plaintiffs allege sufficient facts for Article III standing.

C. Lack of Statutory Authority

Plaintiffs contend the Secretary lacked statutory authority to adopt the Low Wage Index Redistribution and Payment Reduction policies. Defendant contends he is entitled to summary judgment because he, as the Secretary of the HHS, "acted within his delegated statutory authority to determine the so-called 'wage index' component of the payment rate applicable to Plaintiffs and other acute care hospitals for their operating costs of furnishing inpatient services to Medicare beneficiaries in federal fiscal year 2020." Defendant argues he is entitled to summary judgment because the two challenged wage-index policies were issued following notice and comment rulemaking, are consistent with the Secretary's authority under 42 U.S.C. § 1395ww(d)(3)(E)(i) and 42 U.S.C. § 1395ww(d)(5)(I)(i) of the Medicare statute, were fully and rationally explained, and are reasonable.

1) 42 U.S.C. § 1395ww(d)(3)(E)(i)

42 U.S.C. § 1395ww(d)(3)(E)(i) provides that except for certain exceptions, "the Secretary shall adjust the proportion, (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the DRG [diagnosis-related group] prospective payment rates computed under subparagraph (D) for area differences in hospital wage levels by a ***factor*** (established by the Secretary) ***reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage***

level. Not later than October 1, 1990, and October 1, 1993 (and at least every 12 months thereafter), the Secretary shall update the factor under the preceding sentence ***on the basis of a survey*** conducted by the Secretary (and updated as appropriate) of the wages and wage-related costs of subsection (d) hospitals in the United States. . . . Any adjustments or updates made under this subparagraph for a fiscal year (beginning with fiscal year 1991) shall be made in a manner that assures that the aggregate payments under this subsection in the fiscal year are not greater or less than those that would have been made in the year without such adjustment." (Emphasis added.) The "factor" used by the Secretary is the wage index. (Defendant's Motion at 3.) "The wage index measures the ratio of the average hourly wage (AHW) of hospitals in a given geographic area with the nationally calculated AHW." *Skagit*, 80 F.3d at 381.

In connection with the requirement that the Secretary "at least every 12 months ... update the factor ... on the basis of a survey conducted by the Secretary (and updated as appropriate) of the wages and wage-related costs of subsection (d) hospitals in the United States," 42 U.S.C. § 1395ww(d)(3)(E)(i), "[t]he Secretary conducts this survey by compiling wage data from cost reports submitted annually by hospitals." *Anna Jaques Hosp. v. Sebelius*, 583 F.3d 1, 3 (D.C. Cir. 2009) (citing Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates, 69 Fed. Reg. 48,916, 49,049 (Aug. 11, 2004) [hereinafter Final FY 2005 Rates]); *see also* R.R. 00039 ("The FY 2020 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2016," based on the following categories of costs paid under IPPS: salaries and hours from short-term acute care hospitals; home office costs and hours; certain contract labor costs and hours which include direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services; and wage-related costs including pension costs). In other words, the

Secretary is required to update the "factor" (i.e., the wage index) annually based on survey data. 42 U.S.C. § 1395ww(d)(3)(E). "The Secretary removes data from this survey that fail to meet certain criteria for reasonableness," including data that is "incomplete[,] inaccurate ..., or otherwise aberrant. From this scrubbed survey, the Secretary calculates each area's proposed wage index." *Anna Jaques Hosp.*, 583 F.3d at 3 (citing Final FY 2005 Rates, 69 Fed. Reg. at 49,049–50; Final FY 2004 Rates, 68 Fed. Reg. at 45,397); *see also* R.R. 00062 (noting the Secretary, through the Centers for Medicare and Medicaid Services,[5] has "an established multistep, 15-month process for the review and correction of hospital wage data that is used to create the IPPS wage index for the upcoming fiscal year"). "Because of the time required to scrub the data, the Secretary calculates each year's wage index using data from the survey conducted three years earlier." *Id.* (citing Final FY 2005 Rates, 69 Fed. Reg. at 49,049; Final FY 2004 Rates, 68 Fed. Reg. at 45,397); *see also* R.R. 00039 ("The FY 2020 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2016 (the FY 2019 wage indexes were based on data from cost reporting periods beginning during FY 2015); R.R. 00042 (noting the Secretary, through CMS, "gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S–3, Parts II and III of the Medicare cost report for the hospital's cost reporting period relevant to the proposed wage index (in this case, for FY 2020, these were data from cost reports for cost reporting periods beginning on or after October 1, 2015, and before October 1, 2016)); R.R. 00064 ("[T]he wage index calculations rely on historical data."). "The wage index is used to adjust Prospective Payment System rates to reflect local variations in labor costs," and "the wage index in a

[5] The Centers for Medicare and Medicaid Services ("CMS") is "an agency housed in the United States Department of Health and Human Services ("HHS")" which administers the Medicare program. *Sensory Neurostimulation, Inc. v. Azar*, 977 F.3d 969, 973 (9th Cir. 2020).

specific locality affects the amount of Medicare reimbursements." *Skagit*, 80 F.3d at 381, 382.

Here, the Secretary "proposed to increase the wage index values for hospitals with a wage index value in the lowest quartile of the wage index values across all hospitals" in order to address "growing disparities between low and high wage index hospitals" and because "some current wage index policies create barriers to hospitals with low wage index values from being able to increase employee compensation due to the lag between when hospitals increase the compensation and when the increases are reflected in the calculation of the wage index." (R.R. 00064.) The Secretary "proposed to increase the wage index for hospitals with a wage index value below the 25th percentile wage index," so that an "increase in the wage index for these hospitals would be equal to half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals" and that this proposed policy "would be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation." (*Id.*) The Secretary adopted this proposal (the "Low Wage Index Redistribution" policy) in the Final Rule challenged here. The Secretary also adjusted the wage index values of all hospitals in order to implement the Low Wage Index Redistribution Policy without increasing overall Medicare spending (*see* Defendant's Opp. at 1) by adopting a 0.2016% decrease in the standardized payment amounts of all IPPS hospitals to offset the additional payments that hospitals in the bottom quartile would receive (the "Payment Reduction policy" or "budget neutral policy"). (R.R. 00005, 00083.)

42 U.S.C. § 1395ww(d)(3)(E) "expressly delegates substantial authority to the Secretary to determine the composition of the wage index—Congress empowered the Secretary to 'estimate[ ]' the proportion of labor costs and

'establish[ ]' the wage index." *Atrium Med. Ctr. v. U.S. Dep't of Health & Hum. Servs.*, 766 F.3d 560, 568 (6th Cir. 2014). As noted by the Sixth Circuit, "[t]he legislative history confirms that Congress intended to grant the Secretary exceptionally broad discretion to determine the wage index—the relevant conference report simply stated that '[n]o particular methodology for developing the indices is specified.'" *Id*. (citing H.R. Rep. No. 100-495, at 521 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1245, 2313-1267).

Defendant argues the Secretary is not required to calculate the wage index with exactitude. However, "[a]lthough section 1395ww(d)(3)(E) grants the Secretary substantial discretion," the statute's "consistent use of the singular—'the proportion' and 'a factor'—indicates that the wage index must be uniformly determined and applied" and "the index must in fact encompass only 'wages and wage-related costs' and must reasonably 'reflect the relative hospital wage level' in a given area." *Id*. (citing *Sarasota Mem'l Hosp. v. Shalala,* 60 F.3d 1507, 1512-13 (11th Cir. 1995) (§ 1395ww(d)(3)(E) requires both a "uniform picture" of wage levels and "a uniform index")). "[T]he index is based on available wage data from [surveys from] past years," and "at any given time the wage index must reflect the Secretary's best approximation of relative regional wage variations." *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1230 (D.C. Cir. 1994); *see also Anna Jaques Hosp.*, 583 F.3d at 3 (the Secretary "calculates each area's proposed wage index" from survey data). "The crucial consideration is that, whatever definitions the Secretary employs, she applies them consistently in order to avoid distorting the wage index. In other words, section 1395ww(d)(3)(E) precludes the Secretary from treating different types of costs as the same or the same type of cost differently for different hospitals." *Atrium Med. Ctr.*, 766 F.3d at 569.

Defendant argues he acted within his authority to update the wage indexes because he "employed the wage data from the annual surveys" and then applied the Low Wage Index Redistribution policy, and he "ensured that the wage indexes

reflected 'the *relative* hospital wage level in the geographic area of the hospital compared to the national average hospital wage level'" by "maintaining the rank order" of the hospitals. Defendant argues he therefore could not have exceeded his authority to update the wage indexes because the Low Wage Index Redistribution policy "did not abandon the use of survey data."

However, here, after calculating the wage index based on actual survey data, the Secretary then inflated the wage index values he had previously calculated for the hospitals in the lowest quartile.[6] Therefore, because the Low Wage Index Redistribution policy "increase[d] the wage index values for hospitals with a wage index value in the lowest quartile of the wage index values across all hospitals" "equal to half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals" (R.R. 00064), the Secretary did not treat all hospitals consistently and failed to calculate the final wage index values taking into account "the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level" based on the survey data from the prior three years as required under 42 U.S.C. § 1395ww(d)(3)(E)(i). *See Bridgeport Hosp.*, 2022 WL 612658, at *8 (finding "[t]he low wage index hospital policy . . . is not a calculation of 'the' relative wage levels of hospitals in different geographic regions as compared to 'the' national average hospital wage level, and it is not 'uniformly determined and applied'" because "the low wage index policy *inflates* the wage index values of the hospitals in the lowest quartile," and concluding "nothing in the statute suggests that Congress intended to give the agency the authority to adjust upward the wage index values of only those hospitals in the bottom quartile in a manner that does *not* 'reflect[ ] the relative

[6] The Secretary sometimes refers to the inflation of wage index for the bottom quartile as an "upward adjustment" for low wage index hospitals. (*See* Defendant's Opp. at 18.)

hospital wage level in the geographic area of [low wage index] hospital[s] compared to the national average hospital wage level,' as required by 42 U.S.C. § 1395ww(d)(3)(E)(i).").[7] Accordingly, the Secretary's treatment of the lowest quartile of hospitals differently from the rest of the hospitals through the Low Wage Index Redistribution policy violated Section 1395ww(d)(3)(E)(i)'s requirement regarding determination of a uniform wage index. *See Atrium Med. Ctr.*, 766 F.3d at 569 (42 U.S.C. § 1395ww(d)(3)(E)'s "consistent use of the singular—'the proportion' and 'a factor'—indicates that the wage index must be uniformly determined and applied.").[8]

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[7] Contrary to Defendant's contention, the fact that the Secretary "preserve[d] the rank order of hospital wage levels" does not satisfy the requirement that the Secretary adjust "for area differences in wage levels by a factor (i.e., the wage index) . . . . reflecting the relative hospital wage level in the geographic area ***compared to*** the national average hospital wage level." 42 U.S.C. § 1395ww(d)(3)(E)(i) (emphasis added). Commenters to the proposed rule raised this issue during notice and comment rulemaking. (*See* R.R. 07309-10 ("CMS cannot, as the rule seems to argue, arbitrarily alter wage adjustments as long as it ensures that those above the national average are greater than 1.0 while those below the national average are below 1.0. Inherent in the concept of an area's relative wage is the ***proportionality*** of that relativity, which is lost under this proposal.") (emphasis added); R.R. 07612-13 ("Between CMS's proposed inflation of the lowest quartile and its proposed reduction to the highest quartile, it is not reasonable to conclude that the proposed policy change would continue to reflect ". . . the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. . . ." CMS cannot, as the rule seems to argue, arbitrarily alter wage adjustments as long as it ensures that those above the national average are greater than 1.0 while those below the national average are below 1.0. Inherent in the concept of an area's relative wage is the proportionality of that relativity, which is lost under this proposal.").) Therefore, by inflating the wage index only for the lowest quartile of hospitals, the Secretary failed to make an adjustment "reflecting" the proportion of each hospital's wage level in a geographic area "compared to" the national average hospital wage level. 42 U.S.C. § 1395ww(d)(3)(E)(i). *See Atrium Med. Ctr.*, 766 F.3d at 569 (42 U.S.C. § 1395ww(d)(3)(E)'s "consistent use of the singular—'the proportion' and 'a factor'—indicates that the wage index must be uniformly determined and applied.").

[8] *See also Sarasota Mem'l Hosp. v. Shalala*, 60 F.3d 1507, 1513 (11th Cir. 1995) ("Because the Secretary was required to establish a wage index to create a uniform picture of what wage levels were at all provider hospitals in 1982, we hold that the Secretary's exclusion of employee FICA taxes from wages for some hospitals and not others, for purposes of creating the 1982 wage index, was arbitrary and capricious," and "we hold that the Secretary's classification of employee FICA taxes as fringe benefits is unreasonable and inconsistent with the mandate of the Medicare statute requiring a uniform wage index."); *Marshall Cnty. Health Care Authority v. Shalala*, 988 F.2d 1221, 1224 (D.C. Cir. 1993) (noting "Congress has

Moreover, the plain language of 42 U.S.C. § 1395ww(d)(3)(E)(i) required that the Secretary "adjust the proportion, (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the DRG [diagnosis-related group] prospective payment rates computed under subparagraph (D) for area differences in hospital wage levels by a factor (established by the Secretary) ***reflecting*** the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level." (Emphasis added.) The Secretary's contention that he "ensured that the wage indexes reflected 'the *relative* hospital wage level in the geographic area of the hospital compared to the national average hospital wage level'" by "maintaining the rank order" of the hospitals is inconsistent with the plain meaning of "reflect." The dictionary definition of the term "reflect" is "to give back or exhibit as an image, likeness, or outline," or "mirror." "Reflect," *Merriam-Webster.com Dictionary*, Merriam-Webster, available at https://www.merriam-webster.com/dictionary/reflect. Therefore, the Secretary's inflation of the wage index values for the hospitals in the lowest quartile after calculating the wage index based on actual survey data does not "reflect" or "mirror" the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.

Therefore, the Court finds the Secretary did not have authority under 42 U.S.C. § 1395ww(d)(3)(E)(i) to adopt the Low Wage Index Redistribution policy.

2) 42 U.S.C. § 1395ww(d)(5)(I)(i)

Notwithstanding the above, 42 U.S.C. § 1395ww(d)(5)(I)(i) provides: "The Secretary shall provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate."

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provided a rather specific norm ... to guide the Secretary's judgment" and "[w]ere the Secretary arbitrarily to grant an exception for some hospitals and not for others identically situated, one could expect a successful challenge.").

(Hereinafter, the "Exceptions and Adjustments clause").

a. Non-Delegation

Plaintiffs argue interpreting the Exceptions and Adjustments clause to only limit the Secretary to what he "deems appropriate" would give the Secretary "unfettered delegation of power" based on an unintelligible principle as to whatever the Secretary "deems appropriate" which would ultimately be no limitation to the Secretary's authority whatsoever. (Plaintiff's Motion at 16.) Defendant argues the Secretary's interpretation of Section 1395ww(d)(5)(I) does not violate the nondelegation doctrine.

"A statutory delegation is constitutional as long as Congress 'lay[s] down by legislative act an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform.'" *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019) (citation omitted). "These standards are 'not demanding.'" *United States v. Melgar-Diaz*, 2 F.4th 1263, 1267 (9th Cir. 2021), *cert. denied*, 142 S. Ct. 813 (2022); *see also United States v. Reliance Med. Sys., LLC*, 2021 WL 3473927, at *2 (C.D. Cal. Aug. 6, 2021) ("[T]he non-delegation principle sets a low bar."). The Supreme Court has upheld broad guiding principles for delegated authority such as "to regulate in the public interest" and "to protect the public health." *Gundy*, 139 S. Ct. at 2129 (internal quotation marks and citations omitted). "Only twice in this country's history" has the Supreme Court "found a delegation excessive" and in each of those two cases it was because "'Congress had failed to articulate *any* policy or standard' to confine discretion." *Id.*; *see also Melgar-Diaz*, 2 F.4th at 1267 (noting because permissible delegation standards are not demanding, "[t]he Supreme Court has therefore repeatedly turned down many non-delegation challenges, including in cases involving very broad conferrals of authority").

Here, while the delegation to the Secretary to make exceptions and adjustments as he "deems advisable" is broad, the Supreme Court and other

Circuits have upheld other similarly broad delegations of power. *See FPC v. Hope Natural Gas Co.,* 320 U.S. 591, 600-01 (1944) (upholding delegation to Federal Power Commission to determine "just and reasonable" rates); *National Broadcasting Co. v. United States,* 319 U.S. 190, 194, 225-26 (1943) (upholding delegation to the Federal Communications Commission to regulate broadcast licensing as "public interest, convenience, or necessity" require); *Humphrey v. Baker*, 848 F.2d 211, 217 (D.C. Cir. 1988) (delegation to the President of authority to set salary amounts as the President "deems advisable" was not an unconstitutional delegation of legislative power).

Thus, the Court finds the Exceptions and Adjustments clause is not an unconstitutional delegation of power to the Secretary. However, as discussed below, the Secretary did not have authority under the Exceptions and Adjustments clause to adopt the Low Wage Index Redistribution policy at issue here.

b. Statutory Interpretation

The parties disagree as to whether the Secretary had authority to implement the Low Wage Index Redistribution Policy challenged in this action pursuant to the Exceptions and Adjustments clause, 42 U.S.C. § 1395ww(d)(5)(I)(i). The Exceptions and Adjustments clause expressly limits the Secretary's authority to make exceptions and adjustments to "payment amounts" as the Secretary "deems appropriate"—the plain language of the clause does not refer to changes to the "wage index" or "wage levels." Elsewhere in this statute, the legislature used the terms "wage levels" and "wage index." *See Bare v. Barr*, 975 F.3d 952, 968 (9th Cir. 2020) ("It is a well-established canon of statutory interpretation that the use of different words or terms within a statute demonstrates that Congress intended to convey a different meaning for those words" and "[w]e must presume that Congress intended a different meaning when it uses different words in connection with the same subject.") (internal quotations and citations omitted). Therefore, the plain language of the Exceptions and Adjustments clause uses the term "payment

amounts" and did not refer to "wage levels" or the "wage index" (although Congress was aware of those terms and use them elsewhere in the statute) and thus under traditional canons of statutory interpretation it is presumed Congress did not intend for the Exceptions and Adjustments clause to give the Secretary authority to adjust the wage index level for the lowest quartile of hospitals. *See Agredano v. Mutual of Omaha Cos.*, 75 F.3d 541, 544 (9th Cir. 1996) (under canons of statutory interpretation, "terms of the same statute are not to be construed so as to be redundant" and it must be assumed that an enacting body is aware of each term of the statute and therefore would not knowingly use any given term to mean different things within the same statute); *Bridgeport Hosp.*, 2022 WL 612658, at *10 n.11 ("The 'exceptions and adjustments' provision also authorizes adjustments only to 'payment amounts,' not to any wage index value established under § 1395ww(d)(3)(E)(i).").

Even if the Court assumed the Exceptions and Adjustments clause provides the Secretary with authority to make adjustments to items other than payments, the Secretary lacks authority to inflate the wage index value for the lowest quartile of hospitals under that clause. The Court of Appeals for the District of Columbia Circuit has described the Exceptions and Adjustments clause as providing the Secretary with a "broad-spectrum grant of authority." *Adirondack Med. Ctr.*, 740 F.3d at 694. Notwithstanding this broad grant of authority, courts have held the "'exceptions and adjustments' provision does not give the [agency] carte blanche to override the rest of the Act." *Shands Jacksonville Med. Ctr.*, 139 F. Supp. 3d at 251; *see also Bridgeport Hosp.*, 2022 WL 612658, at *10 ("Reading the general 'exceptions and adjustments' provision to allow the agency to adopt the low wage index hospital policy[9] would gut the specific statutory provisions in place to

[9] The district court in *Bridgeport Hospital* addressed the Secretary's authority under the Exceptions and Adjustments clause with respect to the same Low Wage Index Redistribution policy being challenged here in this case.

calculate the wage index."). As the Supreme Court recently recognized:

> Extraordinary grants of regulatory authority are rarely accomplished through modest words, vague terms, or subtle device[s]. Nor does Congress typically use oblique or elliptical language to empower an agency to make a "radical or fundamental change" to a statutory scheme. . . . We presume that Congress intends to make major policy decisions itself, not leave those decisions to agencies.

W. Virginia v. Env't Prot. Agency, 142 S. Ct. 2587, 2609 (2022).

Here, adopting the Secretary's interpretation of the Exceptions and Adjustments clause as granting him authority to inflate the wage index values of the lowest quartile of hospitals would present a fundamental conflict with the specific provisions in the statute prescribing the manner in which the Secretary may "adjust the proportion . . . of hospitals' costs which are attributable to wages and wage-related costs, of the DRG prospective payment rates computed . . . for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level . . . on the basis of a survey conducted by the Secretary (and updated as appropriate) of the wages and wage-related costs" of the hospitals. 42 U.S.C. § 1395ww(d)(3)(E)(i). *See Hibbs v. Winn*, 542 U.S. 88, 101 (2004) ("A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant."); *Varity Corp. v. Howe*, 516 U.S. 489, 511 (1996) ("This Court has understood the present canon ('the specific governs the general') as a warning against applying a general provision when doing so would undermine limitations created by a more specific provision."); *Perez-Martin v. Ashcroft*, 394 F.3d 752, 758 (9th Cir. 2005) ("[I]t is a well-settled canon of statutory interpretation that specific provisions prevail over general provisions.") (citation omitted); *Bridgeport Hosp.*, 2022 WL 612658, at *10 (reading the "exceptions and adjustments" provision to permit the Secretary to "adopt the low wage index hospital policy" would permit the Secretary to "get around clear statutory

directives [requiring the calculation of the relative hospital wage levels of particular geographic regions as compared to the national average] by invoking the exceptions and adjustments provision as a basis of unbounded authority."); *cf. Shands Jacksonville Med. Ctr.*, 139 F. Supp. 3d at 260 ("The challenged 0.2 percent reduction . . . does not present a fundamental conflict with the Act's inpatient prospective payment scheme" and "it therefore suffices to conclude that the Secretary's interpretation of the exceptions and adjustments provision" as authorizing the 0.2 across the board reduction in payments "is a reasonable one.").

Moreover, the Low Wage Index Redistribution and Payment Reduction policies are "major policy decisions" and a "fundamental" change to the manner in which wage indexes are calculated by the Secretary. *W. Virginia v. Env't Prot. Agency*, 142 S. Ct. at 2609. As the Secretary himself explained, he adopted these policies because:

> As CMS and other entities have stated in the past, comprehensive wage index reform would require both statutory and regulatory changes, and could require new data sources. . . . [N]otwithstanding the challenges associated with comprehensive wage index reform, we agree with respondents to the request for information who indicated that some current wage index policies create barriers to hospitals with low wage index values from being able to increase employee compensation due to the lag between when hospitals increase the compensation and when those increases are reflected in the calculation of the wage index. (We noted that this lag results from the fact that the wage index calculations rely on historical data.) We also agreed that addressing this systemic issue does not need to wait for comprehensive wage index reform given the growing disparities between low and high wage index hospitals, including rural hospitals that may be in financial distress and facing potential closure. Therefore, in response to these concerns, in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19395), we proposed a policy that would provide certain low wage index hospitals with an opportunity to increase employee compensation without the usual lag in those increases being reflected in the calculation of the wage index.

(R.R. 00069.) Thus, because the Court must "presume that Congress intends to make major policy decisions itself, not leave those decisions to agencies," and because Congress does not "typically use oblique or elliptical language to empower an agency to make a 'radical or fundamental change' to a statutory

scheme," *see W. Virginia v. Env't Prot. Agency*, 142 S. Ct. at 2609, it is unlikely Congress intended for the Exceptions and Adjustments clause to grant the Secretary with authority to implement major policy decisions such as the Low Wage Index Redistribution and Payment Reduction policies.

Accordingly, the Court finds the Secretary did not have authority under the Exceptions and Adjustments clause to adopt the Low Wage Index Redistribution policy.[10]

c. "By Regulation" Requirement

The Exceptions and Adjustments clause provides: "The Secretary ***shall provide by regulation*** for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate." 42 U.S.C. § 1395ww(d)(5)(I)(i) (emphasis added). Plaintiffs argue even if the Exceptions and Adjustments clause authorized the Secretary to apply the Low Wage Index Redistribution Policy, the Secretary failed to comply the Exceptions and Adjustments clause's "by regulation" requirement because there was no publication of the Low Wage Index Redistribution policy in the Code of Federal Regulations. Defendant argues the Low Index Wage Redistribution policy was a regulation within the meaning of 42 U.S.C. § 1395ww(d)(5)(I)(i)'s Exceptions and Adjustments clause because it was published in the Federal Register and the Secretary was not required to publish the policy in the Code of Federal Regulations.

42 U.S.C. § 1395hh(a)(2) states "[n]o rule, requirement, or other statement

[10] Plaintiffs also contend the Secretary did not invoke his authority under the Exceptions and Adjustments clause to adopt the Low Wage Index Redistribution policy during notice and comment rulemaking, and only invoked his authority under that clause as to the Payment Redistribution policy. However, in the Final Rule in response to comments questioning the Secretary's authority to invoke the policies under 42 U.S.C. § 1395ww(d)(3)(E), the Secretary stated, "we believe we have authority to implement our lowest quartile wage index proposal . . . under section 1886(d)(3)(E) of the Act . . ., and under our exceptions and adjustments authority under section 1886(d)(5)(I) of the Act." (R.R. 00067.)

of policy . . . that establishes or changes a substantive legal standard governing . . . the payment of services . . . shall take effect unless it is promulgated by the Secretary by regulation . . . ." 42 U.S.C. § 1395hh(a)(1) provides that "the term 'regulations' means, unless the context otherwise requires, regulations prescribed by the Secretary." 42 U.S.C. § 1395hh(b)(1) states "before issuing in final form any regulation under subsection (a), the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon."

The issue of whether the Low Wage Index Redistribution policy is a regulation was addressed by the Provider Reimbursement Review Board ("PRRB") in its May 27, 2020 decision granting expedited judicial review of the hospitals' appeal, wherein the PRRB found "the Secretary's determination to finalized a budget neutrality adjustment to the national standardized amount for all hospitals so that the increase in the wage index for low wage index hospitals was implemented in a budget neutral manner was made through notice and comment in the form of an ***uncodified regulation***." (R.R. 000007 (emphasis added).) The PRRB noted although "[t]he Secretary did not incorporate into the Code of Federal Regulations the new policy setting forth a modification to the wage index calculation determination by finalizing a budget neutrality adjustment to the national standardized amount for all hospitals so that there was an increase in the wage index for low wage index hospitals," it was "clear from the use of the following language in the preamble to the FFY 2020 IPPS Final Rule that the Secretary intended to bind the regulated parties and establish a binding uniform payment policy through formal notice and comment":

> We acknowledge, however, that some commenters have presented reasonable policy arguments that we should consider further regarding the relationship between our proposed budget neutrality adjustment targeting high wage hospitals and the design of the wage index to be a relative measure of the wages and wage-related costs of subsection (d) hospitals in the United States. Therefore, given that budget neutrality is required under section 1886(d)(3)(E) of the Act,

> given that even if it were not required, we believe it would be inappropriate to use the wage index to increase or decrease overall IPPS spending, and given that we wish to consider further the policy arguments raised by commenters regarding our budget neutrality proposal, we are finalizing a budget neutrality adjustment for our low wage hospital policy, but we are not finalizing our proposal to target that budget neutrality adjustment on high wage hospitals. Instead, consistent with CMS's current methodology for implementing wage index budget neutrality under section 1886(d)(3)(E) of the Act and the alternative approach we considered in the proposed rule . . ., we are finalizing a budget neutrality adjustment to the national standardized amount for all hospitals so that the increase in the wage index for low wage index hospitals, as finalized in this rule, is implemented in a budget neutral manner.

(R.R. 000008-9.) Accordingly, the PRRB found "the Secretary intended this policy change to be a binding but uncodified regulation," and noted "this finding is consistent with the Secretary's obligations under 42 U.S.C. § 1395hh(a)(2) to promulgate any 'substantive legal standard governing . . . the payment of services' as a regulation." (R.R. 000009.) However, the PRRB's conclusion is circular because it concludes the Secretary must have intended that the Low Wage Index Redistribution policy to be a regulation because the Secretary is required to promulgate any substantive legal standard regarding the payment of services as a regulation.

Here, it is undisputed the Secretary published the Low Wage Index Redistribution policy in the Federal Register in a preamble to the final rule, but did not publish the policy in the Federal Code of Regulations. The fact that the policy was published in the Federal Register in a preamble to the final rule, and not published in the Code of Federal Regulations, demonstrates the Low Wage Index Redistribution policy was not intended to be a regulation regarding a substantive legal standard. In *River Runners for Wilderness v. Martin*, 593 F.3d 1064, 1072 (9th Cir. 2010), the Ninth Circuit concluded that the National Park Service's policies were not enforceable substantive rules because the policies were not published in the Federal Register or the Code of Regulations. The *River Runners* court noted that the Ninth Circuit has established a two-part test for determining when agency pronouncements have the force and effect of law:

> To have the force and effect of law, enforceable against an agency in federal court, the agency pronouncement must (1) prescribe substantive rules—not interpretive rules, general statements of policy or rules of agency organization, procedure or practice—and (2) conform to certain procedural requirements. To satisfy the first requirement the rule must be legislative in nature, affecting individual rights and obligations; to satisfy the second, it must have been promulgated pursuant to a specific statutory grant of authority and in conformance with the procedural requirements imposed by Congress.

Id. at 1071 (citing In *United States v. Fifty–Three (53) Eclectus Parrots*, 685 F.2d 1131 (9th Cir. 1982)). Applying the two-part test, the *River Runners* court found the National Park Services' polices were not enforceable because they failed both parts of the test since the policies "did not prescribe substantive rules, nor were they promulgated in conformance with the procedures of the APA." *Id*. at 1073. As to the second part of the test, the Ninth Circuit noted that the policies were not published in the Federal Register but then emphasized: "What is more important, the Policies were never published in the Code of Federal Regulations. This suggests that the Park Service did not intend to announce substantive rules enforceable by third parties in federal court." *Id.* at 1072.[11]

Moreover, the D.C. Circuit recently found:

> Publication in the Federal Register does not suggest that the matter published was meant to be a regulation, since the APA requires general statements of policy to be published as well.[12] Instead, the real dividing point between the portions of a final rule with and without legal force is designation for publication in the Code of Federal Regulations. To be sure, we have reserved a possibility that statements in a preamble may in some unique cases constitute binding, final agency action susceptible to judicial review. But this is not the norm because [a]gency statements having general applicability and legal effect are to be published in the Code of Federal Regulations.

[11] Defendant relies on *United States v. Cannon*, 345 F. App'x 301 (9th Cir. 2009), wherein the panel rejected the defendant's contention that unpublished hunting regulations are not regulations for the purposes of the Lacey Act because they were not published, reasoning the defendant's "argument is not persuasive" because "[t]here is no case or statute to indicate that publication is a defining and necessary characteristic of a federal regulation." *Id.* at 302. However, *Cannon* is an unpublished decision decided prior to *River Runners*.

[12] *See* 5 U.S.C. § 552(a) (requiring each agency to publish in "statements of the general course" in the Federal Register "for the guidance of the public").

AT&T Corp. v. Fed. Commc'ns Comm'n, 970 F.3d 344, 350-51 (D.C. Cir. 2020) (internal quotations and citations omitted);[13] *see also Brock v. Cathedral Bluffs Shale Oil Co.,* 796 F.2d 533, 539 (D.C. Cir. 1986) ("*Publication* in the Federal Register does *not* suggest that the matter published *was* meant to be a regulation, since the APA requires general statements of policy to be published as well. The real dividing point between regulations and general statements of policy is publication in the Code of Federal Regulations, which the statute authorizes 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.'")[14] (citing 44 U.S.C. § 1510;[15] 1 C.F.R. § 8.1[16]); *Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 569-70 (D.C. Cir. 2002) ("[I]t 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."); *Utah Power & Light Co. v. Sec'y of Labor*, 897 F.2d 447, 450 (10th Cir. 1990) ("[P]reamble to the regulations … is not part of the

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[13] Defendant does not address the *AT&T Corp*. decision.

[14] Defendant argues nothing in the *Brock* decision requires that all regulations must be published in the Code of Federal Regulations. However, the *Brock* decision distinguishes between statements of policy (which are required to be published in the Federal Register) and regulations which it stated are published in the Code of Federal Regulations. *Brock*, 796 F.2d at 539. Thus, *Brock* supports finding the Secretary's publication of the Low Wage Index Redistribution policy in the Federal Register alone fails to demonstrate the policy was intended to be a regulation.

[15] 44 U.S.C. § 1510 provides: "The Administrative Committee of the Federal Register, with the approval of the President, may require, from time to time as it considers necessary, the preparation and publication in special or supplemental editions of the Federal Register of complete codifications of the documents of each agency of the Government ***having general applicability and legal effect, issued or promulgated by the agency by publication in the Federal Register*** or by filing with the Administrative Committee, and are relied upon by the agency as authority for, or are invoked or used by it in the discharge of, its activities or functions, and are in effect as to facts arising on or after dates specified by the Administrative Committee." (Emphasis added.)

[16] 1 C.F.R. § 8.1 provides: "[T]he Director of the Federal Register shall publish periodically a special edition of the Federal Register to present a compact and practical code called the 'Code of Federal Regulations', to contain each Federal regulation of ***general applicability and legal effect***." (Emphasis added.)

regulations as published in the Code of Federal Regulations.").

The Secretary's Office of General Counsel ("OGC") recognized the D.C. Circuit's *AT&T Corp.* decision in an advisory opinion dated December 3, 2020, wherein the OGC opined:

> Social Security Act Section 1871(a)(2) states that no Medicare issuance that establishes or changes a "substantive legal standard" governing the scope of benefits, payment for services, eligibility of individuals to receive benefits, or eligibility of individuals, entities, or organizations to furnish services, "shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1)." Paragraph (1), in turn, explains that "[w]hen used in this title, the term 'regulations' means, unless the context otherwise requires, regulations prescribed by the Secretary." Social Security Act § 1871(a)(1). The Supreme Court in [*Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019)] did not address the procedures that HHS must undertake in order to comply with its "notice-and-comment obligations under § 1395hh(a)(2)." 139 S. Ct. at 1817. The D.C. Circuit recently reiterated that the dividing line "between the portions of a final rule with and without legal force is designation for 'publication in the Code of Federal Regulations.'" *AT&T Corp. v. Fed. Commc'ns Comm'n*, 970 F.3d 344, 350 (D.C. Cir. 2020) (quoting *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 539 (D.C. Cir. 1986) (Scalia, J.)). While preambles often contain interpretive statements that are not binding rules, agencies can satisfy notice-and-comment obligations under § 1395hh(a)(2) without codifying rules in the Code of Federal Regulations. Nonetheless, rulemaking through preambles only should be relatively rare, even for an agency as large as HHS: "statements in a preamble 'may in some unique cases constitute binding, final agency action' . . . . [b]ut 'this is not the norm.'" *AT&T Corp.*, 970 F.3d at 350 (quoting *NRDC v. EPA*, 559 F.3d 561, 565 (D.C. Cir. 2009) and citing 44 U.S.C. § 1510(a)); *see also* 1 C.F.R. § 8.1 (describing how the Code of Federal Regulations shall "contain each Federal regulation of general applicability and legal effect").

Dep't of Health & Human Servs., Office of the Secretary, Office of the General Counsel, Advisory Opinion 20-05 on Implementing *Allina* (Dec. 3, 2020), available at https://www.hhs.gov/sites/default/files/allina-ao.pdf (hereinafter "OGC December 2020 Advisory Opinion"). The OGC further opined, "when HHS engages in notice-and-comment rulemaking through preamble language only, the Department must be sufficiently clear to separate binding legal obligations from the rest of the preamble text that contains nonbinding interpretive statements," and stated "HHS will make clear its intent to engage in rulemaking

through preambles by either: 1) specifically speaking to the Department's intent in both the proposed and final rule preamble text, such as by using the phrase 'HHS intends to bind itself' to the rule, or 2) stating that HHS would engage in notice-and-comment rulemaking in order to change the stated preamble policy." *Id*. Here, Defendant has not identified anything in the record demonstrating the Secretary made it clear that he intended to engage in rulemaking through the preamble to the final rule at issue in this action by using the phrase "HHS intends to bind itself" to the final rule or stating the Secretary "would engage in notice-and-comment rulemaking in order to change the stated preamble policy."[17]

Defendant further argues the Court must reject Plaintiffs' contention that the Low Wage Index Redistribution policy is not a regulation simply because it was not published in the Code of Federal Regulations despite being published in the Federal Register in light of the Ninth Circuit's decision in *Quechan Indian Tribe v. U.S. Dep't of Lab.*, 723 F.2d 733 (9th Cir. 1984). *Quechan*, however, is therefore inapposite because it dealt with a regulation that had previously been published in the Code of Federal Regulations and subsequently deleted. Here, the Low Index Wage Redistribution policy was never published in the Code of Federal Regulations.

Therefore, the Court finds the Secretary failed to implement the Low Wage Index Redistribution policy "by regulation" as required under the Exceptions and Adjustments clause set forth in 42 U.S.C. § 1395ww(d)(5)(I)(i).[18]

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[17] Defendant argues the OGC's Advisory Opinion "is not intended to bind HHS or the federal courts, and it 'does not have the force or effect of law.'" However, the OGC's Advisory Opinion sets forth the OCG's own position regarding what the Secretary must do to promulgate satisfy the "by regulation" requirement for Medicare payments and reaffirms the D.C. Circuit's decision in *AT&T Corp*. Thus, the Secretary's failure to comply with the OCG's opinion further supports this Court's finding the Secretary failed to comply with the "by regulation" requirement in this case.

[18] Plaintiffs also argue the Exceptions and Adjustments clause only permits budget neutrality adjustments for transfer cases, and therefore the Secretary's Payment Reduction policy was not authorized under the Exceptions and Adjustments clause. The Court does not reach this issue, however, because the Court finds the

* * *

For the reasons discussed above, the Secretary's adoption of the Low Wage Index Redistribution and Payment Reduction policies exceeded his authority under the Medicare Act and therefore violated the APA. *See* 5 U.S.C. § 706(2).[19]

D. Remedies

"'Ordinarily when a regulation is not promulgated in compliance with the APA, the regulation is invalid.'" *Organized Vill. of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 970 (9th Cir. 2015) (citing *Paulsen v. Daniels*, 413 F.3d 999, 1008 (9th Cir. 2005); 5 U.S.C. § 706(2)(A)). The Ninth Circuit has noted that "[w]e order remand without vacatur only in 'limited circumstances'" and "[w]e leave an invalid rule in place only 'when equity demands' that we do so.' When determining whether to leave an agency action in place on remand, we weigh the seriousness of the agency's errors against 'the disruptive consequences of an interim change that may itself be changed." *Id*.

Here, while the Secretary committed serious error by adopting the Low Wage Index policy which exceeded his authority under the Medicare Act in violation of the APA, vacatur of the policy creates a serious risk of disruption to the Medicare Prospective Payment System and operation of hospitals. Therefore, the Court finds the proper remedy here is remand without vacatur. *See id*.; *see also City of Los Angeles v. Dickson*, 2021 WL 2850586 (9th Cir. July 8, 2021) (remanding without vacatur where the agency action was a serious error but the consequences of vacatur would cause severe disruption).

IV. CONCLUSION

Accordingly, the Court:

1) **DISMISSES** Plaintiff's sixth cause of action (Mandamus) and seventh cause of action (All Writs Act) **without prejudice**;

Secretary lacked authority to adopt the Low Wage Index Redistribution policy.

[19] Therefore, the Court does not reach the parties' remaining arguments regarding violation of the APA.

2) **GRANTS** Plaintiffs' Motion for Summary Judgment; and

3) **DENIES** Defendant's Cross-Motion for Summary Judgment.

The Court remands the matter to the Secretary for further proceedings consistent with this Order.

IT IS SO ORDERED.

DATED: December 22, 2022.

CONSUELO B. MARSHALL
UNITED STATES DISTRICT JUDGE