PROVIDER REIMBURSEMENT REVIEW BOARD DECISION

2017-D5

PROVIDER –
East Texas Medical Center - Athens

Provider No.: 45-0389

vs.

MEDICARE CONTRACTOR –
Novitas Solutions, Inc.

HEARING DATE –
July 23, 2015

Cost Reporting Periods Ended –
April 30, 2015; April 30, 2016

CASE NOS.: 15-0146; 16-0811

INDEX

ISSUE:

Whether the Centers for Medicare and Medicaid Services ('CMS") have assigned the Provider to the correct Core Based Statistical Area ("CBSA") for the Federal Fiscal Year ("FFY") 2015.[1]

DECISION:

After considering the Medicare law and program instructions, the evidence presented and the parties' contentions, the Provider Reimbursement Review Board ("Board") majority concludes that it does not have the authority to grant the relief sought in this appeal; that is, the redesignation of Henderson County from the Tyler, Texas CBSA to the Dallas-Plano-Irving, Texas CBSA.

INTRODUCTION:

East Texas Medical Center - Athens ("ETMC" or "Provider") is a 127-bed acute care hospital located in Athens, Texas, which is located in Henderson County, Texas. During the time at issue, the Medicare contractor[2] assigned to ETMC was Novitas Solutions, Inc. ("Medicare Contractor").

In the proposed rule published on May 14, 2014 ("FFY 2015 Proposed Rule"), CMS proposed to reassign Henderson County, Texas to the urban CBSA for Tyler, Texas for purposes of the FFY 2015 wage index based on new OMB delineations for statistical areas and the 2010 census data.[3] In the final rule for FFY 2015 published on August 22, 2014 ("FFY 2015 Final Rule"), CMS finalized the reassignment of ETMC to the Tyler CBSA for the FFY 2015 wage index. ETMC timely appealed from the FFY 2015 Final Rule to dispute its redesignation to the Tyler County CBSA.[4] ETMC maintains that CMS should have redesignated it to the Dallas CBSA which would increase both ETMC's wage index and its Medicare reimbursement.

The Board conducted a telephonic hearing on July 23, 2015. ETMC was represented by Andrew Ruskin, Esq. of Morgan, Lewis & Bockius LLP. The Medicare Contractor was represented by Robin Sanders of the Blue Cross and Blue Shield Association. The amount in controversy for this appeal is $930,803.

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[1] Transcript ("Tr") at 7. Subsequent to the hearing, the parties stipulated that PRRB Case No. 16-0811, FYE April 30, 2016 be consolidated for decision based on the arguments submitted and the record compiled for PRRB Case No. 15-0146 that was heard on July 23, 2015.

[2] The term "Medicare contractor" refers to fiscal intermediaries and Medicare administrative contractors.

[3] 79 Fed. Reg. 27978, 280758-28077 (May 15, 2014). CMS represents in the table listing the Lugar Statue designations that the ETMC redesignation as urban in the Tyler CBSA for FFY 2015 was *not* a "new" redesignation. *Id.* at 28077.

[4] 79 Fed. Reg. 49853, 49980 (Aug. 22, 2014). CMS implemented OMB's revised labor market area delineations based on the Census 2010 data for purposes of determining applicable wage indexes for acute care hospitals beginning in FY 2015.

STATEMENT OF FACTS:

42 U.S.C. § 1395ww(d)(8)(B) is known as the "Lugar Statute" and it allows CMS to reassign rural hospitals to a neighboring urban Metropolitan Statistical Area ("MSA") for the purpose of establishing its wage index for Medicare reimbursement.[5] There is no dispute that the ETMC met the conditions set forth in the Lugar Statute to be designated as an urban hospital.[6] The question presented in this case is: to *which* of the two neighboring MSAs should ETMC be assigned – the Dallas CBSA versus the Tyler County CBSA?

Federal law governing the Medicare program[7] requires the Secretary to review the wage index annually and publish any proposed updates or changes in the Federal Register. The FFY 2015 Final Rule redesignated ETMC to the Tyler, Texas CBSA[8] rather than the Dallas-Plano-Irving, Texas CBSA. The Dallas-Plano-Irving CBSA is associated with a higher wage index than the Tyler CBSA. ETMC appealed the published designations for rural counties deemed urban under the Lugar statute,[9] otherwise known as "Lugar counties."

While Henderson County itself is in the rural area of the state, it is contiguous to two separate and distinct urban areas, namely Tyler and "Dallas-Plano-Irving". The Tyler CBSA is comprised of *one* county, Smith County. The Dallas-Plano-Irving CBSA is comprised of *seven* counties. Although all of the seven counties are considered part of the Dallas-Plano-Irving CBSA, the Office of Management and Budget ("OMB") classified four counties as "central" counties and three as "outlying" counties.[10]

To ascertain the CBSA to which ETMC should be assigned, CMS compared the commuting patterns from rural Henderson County to the neighboring CBSAs using the applicable 2010 OMB data.[11] However, CMS' methodology used the data from only the subset of counties designated as "central" counties and excluded the "outlying" counties.[12] With this approach, CMS concluded there was 4,478 commuters from rural Henderson County to urban Smith

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[5] The wage index allows the Secretary to adjust DRG payment rates for regional variations in wage costs by taking into account how the average hospital wage in an area compares to the national average hospital wage. *Palisades General Hospital v. Leavitt*, 426 F3d 400, 401(D.C. Cir. 2005) (citing 44 Fed. Reg. 11612, 11613 (1979)).
[6] *See* Medicare Contractor's Final Position Paper at 4.
[7] 42 U.S.C. § 1395ww(d)(3)(E).
[8] For the purposes of this adjudication, a CBSA or "Core Based Statistical Area" is equivalent in nature to a MSA, both of which are similarly defined and designated by the Office of Management and Budget ("OMB"). *See also*: Provider's Final Position Paper at 5.
[9]The statutory language states as follows: "For purposes of this subsection, the Secretary shall treat a hospital located in a rural county adjacent to one or more urban areas as being located in the urban metropolitan statistical area to which the greatest number of workers in the county commute, if the rural county would otherwise be considered part of an urban area, under the standards for designating Metropolitan Statistical Areas (and for designating New England County Metropolitan Areas) described in clause (ii), if the commuting rates used in determining outlying counties (or, for New England, similar recognized areas) were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of all contiguous Metropolitan Statistical Areas (or New England County Metropolitan Areas)." 42 U.S.C. § 1395ww(d)(8)(B).
[10] Provider's Final Position Paper at 3. For OMB definitions of "central" and "outlying" counties, *see* 75 Fed. Reg. 37246-01, 37250 (copy included at Medicare Contractor Exhibit I-4).
[11] Medicare Contractor's Final Position Paper at 4-6; Medicare Contractor Exhibit I-3.
[12] *See* Provider Exhibit P-4; Medicare Contractor Exhibit I-3.

County (the singular county in the Tyler CBSA), while there was only 3,229 commuters from Henderson County to the "central" counties of the Dallas-Plano-Irving CBSA.[13] Using this "central county only" comparison method, CMS assigned ETMC to the Tyler CBSA and published this assignment in the August 22, 2014 Federal Register.[14]

DISCUSSION, FINDINGS OF FACT, AND CONCLUSIONS OF LAW:

A. ETMC'S CONTENTIONS

ETMC contends that CMS has not followed the plain meaning of the Lugar Statute or its implementing regulation in assigning ETMC to the Tyler CBSA. ETMC asserts that the statute on its face states that hospitals in a Lugar county are to be redesignated to "the urban metropolitan statistical area to which the greatest number of workers in the county commute." The commuting patterns to consider are therefore those to the Metropolitan Statistical Area as a whole, defined as all contiguous counties contained therein, and not to a mere subset of the CBSA's counties.[15]

ETMC states that CMS' methodology excluding commuters to the "outlying" Dallas-Plano-Irving counties is erroneous and contrary to the plain meaning of the Lugar Statute and its implementing regulation, and that any claim for deference to the Secretary must fail.[16] Specifically, ETMC asserts that CMS' decision "violates the statute's manifest intent to even the playing field for hospitals by assigning them to the neighboring urban area with which they have the highest amount of competition for labor."[17]

In support of its position, ETMC points to the OMB definition of MSAs which treats a CBSA as a unified entity when assigning nearby rural counties to an urban CBSA. ETMC explains that OMB rules pertaining to MSAs, rather than CMS' methodology, should be given considerable weight when assessing discrete areas of economic activity. As stated in OMB's rules:

> The general concept of a metropolitan statistical area is that of an area containing a large population nucleus and adjacent communities that have a high degree of integration with that nucleus…The purpose of these statistical areas is unchanged from when metropolitan areas were first delineated: The classification provides a nationally consistent set of delineations for collecting, tabulating, and publishing Federal statistics for geographic areas.[18]

ETMC asserts that the "nucleus" referenced in this excerpt are referred to as the "central" counties of a particular otherwise homogeneous geographic unit. The "adjacent communities" are referred to as the "outlying" counties of that same unit. One of the ways OMB has

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[13] Provider Exhibit P-5 at 10; Medicare Contractor's Final Position Paper at 4; Medicare Contractor Exhibit I-3; Provider Exhibit P-4.
[14] Medicare Contractor Exhibit I-2 at 4.
[15] Provider's Post-Hearing Brief at 20-21.
[16] *Id.* at 28.
[17] *Id.* at 5, 29.
[18] 75 Fed. Reg. 37246, 37246 (June 28, 2010).

determined that a county qualifies as an "outlying" county of a MSA is finding that over 25 percent of that county's workers commute to the central counties of the same MSA.[19] Once the central and outlying counties are qualified as part of a single, unified MSA, they form a discrete unified urban area composed of counties that is distinguishable for statistical purposes from neighboring counties external to the MSA. Accordingly, ETMC asserts that, in this case, the Dallas-Plano-Irving CBSA necessarily includes the outlying counties and their associated commuters.[20]

ETMC contends that, if the additional 1,799 Henderson County commuters that commute to the "outlying" counties of the Dallas-Plano-Irving CBSA are included, then a total of 5,028 Henderson County commuters would be attributed to the Dallas-Plano-Irving CBSA. Based on this new total, the total communters from Henderson County to the Dallas-Plano-Irving CBSA would exceed the 4,478 commuters from Henderson County to the Tyler CBSA.[21] Accordingly, ETMC contends that Henderson County should be assigned to the Dallas-Plano-Irving CBSA.

B. BOARD JURISDICTION AND AUTHORITY

During the hearing the Board questioned whether it, or the Medicare Geographic Classification Review Board ("MGCRB"), has jurisdiction to decide the question raised by ETMC's appeal.[22] Anticipating that the Board would reject its jurisdiction, ETMC appealed to the MCGRB on August 14, 2015[23] and was denied initially for failure to submit a complete application for review.[24] ETMC submitted additional information that was requested[25] but did not hear anything more from the MGCRB.[26] The Medicare Contractor acknowledges the Board's jurisdiction in this case but asserts that the Board is without authority to decide the issue.[27]

As explained below, the Board majority agrees with the Medicare Contractor that it has jurisdiction but that it is without authority to grant the relief that ETMC has requested. With regard to jurisdiction, the Board majority concludes that it rather than the MGCRB has jurisdiction because the Lugar statutory provisions are not located in the area of the Medicare Statute governing the MGCRB[28] and CMS has not included Lugar redesignations as a geographic determination under the authority of the MGCRB.[29] Further, the Board majority note that the wage index is one component of the inpatient prospective payment system ("IPPS") and the Medicare program uses the cost report to gather information necessary for setting the wage index. To this end, the Secretary includes its discussion of the Lugar redesignations in the portion of the preamble governing the wage index generally, namely Section III entitled

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[19] 65 Fed. Reg. 82228, 82233 (Dec. 27, 2000). *See also* 53 Fed. Reg. 38476, 38499 (Sept. 30, 1988).
[20] Provider's Post-Hearing Brief at 21.
[21] *Id.*, at 4.
[22] Tr. 58-64.
[23] *See* Provider Exhibit P-8.
[24] Provider Exhibit P-9.
[25] Provider Exhibit P-10.
[26] Provider's Post-Hearing Brief at 13-15.
[27] Medicare Contractor' Post-Hearing Brief at 3-4.
[28] The Medicare statutory provisions governing the MGCRB are located at XXX while the Lugar statutory provisions are located at 42 U.S.C. § 1395ww(d)(8)(B).
[29] *See* 56 Fed. Reg. 25458, 25459, 25479 (June 4, 1991);

"Changes to the Hospital Wage Index for Acute Care Hospitals."[30] Accordingly, it is clear that wage index determinations affect the amount of payment that hospitals receive under IPPS. Pursuant to 42 U.S.C. § 1395oo(a), the Board has jurisdiction over any final determination of the amount of payment due the provider under IPPS.

In considering whether the Board has the authority to grant the relief requested in this case, the Board majority note that the Board must comply with all of the provisions of Title XVIII of the Act and regulations and must afford "great weight to interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS."[31] With regards to regulations, the D.C. Circuit has confirmed that the language of a preamble to a final rule may be binding regulatory language if that language has "independent legal effect, which . . . is a function of whether the agency's intention to bind either itself or regulated parties."[32] Accordingly, the Board may be bound by CMS policies or determinations stated in the preamble to a final rule if that language has "independent legal effect" as evidenced by an intent to either bind the agency and/or the regulated parties.

Specific to this case, in the preamble to the FFY 2015 Proposed Rule, CMS published a table describing the *counties* that would be designated as part of an urban area and the urban area to which each of these counties were being redesignated:

> After evaluating and analyzing the 2010 Census commuting data, we are proposing that, effective for discharges on or after October 1, 2014, in accordance with section 1886(d)(8)(B) of the Act, *hospitals* ***located in the rural counties*** *listed* in the first column of the following table would be designated as part of the urban area listed in the second column based on the criteria discussed above. We note that rural counties that no longer meet the qualifying criteria to be Lugar are discussed below in section III.H.3.c of the preamble in this proposed rule.[33]

In this table, CMS proposed to redesignate Henderson County, Texas to the CBSA for Tyler, Texas. In addition, neither the preamble discussion nor the table itself stated that this redesignation was "new" suggesting that Henderson County, Texas had previously been redesignated to the CBSA for Tyler, Texas.[34]

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[30] 79 Fed. Reg. at 49857.

[31] 42 C.F.R. § 405.1867.

[32] *Kennecott Utah Copper Corp. v. U.S. Dept. of Interior*, 88 F. 3d 1191, 1223 (D.C. Cir. 1996) ("*Kennecott*"). Courts have applied the *Kennecott* holding in the context of Medicare cases. *See, e.g., Swedish Amer. Hosp. v. Sebelius*, 773 F. Supp. 2d 1, 13-14 (D.D.C. 2011); *Alegent Health-Immanuel Med. Ctr. v. Sebelius*, 34 F. Supp. 3d 160, 171 (D.D.C. 2014). These type of cases may be distinguished from situations where the focus is on the meaning of a regulation and the preamble discussion clarifies that regulation. *See, e.g., Select Specialty Hosp. v. Sebelius*, 820 F. Supp. 2d 13, (D.D.C. 2011).

[33] 79 Fed. Reg. at 28075 (emphasis added).

[34] 79 Fed. Reg. at 280758-28077 (May 15, 2014). Further, ETMC recognizes that it "has been viewed as a 'Lugar' hospital since October 1, 1993 because of the historic commuting patterns to neighboring CBSAs." Provider's Post-Hearing Brief at 5.

In the preamble to the FFY 2015 Final Rule, CMS published the chart of redesignations[35] and finalized them, including the redesignation of Henderson County, Texas to the CBSA for Tyler, Texas. Specifically, CMS stated:

> We are ***finalizing*** that effective for discharges on or after October 1, 2014, in accordance with section 1886(d)(8)(B) of the Act, hospitals located in the first column of the chart below ***will be designated*** as part of the urban area listed in the second column based on the ***finalized*** criteria discussed above.[36]

In this appeal, ETMC seeks to have the Board modify the Lugar-designated CBSA for Henderson County as it applies to ETMC.

The Board majority has determined that it does not have the authority to grant the requested relief. It is clear that CMS went through the notice and comment rulemaking process to propose and finalize the redesignation of Henderson County, Texas to the CBSA for Tyler, Texas. Further, the above language used in the preamble to the final rule confirms that CMS intended to bind all of the hospitals in the counties affected by the Lugar redesignations. As such, the Board majority finds it does not have the authority to grant the relief sought by ETMC, that is, redesignation of Henderson County from the Tyler, Texas CBSA to the Dallas-Plano-Irving, Texas CBSA.

The Board majority's finding that CMS intended the Lugar redesignations to be binding is supported by the very nature and effect of the Lugar redesignations published in the FFY 2015 Final Rule. First, Lugar redesignations are *not* hospital specific but rather apply on a county-wide basis and, as such, affect any hospital located within the redesignated county. Further, 42 U.S.C. § 1395ww(d)(8)(D) requires that the effects of the Lugar redesignations be budget neutral.[37] These aspects of the Lugar redesignations highlight why CMS would go through the notice and comment process to make the Lugar redesignations binding and not subject to Board review.

Finally, the Board notes that it has made similar findings in other cases.[38] One federal court considered this question directly and concluded that the sole issue—whether the Secretary's practice of excluding data from reclassified hospitals in calculating the wage indexes for the hospitals remaining in the urban area violated 42 U.S.C. 1395ww(d)(3)(e)—was a legal question that could not be decided by the Board.[39] Similarly, the issue in the case present here--whether the Secretary can properly exclude commuters from "outlying" counties from the calculation of

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[35] Again, the chart redesignates Henderson County, Texas to the CBSA for Tyler, Texas for FFY 2015 and represents that this redesignation was *not* a "new" redesignation. *Id.* at . 79 Fed. Reg. at 49980.
[36] 79 Fed. Reg. at 49978 (emphasis added.)
[37] *See id.* at 50369.
[38] *See Hunterdon/Somerset 2001 Wage Index,* PRRB Dec. No. 2004-D13 (Apr. 14, 2004); *Santa Cruz, CA 03-05 MSA Hospital Wage Index Group v. Noridian Healthcare Solutions, LLC,* PRRB Dec. No. 2015-D6 (Apr, 2, 2015); *Hospice 2009 BNAF Group Bluegrass v. Blue Cross Blue Shield Ass'n,* PRRB Dec. No. 2009-D17 (April 8, 2009).
[39] *St. Michael's Med. Ctr. v. Sebelius,* 648 F.Supp.2d 18 (D.D.C. 2009).

total commuters in a CBSA for CMS wage index calculation purposes—is a legal question that cannot be decided by the Board.

DECISION AND ORDER

After considering the Medicare law and program instructions, the evidence presented and the parties' contentions, the Board majority concludes that it does not have the authority to grant the relief sought in this appeal, that is, redesignation of Henderson County from the Tyler, Texas CBSA to the Dallas-Plano-Irving, Texas CBSA.

BOARD MEMBERS PARTICIPATING:
Michael W. Harty
Clayton J. Nix, Esq.
L. Sue Andersen, Esq.
Charlotte F. Benson, CPA
Jack Ahern, M.B.A. (Dissenting in part; Concurring in part)

FOR THE BOARD:

/s/
Michael W. Harty
Chairman

DATE: January 27, 2017

Jack Ahern, *Dissenting in part; Concurring in part*.

I concur with the majority decision to accept jurisdiction and agree that the "Lugar Statute" redesignations were published in both the proposed and final rule preambles. However, I respectfully dissent with respect to the majority decision to, once having accepted jurisdiction, proceed no further in this decision in terms of assessing the merits of this case. I do not agree with the majority's rationale which rests on the conclusion that the Board has no authority to provide a remedy because it is bound by the redesignation to the Core Based Statistical Area ("CBSA") published in the preamble to the applicable final rule.

My concern is that, based on my analysis of the facts of this case, it seems possible, if not probable, that the redesignation in question is in direct opposition to the applicable Lugar statute and associated implementing regulations in terms of the long standing methodology used to arrive at redesignations and, as such, likely represents an error in methodology as opposed to a dispute over the Secretary's policy. If there were no credible doubt regarding whether or not the redesignation in question comported with applicable statutory and regulatory requirements I would have concluded that the PRRB has no authority to provide a remedy. However the Provider, East Texas Medal Center ("ETMC"), is not challenging the Lugar statute, nor is it challenging the associated regulations, but only the application thereof as manifest in a table presented in the Federal Register preambles. Therefore, given this fact set, I believe the Board should at a minimum address the merits of the provider's case and reach a conclusion on the central substantive issue which pertains to whether or not the redesignation in question comports with the applicable statutory and regulatory requirements.

In addition, I would like to emphasize my position, that to the extent the Board has chosen to be bound by regulatory preambles, this conclusion is limited in its application to only those portions of a preamble that have satisfied the notice and comment requirement of the Administrative Procedure Act ("APA") and generally meet the requisite conditions to rise to the level of being viewed as the equivalent (in terms of relative authority and deference due) to a substantive rule. In other words, those portions of preambles that either do not meet the applicable APA requirements for notice and comment and / or are merely interpretive in nature are not binding on the Board, particularly in circumstances where they run contrary to corresponding statutory and regulatory mandates.

That said, the majority decision cited multiple cases to support its conclusion which while they are worthy of consideration do not lead me to the same conclusion. They shall be addressed in turn as follows;

ANALYSIS OF PRRB CASE LAW CITED BY BOARD MAJORITY:

While noting that PRRB cases are neither precedential nor binding in any fashion upon the Board, they do provide insight into prior reasoning applied to potentially analogous issues. Perhaps for this reason, the Board majority cites to several cases which I do not believe adequately support the Board's conclusion with respect to lack of authority in this matter because they are substantially distinguishable from the case at hand, both in terms of fact pattern, the

nature of the dispute, and in some cases, the applicable law. The three PRRB cases cited shall be addressed in turn;

Hunterdon / Somerset 2001 Wage Index, PRRB 2004 – D13

The Board majority decision cites to *Hunterdon / Somerset 2001 Wage Index,* PRRB Dec. No. 2004-D13 (Apr. 14, 2004) ("*Hunterdon*"). This wage index decision turns on the provider's right to a remedy to a perceived defect in the regulatory process for correcting a regional wage index because the relevant regulations, as they stood, did not provide standing for affected hospitals to appeal on behalf of a closed hospital.

> "The question addressed by the decision is whether expedited judicial review (EJR) is appropriate because the Board cannot grant the remedy sought by the Providers: a change to the Secretary's policies used to calculate wage indices." (PRRB 2004-D13 at 2), (emphasis added).
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> "The questions posed by the Providers as requiring Board resolution are questions regarding how CMS's policy is made. The Board has no authority to dictate or fashion CMS policy or to retroactively apply policy changes. The Board concludes that it is without authority to direct CMS to exclude the wages of a closed Middlesex County, NJ hospital in calculating the wage index for the Providers or to include the wages for all other hospitals" (2004-D13 at 6) (emphasis added).

As evidenced by the above, in *Hunterdon*, the Board's assessment that it lacked authority to provide a remedy was predicated on the assumption that a change in policy was necessary to effect a remedy. This fact pattern and associated legal reasoning is clearly distinguishable from the ETMC appeal because in ETMC the Secretary's stated policy is not in question, rather the central claim made by the Provider is that the Secretary's policy was not properly applied. As such, the remedy sought would involve the proper application of the applicable regulations in full concert with the Lugar statute which would in no way require any change in the Secretary's policy, but rather would provide for the proper implementation of the long standing policy and use the associated calculational logic claimed by the Provider to have been historically applied to all Lugar hospitals.

Santa Cruz, PRRB 2015 – D6

The Board majority decision also cites to *Santa Cruz, CA 03-05 MSA Hospital Wage Index Group v. Noridian Healthcare Solutions, LLC,* PRRB Dec. No. 2015-D6 (Apr, 2, 2015) *("Santa Cruz"*). Briefly stated, this case involves legal issues rooted in a factual dispute about proper notification, specifically whether or not a letter was sent from the Medicare Administrative Contractor ("MAC") to the California Hospital Association ("CHA"):

> "The Hospitals assert that the Medicare Contractor failed to send the required letter to CHA notifying CHA of Watsonville's non-compliance and that this procedural failure is critical because it is the only protection afforded to the other compliant hospitals located within the same MSA whose prospective payments may be adversely affected."

(PRRB 2015 – D6 at 5)

The Board held that notwithstanding the factual dispute, it lacked authority to provide a remedy since the party that allegedly did not receive the communication, the California Hospital Association, does not have standing before the Board and the applicable regulations provide no remedy for the harmed party:

> "However, the Board finds that it does not need to resolve this issue because CHA is not a party to this appeal and the instructions as set forth in the 2002 Program Memorandum and the August 2003 Final Rule provide no remedy for a State hospital association or a hospital in an MSA in which another hospital is nonresponsive to a wage index audit request for additional information.[ ] In this regard, the Board has no authority to disregard documentation obligations of one hospital to the benefit of other hospitals in an MSA."

The *Santa Cruz* fact pattern is substantially distinguishable from the case at hand insofar as in *Santa Cruz* is there no question of a preamble that is claimed to stand squarely at odds with the applicable statute and associated implementing regulations and ETMC indisputably has standing before the Board.

Hospice 2009 BNAF Group Bluegrass, PRRB 2009-D17

The final PRRB case cited by the Board majority is *Hospice 2009 BNAF Group Bluegrass* v. *Blue Cross Blue Shield Ass'n*, PRRB Dec. No. 2009-D17 (April 8, 2009) ("*Hospice*"). The provider group in this case was seeking expedited judicial review (EJR) of its challenge to the "Secretary's elimination of the budget neutrality adjustment factor (BNAF) used in the calculation of hospice payment rates ..." (PRRB 2009-D17 at 2)

Hospice does not appear to have any application to the case at hand since in *Hospice* the PRRB provides no conclusion or even discussion of the Board's authority to provide a remedy, nor is there any discussion regarding a regulatory preamble, rather the Board dismissed this appeal in its entirety on the basis that "it lacks jurisdiction over the appeals because there is no amount in dispute as required by 42 U.S.C. § 1395oo(a), 42 C.F.R. §§ 405.1835- 405.1840 and 405.1842. " (PRRB 2009-D17 at 5) (emphasis added).

ANALYSIS OF FEDERAL CASE LAW CITED BY BOARD MAJORITY:

Kennecott, 88 F. 3d 1191, 1223 (D.C. Cir. 1996)

The Board majority cites to *Kennecott Utah Copper Corp. v. U.S. Dept. of Interior*, 88 F. 3d 1191, 1223 (D.C. Cir. 1996) ("*Kennecott*") to support its conclusion that it lacks authority to provide a remedy for ETMC's challenge to its Lugar hospital geographic redesignation. *Kennecott* states the possibility that a preamble could have "independent legal effect." Industry Petitioners assert that the United States Department of Interior ("Interior") exceeded its authority when, in the preamble to its final 1994 Regulations, the agency purported to authorize recovery for injury to archaeological and cultural resources. 88 F.3d at 1222. Interior offered 3 arguments

in response: (1) a preamble is nonbinding, explanatory material with no independent legal effect; therefore, it is not reviewable unless and until it is actually applied in a concrete case; (2) even if a preamble may have the force of law, petitioners' challenge is not now ripe for review; and (3) on the merits, Interior contends that recovery for loss of archaeological and cultural resources is authorized by the CERCLA [Act governing this case]. Id. at 1222 (emphasis added). The Court states:

> At the outset, we cannot agree with Interior that there is a categorical bar to judicial review of a preamble. . . . The question of reviewability hinges upon whether the preamble has independent legal effect, which in turn is a function of the agency's intention to bind either itself or regulated parties. Absent an express statement to that effect, we may yet infer that the agency intended the preamble to be binding if what it requires is sufficiently clear. Id. at 1222-23 (citation omitted). (emphasis added)

Notably, although the Court concludes that a preamble may potentially, under some circumstances, be reviewable, but it is not ripe for review in this case. In *Kennecott* the Court does not reach the question of reviewability of the preamble under the APA, however, because it finds that the issue is not ripe for review:

> "Even if we were to determine that the preamble to the 1994 Regulations is reviewable; however, we would not think it fit for review at this time. Interior has indicated only that a trustee could recover damages for an injury to land that reduces archaeological research." Id. at 1223. The petitioners failed to demonstrate that the preamble had a "direct and immediate rather than a distant and speculative impact" upon them. Id. Instead, the Court held that " . . . the question whether a trustee may recover under the CERCLA for injury to archaeological and cultural resources is not ripe." Id. (emphasis added)

However there can be no doubt that with regards to regulations, this decision of the D.C. Circuit has confirmed that the language of a preamble to a final rule may potentially be binding regulatory language if that language has "independent legal effect, which . . . is a function of whether the agency's intention to bind either itself or regulated parties."

Notably, substantive issues are separate and distinct in nature and effect from the gateway issue of judicial reviewability. It must be noted however, that the *Kennecott* Court has not held that the preamble in question had independent legal effect in regards to substantive issues of the case. It does not follow from *Kennecott* that solely because an issue presented in a preamble it may be found to be subject to judicial review since the preamble section has independent legal effect that *ipso facto* the reviewing entity, having accepted jurisdiction, is thereby automatically and irrevocably bound by the very preamble it is reviewing.

Again, although *Kennecott*, states it is possible for a preamble to have "independent legal effect," the Court does not reach the issue pertaining to preamble language because the court found the issue was not ripe for review (Kennecott did not have damages).

Rather, *Kennecott* leads to the conclusion that if an agency publishes a listing in the Federal Register, as was done with the Lugar designations, which is used by providers for their cost reports, then the agency may be intending to bind itself. Therefore, the preamble may have independent legal effect to allow judicial review of a case, which is a threshold issue under the Administrative Procedures Act ("APA"). Therefore, to the extent the Board is determining judicial review (arguably not a determination for the Board) and finds the preamble to be binding, then it should take jurisdiction over the case. Therefore I concur with that portion of the Board majority decision in the ETMC case at hand regarding jurisdiction. However, I see in *Kennecott* no sound basis to prelude the Board from proceeding to a well-reasoned decision under the circumstances presented in the case at hand, where the Provider, ETMC, is challenging neither the Lugar statute nor its implementing regulations but rather the aruably erroneous application thereof.

In summary, because *Kennecott* addresses judicial reviewability (i.e. jurisdiction) over something written in a preamble but in no manner directly addresses the Board's authority to provide a remedy once it has taken jurisdiction over the issue at hand, *Kennecott* does not preclude a decision with respect to whether the Lugar geographic redesignation comports with applicable statutory and regulatory language.

Swedish American, D.D.C. 2011

In support of its conclusion that it lacks authority to provide a remedy in this case, the Board majority decision also cites to a 2011 D.C. District Court decision, *Swedish Amer. Hosp. v. Sebelius*, 773 F. Supp. 2d 1, 13-14 (D.D.C. 2011) ("*Swedish*").

In brief summary, the fact pattern and legal issues in this case revolved around a hospital's claim to have failed to execute the requisite affiliation agreement required for sharing a medical education resident cap solely due to relying on erroneous statements from its MAC. In failing to execute the agreement the provider failed to meet requirements laid down in regulatory preambles which were later incorporated into final rules. The hospital argued that the respective mandates were not binding upon the provider because, according to the doctrine of *equitable estoppel*, the provider reasonably relied on the MAC's inaccurate guidance.

The District Court, citing the Supreme Court precedent set in *Heckler* found that the provider was not justified in relying solely on the MAC's advice. See *Heckler v. Cmty. Health Servs.*, 467 U.S. 51, 59, 104 S.Ct. 2218, 81 L.Ed.2d 42 (1984).

Although *Swedish* provides a cautionary tale with respect to a provider's obligation to independently verify advice provided by its MAC, it does not involve a fact pattern even vaguely similar to the case at hand in which ETMC argues for a remedy in the form of a full and proper implementation of both the Lugar statute and its implementing regulations as they stand. Further, since this opinion was rendered by the District of Columbia District Court, although it may be worthy of consideration, it in no manner provides a binding precedent for the PRRB.

Alegent, D.D.C. 2014

The Board majority also points to *Alegent Health-Immanuel Med. Ctr. v. Sebelius*, 34 F. Supp. 3d 160, 171 (D.D.C. 2014) ("*Alegent*"). In *Alegent* the District Court was faced with a challenge to a regulatory preamble requiring an affiliation agreement for graduate resident FTE cap sharing purposes. The provider argued that the Secretary, by promulgating the requirement in a preamble to a final rule, had failed to meet the applicable APA requirements regarding notice and comment.

In its analysis of this APA argument the Court found that:

> The PRRB's—and therefore the Secretary's—final determination was that: "[b]oth the Federal Register and the regulations in effect at the time made a written agreement necessary to qualify as an affiliated group." [ ] Indeed, the requirement for a written affiliation agreement is evident from the clear language of the preamble to the 1998 final rule." See generally Kennecott Utah Copper Corp. v. U.S. Dep't of Interior, 88 F.3d 1191, 1223 (D.C.Cir.1996) (preamble language has independent legal effect when an agency "inten[ds] to bind either itself or regulated parties"). Specifically, the May 12, 1998 Federal Register stated that "[h]ospitals that qualify to be members of the same affiliated group for the current residency training year and elect an aggregate cap must provide an agreement. ..." 63 Fed.Reg. 26318,26341 (emphasis added)
> [Emphasis added in original opinion by Richard J. Leon, United States Magistrate Judge]

The fact pattern and legal issues in *Alegent* are likewise substantially distinguishable from the ETMC case at hand because in *Alegent* the plaintiff's assertion was that the regulation was improperly promulgated and thereby rendered unenforceable. This challenge is in sharp contrast to ETMC's assertion that the applicable Lugar statute and enabling regulation are fully enforceable and the only problem is that the regulation was improperly applied. It should be noted however, that in *Alegent* notwithstanding the existence of a purportedly binding regulation published in a preamble, the PRRB did not claim it had no authority to make a decision on the merits of the case. See PRRB *Alegent Health-Immanuel Med. Ctr. v. Intermediary, PRRB Decision 2012 – D16.* Again, it should be noted that *Alegent* is a non-binding, non-precedential District of Columbia, District Court decision.

St. Michael's Medical Center, D.D.C. 2009

Finally, the Board majority points to a wage index case, *St. Michael's Med. Ctr. v. Sebelius*, 648 F.Supp.2d 18 (D.D.C. 2009) (*St. Michael's*), likewise a non-binding, non-precedential District Court decision, which nonetheless is very worthy of consideration and deals with the nature of data used to determine the wage index and in which the PRRB concluded that it lacked authority to resolve the dispute and invoked 42 U.S.C. § 395oo(f)(1) to provide for expedite judicial review ("EJR").

The Court concluded, as did the PRRB that the relevant statute was ambiguous, thus meeting the requirements of step one of the seminal Supreme Court decision in *Chevron*. However, per step two of the *Chevron* analysis the District Court found that the exclusion of the disputed data and that the Secretary's policy was a permissible construction.

Further distinguishing *St. Michael's* from the case at hand is the nature of the central issue addressed. The dispute in *St. Michael's* pertains to the Secretary's policy *in general* which is in sharp contrast to the case at hand which addresses only a single county's redesignation and moreover potentially does not even reflect the Secretary's policy but rather a calculational and / or interpretive error in the application of the relevant statute and regulations.

SUMMARY AND CONCLUSION

In conclusion, I concur with the Board majority that the Board has jurisdiction in this case. However I believe this case would have been better served if the Board had rendered an opinion, at a minimum, on whether the specific redesignation at issue, that of East Texas Medical Center to a different geographic Core Based Statistical Area ("CBSA") than previously, as noticed in preambles to both proposed and final rules, was or was not in full concert with the relevant and applicable statutory and regulatory requirements pertaining to Lugar hospitals. Moreover, I find that the case law referenced in support of the majority decision, although worthy of consideration, is neither binding nor convincing.

/s/
Jack Ahern, M.B.A.

DATE: January 27, 2017