PROVIDER REIMBURSEMENT REVIEW BOARD DECISION

2022-D03

PROVIDER –
Hebrew Rehabilitation Center

RECORD HEARING DATE –
March 3, 2021

PROVIDER NO. –
22-2007

YEAR –
Fiscal Year 2019

vs.

MEDICARE CONTRACTOR –
National Government Services, Inc. – (J-K)

CASE NO. –
19-1449

INDEX

ISSUE STATEMENT:

Whether the payment penalty that the Centers for Medicare and Medicaid Services ("CMS") imposed under the Long Term Care Hospital Quality Reporting Program ("LTCH-QRP") which reduced the Provider's payment update for Fiscal Year ("FY") 2019 by two percent was proper?[1]

DECISION:

After considering Medicare law and regulations, arguments presented, and the evidence admitted, the Provider Reimbursement Review Board ("Board" or "PRRB") finds that CMS properly reduced the annual payment update ("APU") for Hebrew Rehabilitation Center ("HRC" or "Provider") for FY 2019 by 2 percent.

INTRODUCTION:

HRC is a licensed long-term chronic care hospital ("LTCH") located in Roslindale, Massachusetts.[2] HRC's designated Medicare contractor[3] is National Government Services, Inc. (the "Medicare Contractor").

By letter dated July 10, 2018, CMS notified HRC that it failed to meet the LTCH QRP requirements and was subject to a two percent reduction in its FY 2019 APU.[4] HRC requested that CMS reconsider its decision regarding the reduction to its FY 2019 Medicare payments[5] and, on September 18, 2018, CMS upheld its decision.[6] On March 18, 2019, HRC timely appealed CMS' denial to the Board and met the jurisdictional requirements for a hearing.

On October 5, 2020, HRC filed an unopposed Request for Record Hearing. Before the Board could render a decision, it issued a Request for Information on December 18, 2020, asking for clarification on HRC's appeal, namely whether its Administrative Procedure Act ("APA") *challenge* necessarily or inherently called into question the procedural or substantive validity of the LTCH QRP regulation at 42 C.F.R. § 412.560 and/or any of the relevant LTCH QRP rulemakings upon which the LTCH QRP issuances at issue are based.[7] On January 4, 2021, HRC filed a response to the Board's inquiry clarified its challenged and confirmed that it "does ***not*** challenge the procedural or substantive validity of any regulation or rule concerning the LTCH QRP" whether under the APA or 42 U.S.C. § 1395hh.[8]

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[1] Medicare Contractor's Preliminary Position Paper (hereinafter "Medicare Contractor's PPP") at 2 (Feb. 26, 2020).
[2] *Id.* at 1; Stipulations ("Stip.") at ¶ 1.
[3] CMS' payment and audit functions under the Medicare program were historically contracted to organizations known as fiscal intermediaries ("FIs") and these functions are now contracted with organizations known as Medicare administrative contractors ("MACs"). The term "Medicare contractor" refers to both FIs and MACs as appropriate.
[4] Stip. at ¶ 10. *See also* Exhibit P-1.
[5] Stip. at ¶ 13. *See also* Exhibit P-2.
[6] Stip. at ¶ 14. *See also* Exhibit C-5 (copy of CMS' denial of reconsideration).
[7] Board's Request for Information ("RFI") (Dec. 18, 2020).
[8] Provider's Response to the Board's RFI (Jan. 4, 2021) (emphasis in original).

The Board approved a record hearing on March 3, 2021. HRC was represented by Geoffrey Raux, Esq. of Foley & Lardner LLP. The Medicare Contractor was represented by Edward Lau, Esq. of Federal Specialized Services.

STATEMENT OF FACTS AND RELEVANT LAW:

Federal statute, 42 U.S.C. § 1395ww(m)(5)(C), requires LTCHs to report on the quality of their services "in a form and manner, and at a time, specified by the Secretary."[9] The implementing regulation is located at 42 C.F.R. § 412.560 and states in relevant part:

> (b) *Submission of data requirements and payment impact.* (1) Except as provided in paragraph (c) of this section, a long-term care hospital ***must*** submit to CMS data on measures specified under sections 1886(m)(5)(D), 1899B(c)(1), and 1899B(d)(1) of the Act, as applicable, *in a form and manner, and at a time, specified by CMS*.
>
> (2) A long-term care hospital that does not submit data in accordance with sections 1886(m)(5)(C) and 1886(m)(5)(F) of the Act with respect to a given fiscal year will have its annual update to the standard Federal rate for discharges for the long-term care hospital during the fiscal year reduced by 2 percentage points.[10]

The Secretary exercised the authority delegated by Congress to define required data and specify the form and manner for LTCHs to submit that data through notices published by CMS as rulemakings in the Federal Register. In the FY 2017 Quality Reporting Requirements for Specific Providers Final Rule,[11] CMS provided updates to the LTCH PPS Quality Reporting Program.[12]

There are three long-term care quality reporting measures: the LTCH Continuity Assessment Record and Evaluation ("CARE") Data Set Measures, the Centers for Disease Control and Prevention's ("CDC") National Healthcare Safety Network ("NHSN") measures, and the Medicare Fee-For-Service Claims-Based Measures.[13] For the FY 2017 reporting year, all Medicare-certified LTCH providers were required to "meet or exceed two separate data completeness thresholds: one threshold set at 80 percent for completion of quality data collected using the LTCH CARE Data Set and submitted through [CMS' Internet Quality Improvement and Evaluation System (iQIES)], and a second threshold set at 100 percent for completion of quality data *collected and submitted* ***using the CDC's NHSN***."[14] Failure to comply with these requirements may result in a two percentage point APU reduction.[15]

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[9] *See also* Patient Protection and Affordable Care Act, Pub. L. 111-148, § 3004(a), 124 Stat. 119, 368-369 (2010) (adding LTCH QRP statutory provisions at 42 U.S.C. § 1395ww(m)(5)).
[10] 42 C.F.R. § 412.560 (2015) (emphasis added). *See also* 80 Fed. Reg. 49325, 49769 (Aug. 17, 2015).
[11] 81 Fed. Reg. 56762, 57193 (Aug. 22, 2016).
[12] *Id.* at 57233 (copy at Exhibit C-2 at 2).
[13] *See* Medicare Contractor's PPP at 5-6.
[14] Exhibit C-3 at 6 (emphasis added) (copy of the CMS, Long-Term Care Hospital Quality Reporting Program (LTCH QRP) Frequently Asked Questions with Answers (Mar. 2019)).
[15] *Id*.

This case concerns the CDC NHSN quality data reporting requirements for central line-associated bloodstream infection ("CLABSI") data, catheter associated urinary tract infection ("CAUTI") data, or ventilator-associated event ("VAE") data.[16] HRC contends that it timely submitted quality data to CMS. For each month during calendar year 2017, HRC entered quality data for the CLABSI, CAUTI, and VAE measures into the CDC's NHSN on or before the deadlines established by CMS. However, for each of the four (4) months of April, June, August, and September 2017, HRC failed to manually check boxes in the associated monthly reporting plans for the CLABSI, CAUTI, and VAE modules to cause any data associated with those modules for those four months to otherwise be transmitted from the CDC's NHSN to CMS.[17] As a result, this data was never transmitted from CDC's NHSN to CMS and, thus, was never received by CMS on or before the established deadline of November 15, 2017 for the months April and June 2017 and the established deadline of February 15, 2018 for the months August and September 2017.[18]

HRC readily admits that it failed to check the appropriate boxes for the CLABSI, CAUTI, and VAE measures in the monthly reporting plans for the months of April, June, August, and September 2017 and that this failure caused the associated data not to be transmitted from the CDC to CMS.[19] However, HRC suggests that submission of the requisite data for the months at issue into the CDC's NHSN prior to the applicable deadlines was sufficient to meet its obligation to submit the data to CMS and avert the two percent penalty.[20]

The Medicare Contractor notes that while the data at issue may have been submit into the CDC's NHSN, "there is no verification as to whether these submissions were **accepted** or whether they included errors."[21] According to the Medicare Contractor, "[r]eports submitted [into the CDC NHSN] with errors (in this case, unchecked boxes in the submission) do not constitute an acceptable submission."[22]

In support of its position, the Medicare Contractor cites to several publications. First, it noted that the FY 2017 LTCH PPS Final Rule encouraged providers to use the CASPER Preview reports to ensure the data was free of errors or corrections:

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[16] Stip. at ¶ 4.
[17] *Id*. at ¶ 5.
[18] *Id*.; 81 Fed. Reg. at 57227.
[19] *See* Provider's Preliminary Position Paper at 6 ("During HRC's investigation into the notice of non-compliance, it discovered that, for the months of April, June, August, and September 2017, manual check boxes in the monthly reporting plans for CLABSI, CAUTI, and VAE data were not checked. This meant that, although HRC had entered all of the required data, the NHSN system never forwarded that data to CMS and never alerted HRC to the fact that the data was not sent."); Exhibit P-4 (copy of HRC's appeal request to Board) ("however, HRC learned that due to a missed checked box for the Monthly Reporting Plans (MRP) relating to device associated modules, CAUTI, CLABSI and VAE for the months of April, June, August and September 2017 caused the HAI data to not be forwarded to CMS by NHSN.").
[20] Provider's Preliminary Position Paper at 3 ("HRC submitted its quality data throughout 2017 in accordance with the deadlines established by CMS.").
[21] Medicare Contractor's PPP at 9.
[22] *Id*. The CDC's NHSN system requires manual data entry into the NHSN web-based application or via file imports. The CDC's NHSN system does not automatically transmit data from NHSN to CMS. The CDC's NHSN system does not send alerts to providers when data that is entered into NHSN is not transmitted from NHSN to CMS. *See* Stip. at ¶¶ 6-8.

> . . . we afford LTCHs a 30-day preview period prior to public display during which LTCHs may preview the performance information on their measures that will be made public. We would like to clarify that we will provide the preview report using the CASPER system, with which LTCHs are familiar. The CASPER preview reports inform providers of their performance on each measure which will be publicly reported. Please note that the CASPER preview reports for the reporting quarter will be available after the 4.5 month correction period and the applicable data submission/correction deadline have passed and are refreshed on a quarterly basis for those measures publicly reported quarterly, and annually for those measure publicly reported annually. We proposed to give LTCHs 30 days to review the preview report beginning from the date on which they can access the report.
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> As already finalized, corrections to the underlying data will not be permitted during this time; however, LTCHs may ask for a correction to their measure calculations during the 30-day preview period. We proposed that if CMS determines that the measure, as it is displayed in the preview report, contains a calculation error, we can suppress the data on the public reporting Web site, recalculate the measure and publish it at the time of the next scheduled public display date.[23]

Second it points to the CMS LTCH QRP Manual which is found on the CMS.gov website and provides detailed instructions for data submission of files. Under the section entitled "5.4 Additional Tips and Hints," the Manual states that:

> Facilities will have approximately 135 days following the end of a quarter before NHSN freezes the NHSN CAUTI Outcome Measure (NQF #0138), the NHSN CLABSI Outcome Measure (NQF #0139), the NHSN Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716), the NHSN Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717), and the NHSN VAE Outcome Measure data, and CDC sends the data to CMS. This applies to the January 1, 2016 to December 31, 2016 and subsequent data collection.[24]

HRC acknowledges the encouragement to use CASPER Preview reports, but asserts that such reports would not have revealed the submission errors at issue in this appeal.[25] HRC has acknowledged that there were errors in the submission data for the months of April, June, August and September, 2017.[26]

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[23] Medicare Contractor's PPP at 9 (quoting 81 Fed. Reg. at 57234 (copy at Exhibit C-2)).
[24] *Id.* at 10 (quoting Exhibit C-4 at 13).
[25] Stip. at ¶ 18.
[26] *Id.* at ¶ 5.

HRC asserts that the key issue in this appeal is whether, under the decision in *Azar* v. *Allina Health Services,* 139 S. Ct. 1804 (2019), CMS's imposition of a two percent penalty to the Fiscal Year 2019 annual payment update was invalid and arbitrary and capricious for the reason that data submission requirements were allegedly not promulgated through statutory notice-and comment.[27] Therefore, under *Allina,* HRC argues that the submission deadlines and requirements cannot serve as the basis for enforcement of a penalty, reducing their "payment for services."[28]

The Medicare Contractor relies upon 42 C.F.R § 405.1867 for its argument that the Board does not have the authority to eliminate the imposition of the two percent reduction to HRC's APU based on how the two percent APU reduction was implemented.[29]

> **§ 405.1867 Scope of Board's legal authority**.
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> In exercising its authority to conduct proceedings under this subpart, the Board *must comply* with all the provisions of Title XVIII of the Act and regulations issued thereunder, as well as CMS Rulings issued under the authority of the Administrator as described in § 401.108 of this subchapter. The Board shall afford great weight to interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.[30]

The Medicare Contractor argues that, in the FY 2017 Final Rule,[31] CMS published the deadlines for the calendar year 2017 reporting period, but that the deadlines are a procedural requirement that did not alter or establish a substantive legal standard that impacted the hospitals. As such, these deadlines did not need to go through the notice and comment process.[32] Further, the regulation and the relevant preambles to the Final Rules[33] authorize the Secretary to specify the time, form and manner in sub-regulatory guidance and, indeed, these preambles even reference the manuals at issue.

The Medicare Contractor's Supplement identifies 42 U.S.C. § 1395ww(m)(5) as the statutory source and authority for the imposition of the two percent rate reduction.[34] The Medicare Contractor argues that, in *Allina*, the Supreme Court focused on the specific facts in that case,

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[27] *Id*. at ¶ 19.
[28] Provider's Final Position Paper at 1 (Sept. 28, 2020) (hereinafter "Provider's FPP").
[29] Medicare Contractor's Supplement in Response to Provider's Allina Arguments at 2 (Nov. 23, 2020) (*hereinafter* "Medicare Contractor's Supplement").
[30] 42 C.F.R. § 405.1867 (italics emphasis added).
[31] 81 Fed. Reg. 56762, 57227 (Aug 22, 2016).
[32] Medicare Contractor's Supplement at 7-8.
[33] *See* 81 Fed. Reg. at 57193 ("Beginning with the FY 2014 payment determination and subsequent years, the Secretary is required to reduce any annual update to the LTCH PPS standard Federal rate for discharges occurring during such fiscal year by 2 percentage points for any LTCH that does not comply with the requirements established by the Secretary. Section 1886(m)(5) of the Act requires that for the FY 2014 payment determination and subsequent years, each LTCH submit data on quality measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary.").
[34] Medicare Contractor's Supplement at 1-2.

where it was determined that CMS established a new rate calculation that rose to the level of a "substantive legal standard" that required notice and comment through the rule making process.[35] It was the nature of the change to the rate calculation that triggered the requirement of notice and comment. Thus, one question to be addressed in the instant appeal is whether the deadlines for the submission of quality reporting data set by CMS established or changed an existing policy that required notice and comment.[36]

In the first paragraph of the *Allina* opinion, the Supreme Court identified the underlying dispute in that case as follows:

> One way or another, Medicare touches the lives of nearly all Americans. Recognizing this reality, Congress has told the government that, when it wishes to establish or change a "substantive legal standard" affecting Medicare benefits, it must first afford the public notice and a chance to comment. 42 U.S.C. § 1395hh(a)(2). In 2014, the government revealed a new policy on its website that dramatically—and retroactively—reduced payments to hospitals serving low-income patients. Because affected members of the public received no advance warning and no chance to comment first, and because the government has not identified a lawful excuse for neglecting its statutory notice-and-comment obligations, we agree with the court of appeals that the new policy cannot stand.[37]

The Medicare Contractor notes that the *Allina* decision does not clarify whether *any impact* on payment automatically turns a rule into a substantive rule.[38] The Court also avoided making a broader ruling about how much of the lengthy Medicare operation manuals could be swept into its holding, and instead considered only the policy change before it. In its decision, the Supreme Court stated:

> In the end, all of the available evidence persuades us that the phrase "substantive legal standard," which appears in §13955hh(a)(2) and apparently nowhere else in the U.S. Code, cannot bear the same construction as the term "substantive rule" in the APA. We need not, however, go so far as to say that the hospitals' interpretation, adopted by the court of appeals, is correct in every particular. To affirm the judgment before us, it is enough to say the government's arguments for reversal fail to withstand scrutiny. Other questions about the statute's meaning can await other cases.[39]

The Medicare Contractor asserts that HRC's argument that it was harmed by not being able to comment on the quality data submission guidelines, causing it to be denied its desired

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[35] *Id.* at 4.
[36] *Id.*
[37] *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019).
[38] Medicare Contractor's Supplement at 5.
[39] *Id. See also Allina,* 139 S. Ct. at 1814.

reimbursement, does not rise to the level of harm in *Allina*.[40] The Medicare Contractor states that public comments were solicited on the quality data submission guidelines, and HRC has offered nothing to suggest how it was injured or impacted by the inability to comment on any element of the implementation of the LTCH QRP.[41]

The Medicare Contractor further notes that the scope of the Medicare statute's notice and comment requirement is not unlimited. For example, CMS' thresholds for triggering the recoupment of interim outlier payments—namely, an interim cost to charge ratio that differs by more than 10 percent from the audited cost to charge ratio and outlier payments totaling more than $500,000—are only found in manuals. After issuing its decision in "*Allina II"*, the D.C. Circuit was called upon to decide whether those recoupment thresholds required notice and comment under the Medicare statute in the *Clarian* decision.[42]

In 2010, the Department of Health and Human Services ("HHS") established instructions governing the selection process.[43] *Clarian* challenged the 2010 Manual instructions before the District Court. Set forth in a manual for Medicare payment contractors, the instructions provided two criteria for payments that should be recalculated and reconciled.[44] In 2012, HHS and its contractor determined that Appellee Clarian Health West ("*Clarian*") met the criteria for outlier payments made to it for services provided in fiscal year 2007. The hospital was subjected to reconciliation, and it was ultimately required to pay back over $2 million in outlier payments.[45]

Clarian asserted, *inter alia*, that both the APA, 5 U.S.C. § 553, and the Medicare Act, 42 U.S.C. §§ 1395hh(a)(1), (b)(1), required HHS to promulgate the criteria for selecting hospitals for reconciliation by regulation after notice-and-comment rule making. *Clarian* claimed that the instructions and the reconciliation were procedurally invalid.[46]

The District Court concluded that, under the Medicare Act, HHS was required to promulgate the 2010 instructions through notice-and-comment rule making.[47] But on appeal, the D.C. Circuit reversed the District Court and found that those policies did not require notice and comment rulemaking. Specifically, the D.C. Circuit held that those reconciliation instructions were not a "substantive legal standard governing payment" under the Medicare statute, since they merely provided procedural guidance to Medicare contractors on how to allocate auditing resources.[48] It did not affect the underlying substantive legal standard for reimbursement, the court reasoned, because that standard would allow for recoupment whenever the interim cost to charge ratio differed from the actual ratio.[49]

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[40] *Id*. at 5.
[41] *Id*. at 6.
[42] *Id*.; *Allina Health Services v. Price*, 863 F.3d 937 (D.C. Cir. 2017); *Clarian Health West, LLC v. Hargan*, 878 F.3d 346 (D.C. Cir. 2017) (hereinafter "*Clarian*").
[43] *Id*. at 6.
[44] *Id*.; Medicare Claims Processing Manual, CMS Pub. 100-04, Ch. 3, § 20.1.2.5(A) (Dec. 3, 2010), (hereinafter "CMS Manual").
[45] *Id*. at 6.
[46] *Clarian* 878 F.3d at 351–55.
[47] *Id.* at 352 (citing *Clarian Health West, LLC v. Burwell*, 206 F>Supp.3d 393, 420 (D.D.C. 2016).
[48] *See id*. at 356.
[49] Medicare Contractor's Supplement at 7.

In its response to the Board's RFI,[50] which asked HRC for clarification as to whether HRC's APA challenge also challenges the procedural or substantive validity of the regulations and rulemakings upon which the LTCH QRP issuances are based, HRC asserted that its position is that the imposition of the penalty in this case is particularly arbitrary and capricious given that the Medicare Contractor has often reversed penalties in other cases where technical errors prevented the proper submission of quality data, especially where those technical errors were attributable to CMS and its systems.[51] "Simply put, [HRC's] position is that a technical error, whether attributable to a provider or to CMS, should not be the basis for a financial penalty when there has otherwise been a good faith attempt to comply with the quality data submission requirements."[52]

HRC was also clear in its response to the Board's RFI that its argument under the APA does *not* challenge the procedural or substantive validity of any regulation or rule concerning the LTCH QRP.[53] Rather, HRC advances a separate argument under 42 U.S.C. § 1395hh that, it claims, is wholly independent from its arguments under the APA.[54] This argument is that the Medicare Contractor cannot enforce a two percent penalty against HRC for its failure to comply with certain data submission requirements that were not promulgated through notice and comment.[55] The data submission requirements challenged by HRC in this appeal are the temporal deadlines for submission of quality data, and the correct use of monthly reporting plans for submitting quality data.[56] HRC argues there is no dispute that its only "failure" in this case was not checking a box in the completion of its monthly reporting plans for the months of April, June, August, and September 2017, which meant that quality data submitted to the NHSN did not ultimately get forwarded to CMS by the applicable deadline.[57] HRC argues that it did everything *else* it was supposed to do. The two percent penalty in this case is based solely on HRC's failure to prepare and fill out monthly reporting plans in the correct way so that data made it to CMS by a certain date.[58]

Pursuant to 42 U.S.C. § 1395hh, as illuminated through the Supreme Court's decision in *Azar v. Allina,* 139 S. Ct. 1804 (2019), it is unlawful for CMS to impose any requirement that governs the scope of benefits or the payment for services without first promulgating that rule or requirement through notice and comment. Here, HRC asserts the particular requirements at issue were not promulgated through notice and comment, hence, noncompliance with them cannot serve as the basis for penalizing HRC.[59]

HRC has acknowledged that Congress delegated authority to the Secretary to specify the type of data, and the form and manner for LTCH's to submit that data, and that the Secretary did promulgate certain regulations and adopt certain rules through notice and comment.[60] HRC

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[50] Board's Request for Information (Dec. 18, 2020).
[51] Provider's Response to Board Request for Information at 1 (Jan. 4, 2021).
[52] *Id*.
[53] *Id*.
[54] *Id.*
[55] *Id*. at 1-2
[56] *Id*. at 2.
[57] *Id*.; *See also* Stip. at ¶ 5.
[58] Provider's Response to Board Request for Information at 2.
[59] *Id*.
[60] *Id*.; *See also* Stip. at ¶ 12

acknowledges that those regulations and rules, however, are not at issue in this appeal.[61] HRC is only challenging the sub-regulatory requirements imposed by CMS with respect to submitting data through monthly reporting plans and submitting data by certain temporal deadlines.[62] Those particular requirements - which, again, are the only things HRC asserts it failed to follow, were not promulgated through notice and comment.[63] Thus, under 42 U.S.C. § 1395hh, HRC argues the submission requirements cannot serve as the sole basis for the imposition of a 2 percent penalty against HRC and the reduction of its payments for services.[64]

HRC thus requests that the Board reverse CMS's denial of its reconsideration request, instruct CMS to set aside the two percent penalty to its APU for FY 2019, and otherwise render it a favorable ruling in its appeal.

DISCUSSION, FINDINGS OF FACT AND CONCLUSIONS OF LAW:

The facts in this case are not in dispute. During calendar year ("CY") 2017, HRC entered quality data into the CDC NHSN system on or before the deadlines established by CMS. However, for the four (4) months of April, June, August, and September 2017, HRC failed to properly complete the monthly reporting plan in the CDC NHSN system for those four months. Specifically, for these four months, HRC failed to check the boxes in the monthly reporting plans for the CLABSI, CAUTI, and VAE measures to thereby notify to the CDC NSHN system that data was being collected and submitted and to cause that data to be transmitted from the CDC NSHN system to CMS on the established deadlines. This is confirmed by the following email that HRC received from the CDC on July 30, 2018 when HRC inquired as to why it received the two percent penalty:

> You has [*sic*] all of your data entered, but you only included CLABSI, CAUTI, and VAE in your May and July monthly reporting plans for Q2 and Q3 of 2017. This is why you were non-compliant. A reporting plan has to include your CMS required data every month.[65]

Thus, CMS never received that four months of data for those three measures on or before the established deadlines. Here, the April and June 2017 data were due on November 15, 2017 and the August and September 2017 data were due on February 15, 2018.[66]

HRC does not dispute that both the Board and Federal Courts, faced with appeals concerning imposition of a two percent penalty, have upheld it on facts and arguments similar to those put forward in this appeal.[67] However, HRC argues those decisions occurred before the Supreme Court decided *Allina* and that the rationale in the *Allina* decision, and its impact on this appeal, is

[61] Provider's Response to Board Request for Information at 2.
[62] *Id*.
[63] *Id*.
[64] *Id*.
[65] Exhibit P-5.
[66] 81 Fed. Reg. at 57227.
[67] Provider's FPP at 2.

binding.[68] HRC argues that the specific data submission deadlines and requirements that serve as the basis for the imposition of a two percent penalty against it were not promulgated through the notice and comment process mandated by 42 U.S.C. § 1395hh and, therefore, under *Allina,* they cannot serve as the basis for enforcement of a penalty reducing HRC's "payment for services."[69]

The Medicare Contractor urges the Board to consider whether "the submission deadlines set by CMS affect the underlying substantive legal standard for payment."[70] The Medicare Contractor submits that the submission deadlines are "procedural obligation(s)" that do not rise to the level of a substantive legal standard, and that "[t]he applicable legal standard is 'the Provider must submit certain quality data in a place time and manner as determined by the Secretary. The failure to do so will result in the 2% rate reduction.'"[71]

The Board finds, in accordance with *Allina,* that the submission deadlines in this case are *procedural* requirements, and do not require notice and comment rulemaking. One objective of the notice and comment requirement is to avoid surprises to the provider community. It is unreasonable for a provider to claim that they were unfairly surprised that submission deadlines were set when faced with the mandatory reporting of data. Further, the regulation implementing the statute specifies that LTCHs must submit in the form and manner and at the *time* specified by the Secretary.[72] The Board is bound by that regulation.[73] Furthermore, the actual deadlines for the 2017 reporting period were published in the Federal Register preamble for the FY 2017 Final Rule, and therefore did, in fact, go through notice and comment.[74] As a result, the Board is bound by these published deadlines as they were intended to be binding on all LTCHs when published in the Federal Register. Consistent with the statutory provisions governing each of the quality reporting programs at issue, the Secretary specified the "*form and manner, and . . . time*" by which data was required to be submitted for the APU determination under appeal.[75] The data was required to be properly entered into the CDC NHSN by the deadline (*i.e.*, in the specified form, manner and time) so that it could be submitted from the CDC NHSN to CMS.

The Board finds that the applicable legal standard is located at 42 C.F.R. § 412.560(b)(1)-(2) (2015) which states:

> (1) Except as provided in paragraph (c) of this section, a long-term care hospital ***must*** submit to CMS data on measures specified under sections 1886(m)(5)(D), 1899B(c)(1) and 1899B(d)(1) of the Act, and standardized patient assessment data required under section 1899B(b)(1) of the Act. *Such data **must** be submitted in a form and manner, and at a time, specified by CMS.*

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[68] *Id.*
[69] *Id.*
[70] Medicare Contractor's Supplement at 7.
[71] *Id.*
[72] 42 C.F.R. § 412.560(b) (2015).
[73] 42 C.F.R. § 405.1867.
[74] 81 Fed. Reg. at 57227.
[75] (Emphasis added.)

> (2) *A long-term care hospital that does not submit data* in accordance with sections 1886(m)(5)(C) and 1886(m)(5)(F) of the Act with respect to a given fiscal year *will have its annual update* to the standard Federal rate for discharges for the long-term care hospital during the fiscal year *reduced by 2 percentage points*.[76]

Accordingly, a provider *must* submit certain quality data *in a place, time **and** manner* as determined by CMS, and the failure to do so will result in the two percent rate reduction.[77] This legal standard was not changed or impacted by the procedural requirement of the submission deadlines. Here, the Secretary adopted, through notice and comment, the reporting of the CLABSI and CAUTI measures beginning October 1, 2012[78] and the VAE measure beginning October 1, 2015[79] using the CDC NHSN platform. In adopting the NHSN platform for the reporting of these measures, the Secretary noted:

> The NHSN is a secure, Internet-based surveillance system that is maintained and managed by CDC. Many LTCHs already submit data to the NHSN either voluntarily or as part of mandatory State reporting requirements for HAIs.[80]

The LTCH Quality Reporting Program Manual (Version 3.0)[81] provided the following general instruction in § 5.1 regarding NHSN:

> CDC submits the data to CMS on behalf of the facility, ***according to the facility's monthly reporting plan***. Data submitted to CDC more than 135 days after the end of the reporting quarter, such as data submitted to the CDC NHSN after August 15, 2016, for Q1 2016, will not be provided to CMS, and will not be considered for the purpose of compliance determination. LTCHs are able to review data submitted to CMS on their behalf through the "Analysis – Output Options" function within NHSN. More information regarding the location and interpretation of these

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[76] (Emphasis added.)
[77] 42 C.F.R. § 412.560(b) (2015).
[78] 77 Fed. Reg. 53258, 53668 (Aug. 31, 2012) ("LTCH providers will begin to use the NHSN system to report CAUTI and CLABSI data on October 1, 2012. By the time that any new measures are finalized and reporting of the same begins, LTCH providers should be very familiar and comfortable with the NHSN reporting system.").
[79] 79 Fed. Reg. 49854, 50305 (Aug. 22, 2014) ("In addition to soliciting comments on our proposal to adopt the NHSN VAE Outcome measure for the LTCHQR Program, we also invited comments on our proposal to use the CDC's NHSN system for data collection and submission for this measure. We received no comments on the use of the NHSN system for data collection and submission of the VAE Outcome measure. Therefore we are finalizing the National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure, as proposed, for FY 2018 payment update determination and subsequent years.")
[80] 77 Fed. Reg. at 53668.
[81] Copy at Exhibit C-4. Version 3.0 of the LTCH Quality Reporting Program Manual was issued in March 2017; however, Chapter 5 was last revised in October 2015. A complete copy of Version 3.0 is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/-LTCH-Quality-Reporting-Archives (last visited on Nov. 26, 2021).

> reports can be found on the CDC Web site: http://www.cdc.gov/nhsn/cms/index.html.[82]

In addition, § 5.1 provides the following instruction, in pertinent part, regarding the NHSN CAUTI Outcome Measure and the NHSN CLABSI Outcome Measure:

> Monthly reporting plans must be created or updated to include CAUTI and CLABSI surveillance in all locations that require reporting (i.e., surveillance must be "in-plan"). All required data fields in the numerator and the denominator, including the "no events" field for any month during which no CAUTIs or CLABSIs were identified, must be submitted to NHSN.[83]

This section similarly provides the following instruction, in pertinent part, for the NHSN VAE Outcome Measure:

> Monthly denominator data must be reported on VAEs for all adult locations, regardless of whether a ventilator-associated infection or other event occurred in the LTCH. Monthly reporting plans must be created or updated to include VAE surveillance in all locations that require reporting (i.e., surveillance must be "in-plan"). All required data fields in the numerator and the denominator, including the "no events" field for any month during which no VAEs were identified, must be submitted to NHSN. For additional guidance on reporting this measure, please refer to: http://www.cdc.gov/nhsn/ltach/vae/index.html[84]

Finally, § 5.3 is entitled "Basic Steps to NHSN Enrollment and Data Submission" and provides the following instruction, in pertinent part, on monthly reporting plans:

> 8. All patient care units will need to be added as location(s) and mapped in NHSN in advance by a facility user. They ***must*** also be added to the monthly reporting plan *under the device-associated module section for* ***each*** *month you plan on submitting* the NHSN CAUTI Outcome Measure (NQF #0138), the NHSN CLABSI Outcome Measure (NQF #0139), and the NHSN VAE Outcome Measure data to CMS. After adding the location, please remember to check the "CAUTI," "CLABSI,"

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[82] Exhibit C-4 at 4-5 (emphasis added). *See also* CDC webpage for "CMS Quality Reporting Programs Frequently Asked Questions" *available at* https://www.cdc.gov/nhsn/faqs/cms/faq_cms_hai.html#q8 (webpage last reviewed Mar. 30, 2015) (last accessed Nov. 26, 2021) ("Do I need to confer rights or join a CMS group in order to share my data with CMS for reporting purposes? • No. As long as the facility has entered their CMS Certification Number (CCN) in NHSN correctly, ***completed the monthly reporting plans***, and entered data appropriately, data will be automatically sent to CMS for required reporting programs." (emphasis added)).

[83] Exhibit C-4 at 8.

[84] *Id.* at 8.

> and "VAE" boxes to ensure that the data will be appropriately sent to CMS.
>
> ***
>
> 15. If no CAUTI, CLABSI, or VAE events were identified for the month, the "Report No Events" box must be checked for the appropriate surveillance type on the Denominator for "Intensive Care Unit/Other Locations" screen within the NHSN application.[85]

The Secretary has specified that CMS may grant an exception or extension to the LTCH quality reporting requirements. Specifically, the regulation at 42 C.F.R. § 412.560(c) provides that "*[u]pon request of a long-term care hospital*, CMS may grant an exception or extension with respect to the quality data reporting requirements, for one or more quarters, in the event of certain extraordinary circumstances beyond the control of the long-term care hospital," subject to certain conditions.[86] While this regulation is directed to CMS (rather than the Board), it requires the LTCH to submit a request to CMS in order for an exception or extension to be considered. The Board notes that the key phrase in the regulation, determining whether an LTCH would qualify for an exception, is that the "extraordinary circumstance" must be "beyond the control of the long-term care hospital."[87] In this case the Board finds that, even if the regulation were applicable (*i.e.,* HRC had submitted a proper request to CMS), HRC has failed to demonstrate that its failure to properly mark the checkboxes in the relevant monthly reporting plans for April, June, August, and September, 2017 for the CAUTI, CLABSI, and VAE device associated modules was an "extraordinary circumstance beyond [its] control."

Indeed, what is perplexing is that data for the month of May 2017 had the same submission due date of November 15, 2017 as the months of April and June 2017 and that the month of July 2017 had the same submission due date of February 15, 2018 as the months of August and September 2017. However, neither May 2017 nor July 2017 are at issue here as the data for these two months was transmitted from CDC to CMS *per the requisite monthly reporting plan*.[88] Thus, the Board is presented with a situation of administrative error because HRC was able to properly submit the data for May and July 2017 in the manner and form specified by the Secretary (including properly completing the requisite monthly reporting plans for May and July 2017) but was unable to do so for April, June, August, and September 2017 due to its failure to check the box(es) for CAUTI, CLABSI, and VAE on the monthly reporting plans for April, June, August, and September 2017.[89]

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[85] *Id.* at 11 (emphasis added).
[86] (Emphasis added.)
[87] 42 C.F.R. § 412.560(c).
[88] *See* Exhibit P-5.
[89] The Medicare Contractor suggests that HRC could have caught its mistake by generating a CASPER report (*see supra* note 23 and accompanying text). However, the Medicare Contractor is incorrect as CASPER reports are only used relative to correcting data prior to issuing that data to the public (as opposed to correction of data prior to the data submission deadline which in this case was November 15, 2017 for the months April and June 2017 and February 15, 2018 for the months August and September 2017). The relevant reports are called SIR reports and providers may use SIR reports to confirm whether information has been entered into the CDC NSHN correctly. *See, e.g.*, Using the "SIR – CLAB Data for Hospital IQR" Output Option (Updated Dec. 2016) (*available at*:

The Board also recognizes that § 412.560(c)(4) (2015) provides for certain systemic or regional situations where a request need not be submitted:

> CMS may grant an exception or extension to a long-term care hospital *that has not been requested* by the long-term care hospital if CMS determines that -
>
> (i) An extraordinary circumstance affects an entire region or locale; or
>
> (ii) A systemic problem with one of CMS' data collection systems directly affected the ability of the long-term care hospital to submit quality data.[90]

However, this regulation is not applicable here because, as noted above, there is no evidence in the record of *extraordinary* circumstances beyond HRC's control that caused HRC to not submit the data, much less any evidence that HRC submitted a request to CMS for an extraordinary circumstance exception.

Based on the above findings, the Board finds that there was no evidence submitted of any systemic problem with the NHSN system that caused HRC's failure to timely submit the required data. Rather, the record before the Board demonstrates that Hebrew was at fault for its failure to timely submit said data. The Board's ruling in this case is consistent with other cases where the provider failed to enter a monthly reporting plan.[91]

DECISION AND ORDER:

After considering Medicare law and regulations, arguments presented, and the evidence admitted, the Board finds that CMS properly reduced HRC's APU for FY 2019 by 2 percent.

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https://www.cdc.gov/nhsn/pdfs/cms/cms-ipps-clabsi-sir.pdf (last accessed Nov. 26, 2021)) ("The NHSN Analysis Output Option, "SIR – CLAB Data for Hospital IQR" was created in order to allow facilities to review those data that would be submitted to CMS on their behalf. . . . What can be done if data are incomplete . . ., or if the number of infections or central line days is incorrect? . . . If summary data have been entered, double-check your monthly reporting plan for each month in the quarter. Check to make sure that each location is included in your monthly reporting plan, with the CLABSI box checked."); Acute Care Hospitals: Troubleshooting your CLABSI and COUTI SIRs (May 2015) (*available at* https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/clabsicauti_sirtroubleshooting_2015update.pdf (last accessed Nov. 26, 2021)) ("Problem#2: My quarterly SIR for CMS IPPS shows fewer CLABSI (or CAUTI) events and/or fewer device days than I have entered in NHSN. . . . Solution: • Step 1: *Check your monthly reporting plans for all 3 months of the quarter*. Be sure that all applicable ICU and select ward locations are included in your monthly reporting plans for CLABSI (or CAUTI) surveillance." (Emphasis added)).

[90] (Emphasis added.) *See also* 81 Fed. Reg. at 56774 (stating that "we are changing the timing for submission of exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an LTCH from submitting their quality data for the LTCH QRP.").

[91] *See, e.g., Landmark Hosp. of Salt Lake City, LLC v. Cahaba Gov't Benefit Adm'rs, LLC*, PRRB Dec. No. 2019-D16 (Feb. 26, 2019). *See also id*. at n. 36 (listing additional examples of Board decisions where the provider failed to enter a monthly reporting plan).

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11/30/2021

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