PROVIDER REIMBURSEMENT REVIEW BOARD

ON THE RECORD
2024-D31

PROVIDER –
Lakeview Specialty Hospital & Rehab Center

PROVIDER NO. –
52-2005

vs.

MEDICARE CONTRACTOR –
WPS Government Health Administrators (J-5)

DATE OF RECORD HEARING –
September 29, 2023

FEDERAL FISCAL YEAR –
2021

CASE NO. 21-0995

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ISSUE STATEMENT:

Whether the Centers for Medicare & Medicaid Services ("CMS") properly imposed a two percent reduction to the Provider's payment update for Fiscal Year ("FY") 2021 because the Provider allegedly failed to meet the requirements of the Long-Term Care Hospital Quality Reporting Program ("LTCH QRP")?[1]

DECISION:

After considering Medicare law and regulations, the arguments presented, and the evidence admitted, the Provider Reimbursement Review Board ("Board" or "PRRB") finds that CMS properly reduced the FY 2021 annual payment update ("APU") for Lakeview Specialty Hospital & Rehab Center ("Provider or Lakeview") by 2 percentage points.

INTRODUCTION:

Lakeview Specialty Hospital & Rehab Center ("Lakeview" or "Provider") is "a Medicare-certified long-term care hospital ("LTCH") located in Waterford, Wisconsin."[2] Lakeview's assigned Medicare contractor[3] is WPS Government Health Administrators (the "Medicare Contractor").

CMS reviews all LTCH QRP requirements to make APU decisions, including QRP reduction penalties for program noncompliance. To receive the full APU for FY 2021 reimbursement under the LTCH QRP, participating hospitals were required to submit data on certain quality measures during calendar year ("CY") 2019.

By letter dated July 13, 2020, CMS notified Lakeview that it failed to meet the LTCH QRP requirements and was subject to a 2 percent reduction in its FY 2021 APU.[4] On August 10, 2020, Lakeview requested that CMS reconsider its decision regarding the reduction to its FY 2021 Medicare payment.[5] On September 11, 2020, CMS upheld its decision.[6] On March 8, 2021, Lakeview timely appealed CMS' denial to the Board and met the jurisdictional requirements for a hearing.[7]

On September 29, 2023, the Board issued a Notice of Hearing on the Record and closed the record on October 30, 2023. The Provider was represented by Jason M. Healy, Esq. of The Law Offices

[1] Stipulations at ¶¶ 3, 6 (Sept. 20, 2023).
[2] *Id*. 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] Stipulations at ¶ 8 (September 20, 2023). *See also* Exhibits (hereinafter "Exs.") P-2, C-1. The Medicare Contractor also issued a letter to the Provider dated July 6, 2020. *See* Stipulations at ¶ 7; Exs. P-1, C-2.
[5] Stipulations at ¶ 13. *See also* Ex. P-4.
[6] Stipulations at ¶ 15. *See also* Ex. P-5.
[7] Stipulations at ¶ 17. *See also* Ex. P-9.

of Jason M. Healy, PLLC. The Medicare Contractor was represented by Scott Berends, Esq. of Federal Specialized Services, LLC.

STATEMENT OF RELEVANT FACTS AND RELEVANT LAW:

A. Relevant Factual Background

LTCH FY 2021 payment determinations were based on the timely submission of quality data on certain quality measures collected during calendar year ("CY") 2019 (reporting period of January 1, 2019, through December 31, 2019).[8] This appeal focuses on the quality data that was required to be submitted during CY 2019 on the quality measures for Central Line-Associated Bloodstream Infection events ("CLABSI" or "BSI") and Catheter-Associated Urinary Tract Infection events ("CAUTI" or "UTI"). CMS set the following deadlines for the submission of the LTCH QRP CY 2019 quality measures data for FY 2021 payment determination:

> Q1 (January 1-March 31, 2019) – August 15, 2019
> Q2 (April 1-June 30, 2019) – November 15, 2019
> Q3 (July 1-September 30, 2019) – February 15, 2020
> Q4 (October 1-December 31, 2019) – May 15, 2020[9]

However, as a result of the COVID-19 pandemic, CMS exempted LTCHs from submitting quality data for Q4 2019.[10]

For the reporting periods above, CMS required LTCHs to submit the required quality measures data via the Center for Disease Control and Prevention's ("CDC") National Healthcare Safety Network ("NHSN").[11] To offer guidance to LTCHs regarding the collection, submission and reporting of quality data to CMS for compliance with the LTCH Quality Reporting Program, CMS issued a Long-Term Care Hospital Quality Reporting Manual. The revised version 4.0, effective July 1, 2018, applies to this case. Particularly, *Chapter 5.1 Overview* states in pertinent parts:

> Each LTCH must submit data for the NHSN CAUTI Outcome Measure (NQF #0138), the NHSN CLABSI Outcome Measure (NQF #0139), and the NHSN Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717) on all patients from all inpatient locations, regardless of payer.
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> In the event that no patients have the infection or event of interest during the reporting period, ***the LTCH is still required to submit monthly denominator counts (i.e., device days and patient days) along with the "no event" indicators to CDC's NHSN.***

[8] Stipulations at ¶ 5.
[9] Ex. C-10 (copy of the LTCH QRP deadlines for FY 2021 LTCH QRP).
[10] CMS Covid-19 Quality Reporting Programs Guidance Memorandum at 2 (Mar. 27, 2020) (available at: https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf (last visited Sept. 23, 2024)).
[11] Ex. C-7 at C-0038.

> ****
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> Reporting of the NHSN CAUTI Outcome Measure (NQF #0138), the NHSN CLABSI Outcome Measure (NQF #0139), and the NHSN Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717) data are required. For these quality measures, the reporting period consists of the four quarters in a given CY, with the fourth quarter's data to be submitted by May 15 of the subsequent year. To fulfill the CMS LTCH QRP requirements, each facility's data for the NHSN CAUTI Outcome Measure (NQF #0138), the NHSN CLABSI Outcome Measure (NQF #0139), and the NHSN Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717) must be entered into the CDC's NHSN no later than 135 days after the end of the reporting quarter. In other words, for first quarter (Q1) data (January 1–March 31) to be shared with CMS, data must be entered into NHSN by August 15.
>
> ***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, for Q1, of that same CY 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 – Reports" function within NHSN***. More information regarding the location and interpretation of these reports can be found on the CDC Web site: https://www.cdc.gov/nhsn/cms/index.html.[12]

In particular, the above guidance makes clear that the CDC NHSN system transmits quality reporting data to CMS based on the monthly reporting plan completed by the provider to confirm the specific quality measures on which data will be transmitted to CMS for that month (*e.g.*, if the CAUTI quality measure is marked on the monthly reporting plan, the NHSN will transmit CAUTI quality reporting data for that month to CMS upon expiration of the relevant deadline). *Chapter 5.3 Basic Steps to NHSN Enrollment and Data Submission* provides, in pertinent part, additional guidance relating to the monthly reporting plan:

> 6. All patient care units will need to be added as location(s) and mapped in NHSN in advance by a facility user.
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> ****
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> 8. *The locations 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) and the NHSN CLABSI Outcome Measure (NQF

[12] Ex. C-7 at C-0035-36 (emphasis added).

> #0139) data to CMS. After adding the location, ***please remember to check the "CAUTI" and "CLABSI" boxes to ensure that the data will be appropriately sent to CMS***.
>
> ****
>
> 12. ***If no CAUTI or CLABSI 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.[13]

Chapter 5.4 Additional Tips and Hints provides in pertinent part:

> - Be sure that all events entered into NHSN are completed. Although an event may be saved without "completing" the event, only data for completed events will be sent by CDC to CMS.[14]

Additionally, NHSN provides tools such as National Standardized Infection Ratio reports ("SIR Reports") that can be used by providers to confirm whether information has been entered into the CDC NHSN correctly.[15] In particular, whenever a month is missing from a SIR Report for CLABSI, the CDC guidance on SIR Reports recommends double checking certain data elements including: "If summary data have been entered, *double-check your monthly reporting plan* for that month. Check to make sure that each location is included in your monthly reporting plan, with the CLABSI box checked."[16] The guidance also recommends that the SIR reports "be used in conjunction with the document, 'Monthly Checklist for the CMS [LTCH QRP]', available at https://www.cdc.gov/nhsn/pdfs/cms/ltch-monthly-checklist-cms-iqr.pdf."[17]

As previously stated, the reporting period for Q1 was January 1-March 31, 2019, and the deadline for the submission of the CY 2019 LTCH quality data measures was August 15, 2019. In January 2019, Lakeview's Director of Quality Assurance ("QA") was promoted to serve as both the Administrator and Chief Operating Officer of the hospital.[18] At that time, she still retained primary responsibility for QA and compliance, including the LTCH QRP reporting requirements (which included reporting plan submissions).[19] As of January 2019, Lakeview's Infection Preventionist assumed responsibility for the tracking, compiling, and uploading of data tasks associated with the

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[13] Ex. C-7 at C-0040-41 (emphasis added). *See also id.* at -0036 (stating; "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')." (emphasis added)).
[14] Ex. C-7 at C-0042.
[15] Ex. C-12.
[16] Ex. C12 at C-0080 (emphasis added). This guidance further advises "REMEMBER: If you have made any changes to your data, regenerate your datasets in order to review your output options with the most-up-to-date data in NHSN."
[17] Ex. C-12 at C-0073.
[18] Provider's Final Position Paper (hereinafter "Provider's FPP") at 2.
[19] *Id*.

LTCH QRP.[20] At some point during the month of August 2019,[21] the Administrator/COO became seriously ill, and the quality outcome measures for urinary tract infections and blood stream infections due on August 15, 2019, were not submitted. Unfortunately, the Administrator/ COO succumbed to her illness and passed away eight months later on April 28, 2020.[22]

Lakeview first became aware that some aspect of their quality submissions for CY 2019 were noncompliant when it received a July 6, 2020 Notice of Reduction from WPS for the FY 2021 Payment Year.[23] The notice did not specifically state which requirement Lakeview failed to meet; however, on July 13, 2020, Lakeview received the Notice of Noncompliance from CMS citing that Lakeview failed to submit all of the required months of quality data on the NQF #0138 CAUTI and NQF #0139 CLABSI Outcome Measures.[24] However, this letter also provided no details as to which of the required months were incomplete or missing.

On August 10, 2020, Lakeview requested reconsideration and, in support of its request, submitted certain NHSN reports dated August 6, 2020 showing the "last entry created and/or modified for CAUTI/CLABSI was on 5/28/2019[,] which was before the required deadline submission date of 8/15/2019."[25] Specifically, the NHSN Line Listing for All Report showed that, during the reporting period for Q1 (January 1 – March 31), the following two (2) CLABSI event dates were entered.[26]

Event Date	**Entry Creation Date**	**Entry Modification Date**
January 24, 2019	March 14, 2019 at 17:16	March 14, 2019 at 17:16
February 1, 2019	March 22, 2019 at 11:12	March 22, 2019 at 11:12

For CAUTI, the following four (4) events were entered.[27]

Event Date	**Entry Creation Date**	**Entry Modification Date**
January 18, 2019	March 14, 2019 at 15:55	March 14, 2019 at 15:55
January 28, 2019	March 14, 2019 at 17:35	March 14, 2019 at 17:35
February 22, 2019	March 22, 2019 at 11:52	May 28, 2019 at 12:54
March 15, 2019	May 24, 2019 at 17:19	May 24, 2019 at 17:19

On September 11, 2020, CMS notified Lakeview that after reconsideration, the noncompliance decision and 2 percent APU reduction was upheld.[28] The reconsideration decision did not specifically identify the incomplete month(s).[29]

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[20] *Id*.
[21] The Provider does not provide an exact date or indicate whether the onset of the illness occurred before or after the August 15, 2019 deadline.
[22] Ex. P-14 at P0033-34.
[23] Ex. C-2 at C-0007.
[24] Ex. P-2 at P003.
[25] Ex. P-4 at P006-07.
[26] *Id.* at P007.
[27] *Id*.
[28] Ex. P-5 at P008.
[29] *Id*.

Lakeview hired a new Director of Quality Assurance ("QA") who was experienced in QRP reporting requirements.[30] The QA Director was hired "to help identify reporting deficiencies"[31] and to make further inquiry into and investigation of the specific month(s) of measures alleged to be incomplete in the July 13, 2019 CMS Notice of Noncompliance,[32] and the QA Director summarized those inquiries and investigative efforts in an email dated October 6, 2020.[33] In particular, the QA Director's email notes that she had been informed by a representative of the Wisconsin Department of Health Services ("DHS")[34] that it was probable that the reporting plan box for the month(s) in question was not checked; but this could not be verified because a subsequent modification had been made to the March reporting plan itself in November 2019, which overrode any prior modification history.[35] Upon further review, the Wisconsin DHS representative confirmed with her on October 22, 2022 that the monthly reporting plan for March 2019 did not include reporting on the CLABSI and CAUTI quality measures and that "[t]hose omissions would trigger the noncompliance."[36] Immediately following that email, the QA Director communicated the following to certain Lakeview staff:

> Unfortunately the NHSN analyst has determined the reporting plans were not checked for CAUTI and CLABSI March 2019 for the Qu1 deadline. This means the data would not have flowed to CMS. This is the reason we received the penalty. I wish I had better news. Going forward Arturo knows what report to run and save before the deadline and I also have on my calendar to double check as well.[37]

On October 27, 2020, the Wisconsin DHS representative further confirmed that, while the monthly reporting plan for March 2019 was created on May 24, 2019 at 11:41 am, the data for the CAUTI and CLABSI quality measures were not transmitted from CDC to CMS because CAUTI and CLABSI quality measures were not marked on that monthly reporting plan.[38] She also clarified that data for a particular month can be entered into NHSN without having the relevant quality measure module checked in that month's reporting plan, and if not checked, it would *not* be transmitted when CMS pulls the data and plans from NHSN according to the monthly reporting plan.[39] ***Here, it is imperative to make clear that the summary data for March 2019***

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[30] Provider's FPP at 3, n.1.
[31] *Id.*
[32] Provider's FPP at 4.
[33] Ex. P-6.
[34] Based on the record before the Board, it is unclear what this state official's relationship is with the CDC NHSN system. However, state health departments may have special user rights and access to the CDC NHSN system as it relates to certain HAI data being reported by hospitals within their respective state. In this respect, the CDC NHSN system is used for other HAI-tracking purposes outside of quality reporting for the Medicare Program. *See* NHSN webpage entitled "About NHSN" https://www.cdc.gov/nhsn/about-nhsn/index.html.
[35] Ex. P-6 at P0010.
[36] Ex. P-7 at P0011.
[37] *Id.*
[38] Ex. P-8 at P0012.
[39] *Id*.

does not reflect an entry/modification date of August 4, 2019, but rather August 4, 2020, nearly one (1) year after the August 15, 2019 deadline.[40]

With reference to alerts from NHSN, the Wisconsin DHS representative informed Lakeview that, "Unfortunately, if something is missing from the plan, you won't get a missing data alert like you do if the plan is complete and the data weren't entered."[41] However, *Step 4: Resolve Alerts* of the *NHSN Monthly Checklist for Reporting to CMS LTCHQR Program* (referenced in Step 7 of Chapter 5.3 of the Program Manual) indicates that alerts may result in six instances: (1) Incomplete Events, (2) Missing Events, (3) Incomplete Summary Data, (4) Missing Summary Data, (5) Unusual Susceptibility Profile, and (6) Confirm CDI test type.[42]

The communications with the Wisconsin DHS representative were forwarded internally within Lakeview. Subsequently, Lakeview appealed CMS' reconsideration determination to the Board and the foregoing procedural history ensued.

B. Relevant Applicable Law

1. Burden of Proof and Standard of Review

A Board decision must include findings of fact and conclusions of law that "the provider carried its burden of production of evidence and burden of proof by establishing, by a preponderance of the evidence, that the provider is entitled to relief on the merits of the matter at issue."[43] Additionally, "[a] decision by the Board shall be based upon the record made at such hearing, which shall include the evidence considered by the [Medicare contractor] and such other evidence as may be obtained or received by the Board, and shall be supported by substantial evidence when the record is viewed as a whole."[44] In *Consolidated Edison Co. v. NLRB*, 305

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[40] Ex. P-8 at P0013, excerpt from exhibit:

Hi,

The March plan was created 8/4/2019. Are we saying it was unchecked then before 8/15/19 when the data would have went to CMS? Is there any way to see the additional modify dates before the one on 11-12-19?

daPlan	entityType	eventtype	factype	summaryYM	numpatdays	modifyUserID	modifyDate	createUserID	createDa
Y		CAU	HOSP-LTAC	Jan-19	879	392573	3/14/2019 15:34	392573	3/14/201 12:2
Y		CLAB	HOSP-LTAC	Jan-19	879	392573	3/14/2019 15:34	392573	3/14/201 12:2
Y		CAU	HOSP-LTAC	Feb-19	916	392573	3/22/2019 10:44	392573	3/22/201 10:4
Y		CLAB	HOSP-LTAC	Feb-19	916	392573	3/22/2019 10:44	392573	3/22/201 10:4
Y		CAU	HOSP-LTAC	Mar-19	1025	392573	8/4/2020 14:28	392573	8/4/202 14:1
Y		CLAB	HOSP-LTAC	Mar-19	1025	392573	8/4/2020 14:28	392573	8/4/202 14:1

Similarly, the March 2019 denominator data in Ex. 10 at P0019 has a printout date of "12/10/21, 9:25 AM, well after the Augut 15, 2019 deadline. Finally, the data charts in Exs. P-12 at P0023-26 and P-13 at P0028-31 are date-stamped "as of: December 13, 2021" which is *well after the August 15, 2019 reporting deadline*.

[41] *Id*.

[42] *See* Chapter 5.3, Step 7 of the Reporting Manual, Ex. C-8, p. C-0040, citing to http://www.cdc.gov/nhsn/pdfs/cms/ltch-monthly-checklist-cms-iqr.pdf (last visited September 24, 2024).

[43] 42 C.F.R. § 405.1871(a)(3) (as of Oct. 1, 2020).

[44] 42 U.S.C. § 1395oo(d). This statutory provision further confirms that "[t]he Board shall have the power to affirm, modify, or reverse a final determination of the fiscal intermediary with respect to a cost report and to make any other revisions on matters covered by such cost report (including revisions adverse to the provider of services) even though such matters were not considered by the intermediary in making such final determination." *But also see* 42 C.F.R. § 405.1869(a).

U.S. 197, 230 (1938), the U.S. Supreme Court held, "[s]ubstantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion."[45] Accordingly, in an appeal before the Board, a provider must prove by a preponderance of substantial, relevant evidence that it is entitled to the relief sought.

2. Requirements under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

Contrary to the parties' stipulation that CMS reconsiderations for FY 2021 payment determinations are ***governed*** in part by the FY 2015 IPPS/LTCH PPS Final Rule,[46] the FY 2015 LTCH IPPS Final Rule was superseded by the FY 2016 IPPS Final Rule, which codified the applicable law in this matter effective "for the FY 2017 Payment Determination and Subsequent Years."[47] Accordingly, the regulations set forth in 42 C.F.R. § 412.560 that were in effect on August 10, 2020 (the date of Provider's reconsideration request) apply as they fully address the reconsideration process at that time.[48]

42 C.F.R. § 412.560 (October 1, 2019)[49] in pertinent part states:

> (b) ***Data submission 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, 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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> (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.
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[45] *See also Pomona Valley Hosp. Med. Ctr. v. Becerra*, 82 F.4th 1252, 1258-59 (D.C. Cir. 2023).

[46] Stipulations at ¶ 12.

[47] As part of the FY 2016 LTCH IPPS Final Rule, the Secretary codified at 42 C.F.R. §§ 412.560(c), (d) and (e) her policies for both the LTCH QRP Reconsideration and Appeals Procedures and LTCH QRP Submission Exception and Extension Requirements effective "for the FY 2017 Payment Determination and Subsequent Years." 80 Fed. Reg. 49326, 49755-56 (Aug. 17, 2015) (Sections VIII(A)(13) and (14) of the preamble codified these provisions and the headers make clear that this codification was effective "for the FY 2017 Payment Determination and Subsequent Years").

[48] For FY 2017 payment determinations and subsequent years, the FY 2016 IPPS/LTCH PPS Final Rule codified the LTCH QRP exception and extension requirements specifying the extraordinary circumstances standard as well as the procedure for requesting reconsideration of a noncompliance decision. *See* 80 Fed. Reg. 49326, 49755-56, 49769-70. *See* further discussion, *infra*.

[49] Available at https://www.ecfr.gov/on/2019-10-01/title-42/section-412.560 (last visited Setp. 26, 2024). Subsequent changes to the regulation were made on August 28, 2023; thus, the October 1, 2019 version is relevant to this matter.

(c) *Exception and extension request requirements.* Upon request by a long-term care hospital, CMS may grant an exception or extension with respect to the measures data and standardized patient assessment 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 the following:

(1) A long-term care hospital that wishes to request an exception or extension with respect to measures data and standardized patient assessment data reporting requirements must submit its request to CMS within 90 days of the date that the extraordinary circumstances occurred.

(2) A long-term care hospital must submit its request for an exception or extension to CMS via email. Email is the only form that may be used to submit to CMS a request for an exception or an extension.

(3) The email request for an exception or extension must contain the following information:

(i) The CCN for the long-term care hospital.

(ii) The business name of the long-term care hospital.

(iii) The business address of the long-term care hospital.

(iv) Contact information for the long-term care hospital's chief executive officer or designated personnel, including the name, telephone number, title, email address, and physical mailing address. (The mailing address may not be a post office box.)

(v) A statement of the reason for the request for the exception or extension.

(vi) Evidence of the impact of the extraordinary circumstances, including, but not limited to, photographs, newspaper articles, and other media.

(vii) The date on which the long-term care hospital will be able to again submit measures data and standardized patient assessment data under the LTCH QRP and a justification for the proposed date.

(4) 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 measures data and standardized patient assessment data.

(d) *Reconsiderations of noncompliance decisions*—(1) *Written letter of non-compliance decision.* Long-term care hospitals that do not meet the requirement in paragraph (b) of this section for a program year will receive a notification of non-compliance sent through at least one of the following methods: The CMS designated data submission system, the United States Postal Service, or via an email from the MAC

(2) *Request for reconsideration of noncompliance decision.* A long-term care hospital may request a reconsideration of CMS' decision of noncompliance no later than 30 calendar days from the date of the written notification of noncompliance. The reconsideration request by the long-term care hospital must be submitted to CMS via email and must contain the following information:

(i) The CCN for the long-term care hospital.

(ii) The business name of the long-term care hospital.

(iii) The business address of the long-term care hospital.

(iv) Contact information for the long-term care hospital's chief executive officer or designated personnel, including each individual's name, title, email address, telephone number, and physical mailing address. (The physical address may not be a post office box.)

(v) CMS's identified reason(s) for the noncompliance decision from the written notification of noncompliance.

(vi) **The reason for requesting reconsideration of CMS' noncompliance decision.**

(vii) **Accompanying documentation that demonstrates compliance of the long-term care hospital with the LTCH QRP requirements.** This documentation must be submitted electronically at the same time as the reconsideration request as an attachment to the email.

(3) *CMS decision on reconsideration request.* CMS will notify long-term care hospitals, in writing, of its final decision regarding any reconsideration request through at least one of the following

> methods: The CMS designated data submission system, the United States Postal Service, or via an email from the MAC.
>
> (e) *Appeals of reconsideration requests.* A long-term care hospital that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board under part 405, subpart R, of this chapter.[50]

DISCUSSION, FINDINGS OF FACT AND CONCLUSIONS OF LAW:

The Medicare statute at 42 U.S.C. § 1395ww(m)(5)(C) specifies that LTCHs "shall submit to the Secretary data on quality measures . . . " and that "[s]uch data shall be submitted in a form and manner, and at a time, specified by the Secretary."[51] In relevant part, the Medicare statute further provides in § 1395ww(m)(5)(A) that a long-term care hospital that fails to submit data in accordance with § 1395ww(m)(5)(C) 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.[52]

Lakeview contends it is entitled to reversal of the 2 percent payment penalty because: (1) the CMS reconsideration decision failed to follow the reconsideration process established in the regulation and preamble to the FY 2015 Final Rule; (2) any perceived noncompliance was mitigated by extenuating circumstances; (3) the unexpected deaths of Lakeview quality assurance staff and the Covid-19 pandemic qualify as extraordinary circumstances that may have affected LTCH QRP compliance; and (4) the monthly reporting plan requirement violates the APA and the Medicare Act's notice and comment rulemaking requirement.[53] These arguments are addressed as follows:

1. ***Whether the CMS reconsideration decision failed to follow the reconsideration process established in the regulation and preamble to the FY 2015 Final Rule.***

To support its argument that CMS failed to follow the reconsideration process, Lakeview relies on the preamble to the FY 2015 Final Rule, which states that a provider's request for reconsideration must include evidence demonstrating: "1) full compliance with all LTCH QR Program reporting requirements during the reporting period; or 2) extenuating circumstances that affected noncompliance if the LTCH was not able to comply with the requirements during the reporting period."[54] Lakeview asserts that it met both of these reconsideration request requirements and that entitles them to exemption from the 2 percentage point reduction penalty. The Board disagrees.

First, as previously addressed above in the RELEVANT APPLICABLE LAW Section, the codified regulation at 42 CFR 412.560(d) fully addressed the reconsideration process in effect on August 10, 2020, when Lakeview requested reconsideration. Specifically, 42 C.F.R. § 412.560(d)(2)(vi)

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[50] (Bold and underlined emphasis added.)
[51] *See also* Patient Protection and Affordable Care Act, Pub. L. 111-148, § 3004(a), 124 Stat. 119, 368-369 (adding LTCH QRP statutory provisions at 42 U.S.C. § 1395ww(m)(5)).
[52] *See also* 42 C.F.R. § 412.560(b)(2).
[53] Provider's FPP at 11-12.
[54] *Id.* at 12.

and (vii) state that a provider's reconsideration request must state the reason for the request and include documentation substantiating compliance with the program requirements. Thus, although superseded, the reconsideration request requirements of the 2015 Final Rule were fully encompassed in 42 C.F.R. § 412.560(d)(2)(vi) and (vii)—a provider may include, in its stated reasons, any circumstances it perceived as extenuating that effectuated noncompliance, and it is required to submit documentation demonstrating compliance (with the codification of the regulation, both are required for a reconsideration request).

However, nothing in regulation states or implies that the mere submission of a reconsideration request stating the reason and providing documentation will automatically absolve a provider of a noncompliance reduction penalty—such does not guarantee that CMS will decide in a provider's favor. Upon submission of the reconsideration request, CMS evaluates the reason(s) and documentation to determine whether a reduction penalty for noncompliance should be reversed or upheld. Furthermore, fulfilling the procedural reconsideration request requirements to be reviewed by CMS is not synonymous with meeting its burdens of production and proof by a preponderance of the substantial evidence before the Board. In the instant appeal, even if the Board concludes as a matter of law that Lakeview's request for reconsideration met the procedural filing requirements of 42 C.F.R. § 412.560(d)(2)(vi) and (vii) (it provided its reasons and documentation it believes demonstrates compliance), that does not equate to a conclusion of law that Lakeview indeed met the requirements of 42 C.F.R. § 412.560(b)(1), which requires the submission of data on the specified measures "in a form and manner, and at a time, specified by CMS [or the Secretary]" to avoid a 2 percent APU reduction or the requirements of 42 C.F.R. § 412.560(c)(4).

Notwithstanding the foregoing regarding the applicable law, even if the Board were to rely on the prong 1 of the 2015 Final Rule Preamble reconsideration request language cited by Lakeview or 42 C.F.R. § 412. 560(d)(2)(vii), the outcome is the same—the Board finds the Provider failed to submit evidence demonstrating full compliance with all LTCH QRP reporting requirements during the Q1 2019 reporting period.

First, the sole document that Lakeview submitted with its reconsideration request was a "Line Listing for All,"[55] report for various event dates for "BSI" and "UTI" event types. In that report, for March 2019, there were no events listed for BSI and one event created for UTI on May 24, 2019 at 17:19.[56] While several hours earlier at 11:41, a reporting plan was created for March 2019 (*i.e.*, "2019M03"), Lakeview did not include reporting of CAUTI or CLABSI quality measures as part of the reporting plan for that month.[57] As a result of this failure, the NHSN system was not prompted to transmit CAUTI or CLABSI quality data for March 2019 to CMS. Further, the CAUTI and CLABSI summary data for both measures was not created until ***August 4, 2020 (not August 4, 2019)*** as indicated in the screenshot sent to the Wisconsin DHS

[55] *See* Ex. P-4.
[56] Ex. P-4 at P0007; *But see* Ex. P-10 at P0019 (the December 10, 2021 *Denominators for Intensive Care Unit/Other Locations* form for March 2019). Ex. P-10 at P0119 indicates that, for March 2019, there were no report events for UTI as indicated by the checked box for CAUTI. However, that document is not probative, as it is dated December 10, 2021, well after the August 15, 2019 deadline for submitting the March 2019 data.
[57] Ex. P-8 at P0012. The Board recognizes that the Provider has included a copy of the March 2019 reporting plan at Ex. P-10; however, that document is not probative, as it is dated July 17, 2020, well after the August 15, 2019 deadline.

representative on October 27, 2020.[58] As a result, it does not appear that Lakeview had entered into NHSN all of the requisite CAUTI and CLABSI reporting data for March 2019. As a result, it appears that, even if Lakeview had properly completed its monthly reporting plan for March 2019 to prompt the NHSN system to sweep for Lakeview's March 2019 CAUTI and CLABSI quality data, Lakeview would still have been subject to the 2 percentage point penalty because it had not entered all of the requisite CAUTI and CLABSI data for March 2019 by the reporting deadline.

Second, the Board notes that there were NHSN tools available to troubleshoot and identify errors such as the SIR Reports. As described above, these reports could have been used by the provider to confirm whether information had been entered into the CDC NHSN correctly. And although Lakeview provides SIR reports for CY 2019, these SIR Reports were run on December 13, 2021, over two years after the August 15, 2019 deadline, and the *Using the "SIR – CLAB Data for LTCHQR" Report* guidance explicitly states, "The data in this report will represent data current as of the last time you generated datasets…***any changes made to these data in NHSN after the final submission deadline will not be reflected in data shared with CMS***."[59] Unfortunately, based on the *post-hoc* investigative findings of the new QA Director, it appears that Lakeview did not have these quality assurance checks in place.[60]

Finally, contrary to the Provider's assertions that it fully complied with the reporting requirements, in its December 15, 2021 Preliminary Position Paper, the Provider ultimately admits: "[A]s the March 2019 reporting plan for CLABSI and CAUTI came due – Provider's monthly reporting plans ***did not include CLABSI and CAUTI data for March 2019***.[61] Additionally, in the Provider's Preliminary Position Paper, Footnote 4, the Provider states: "[w]hile the March 2019 reporting plan ***was not submitted to CMS in a timely manner***, the underlying data was tracked, compiled, uploaded, and timely submitted (and available) to NHSN."[62] Finally, Provider states, "[]Provider ***concluded (in error) that it had complied with the QRP reporting requirements***, and Provider timely submitted a request for reconsideration asserting that ***errant conclusion***."[63] Accordingly, it is clear that the Provider understands and acknowledges that it failed to timely and properly submit CLABSI and CAUTI data for March 2019 to CMS.

After admitting that it failed to submit the CLABSI and CAUTI data for March 2019 as required, Provider next argues that its case is similar to those in *PAM Squared*[64] and other district and circuit cases[65] However, the instant appeal is distinguishable from *PAM Squared* and the other cases. As established above, all of the required measures data for Q1 were not properly reported to CMS in the manner specified—through the reporting plans—as the summary data was not even

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[58] Ex. P-8 at P0013. All of the other data included in the record is discussed at *supra* note 40, and this other data has no probative value as it is all dated after the August 15, 2019 reporting deadline.
[59] Exs. P-12, P-13, C-12 (emphasis added).
[60] Ex. P-7 at P0011 (email from the QA Director stating: "Unfortunately the NHSN analysist has determined the reporting plans were not checked for CAUTI and CLABSI March 2019 for the Qu1 deadline. This means the data would not have flowed to CMS. This is the reason we received the penalty. I wish I had better news. ***Going forward*** *Arturo knows what report to run and save before the deadline and I also have on my calendar to double check as well*." (emphasis added)).
[61] Provider's Preliminary Position Paper (hereinafter "Provider's PPP") at 6 (emphasis added).
[62] *Supra,* note 4 (emphasis added).
[63] Provider's PPP at 6 (emphasis added).
[64] *PAM Squared at Texarkana, LLC v. Azar*, 436 F. Supp. 3d 52 (D.D.C. 2020).
[65] *See* Provider's FPP at 15-20.

created before the August 15, 2019 deadline. Moreover, in absence of the summary data prior to the deadline, Lakeview's failure to ensure that all of the required measures data were transmitted was not a simple typographical error (in a location code) resulting in NHSN's failure to transmit the data to CMS as was addressed in *PAM Squared*.

Next, the Board recognizes Lakeview has alleged that it marked "the CAUTI and CLABSI checkboxes" on its March 2019 monthly reporting plan and that the markings disappeared from the reporting plans.[66] However, its assertion that there should be an alert or error message in such a situation presupposes that the alleged disappearances actually occurred. None of the investigative work documented by the new QA Director suggests that potential disappearances was a concern. Again, Lakeview had tools available to confirm if there were errors and here there were two errors – the failure to mark CAUTI and CLABSI checkboxes on the March 2019 monthly reporting plan and the failure to timely enter the requisite CAUTI and CLABSI summary data for March 2019. Thus, the Board finds the record before it demonstrates that the Provider was at fault for its failure to submit the required data.

Finally, the Board finds Lakeview's assertion that reporting plans are not data subject to the 2 percentage point penalty[67] and that "monthly reporting plans only serve as a signal for the CDC to send data to CMS, after the provider has already reported the quality data" moot in this instance and overall, unconvincing.[68] Providers are required to submit data in a form, manner and at a time specified by the Secretary. Thus, Lakeview was required to check the boxes for the CAUTI and CLABSI data on the March 2019 monthly reporting plan in order to prompt the CDC NHSN system to send its data on those quality measures to CMS. The monthly reporting plan is just one of the form and manner requirements for successful submission to CMS. Here, Lakeview not only failed to comply with that form-and-manner requirement but also with the time-form-and-manner requirement to enter into NHSN the requisite CAUTI and CLABSI summary data for March 2019, prior to the reporting deadline for Q1 2019.

2. Whether any perceived noncompliance should be mitigated by extenuating or extraordinary circumstances.

Lakeview asserts that even if there was any perceived non-compliance with the LTCH QRP requirements, the Board should still reverse the Reconsideration under the second prong of the 2015 Final Rule preamble reconsideration request language because its evidence demonstrated extenuating circumstances that affected noncompliance.[69] The Board finds Lakeview also failed to meet the second prong, which is incorporated into 42 C.F.R. § 412. 560(d)(2)(vi), and requires Lakeview's reconsideration request to state its reasons for the reconsideration request which may include a demonstration of extenuating circumstances that affected non-compliance during the reporting period.

Lakeview asserts, as extenuating circumstances, that the only explanation for the failed transmission of data from the NHSN system to CMS was a technical problem with the system

[66] Provider's FPP at 15.
[67] *Id.*
[68] *Id.* at 16.
[69] *Id.* at 20.

itself and a lack of software system flags or notifications for failed transmissions.[70] These arguments lack merit because, as previously stated, there was no March 2019 BSI or UTI summary data to transmit via a reporting plan, considering that it was not created until August 4, 2020.

Additionally, Lakeview contends that the onset of the severe illness of its Administrator and Chief Operating Officer, *as the first quarter reporting deadline approached* is an extenuating circumstance that also must be considered.[71] Taking the onset of her severe illness under consideration as an extenuating circumstance, the Board must also acknowledge that she was the former Director of Quality Assurance and was promoted to serve as both Administrator and Chief Operating Officer in January 2019, seven months prior. At that time, the Infection Preventionist assumed the responsibility for tracking, compiling, and uploading the relevant data.[72] However, the Board finds that it is unclear what level of supervision and training was given to the Infection Preventionist from January 2019 through August 2019, and that it was Lakeview's duty to ensure that someone was adequately trained to properly complete the monthly reporting plans to include reporting on the CAUTI and CLABSI quality measures by the August 15, 2019 reporting deadline.

Moreover, 42 C.F.R. § 412.560(c)(1) allowed Lakeview to request an exception or extension due to extraordinary circumstances within 90 days of the date that the circumstance occurred. However, Lakeview did not make this request upon the onset of the Administrator's illness. And although extremely unfortunate, the Administrator's death on April 28, 2020, was eight months *after* the deadline. Additionally, the Board finds that the new QA Director, who was hired after the penalty notice and who unfortunately passed away on September 21, 2021,[73] was not involved prior to the Q1 2019 deadline or within 90 days of the extension request deadline.

The Board also finds Lakeview's contention that the COVID-19 pandemic was an extraordinary circumstance that affected it during this period and should excuse any data transmission issue from NHSN to CMS also unpersuasive. Lakeview asserted that the impact of the pandemic made it difficult for it to complete all of the reporting verifications that may have helped identify an issue with the March 2019 monthly reporting plan in a timely manner. The reporting period for the 2021 payment determination was January 1, 2019, through March 31, 2019. The deadline to submit CAUTI and CLABSI data was August 15, 2019. As the COVID-19 pandemic did not begin until on or about March 2020, it did not affect Lakeview's ability to timely and properly submit its CAUTI and CLABSI data for March 2019 (including the completion of the March 2019 monthly reporting plan).

3. ***Whether the monthly reporting plan requirement violates the APA and the Medicare Act's notice and comment rulemaking requirements.***[74]

The Board finds meritless Lakeview's assertions that: 1) the monthly reporting requirement "violates the APA because CMS and the CDC established an unreasonable and confusing system

[70] Provider's FPP at 24-27.
[71] *Id.* at 22.
[72] *Id.* at 2.
[73] Provider's FPP at 3, n.1.
[74] Provider's FPP at 31-34.

that does not automatically pre[-]populate information in the monthly reporting plan"[75] and 2) that CMS violated the Medicare Act when it applied the monthly reporting plan requirement without first utilizing the notice-and-comment rulemaking procedures.[76]

In its Final Position Paper, Lakeview states, "The Provider is familiar with the LTCH QRP, and the Provider has consistently complied with the QRP reporting requirements. From October 2017 through the end of 2019, the Provider's compliance with the reporting requirements was attributable to the efforts and diligence of [their deceased Administrator and COO]."[77] Accordingly, now that Lakeview has failed to meet the requirements, the argument that the system is unreasonable and confusing and lacks auto-population is disingenuous.

Finally, Lakeview's argument that the monthly reporting plan requirement was not subject to notice and comment is misplaced. Pursuant to 42 U.S.C. § 1395ww(m)(5), as added by § 3004 of the Patient Protection and Affordable Care Act,[78] the Secretary established the LTCH Quality Reporting Program including penalties for noncompliance. It was implemented in Section VII.C of the FY 2012 IPPS/LTCH PPS final rule,[79] and irrefutably opened the data submission process to notice-and-comment:

> 4. ***Data Submission Methods*** and Timelines
>
> a. Method of Data Submission for HAIs [Hospital Acquired Infections]
>
> In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25988 through 25890), we proposed to adopt two HAI quality measures, Central Line Catheter-Associated Bloodstream Infection (CLABSI) Event: CLABSI rate per 1000 central line days, and Urinary Catheter Associated Urinary Tract Infection (CAUTI) Event: CAUTI rate per 1000 urinary catheter days. We proposed to use CDC/NHSN for data collection and reporting for these two HAI measures (http://www.cdc.gov/nhsn/).
>
> As we noted above, the NHSN is a secure, Internet-based surveillance system. It is maintained by CDC, and can be utilized by all types of healthcare facilities in the United States, including LTCHs, acute care hospitals that collect and report HAIs through the NHSN as part of our Hospital IQR Program, as well as psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, and ambulatory surgery centers. The NHSN enables health care facilities to submit their HAI event data, and access their data for the purposes of internal infection-surveillance.

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[75] Provider's FPP at 31.
[76] *Id.*
[77] Provider's FPP at 1-2.
[78] Pub. L. 111-149, § 3004, 124 Stat. 119, 368 (2010).
[79] 76 Fed. Reg. 51476, 51743-51756 (Aug. 18, 2011).

> ****
>
> Currently the NHSN has data collection forms, data submission, and reporting mechanisms in place that are in use by LTCHs for both CLABSI and CAUTI measures. ***Details related to the procedures using the NHSN for data submission can be found at: http:// www.cdc.gov/nhsn.***
>
> ****
>
> We solicited public comment on the ***proposed methods of data submission*** for the CLABSI and CAUTI measures in the FY 2012 IPPS/LTCH PPS proposed rule for the quality reporting program for LTCHs.
>
> ****
>
> After consideration of the public comments received, we are adopting as final our ***proposed method of data submission for HAIs using the CDC/NHSN***, with the first reporting period to begin October 1, 2012, for the FY 2014 payment determination.[80]

Accordingly, the Board finds that CMS' monthly reporting plan requirement does not run afoul of 42 U.S.C. § 1395hh(a)(2) or the holding in *Allina*.

DECISION:

After considering Medicare law and regulations, the arguments presented, and the evidence admitted, the Board finds that CMS properly reduced the FY 2021 APU for the Provider by 2 percentage points.

Board Members Participating:

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For the Board:

9/27/2024

X Clayton J. Nix

Clayton J. Nix, Esq.
Chair
Signed by: PIV

[80] *Id.* at 51751-53 (emphasis added).