PROVIDER REIMBURSEMENT REVIEW BOARD

2024-D16

RECORD HEARING PROVIDER – **NOTICE DATE –** Post Acute Medical Specialty Hospital of March 13, 2023 Texarkana North FEDERAL FISCAL YEAR -**PROVIDER NO.** – 45-2061 2017 VS. CASE NO. – 21-1676 **MEDICARE CONTRACTOR –** Novitas Solutions, Inc. (J-H) INDEX Page No. **Issue Statement**

ISSUE STATEMENT:

Whether the payment penalty that the Centers for Medicare & Medicaid Services ("CMS") imposed under the Long-Term Care Hospital Quality Reporting Program ("LTCH QRP") to reduce the Provider's payment update for Fiscal Year ("FY") 2017 by two percentage points was proper?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 2017 annual payment update ("APU") for Post Acute Medical Specialty Hospital of Texarkana North ("Provider") by 2 percentage points.

INTRODUCTION:

The Provider is a Medicare certified long-term care hospital ("LTCH") located in Texarkana, Texas.² The Provider's assigned Medicare contractor³ is Novitas Solutions, Inc. (the "Medicare Contractor").

In an e-mail letter dated March 11, 2021,⁴ CMS notified the Provider that it failed to meet LTCH quality reporting program ("QRP") requirements during the data reporting period for calendar year 2015 ("CY 2015") and, as a result, was subject to a 2 percentage point reduction to its FFY 2017 APU. This final determination letter was the second letter which CMS issued regarding this matter.⁵ The Provider previously appealed the first final determination letter dated July 14, 2016, which resulted in PRRB Decision 2018-D47.⁶ However, the Provider then appealed to the U.S. District Court for the District of Columbia ("D.C. District Court") resulting in the following decision: *PAM Squared at Texarkana, LLC v. Azar*, 436 F. Supp. 3d 52 (D.D.C. 2020) ("*PAM Squared*").⁷ In *PAM Squared*, the D.C. District Court vacated PRRB Decision 2018-D47 and remanded the case back to the agency for reconsideration. Following this remand, CMS issued the reconsideration determination dated March 11, 2021 discussed above. The Provider has timely appealed CMS' reconsideration determination to the Board and has met the jurisdictional requirements for a hearing.

On March 13, 2023, the Board issued a Notice of Hearing on the Record, and closed the record on April 13, 2023. The Provider was represented by Jason M. Healy, Esq. of The Law Offices of Jason M. Healy, PLLC. The Medicare Contractor was represented by Jerrod Olszewski, Esq. of Federal Specialized Services, LLC.

¹ Stipulations at ¶3 (Mar. 9, 2023).

 ² Stipulations at ¶1. See also Provider's Preliminary Position Paper (May 5, 2022) (hereinafter "Provider's PPP") at 3.
 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 Exhibit (hereinafter "Ex.") Ex. P-13 at P0106-08.

⁵ Stipulations at ¶¶17, 22.

⁶ *Id.* at ¶20.

⁷ *Id.* at $\P21$.

STATEMENT OF FACTS AND RELEVANT LAW:

The Medicare statute at 42 U.S.C. § 1395ww(m)(5)(C) requires LTCHs to submit certain data to the Secretary of Health and Human Services ("Secretary") on specified quality measures of their services "in a form and manner, and at a time, specified by the Secretary."⁸ The Secretary implemented this statutory provision in the following regulation location at 42 C.F.R. § 412.560(b) (2015):

(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.⁹

In the FY 2015 PPS/LTCH PPS Final Rule,¹⁰ CMS finalized the reconsideration and appeals procedures for the LTCH QRP payment determinations for FY 2016 and subsequent years; *however, CMS did not codify these procedures in the Code of Federal Regulations*. Under these *uncodified* procedures, CMS requires any LTCH submitting a request for reconsideration to submit all supporting documentation and evidence demonstrating:

1) Full compliance with all LTCHQR Program reporting requirements during the reporting period; or

2) extenuating circumstances that affected non-compliance if the LTCH was not able to comply with the requirements during the reporting period.¹¹

The FY 2015 PPS/LTCH Final Rule went on to state:

...[t]he documentation and evidence may include copies of any communications that demonstrate its compliance with the program's requirements, **as well as any other records that support the LTCH's rationale for seeking reconsideration**. A sample list of acceptable supporting documentation and evidence, as well as instructions for LTCHs to retrieve copies of the data submitted to CMS for the appropriate program year can be found on our Web site

⁸ 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)).

⁹ 42 C.F.R. § 412.560 (2015). *See also* 79 Fed. Reg. 49854, 50317 (Aug. 22, 2014). (bold emphasis added) ¹⁰ 79 Fed. Reg. at 50317-50318 (Aug. 22, 2014).

¹¹ *Id.* at 50317.

at: <u>http://www.cms.gov/Medicare/Quality-Initiatives-Patient-</u> <u>Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-</u> <u>Reporting-Reconsideration-and-Disaster-Waiver-Requests.html.</u>¹²

As part of the FY 2016 IPPS/LTCH PPS Final Rule, published on August 17, 2015, the Secretary "finaliz[ed] our proposal to codify the LTCH QRP submission exception and extension requirements at new [42 C.F.R.] §§ 412.560(c) *and* (d)"¹³ and the codified process uses an "extraordinary circumstances beyond the control of the [LTCH]" standard effective for FY 2017 payment determinations.¹⁴ The FY 2016 IPPS Final Rule also "codif[ied] the LTCH QRP reconsideration and appeal procedures at new proposed §§ 412.560(d) *and* (e)" and specified that they were applicable to the "*FY 2017* Payment Determination and Subsequent Years."¹⁵ As the payment determination at issue in this appeal is the Provider's FY 2017 payment determination, the FY 2016 IPPS Final Rule changes to § 412.560(c)- (e) are applicable to this appeal.

(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 quality data reporting requirements, for one or more quarters, in the event of <u>certain</u> extraordinary circumstances <u>beyond the control</u> 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 quality data reporting requirements must submit its request to CMS within 30 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.

¹² Id. (bold emphasis added). See also Exhibit ("Ex.") P-10.

 ¹³ 80 Fed. Reg. 49326, 49756 (Aug. 17, 2015) (emphasis added). *See also* 80 Fed. Reg. 24324, 24611 (Apr. 30, 2015).
 ¹⁴ 80 Fed. Reg. at 49769-70 (full section, beginning at 49756, is entitled "Previously Adopted and Proposed LTCH QRP Submission Exception and Extension Requirements *for the FY 2017 Payment Determination and Subsequent Years*" (emphasis added)). *See also* 82 Fed. Reg. 37990, 38513-14 (Aug. 14, 2017).

¹⁵ 80 Fed. Reg. at 49755 (emphasis added) (full section, beginning at 49755, is entitled "Previously Adopted and Finalized LTCH QRP Reconsideration and Appeals Procedures *for the <u>FY 2017</u> Payment Determination* and Subsequent Years" (emphasis added). The D.C. District Court in *PAM Squared* refers to FY 2016 IPPS Final Rule as the "2015 Regulation." 436 F. Supp. 3d at 58.

(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 quality data under the LTCHQR Program 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 quality data.

(d) *Reconsiderations of noncompliance decisions*—(1) *Written notification of noncompliance decisions*. CMS will send a long-term care hospital written notification of a decision of noncompliance with the quality data reporting requirements for a particular fiscal year. CMS also will use the Quality Improvement and Evaluation system (QIES) Assessment Submission and Processing (ASAP) System to provide notification of noncompliance to the long-term care hospital.

(2) *Request for reconsideration of noncompliance decision*. A longterm 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 quality reporting require-ments. This documentation must be submitted electronically at the same time as the reconsideration request as an attachment to the email. Any reconsideration request that fails to provide sufficient evidence of compliance will not be reviewed.

(3) *CMS decision on reconsideration request*. CMS will notify the long-term care hospital, in writing, of its final decision regarding any reconsideration request. CMS also will use the QIES ASAP System to provide notice of its final decision on the reconsideration request.

(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.¹⁶

The LTCH QRP data requirements for the FY 2017 payment determination at issue in this appeal are also set forth in the FY 2016 IPPS/LTCH PPS Final Rule.¹⁷ The FY 2017 payment determination was based on the timely submission of quality data collected during calendar year ("CY") 2015 (reporting period of January 1, 2015, through December 31, 2015), except for the quality measure #0431 (Influenza Vaccination Coverage among Healthcare Personnel).¹⁸

CMS set the following deadlines for the submission of the LTCH QRP CY 2015 quality measures data for FY 2017 payment determination:

Q1 (January-March 2015) – February 15, 2016 Q2 (April-June 2015) – February 15, 2016 Q3 (July-September 2015) – February 15, 2016 Q4 (October-December 2015) – May 15, 2016¹⁹

CMS recommended that providers "run the applicable CMS output reports within their facility prior to each quarterly reporting deadline."²⁰ CMS provided guidance on how to run output reports, as well as NHSN reporting checklists. CMS also recommended that providers "run the advanced analysis reports within NHSN to view when each data element was first entered and last modified to determine whether all data were complete at the time of the reporting deadline."²¹

¹⁶ 80 Fed. Reg. at 49769-70; 42 C.F.R. § 412.560(c)-(e) (Oct. 1, 2015).

¹⁷ See 80 Fed. Reg. at 49750 (Aug. 17, 2015). See also Ex. P-9.

¹⁸ Healthcare influenza vaccine coverage data was only required for October 1, 2015 through March 31, 2016.

¹⁹As noted by CMS in the Provider's Exhibit P-9, the original submission deadlines for CY 2015 published in the FY 2016 IPPS Final Rule (80 Fed. Reg. 49325, 49750 (Aug. 17, 2015)) were revised to these deadlines. ²⁰ Ex. P-9 at 3.

This case concerns the quality data reporting requirements for NQF²² #1717 entitled "NHSN Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure,"²³ also referred to as *C. Difficile* data. The Board will hereinafter refer to it as the "CDI Measure." In the FY 2014 IPPS Final Rule, CMS adopted this measure to be reported during calendar year ("CY") 2015 for use in the FY 2017 payment determinations:

We proposed to use the CDC's NHSN reporting and submission infrastructure for reporting of the proposed NHSN Facility-wide Inpatient Hospital-onset Clostridium difficile Outcome Measure (NOF #1717). CDC's NHSN is the data collection and submission framework currently used for reporting the CAUTI, CLABSI and Influenza Vaccination Coverage among Healthcare Personnel measures. Similar to the NHSN MRSA Bacteremia Outcome Measure we proposed above, details related to the procedures for using NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the proposed NHSN Facility-wide Inpatient Hospital-onset Clostridium difficile Outcome Measure (NOF #1717) can be found at: http://www.qualityforum.org/QPS/1717 and http://www.cdc.gov/nhsn/PDFs/pscManual/12pscMDRO-CDADcurrent.pdf. For January 2012 through January 2013, an estimated 46 LTCHs reported laboratory-identified C. difficile event data into NHSN. By building on the CDC's NHSN reporting and submission infrastructure, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program.

We refer readers to section IX.C.9. of the preamble of this final rule for more information on data collection and submission. We invited public comment on this proposed measure and data collection and submission for the proposed measure for the FY 2017 payment determination and subsequent years.²⁴

Comment: Some commenters recommended that CMS delay the adoption of this proposed measure until such time as LTCH personnel can be trained in the quality measure collection and submission procedures. Commenters were concerned that hospitals and states had not had enough time to develop the proper infrastructure to report these data, because only 3 States currently require hospitals to report these data. Other commenters noted that the burden of data collection must be considered in order to allow these facilities to acquire the resources to focus on improvement efforts and not completely on data collection and submission alone. Commenters furthermore recommended development of robust training and technical support for NHSN collection. One

²² National Quality Forum. *See* 78 Fed. Reg. 50496, 50865-6 (Aug. 19, 2013) ("The measure [NQF #1717] was developed by the CDC and is NQF-endorsed. . . . and can be found [on the NQF Web site] at: http://www.qualityforum.org/QPS/1717.")

²³ 79 Fed. Reg. at 50289.

²⁴ 78 Fed. Reg. at 50866 (footnote omitted); *id* at 50960 ("For the FY 2017 payment determination, in addition to the CAUTI, CLABSI, and Influenza Vaccination Coverage Among Healthcare Personnel measures, we are finalizing our proposal that LTCHs would report quality data related to the MRSA and CDI measures to the CDC's NHSN data submission system (http:// www.cdc.gov/nhsn/). The NHSN is a secure, Internet-based healthcare associated infection tracking system that is maintained and managed by CDC."). *See also id.* at 50867-68 stating:

In adopting the CDI Measure, the Secretary maintained that the compliance burden on LTCHs would be minimal since LTCHs are already familiar with the NHSN submission process due to the then-existing requirement to report CAUTI and CLABSI measures which began October 1, 2012 for the FY 2014 payment determination:

We believe that any burden increase related to complying with the LTCHQR Program requirements for submission of the MRSA and CDI measures will be minimal for those LTCHs that are already familiar with the NHSN submission process, for several reasons. First, these LTCHs have already completed initial setup and have become familiar with reporting data in the NHSN system due to the requirement to report CAUTI and CLABSI measures beginning on October 1, 2012 for the FY 2014 payment determination, and are continuing to report for CY 2013 for the FY 2015 payment determination. Second, due to their participation in a wide range of mandatory reporting and quality improvement programs, as of January 2013, there are approximately 42 LTCHs reporting MRSA measure data and approximately 46 LTCHs reporting CDI measure data into the NHSN. Third, there has been no change in the registration and training requirements for LTCHs that are already acquainted with the NHSN. Therefore, we believe that most LTCHs should be very comfortable using the NHSN for continuing with the reporting of data for CAUTI and CLABSI measures for CY 2014 for the FY 2016 payment determination and for submission of the finalized MRSA and CDI measures for CY 2015 for the FY 2017 payment determination. . . .

The most significant burden associated with these quality measures is the time and effort associated with collecting and submitting the data on the CAUTI, CLABSI, Influenza Vaccination Coverage among Healthcare Personnel, MRSA, and CDI measures for LTCHs that are not currently reporting any measures data into the CDC's NHSN system.²⁵

As noted above, concurrent with the adoption of the CDI Measure, the Secretary also adopted another *facility-wide* measure for MRSA.²⁶

commenter recommended delaying the proposed adoption of this measure until there is adequate vendor support for hospitals to electronically interface with the NHSN for reporting. *Response*: As of May 15, 2013, based on CMS and CDC analysis of first quarter (October 1-December 31, 2012) data reporting for CLABSI and CAUTI measures, there is current and successful use of CDC's NHSN reporting infrastructure by about 399 of the approximately 440 certified LTCHs. This widespread adoption of NHSN reporting in LTCHs clearly indicates that training, technical and infrastructure support for NHSN data collection has been adequate. By utilizing CDC's NHSN for CDI reporting, we intend to build upon LTCHs ongoing experience with data reporting via NHSN, thus avoiding adding in new systems and infrastructure requirements for the LTCHQR Program.

²⁵ 78 Fed. Reg. at 50960-61.

²⁶ The Board takes administrative notice that archived newsletters from NHSN in 2015 and 2016 confirm that, for CY 2015 to be used for FY 2017 payment determinations, LTCHs participating in the LTCHQR Program were required to report "MRSA Bacteremia <u>and</u> C. difficile LabID Events (FacWideIN, all healthcare onset and community onset)."

In this case, the Provider is alleged to have failed to report data for the CDI Measure for both the 2nd and 3rd quarters in Calendar Year 2015²⁷ which impacted the FY 2017 payment determination. Significantly, the Provider *did properly report* the other *facility-wide* MRSA measure for CY 2015 in the form and manner specified by the Secretary and, as such, that measure is not at issue in this appeal.

As mentioned above in the Introduction section, the Provider previously appealed the first final determination letter dated July 14, 2016, which resulted in PRRB Decision 2018-D47. On appeal, the D.C. District Court issued its decision in *PAM Squared* and vacated the Board's decision. Specifically, in that decision, the Court found the following:

The Board's reliance on the 2013 Rule was more than a wrong citation or clerical error. It, in fact, quoted and cited exclusively from that rule. It based its entire analysis of CMS's decision on the assumption that the 2013 Rule governs. A.R. at 9–10. It not only misstated CMS's standard of review for reconsideration, *id.* at 9, but used that incorrect standard to determine independently that PAM Squared was not entitled to equitable relief, *id.* at 9 n.29 (noting that it is "unclear whether the Board has the authority to consider a 'justifiable excuse,' " but that "the Provider has not documented any ... problem that may have constituted a justifiable excuse"). And it incorrectly concluded that CMS reconsideration is a voluntary—rather than mandatory—process. *Id.* at 9.

True, no specific language in the 2015 Regulation undermines the Board's conclusion that CMS could permissibly use "uniform language in a form letter." A.R. at 10. And perhaps it may have reached the same decision following the correct regulation or the 2014 Rule. But it is also possible that, on remand, the mandatory—rather than voluntary—nature of CMS reconsideration will alter the agency's review. Or that, as the hospital argues, the 2014 Rule and the Regulation provided CMS a new standard of review that is favorable to PAM Squared.

It is not the Court's role to guide the agency through its own regulations. Nor should it hypothesize how the correct regulation might alter the Board's analysis. The Court must evaluate the rationale that the agency itself has given. *Motor Vehicle Mfrs.*

NHSN e-News, Vol 10, Issue 1, at 4 (available at: <u>https://www.cdc.gov/nhsn/pdfs/newsletters/NHSN-NL-March_2015.pdf</u> (last accessed Mar. 29, 2024)); NHSN e-News, Vol. 10, Issue 2, at 6 (available at: <u>https://www.cdc.gov/nhsn/pdfs/newsletters/eNewsletter_June-2015_Final.pdf</u> (last accessed March 29, 2024)); NSHN e-News, Vol. 10, Issue 3, at 12 (available at: <u>https://www.cdc.gov/nhsn/pdfs/newsletters/NHSN-eNews</u>, Vol. 10, Issue 4, at 12c(Dec. 2015) (available at: <u>https://www.cdc.gov/nhsn/pdfs/newsletters/NHSN-eNews</u>, Vol. 10, Issue 4, at 12c(Dec. 2015) (available at: <u>https://www.cdc.gov/nhsn/pdfs/newsletters/NHSN-eNews</u>, Vol. 10, Issue 4, at 12c(Dec. 2015) (available at: <u>https://www.cdc.gov/nhsn/pdfs/newsletters/NHSN-eNews</u>, Vol. 11, Issue 1, at 11 (available at: https://www.cdc.gov/nhsn/pdfs/newsletters/NHSN-NL-March-2016.pdf (last accessed Mar. 29, 2024)).

²⁷ The 2nd quarter time frame covered April 1, 2015 through June 30, 2015. The 3rd quarter time frame covered July 1, 2015 through September 30, 2015. *See* Exs. P-9, P-13.

Ass'n, 463 U.S. at 43, 103 S.Ct. 2856. And here the Board's reasoning came about by reviewing the CMS reconsideration through the tainted lens of the wrong regulation. The Court should not "attempt itself to make up for [the Board's] deficiencies." *Id.*

[H]ere the Court has more than the "the slightest uncertainty" about the agency's decision on remand. Perhaps the typo does justify the full two-percent penalty. But perhaps, now applying the proper standard, the Board will come to a different conclusion. **The appropriate remedy here is to remand the case to the agency**. See Air Cargo v. U.S. Postal Serv., 674 F.3d 852, 861 (D.C. Cir. 2012) ("When a district court reverses agency action and determines that the agency acted unlawfully, ordinarily the appropriate course is simply to identify a legal error and then remand to the agency, because the role of the district court in such situations is to act as an appellate tribunal.").²⁸

Accordingly, the D.C. District Court remanded the PAM Squared case back to CMS.

In response to the *PAM Squared* remand, CMS issued a new reconsideration determination dated March 11, 2021. CMS stated in its determination:

... CMS has carefully reviewed your reconsideration request along with the supporting documentation you submitted along with your reconsideration request and the information in connection with the administrative proceeding before the PRRB and the federal district court proceeding. Based on this review, CMS has decided to uphold its determination of noncompliance and the imposition of a 2% Medicare reimbursement penalty. This determination is based on CMS's finding that your LTCH failed to submit the required QRP data in the correct form and manner as required by statute. 42 U.S.C. §§ 1395ww(m)(5)(A) and (C). Specifically, your LTCH failed to submit data to HHS for the 2015 calendar year impacting the FY 2017 payment determination. *PAM Squared failed to submit to HHS the required C. difficile data for the 2nd and 3rd Quarters of 2015* by the applicable deadline.

CMS has also determined that your reconsideration request *did <u>not</u> provide a valid or justifiable excuse for non-compliance*. Specifically, the facts your LTCH presented do not demonstrate the existence of extraordinary or extenuating circumstances that would excuse your LTCH's failure to comply with the QRP requirements.

²⁸ 436 F. Supp. 3d at 60-61 (bold and underline emphasis added and footnote omitted).

• LTCHs may file for reconsideration if they believe the finding of non-compliance is an error, or they have evidence of the impact of extraordinary circumstances that prevented timely submission of data.

• An LTCH disagreeing with the compliance determination and the impending payment reduction decision may submit a request for reconsideration to CMS at the following email address: LTCHQRPReconsiderations@cms.hhs.gov.

• LTCHs dissatisfied with the QRP reconsideration ruling may file a claim under 42 CFR Part 405, Subpart R (a Provider Reimbursement Review Board [PRRB] appeal). Details are available on the <u>CMS.gov PRRB Review Instructions website</u>. You must follow the instructions listed on that website to file with the PRRB.²⁹

Significantly, in the following footnote CMS discussed the fact that, based on its review of the record, it disagreed with the District Court's factual representations and then made the following factual findings:

CMS has determined that the Court's representations of the facts are inconsistent with the record. PAM Squared had entered the data at issue into the system **using an incorrect location code**. As a result of this erroneous data entry, CMS could not view the required data. After entering the data incorrectly, **PAM Squared** also failed to run an output report which would have alerted the facility to the fact that it had inputted the data incorrectly. The record demonstrates the data entry error was caused by a failure to follow data entry directions and was not a "typo." The record further demonstrates the data entry error was so significant that CMS could not view the information from one Department to another.³⁰

Thus, the reconsideration decision clearly found that the Provider "fail[ed] to follow data entry directions and [the erroneous data entry] was not a 'typo.'"

The Provider argues it fully reported quality data on all quality measures before the reporting deadlines, and evidence of full compliance with program requirements has been supplied with its reconsideration request submitted to CMS.³¹ The Provider refers to the testimony of its witness Ms. Brown, who stated that all quality data was reported by the deadline of February 15, 2016.³² The Provider has submitted into evidence NHSN screen shots which it states "show that April through September 2015 CDI data were timely reported."³³ The Provider believes these screen shots of input data prove the data was reported.

²⁹ Ex. P-13 at P0107 (footnote omitted and emphasis added).

³⁰ *Id.* (Footnote 1).

³¹ Provider's PPP at 19-20.

³² Ex. P-14 at P0135.

³³ Provider's PPP at 20. See also Ex. P-3 at P0027-28; P-14 at P0135-38.

The Provider contends that "CMS imposed the payment penalty only because of a typo to a location identifier on the [Provider's] NHSN monthly reporting plan."³⁴ The Provider explains that several months after the data reporting deadline, on July 14, 2016, it changed the location identifier in its NHSN monthly reporting plan for the months of April through September 2015. The Provider states this was done as an immediate correction at the instruction of NHSN staff after the Provider was notified it failed to comply with LTCH QRP requirements.³⁵ The Provider's position is that the data was submitted "to one arm of the Department of Health and Human Services" (National Healthy Safety Network), even if its typo error prevented some data from being sent to CMS.³⁶

The Provider claims the NHSN monthly reporting plan is an unnecessary extra step in the quality data collection process, and that data should automatically be sent from the Centers for Disease Control's NHSN system to CMS. The Provider argues that data received by one component of the Department of Health and Human Services should be deemed received by another component, and that neither the notice of non-compliance letter at Exhibit P-2, nor the CMS reconsideration decision letters, state the specific reasons why the Provider allegedly failed to comply with the QRP.³⁷

The Provider asserts that, even if CMS found that the evidence submitted by the Provider did not demonstrate proof of full compliance, that the payment penalty should be reversed on reconsideration under the second standard of review "when the provider's evidence demonstrates extenuating circumstances that affected non-compliance if the LTCH was not able to comply with the requirements during the reporting period."³⁸ The Provider cites to the Secretary's discussion on the LTCH QRP reconsideration process in the FY 2015 IPPS Final Rule published on August 22, 2014³⁹ in support of its position:

The second standard of review requires reversal of the payment penalty when the provider's evidence demonstrates "extenuating circumstances that affected noncompliance if the LTCH was not able to comply with the requirements during the reporting period." 79 Fed. Reg. at 50317. This second standard of review is an equitable standard where CMS is tasked with evaluating the hospital's reasons for less than full compliance with the LTCH QRP.⁴⁰

The Provider asserts "extenuating circumstances are moderating factors that make someone's actions excusable or less blameworthy. . . . They are reasonable excuses for less than full compliance."⁴¹ The Provider contends this standard is "a subjective standard" that requires CMS to evaluate the extenuating circumstances that [the Provider] has claimed.⁴²

- ³⁶ *Id.* at 29-32.
- ³⁷ *Id.* at 31-35.
- ³⁸ *Id*. at 36.
- ³⁹ 79 Fed. Reg. at 50317.
- ⁴⁰ Provider's PPP at 36.
- ⁴¹ *Id*.
- ⁴² Id.

³⁴ Provider's PPP at 23.

³⁵ *Id.* at 21-26.

The Provider also contends that "[t]he rulemaking record [for the <u>August 22, 2014</u> final rule] shows that CMS was allowing providers to submit documentation of reasonable excuses to explain why they were not able to achieve full compliance."⁴³ The Provider asserts that "[t]he scope of CMS' equitable discretion to reverse payment penalties in LTCH QRP cases under this second standard of review is broad," and is separate from CMS' disaster waiver process.⁴⁴ According to the Provider's Preliminary Position Paper, "the second standard of review under the reconsideration process allows CMS to exercise equitable discretion and forgive non-compliance with the LTCH QRP for any reason, other than a natural or man-made disaster, as long as the provider has evidence of 'extenuating circumstances that affected noncompliance."⁴⁵

The Provider references the HHS COVID-19 Provider Relief Fund ("PRF") reporting requirements in support of its argument that the range of issues that could qualify as extenuating circumstances is broad. The Provider reports that HHS allows providers to request to submit their reports on the use of funds *after* the reporting deadline if an extenuation circumstance applies. Included in the examples of extenuating circumstances for the PRF is "Failure to click "Submit" for a report in the PRF Reporting Portal.⁴⁶ The Provider postures this HHS guidance is "persuasive authority here because it shows the types of situations that the agency considers under an extenuating circumstances standard for LTCHs and other Medicare providers that received PRF funds," but that HHS refuses to consider such under the LTCH QRP.⁴⁷

In support of its position, the Provider's Preliminary Position Paper references the decision of the D.C. District Court in *Landmark Hosp. of Salt Lake City v. Azar* ("*Landmark*").⁴⁸ The Provider contends *Landmark* clarifies "that the extenuating circumstances standard for LTCH QRP reconsiderations is distinct from the extraordinary circumstances standard that CMS uses for LTCH QRP extension and exception requests."⁴⁹ The Provider avers in the instant case that "CMS has conflated extenuating circumstances with extraordinary circumstances, using them interchangeably. . . ."⁵⁰ The Provider argues that the CMS reconsideration determination it appealed fails "to apply the correct LTCH QRP standards – namely, the extenuating circumstances standard."⁵¹ The Provider believes the situation surrounding the data it entered, including the location identifier typo, qualifies as "extenuating circumstances."⁵²

The Provider suggests there are problems with the NHSN system that "may have interfered with the accurate review of the Provider's reported quality data and transmission to CMS for the FY 2017 payment determination."⁵³ The Provider cites to Cornerstone Hosp. West Monroe v. Novitas Solutions, Inc., PRRB Dec. No. 2017-D3 (Jan. 26, 2017) in which the concurring Board opinion recognized "that the CMS Manual 'did not tell the user that the data was simply 'displayed' on the

- ⁵¹ Id.
- ⁵² *Id.*
- ⁵³ Id. at 46.

⁴³ *Id.* (citing to 79 Fed. Reg. at 50317).

⁴⁴ Id. at 37.

⁴⁵ *Id.* (citing to 79 Fed. Reg. at 50317).

⁴⁶ *Id.* at 37-38.

⁴⁷ *Id.* at 38.

⁴⁸ Landmark Hosp. of Salt Lake City v. Azar, 442 F. Supp. 3d, 327, 330 (D.D.C. 2020).

⁴⁹ Provider's PPP at 39.

⁵⁰ *Id*. at 40.

NHSN website and that it took another step for the data to actually be transmitted to CMS.³⁵⁴ The Provider distinguished the case at hand from *Cornerstone* by stating "[i]n contrast, the Provider here has thoroughly demonstrated through its documentation that all quality data for the FY 2017 payment determination were timely submitted to the NHSN system.³⁵⁵

The Provider next claims that the March 11, 2021 CMS reconsideration determination⁵⁶ "suffers from defects that are materially the same as the previous CMS reconsideration and PRRB decision at issue in the *PAM Squared* court decision⁵⁷ and the CMS reconsiderations and PRRB decisions at issue in the [*Landmark*⁵⁸] court decision."⁵⁹ The Provider argues that the CMS Reconsideration Determination letter "includes little discussion of the Provider's arguments establishing proof of full compliance with the LTCH QRP for the FY 2017 payment determination and the Provider's evidence of extenuating circumstances."⁶⁰ The Provider believes CMS' actions to be arbitrary and capricious under the Administrative Procedure Act ("APA")⁶¹ because the CMS Reconsideration Determination letter "contains only conclusory statements that make no attempt to apply either of the two standards of review with any analysis or explanation, and it therefore violates the APA's arbitrary and capricious standard because it is not the product of reasoned decision-making."⁶²

The Provider takes issue with the fact that the March 11, 2021 CMS reconsideration determination is only one page, and "includes minimal discussion of the Provider's arguments establishing proof of full compliance...and the Provider's evidence of full compliance and extenuating circumstances."⁶³ The Provider also alleges that the reconsideration determination does not set forth the relevant factors on which the agency based its decision, does not provide a reason based upon evidence, does not discuss the standards of review contained in the FY 2015 Final Rule.⁶⁴

Similarly, the Provider alleges the March 11, 2021 CMS reconsideration determination has improperly combined the two terms "extenuating circumstances" and "extraordinary circumstances" into one because the letter states "the facts your LTCH presented do not demonstrate the existence of extraordinary <u>or</u> extenuating circumstances that would excuse your LTCH's failure to comply with the QRP requirements."⁶⁵ The Provider insists that CMS is bound to consider "extenuating circumstances" during the reconsideration process, and that CMS *may* consider "extraordinary circumstances" during the process as well. However, the two terms are <u>not</u> the same.⁶⁶

Lastly, the Provider argues it has substantially complied with program requirements, and the imposition of a penalty in this case is contrary to the intent and goals of the LTCH QRP.⁶⁷

⁵⁶ Ex. P-13 at P0107.

- ⁵⁸ Landmark Hosp. of Salt Lake City v. Azar, 442 F. Supp. 3d 327 (D.D.C. 2020).
- ⁵⁹ Provider's PPP at 52.
- ⁶⁰ Id.

- ⁶³ *Id.* at 57-58.
- ⁶⁴ *Id.* at 58-59.

⁶⁶ *Id.* at 55.

⁵⁴ *Id.* at 47.

⁵⁵ Id.

⁵⁷ PAM Squared at Texarkana, LLC v. Azar, 436 F. Supp. 3d 52 (D.D.C. 2020).

⁶¹ 5 U.S.C. § 706(2)(A).

⁶² Provider's PPP at 53.

⁶⁵ Provider's PPP at 54. *See also* P-13 at P0107 (emphasis added).

⁶⁷ Id. at 63-65. See also 76 Fed. Reg. 51476, 51743 (Aug. 18, 2011).

On March 9, 2023, the parties agreed to Stipulations of Facts in this case which state the following, in pertinent part:

- 4. The Provider reported data to CMS for the fiscal year ("FY") 2017 payment determination using the required National Healthcare Safety Network ("NHSN") system operated by the Centers for Disease Control and Prevention ("CDC") and the LTCH CARE Data Set via the Quality Improvement Evaluation System ("QIES") Assessment Submission and Processing ("ASAP") system.
- 5. The FY 2017 payment determination under the LTCH QRP is based upon quality data from calendar year 2015, except for quality measure NQF #0431 (Influenza Vaccination Coverage among Healthcare Personnel), which is based upon data from October 2015 through March 2016.
- 6. The Provider received a notice of LTCH QRP non-compliance letter dated July 14, 2016, from the Medicare Contractor (Exhibit P-2), officially notifying the Provider that it did not meet the LTCH QRP requirements for FY 2017.
- 7. The July 14, 2016 Medicare Contractor letter stated that the Provider is subject to a two percent (2%) reduction in Medicare payments for FY 2017 for the following reasons: "The LTCH failed to submit the required data to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network; and/or The LTCH failed to submit the required quality measures that are to be submitted to the CMS Quality Improvement Evaluation Systems (QIES) system."
- 8. The July 14, 2016 Medicare Contractor letter to the Provider is a threepage letter that does not state the specific measure or months of data the Provider did not submit, or any specific LTCH QRP requirements for the FY 2017 payment determination that the Provider did not meet.
- 9. The HCIS Post Acute Care Help Desk told the Provider that it was missing data for the Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) for the months of April through September 2015. This is the only measure at issue. Data for this measure is reported to CMS using the NHSN system.
- 10. The Medicare Contractor's Notification of Non-Compliance letter to the Provider (<u>Exhibits</u> P-2), the HCIS – Post Acute Care Help Desk email to the Provider (<u>Exhibit</u> P-5), and the CMS Reconsideration Determination letter to the Provider (<u>Exhibit</u> P-4) did not state that the Provider was noncompliant with any of the other six quality measures for the FY 2017 payment determination: Catheter-Associated Urinary Tract Infection Outcome measure (NQF #0138), Central Line-

Associated Bloodstream Infection Outcome measure (NQF #0139), Percent of Residents with Pressure Ulcers That Are New or Worsened (short-stay) (NQF #0678), Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431), Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* Bacteremia Outcome (NQF #1716), and All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals (NQF #2512).

- 13. Reconsiderations for the FY 2017 payment determination are governed by the reconsideration regulation at 42 C.F.R. § 412.560(d), and the FY 2015 IPPS/LTCH PPS Final Rule, 79 Fed. Reg. 49854, 50317 (Aug. 22, 2014) stating that LTCHs requesting reconsideration are "to submit all supporting documentation and evidence demonstrating (1) Full compliance with all LTCHQR 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."
- 14. The Provider appealed the 2% payment penalty by submitting a request for reconsideration to CMS dated July 18, 2016 (Exhibit P-3).
- 15. The Provider's request for reconsideration included arguments and evidence supporting its request that CMS reverse the 2% payment penalty.
- 16. The Provider submitted supporting documents with its request for reconsideration, including NHSN data submission reports (<u>Exhibit</u> P-3 at P0026-P0048) showing that the Provider timely reported all required quality data to NHSN for the FY 2017 payment determination.
- On September 21, 2016, CMS issued a one-page reconsideration decision ("Original Reconsideration") that upheld its original decision to impose a 2% reduction in the Provider's FY 2017 Medicare Payments (<u>Exhibit</u> P-4).
- 18. A LTCH that is dissatisfied with CMS' reconsideration may appeal that determination to the PRRB pursuant to 42 C.F.R. § 412.560(e).
- 19. On February 9, 2017, the Provider submitted a timely individual appeal request to the PRRB to dispute the Original Reconsideration (Exhibit P-1).
- 20. The PRRB held a hearing on November 16, 2017 (Exhibit P-14). On September 6, 2018, the PRRB issued a decision upholding the Original Reconsideration and CMS's decision to apply the 2% payment penalty to the Provider's FY 2017 Medicare payments. (Exhibit P-15).

- 21. The Provider filed a complaint on November 2, 2018 in the United States District Court for the District of Columbia seeking judicial review of the PRRB's decision. On January 22, 2020, the court denied the Secretary's motion for summary judgment and granted the Provider's motion for summary judgment in part. The court found that the PRRB's decision was arbitrary and capricious because the PRRB did not apply the correct standards of review to the Provider's appeal (Exhibit P-19 at P0203-P0204). The court vacated the PRRB decision and remanded the case back to the agency for further proceedings (Exhibit P-20).
- 22. On March 11, 2021, CMS issued a new reconsideration decision (the "Reconsideration") that again upheld the 2% payment penalty applied to the Provider's FY 2017 Medicare payments (Exhibit P-13 at P0106-P0107). The Reconsideration states that "CMS has decided to uphold its determination of noncompliance and the imposition of a 2% Medicare reimbursement penalty." (Exhibit P-13 at P0107).
- 23. On September 7, 2021, the Provider submitted a timely individual appeal request to the PRRB to dispute the Reconsideration CMS issued after the court's remand (<u>Exhibit</u> P-13).
- 24. The amount in controversy is approximately \$372,965, based on the Provider's estimate of the 2% payment penalty applied to its FY 2017 Medicare payments (Exhibit P-13 at P0108, P0114).⁶⁸

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."⁶⁹ 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.⁷⁰

The Board finds this case focuses on whether the Provider *properly* submitted to CMS certain quality data on the CDI Measure for the CY 2015 reporting period, as required under the LTCH QRP, in order to receive the full annual payment update for FY 2017. More specifically, the parties dispute whether the Provider *properly* submitted to CMS the requisite data on the CDI Measure for April through September 2015 (*i.e.*, dispute whether the CDI Measure data at issue was "submitted in a form and manner, and at a time, specified by the Secretary," as required by 42 C.F.R. § 412.560(b) (2015)).⁷¹ As set forth below, the Board finds the Provider failed to

⁷⁰ See also 42 C.F.R. § 412.560(b)(2).

⁶⁸ Stipulations.

⁶⁹ See also Patient Protection and Affordable Care Act at § 3004(a), 124 Stat. at 368-369 (adding LTCH QRP statutory provisions at 42 U.S.C. § 1395ww(m)(5)).

⁷¹ Ex. P-13 at P0107. See also P-5.

properly submit CDI Measure data at issue in the form, manner, and at the time, specified by the Secretary and that the Provider failed to qualify for an exception or extension relative to the CDI Measure data at issue.

The Provider asserts that, under the first standard of review, "CMS must reverse the initial finding of non-compliance if the LTCH's evidence demonstrates 'full compliance with all LTCHQR Program reporting requirements during the reporting period."⁷² The Provider contends that it "met this first standard because it reported all required quality data by the applicable deadlines."⁷³ The deadline for Q2 and Q3 2015 CDI data was February 15, 2016.⁷⁴

42 U.S.C. § 1395ww(m)(5)(C) establishes the standards for reporting under the LTCH QRP in effect for the CY 2015 reporting period and it requires LTCHs to submit to the Secretary the requisite data on the specified quality measures of their services "in a form and manner, and at a time, specified by the Secretary." The Secretary instructed LTCHs that the data on the CDI Measure must be submitted to CMS using the CDC NHSN system.⁷⁵ The operational guidance for the CDC NHSN system instructed LTCHs that monthly reporting plans *must* be created (and updated as relevant) to include surveillance of the CDI Measure *in order for data associated with the outcome measure for the relevant month to be transmitted from the CDC NHSN system to CMS.*⁷⁶ Specifically, the CDC NHSN operational guidance states: "[m]onthly reporting plans *must be created* or updated in NHSN *to include FacWideIN CDI LabID events*, i.e. FacWideIN *CDI* LabID *event surveillance must be in the monthly reporting plans* ("in-plan") *in order for data to be shared <u>with CMS</u>.*^{*78} The guidance continues, stating "CDC will share all in-plan FacWideIN healthcare facility-onset (HO) CDI LabID event data from participating LTCHs."⁷⁸

Consistent with the District Court's remand in *Pam Squared*,⁷⁹ the Board has reviewed the record and applicable regulatory and manual guidance and reaffirms CMS' denial of the Provider's reconsideration request. The Board acknowledges that its original decision cited the incorrect regulation but, as set forth below, concludes that the application of the correct regulation does not alter its finding that CMS properly assessed the 2 percentage point APU penalty due to the Provider's failure to submit the quality data at issue concerning the CDI Measure in the time, form and manner specified by the Secretary.

⁷² Provider's PPP at 20 (citing 79 Fed. Reg. at 50317) (emphasis added).

⁷³ Id.

⁷⁴ *Id.* at 22.

⁷⁵ 80 Fed. Reg. at 49751. *See also* 79 Fed. Reg. at 50312 (stating "The LTCHQR Program, through the FY 2012, FY 2013, and FY 2014 IPPS/LTCH PPS final rules, requires LTCHs to submit quality data using two separate data collection/submission mechanisms: Measures collected using the LTCH CARE Data Set (LCDS) are submitted through the CMS Quality Improvement Evaluation System (QIES); and measures stewarded by the CDC (such as Healthcare-Acquired Infection (HAI) and vaccination measures), are submitted using the CDC's National Healthcare Safety Network (NHSN)."

⁷⁶ Operational Guidance for Long Term Care Hospitals to Report Facility-Wide Inpatient (FacWideIN) *Clostridium difficile* Infection (CDI) Laboratory-Identified (LabID) Event Data to CDC's NHSN for the Purpose of Fulfilling CMS's Long Term Care Hospital Quality Reporting Requirements, 2 (2015), available at https://www.cdc.gov/nhsn/PDFs/CMS/LTACH-CDI-Op-Guidance2015.pdf

 $^{^{77}}$ Id. (emphasis added).

 $^{^{78}}$ *Id.* at 3.

⁷⁹ Ex. P-19.

Pursuant to the reconsideration process prescribed at 42 C.F.R. § 412.560(d)(2)(vii)(Oct. 2015), LTCHs requesting reconsideration are required to submit *all* supporting documentation and evidence that "demonstrates compliance of the long-term care hospital with the quality reporting requirements." However, the Provider has admitted that an input error on its monthly reporting plan, specifically the location identifier, resulted in the failure of the data to be transmitted from CDC NHSN system *to CMS*.⁸⁰ As such, there is no evidence to demonstrate full compliance with all LTCH QRP reporting requirements during the reporting period as required by the regulation at 42 C.F.R. § 412.560(d)(2)(vii) and in the relevant final rules (*i.e.*, the Provider has admitted it did not submit to the CDI data at issue "in a form and manner, and at a time, specified by the Secretary"). Accordingly, the Board finds the Provider did *not* properly report the requisite data on its CDI Measure to CMS for the second and third quarters of CY 2015, in a form and manner and at a time as specified by the Secretary.

The Secretary prescribed a "form and manner" by which LTCHs are to report on the quality of their services. The prescribed form and manner for reporting includes creating and updating monthly reporting plans by checking/marking the applicable monthly reporting plan boxes for purposes of prompting the CDC NHSN system to transmit the underlying data to CMS upon expiration of the applicable reporting deadline. This "form and manner" requirement ensures that the relevant quality data, from all locations which are required to report, is captured and then transmitted/reported from the CDC NHSN system *to CMS*, appropriately. The Board finds the Provider acknowledges that, due to its own error, the monthly reporting plan boxes were not properly checked/marked for the data/completed on the CDI Measure for the second and third quarter of CY 2015. Accordingly, it is clear that the associated quality data at issue for the CDI Measure could not and did not transmit from the CDC NHSN system to CMS and that the Provider failed to comply with the prescribed "form and manner" to report its data on the CDI Measure to CMS for the second and third quarters of CY 2015.

The Provider also contends that, due to "extenuating circumstances," it qualifies for an exception and, thereby, should be excused for its noncompliance with respect to the CDI Measure data at issue. Specifically, the Provider asserts that to qualify for the "extenuating circumstances" exception is a *subject standard* and that it need only establish "moderating factors that make someone's actions excusable or less blameworthy" and need only be "reasonable excuses for less than full compliance."⁸¹ Finally, the Provider asserts that the FY 2015 IPPS Final Rule at 79 Fed. Reg. at 50317 confirms that "CMS was allowing providers to submit documentation of reasonable excuses to explain why they were not able to achieve full compliance."⁸² The Provider contends the following series of facts qualifies as an "extenuating circumstances" exception:

Due to the location identifier typo, it appears that the NHSN system or CMS failed to recognize that all data for the CDI quality measure (NQF #1717) were submitted for 2015. <u>See</u> Exhibit P-14 at P0145 ("Q. [Mr. Healy] [I]f CMS went into the NHSN system [the data] would have been there, correct? A. [Ms. Brown] Correct. They would have seen all the events were entered, the specific information was entered, the event IDs were all entered, everything was entered as it

⁸⁰ Ex. P-7. See also P-8.

⁸¹ Provider's PPP at 36.

⁸² Id.

should have been."). The Provider did as NHSN staff suggested and changed the location identifier to facility wide. Exhibits P-7 and P-8. However, this change did not alter any of the quality data that was previously reported to NHSN for the FY 2017 payment determination. <u>Id</u>. Accordingly, this situation qualifies as extenuating circumstances. Exhibit P-14 at P0139 ("Q. [Mr. Healy] And do you think the location identifiers should qualify as an extenuating circumstance for any perceived noncompliance? A. [Ms. Brown] I do, because if you're looking at the system and understanding the system, so if it's a unit or a fac-wide, it's -- we have a unit, so it truly is fac-wide. And so, therefore, it didn't negate that all the information was there and correct. It was a checkbox that wasn't in the system that could help run the report."). The Provider's attachments documented that all quality data were submitted for the only quality measure and months at issue. Exhibit P-3 at P0026-P0048.⁸³

In support of its position, the Provider has included what it considers "persuasive evidence" at Exhibit P-16, reflecting certain 2022 reporting requirements adopted by a sister agency, the Health Resources & Services Administration ("HRSA"). In pertinent part, HRSA published guidance in 2022 allowing providers to submit a "Request to Report Late Due to Extenuating Circumstances" in connection with the Provider Relief Fund.⁸⁴ However, the Board declines to consider HRSA's definition of extenuating circumstances for a myriad of reasons. First, it was not created for the Medicare program (much less for the Medicare quality data reporting requirements). Second, HRSA is a sister agency and CMS had no role in creating those standards nor did CMS adopt them. Finally, these HRSA standards were adopted in 2022, *more than 6 years after the quality data reporting period at issue (i.e.*, CY 2015).

The Board disagrees with the Provider's position that it should be excused for its failure to comply with the LTCH QRP requirements. The Board finds that the Provider alone has the responsibility for submitting the required data by the relevant quarterly deadline and the Provider

- Lack of receipt of reporting communications an incorrect email or mailing address on file with HRSA prevented the organization from receiving instructions prior to the Reporting Period deadline.
- Failure to click "Submit" the organization registered and prepared a report in the PRF Reporting Portal, but failed to take the final step to click "Submit" prior to deadline.
- Internal miscommunication or error internal miscommunication or error regarding the individual who was authorized and expected to submit the report on behalf of the organization and/or the registered point of contact in the PRF Reporting Portal.
- **Incomplete Targeted Distribution payments** the organization's parent entity completed all General Distribution payments, but a Targeted Distribution(s) was not reported on by the subsidiary.

⁸³ *Id.* at 40-41.

⁸⁴ Indeed, the HRSA guidance specifies that *only* the following 6 circumstances are "*allowable* extenuating circumstances" (emphasis added) and they are very specific to the PRF (not to Medicare or the Medicare quality reporting programs):

[•] Severe illness or death – a severe medical condition or death of a provider or key staff member responsible for reporting hindered the organization's ability to complete the report during the Reporting Period.

[•] Impacted by natural disaster – a natural disaster occurred during or in close proximity of the end of the Reporting Period damaging the organization's records or information technology.

does not dispute that CMS did not receive the CDI data at issue from the CDC NHSN system due to its failure to check the CDI outcome measure for the second and third quarters for CY 2015. The Provider also acknowledges that it has the responsibility to make sure that the monthly reporting plan boxes for each relevant outcome measure to be reported (*e.g.*, CAUTI, CLABSI, VAE, and CDI outcome measures) is checked/marked/completed to reflect the correct location, and also admitted that it failed to do so.⁸⁵

Further, the record suggests that, for the months at issue, the Provider failed to follow its protocol of documenting that not only the relevant monthly data was entered into the NHSN system but also that a rate table could be generated from the NHSN system for the relevant months (*i.e.*, April through September 2015). In this respect, the Provider's witness testified:

[S]o we have a protocol in the company. We like our hospitals to submit their data the 10^{th} – by the 10^{th} of the month for the previous month, to make sure it gets in the system and we can meet that deadline. Sometimes there's some circumstances and they might get it on the 12^{th} , or whatever, but we like it within the first two weeks for the previous month – reporting month. And after they do that, they will take screenshots from the websites and they'll report these up through, *and run the rate tables and send those up to myself and a couple other administrators*, they review then with their administrators and send them through. So we know that that data has been submitted in a timely manner, and we're not waiting until the last minute on a deadline reporting period.⁸⁶

Notwithstanding that protocol, for the months at issue, the record reflects that the protocol was not followed because the confirmation email for the months at issue only confirmed that the data was entered into the NHSN system and did not include any rate tables.⁸⁷ In this regard, it is unclear why the Provider was able to comply with one facility wide quality reporting measure for the months at issue (the facility-wide MRSA quality measure) but not the one at issue here (the facility-wide CDI Measure). As discussed above, both facility-wide measures were implemented at the same time.

Second, the Provider points to the wrong standard to excuse its failure. It is not simply "extenuating circumstances" but it is a narrower standard in that *potential* qualifying extenuating circumstances are limited to "extraordinary circumstances beyond the control of the [LTCH]" (*i.e.*, the only *allowable* "extenuating circumstances" are those that are "extraordinary circumstances").⁸⁸ Specifically, when the Secretary codified the processes for

⁸⁵ Ex. P-14 (Original Hearing Transcript, dated November 16, 2017) at P0147.

⁸⁶ *Id.* at P0131.45-46.

⁸⁷ Ex. P-3 ("MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring" Reports) at P0028-29, P0032-33, P0036-37, P0040-43, and P0046-48.

⁸⁸ 42 C.F.R. § 412.560(c). *See also* Ex. P-17 (April 22, 2022 print out of CMS website entitled "Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP) Reconsideration and Exception & Extension" which refers to the "extraordinary circumstances **beyond their control**" standard in reference to exception and extension requests, and requires, as part of a reconsideration request the LTCH include "information supporting the LTCH belief that the non-compliance finding is error, or evidence of the impact of **extraordinary circumstances that prevented timely submission** of data" (emphasis added)).

exceptions/extensions and reconsiderations into the LTCH QRP regulations effective for FY 2017 payment determinations (as explained above), the Secretary codified the narrower standard of "extraordinary circumstances beyond the control of the [LTCH]" as set forth in 42 C.F.R. § 412.560(c). This codification is consistent with the standard used elsewhere with other quality reporting programs⁸⁹ as well for extension of certain filing deadlines under Board processes.⁹⁰ Here, it is clear that the Provider's failure was *not* due to extraordinary circumstances, much less beyond its control, since it admits its administrative error in not accurately completing the relevant requisite monthly reporting plans and, as noted above, acknowledges that neither the CDC nor CMS has an obligation to send a notice, prior to a quality reporting deadline, notifying a provider of any issue with its upcoming data submission.⁹¹ Moreover, CMS' decision on whether to grant an exception or extension is *discretionary/permissive* as demonstrated by the facts that 42 C.F.R. § 412.560(c) uses the words "CMS may grant" and that CMS consideration is triggered only if: (a) the provider timely and properly requests it (42 C.F.R. § 412.560(c)(1)-(3)); or (b) CMS determines that an extraordinary regional circumstance existed or a systemic problem directly affected the ability of LTCHs to properly submit the quality data.⁹² Here, neither review was triggered. First, the Provider did not timely request an exception/extension within 90 days of the triggering event (*i.e.*, within 90 days of the relevant reporting deadline(s) since the triggering event in this case appears to be Provider's failure to properly complete the relevant monthly reporting plans on or before that deadline(s)). Second, CMS did not consider (nor did the Provider raise) a systemic or regional issue in its reconsideration request.

Regardless, even if the standard were simply "extenuating circumstances"⁹³ and the Board had the authority to otherwise consider granting an exception/extension as part of the present Board appeal,⁹⁴ the evidence would not support a finding of "extenuating circumstances" affecting the Provider's non-compliance with the LTCHQR Program requirements. Here, properly completing the monthly reporting plan is itself part of "form and manner" requirements for submitting data from the CDC NHSN system *to the CMS* and, as such, the Provider has not specified any extenuating circumstances for its failure to comply with that requirement (*i.e.*, the very thing it said it did not do is part of the "form and manner" and it gives no "extenuating

⁸⁹ In the quality reporting programs for the following provider types, the Secretary had codified the "circumstances beyond its control" standard as of October 2019: hospital IPPS (42 C.F.R. § 412.140(c)(2)); inpatient rehabilitation facilities (42 C.F.R. §412.634(c)(1)); skilled nursing facilities (42 C.F.R. § 413.360(c)(1)); ambulatory surgical centers (42 C.F.R. § 416.310(d)); hospital OPPS (42 C.F.R. § 419.46(e)); home health agencies (42 C.F.R. § 484.250(d)).
⁹⁰ See 42 C.F.R. § 405.1801(d)(2) (concerning calculation of certain filing deadlines); 42 C.F.R. § 405.1836(b) (concerning good cause extension of time limit for requesting a Board hearing).

⁹¹ The nature of the Provider's administrative error is further highlighted by the fact that it was apparently able to properly complete the monthly reporting plan for the months at issue for another facility-wide quality measure related to MRSA, which was also implemented at the same time as the CDI Measure, as explained *supra*.

 $^{^{92}}$ It is unclear whether CMS alone has the authority and discretion to consider (1) an exception/extension request due to "circumstances beyond the control of the [LTCH]" or "justifiable excuse"; or (2) on its own initiative, whether a qualifying regional extraordinary circumstance or systemic problem exists. In this regard, the Board notes that 42 C.F.R. § 412.560(c) states "CMS may grant an exception or extension" and does not explicitly permit Board appeals of a CMS denial of an exception/extension request (unlike reconsideration request per § 412.560(e)). However, the Board need not resolve this issue as it is clear that the Provider's admitted administrative error does not meet the regulatory criteria.

⁹³ The Law Dictionary Online defines the term "extenuating circumstances" as "Such as render a delict or crime less 'aggravated, heinous, or reprehensible['] than it would otherwise be, or tend to palliate or lessen its guilt. . . ." The Law Dictionary Online https://thelawdictionary.org/extenuating-circumstances/ (last visited Mar. 3, 2024).

⁹⁴ See supra note 92 and accompanying text.

circumstances" for its failure to comply with that "form and manner" requirement). Indeed, this is highlighted by the following findings by CMS in its reconsideration determination:

PAM Squared had entered the data at issue into the system *using an incorrect location code*. As a result of this erroneous data entry, CMS could not view the required data. After entering the data incorrectly, *PAM Squared* also *failed to run an output report* which would have alerted the facility to the fact that it had inputted the data incorrectly. The record demonstrates the data entry error was caused by a *failure to follow data entry directions* and was not a "typo." The record further demonstrates the data entry error was so significant that CMS could not view the data and was not a failure on the part of the government to send the information from one Department to another.⁹⁵

Indeed, the fact that the Provider was able to properly complete the monthly reporting plan for the other facility-wide quality measure, MRSA, further undercuts the Provider's allegation of extenuating circumstances.⁹⁶ Thus, the Board agrees with CMS' findings in the reconsideration decision and finds that the Provider's attempts to demonstrate "extenuating circumstances" fell short as they did not provide any bases which warrant a reversal of the 2 percentage point payment penalty. In summary, the Provider failed to provide evidence that reduces, or eliminates, its culpability for not submitting its data in the form, manner, and at the time, specified by the Secretary.

DECISION:

After considering Medicare law and regulations, the arguments presented, and the evidence admitted, the Board finds that CMS properly reduced the FY 2017 APU for the Provider by 2 percentage points.

BOARD MEMBERS PARTICIPATING:

Clayton J. Nix, Esq. Kevin D. Smith, CPA Ratina Kelly, CPA

FOR THE BOARD:

5/31/2024

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

⁹⁵ Ex. P-13 at P0107 (CMS Reconsideration Determination at n.1) (emphasis added).

⁹⁶ The Board disagrees with the Provider's characterization of the issue as simply a "typo" as it trivializes the issue. The incorrect location identifier was entered as "452061" while the correct location identifier that should have been entered was "FACWIDEIN" (facility wide). This is not a case of mis-typing, indeed if it was typed, the two location identifiers bear no resemblance to each other, whatsoever. Similarly, if it was chosen from a drop-down menu, there remained a specific choice involved in the action.