# PROVIDER REIMBURSEMENT REVIEW BOARD DECISION

2023-D35

**PROVIDER**– AdventHealth Connerton

**PROVIDER NUMBER-** 10-2026

VS.

**MEDICARE CONTRACTOR** – First Coast Service Options, Inc. (J-N)

**DATE OF HEARING** – March 31, 2021

FISCAL YEAR-2020

**CASE NUMBER** – 20-0218

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### **ISSUE STATEMENT:**

Whether the payment penalty that Centers for Medicare and Medicaid Services ("CMS") imposed under the Long-Term Care Hospital Quality Reporting Program ("LTCH-QRP") which reduced the Provider's payment update for Federal Fiscal Year ("FFY") 2020 by two percent was proper?<sup>1</sup>

### **DECISION:**

After considering Medicare law and regulations, arguments presented, and the evidence admitted, the Provider Reimbursement Review Board ("Board" or "PRRB") finds that CMS properly reduced the annual payment update ("APU") for AdventHealth Connerton ("AdventHealth" or "Provider") for FY 2020 by 2 percentage points.

# **INTRODUCTION:**

AdventHealth is a Medicare certified long-term care hospital ("LTCH") located in Land O' Lakes, Florida.<sup>2</sup> AdventHealth's assigned Medicare Administrative Contractor<sup>3</sup> is First Coast Service Options, Inc. (the "Medicare Contractor").

By letter dated July 10, 2019, the Medicare Contractor notified AdventHealth that it failed to meet the LTCH quality reporting program ("QRP") requirements and was subject to a 2 percentage point reduction to its FFY 2020 annual payment update ("APU"). On July 16, 2019, CMS also notified AdventHealth, by letter, that it had failed to meet the LTCH QRP requirements and was subject to a 2 percentage point reduction of its APU.<sup>5</sup> AdventHealth requested that CMS reconsider its decision regarding the 2 percentage point reduction affecting its FY 2020 Medicare payments<sup>6</sup> and, on September 11, 2019, CMS upheld its decision. On October 24, 2019, AdventHealth timely appealed CMS' denial to the Board and met the jurisdictional requirements for a hearing.<sup>8</sup>

The Board held a live video hearing on March 31, 2021. AdventHealth was represented by Jason M. Healy, Esq. of The Law Offices of Jason M. Healy, PLLC. The Medicare Contractor was represented by Scott Berends, Esq. of Federal Specialized Services.

#### STATEMENT OF FACTS AND RELEVANT LAW:

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

<sup>&</sup>lt;sup>1</sup> Hearing Transcript ("Tr.") at 6 (Mar. 31, 2021).

<sup>&</sup>lt;sup>2</sup> Provider's Final Position Paper (hereinafter Provider's FPP) at 2 (Dec. 30, 2020).

<sup>&</sup>lt;sup>3</sup> 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.

<sup>&</sup>lt;sup>4</sup> Exhibit ("Ex.") P-2.

<sup>&</sup>lt;sup>5</sup> Ex. P-3.

<sup>&</sup>lt;sup>6</sup> Ex. P-5.

<sup>&</sup>lt;sup>7</sup> Ex. P-6.

<sup>&</sup>lt;sup>8</sup> Ex. P-1.

<sup>&</sup>lt;sup>9</sup> 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)).

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(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.

(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. <sup>10</sup>

The LTCH QRP requirements for the FY 2020 payment determination at issue in this appeal are set forth in the FY 2017 IPPS/LTCH PPS Final Rule. <sup>11</sup> In the preamble of this Final Rule, the Secretary set out the deadlines for submitting required data for the FY 2020 payment determination. The FFY 2020 payment determination was based on the timely submission of quality data collected during calendar year ("CY") 2018 (reporting period of January 1, 2018, through December 31, 2018), except for the quality measure NQF#0431 (Influenza Vaccination Coverage among Healthcare Personnel), which is based upon data from October 2018 through March 2019. Moreover, as part of the FY 2016 IPPS/LTCH PPS Final Rule, 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)" and the codified process uses an "extraordinary circumstances beyond the control of the [LTCH]" standard. <sup>13</sup> As of 2019, these regulatory provisions read, in pertinent part:

- (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 <u>must</u> submit its request to CMS <u>within 90 days</u> 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**

<sup>&</sup>lt;sup>10</sup> 42 C.F.R. § 412.560 (2017) (emphasis added). See also 80 Fed. Reg. 49325, 49769 (Aug. 17, 2015).

<sup>&</sup>lt;sup>11</sup> 81 Fed. Reg. 56762, 57219-27 (Aug. 22, 2016).

<sup>&</sup>lt;sup>12</sup> 80 Fed. Reg. at 49756. See also 80 Fed. Reg. 24324, 24611 (Apr. 30, 2015).

<sup>&</sup>lt;sup>13</sup> 80 Fed. Reg. at 49769-70. See also 82 Fed. Reg. 37990, 38513-14 (Aug. 14, 2017).

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# 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 . . . .
  - (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 <u>may</u> grant an exception or extension to a long-term care hospital that has not been requested by the long-term care hospital <u>if CMS determines that</u>—
  - (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 <u>must</u> 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.

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- (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 . . . .
- (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.<sup>14</sup>

Significantly, as part of the 2015 codification, the Secretary specified that requests for exceptions/extensions and requests for reconsideration must be sent by email to CMS using the <u>same</u> email address for both types of requests, namely <u>LTCHQRPReconsiderations@cms.hhs.gov</u>. To this end, CMS has a dedicated webpage for both types of requests and it continues to specify that both types of requests must be sent to this same email address. The same email address to the same email address.

Data from the first quarter of CY 2018 (January 1-March 31, 2018) was required to be submitted by August 15, 2018. Third quarter data (April 1-June 30, 2018) was due by November 15, 2018. Third quarter data (July 1-September 30, 2018) was originally due by February 15, 2019, 18 however, CMS extended the quality data submission deadline for the third quarter until February 21, 2019. Fourth quarter data (October 1-December 31, 2018) was due by May 15, 2019. 20

This case concerns CMS' finding that AdventHealth failed to submit to CMS the requisite data on the following outcome measures for the first and second quarters of the CY 2018 reporting period:

- 1. For the first and second quarters of CY 2018:
  - The catheter associated urinary tract infection ("CAUTI") outcome measure;
  - The central line-associated bloodstream infection ("CLABSI") outcome measure; and
  - The ventilator-associated event ("VAE") outcome measure.

<sup>&</sup>lt;sup>14</sup> Oct. 1, 2017 version (italics emphasis in original and italics and underline emphasis added) (available at: https://www.govinfo.gov/content/pkg/CFR-2017-title42-vol2/pdf/CFR-2017-title42-vol2-sec412-560.pdf).

<sup>&</sup>lt;sup>15</sup> 80 Fed. Reg. at 24610, 49755 (email address for reconsiderations in both proposed and final rules); 80 Fed. Reg. at 24611, 49756 (email for exceptions/extensions in both proposed and final rules).

<sup>&</sup>lt;sup>16</sup> Ex. P-8 (printout of CMS webpage for the "LTCH Quality Reporting Reconsideration and Exception & Extension Process and specifying that both types of requests must be emailed to <u>LTCHQRPReconsiderations@cms.hhs.gov</u>). <sup>17</sup> 81 Fed. Reg. at 57227.

<sup>&</sup>lt;sup>18</sup> *Id*.

<sup>&</sup>lt;sup>19</sup> Ex. P-7.

<sup>&</sup>lt;sup>20</sup> 81 Fed. Reg. at 57227.

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- 2. For the second quarter of CY 2018 only:
  - The Clostridium Difficile Infection ("CDI") outcome measure. <sup>21</sup>

Specifically, LTCHs had to collect data related to these outcome measures and submit that data *to CMS* for the first quarter of CY 2018 by August 15, 2018, and for the second quarter of CY 2018 by November 15, 2018 (as well as the other quarter of CY 2018 which are not at issue in this case) in order to receive the full APU for FFY 2020.

By letter dated July 16, 2019, CMS initially advised AdventHealth that it "[d]id not submit all required months of complete . . . data" for the following outcome measures:

- 1. CAUTI Outcome Measure (NQF #0138);
- 2. CLABSI Outcome Measure (NQF #0139);
- 3. Facility-Wide Inpatient Hospital-Onset Clostridium Difficile Infection ("CDI") Outcome Measure (NQF #1717); and
- 4. Ventilator-Associated Event ("VAE") Outcome Measure. 22

After receiving the non-compliance determination, AdventHealth contacted the Centers for Disease Control National Healthcare Safety Network ("CDC NHSN") Helpdesk to obtain additional information. The CDC NHSN Helpdesk responded that the following data were *not* sent/transmitted to CMS "because your [monthly] reporting plan was *not* complete for those months":

- CAUTI/CLABSI/VAE data for March and April 2018; and
- CDI data for May and June 2018.<sup>23</sup>

AdventHealth contends that it was in full compliance with the LTCH QRP because it reported the event data for each of the measures (CAUTI, CLABSI, VAE, and CDI) "by the applicable deadlines to the agency's designated reporting system, the [CDC] NHSN."<sup>24</sup> AdventHealth asserts that, because it had entered all of the requisite date for the first and second quarters of CY 2018 *into the CDC NHSN system*, all of the quality data at issue "were in the government's hands before the reporting deadlines" and "[a]ccordingly, CMS should have reversed the 2 [percent] penalty on reconsideration."<sup>25</sup> Further, AdventHealth argues that CMS "issued a reconsideration decision that any reasonable person would find deficient because it: (1) does not explain how the Provider's evidence failed to show full compliance, the first LTCH QRP standard of review; (2) completely fails to address whether the Provider submitted evidence of extenuating circumstances for any alleged non-compliance, which is the second LTCH QRP standard of review; and (3) violates the Administrative Procedure Act ("APA") by using a form letter that does not apply the LTCH QRP reconsideration standards of review and makes only conclusory statements with no indication that CMS engaged in reasoned decision making."<sup>26</sup>

<sup>&</sup>lt;sup>21</sup> Ex. P-6 at 1 (copy of the CMS reconsideration determination dated Sept. 11, 2019). *See also* Ex. P-3 at 1 (copy of CMS' initial determination of noncompliance dated July 16, 2019).

<sup>&</sup>lt;sup>22</sup> Ex. P-3 at 1.

<sup>&</sup>lt;sup>23</sup> Ex. P-4 at 1 (emphasis added).

<sup>&</sup>lt;sup>24</sup> Provider's FPP at 1.

<sup>&</sup>lt;sup>25</sup> *Id*.

<sup>&</sup>lt;sup>26</sup> *Id.* at 1-2.

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AdventHealth states that the LTCH QRP reconsideration regulation, found at 42 C.F.R. § 412.560(d)(2)(vii), "requires that CMS reverse the initial finding of non-compliance if the reasons for requesting reconsideration are supported by documentation that demonstrates compliance of the long-term care hospital with the quality reporting requirements." The preamble to the FY 2015 IPPS Final Rule states:

We also proposed that as part of the LTCH's request for reconsideration, the LTCH would be required 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.<sup>28</sup>

CMS finalized these reconsideration procedures as proposed.<sup>29</sup> AdventHealth contends that, in the above Final Rule, the "[u]se of the word "or" means that the agency's initial non-compliance decision is reversed if either statement is true."<sup>30</sup> More specifically, AdventHealth argues that:

CMS established an LTCH QRP reconsideration process with two standards of review. The first standard is full compliance with the LTCH QRP requirements. Under this first standard, 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.<sup>31</sup>

AdventHealth then argues it "met this first standard [of review] because it reported all required data by the applicable deadlines," including "[a]ll required data for the first and second quarters of 2018 by the August 15, 2018 and November 15, 2018 deadlines." In addition, AdventHealth asserts that "[t]his is not a case where there was a failure to report data. . . . Here, [it] fully reported its quality data for each applicable quality measure and each month of the reporting period before the reporting deadlines." AdventHealth contends its request for reconsideration "provided proof of timely reporting of all CAUTI events, all CLABSI events, all VAEs, and all CDI events. . ." in the CDC NHSN screenshots it included with its reconsideration request. In addition, AdventHealth maintains that the sworn declaration of its Director of Quality Administration "confirms that she submitted all event data for this reporting period prior to the reporting deadlines." AdventHealth asserts the CDC NHSN system "provided no indication that there was any error or other discrepancy with [its] data." data."

<sup>27</sup> *Id.* at 8.

<sup>&</sup>lt;sup>28</sup> 79 Fed. Reg. 49854, 50317 (Aug. 22, 2014).

<sup>&</sup>lt;sup>29</sup> *Id.* at 50318.

<sup>&</sup>lt;sup>30</sup> Provider's FPP at 9.

<sup>&</sup>lt;sup>31</sup> *Id.* at 14 (citing 79 Fed. Reg. at 50317).

<sup>&</sup>lt;sup>32</sup> *Id.* (citations omitted).

<sup>&</sup>lt;sup>33</sup> *Id*.

<sup>&</sup>lt;sup>34</sup> *Id.* at 15.

<sup>&</sup>lt;sup>35</sup> *Id.* (citation omitted).

<sup>&</sup>lt;sup>36</sup> *Id*.

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AdventHealth's position focuses on the *monthly reporting plans* and asserts that "[o]nly two months of *reporting plans* for CAUTI, CLABSI, VAE, and CDI data are potentially at issue."<sup>37</sup> As a result, AdventHealth essentially contends that LTCH QRP payment penalty at issue is not applicable to the failure to complete monthly reporting plans:

Reporting plans are not data subject to the 2 percent penalty. The statute [at § 1395ww(m)(5)(A), (C)] is clear that the reduction in payment is *only* for a hospital that does not submit data on quality measures. The 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.<sup>38</sup>

In support of its position, AdventHealth references the decision of the U.S. District Court for the District of Columbia ("D.C. Court") in *Landmark Hosp. of Salt Lake City v. Azar* ("*Landmark*").<sup>39</sup> AdventHealth describes *Landmark* as "a case involving another LTCH's appeal of the LTCH QRP payment penalty where some monthly reporting plan boxes were allegedly not checked in [the CDC] NHSN [system], CMS assessed the penalty even though the LTCH had confirmed that there were no error messages in the reporting website prior to the deadline."<sup>40</sup> AdventHealth maintains that the D.C. Court "evaluated the facts and determined that CMS applied the payment penalty due to a 'typographical error."<sup>41</sup> AdventHealth further contends that the D.C. Court found in *Landmark* that:

[T]he Board made a "hyper-technical finding" when it determined that there was no documentary evidence regarding this LTCH's timely submission of data because "the Board never mentioned a Landmark officer's *testimonial* evidence that she and the Salt Lake City DQM personally verified all reporting data in the online system before the deadline."

AdventHealth argues that, similar to the LTCH in *Landmark*, it "has documentary evidence, the NHSN reports and the sworn Declaration of Maria Brockway, [its Director of Quality Administration,] establishing that all quality data were reported prior to the applicable deadlines."<sup>43</sup> In further support, AdventHealth cites to the D.C. Court's decision in *PAM Squared at Texarkana*, *LLC v. Azar* ("*PAM Squared*"),<sup>44</sup> a LTCH QRP case where the LTCH allegedly made a typo in its location code field associated with one quality measure in the CDC NHSN system. AdventHealth states that, similar to the LTCH in *Pam Squared*, it:

<sup>&</sup>lt;sup>37</sup> *Id.* at 16.

<sup>&</sup>lt;sup>38</sup> *Id.* (bold and italics emphasis included). *See also* CMS LTCH QRP Manual, Chapter 5 "Guidance for the Reporting of Data into the National Healthcare Safety Network" Version 2.0 (Nov. 2013), <a href="https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/2013-LTCH-QR-Program-Manual-v20-Final.zip.">https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/2013-LTCH-QR-Program-Manual-v20-Final.zip.</a>

<sup>&</sup>lt;sup>39</sup> Landmark Hosp. of Salt Lake City v. Azar, 442 F. Supp. 3d, 327, 330 (D.D.C. 2020).

<sup>&</sup>lt;sup>40</sup> Provider's FPP at 17.

<sup>&</sup>lt;sup>41</sup> Id. (quoting Landmark, 442 F. Supp. 3d at 329).

<sup>&</sup>lt;sup>42</sup> *Id.* (quoting *Landmark*, 442 F. Supp. 3d at 332).

<sup>&</sup>lt;sup>43</sup> *Id.* (citation omitted).

<sup>&</sup>lt;sup>44</sup> 436 F. Supp.3d 52, 55 (D.D.C 2020).

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[A]ctually reported all of its quality data prior to the reporting deadlines. If there was any issue with the boxes not being checked for a few of [its] monthly reporting plans, this did not change the fact that the [CDC] NHSN [system] had all of [its] event data by the applicable LTCH QRP reporting deadlines.<sup>45</sup>

AdventHealth further contends that there was a "typo[graphical error]" and that other courts have treated data reported to one component of HHS as having been received by another component of HHS. 46 Thus, AdventHealth argues that "CMS possesses all required data from [it] for the FY 2020 payment determination." 47 More specifically, AdventHealth asserts it "complied with the LTCH QRP reporting requirements when its quality data were submitted to the CDC." 48 AdventHealth further claims that "[t]he lack of specificity in the CMS notice of non-compliance about which quality data were allegedly missing further supports the conclusion that only the submission of data from [AdventHealth] to CDC NHSN is relevant to the [Board's] analysis." 49

In its response to the Medicare Contractor's Final Position Paper, AdventHealth argues that, if the monthly reporting plans were relevant to its compliance, then CMS should have identified and addressed the monthly reporting plans at issue in both its initial notice of non-compliance and its reconsideration decision. Furthermore, AdventHealth maintains that "CMS should have reversed the payment penalty under the first standard of review because the Provider fully complied with the LTCH QRP reporting requirements" and because "[t]he transmission of quality data from [the CDC] NHSN [system] to CMS is not relevant for purposes of determining compliance with the [LTCH] QRP." <sup>52</sup>

AdventHealth believes that, even if CMS did not find that the evidence demonstrated full compliance, the payment penalty should be reversed on reconsideration, under the second standard of review – whether AdventHealth's evidence demonstrated "extenuating circumstances" that affected non-compliance.<sup>53</sup> AdventHealth cites to the Secretary's discussion on the LTCH QRP reconsideration process in the FY 2015 IPPS Final Rule published on August 22, 2014<sup>54</sup> 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

<sup>&</sup>lt;sup>45</sup> Provider's FPP at 18.

<sup>&</sup>lt;sup>46</sup> *Id.* (with supporting citation string: "See United States ex rel. Coyne v. Amgen, Inc., 229 F. Supp. 3d 159, 171 (E.D.N.Y 2017) (finding that company's disclosure of data to the FDA meant that data was also disclosed to CMS); In Def. of Animals v. Nat'l Institutes of Health, 543 F. Supp. 2d. 70, 77 (D.D.C. 2008) ('[T]he D.C. Circuit has made clear that records need not be generated by an agency, or in the actual possession of an agency, for the records to be considered 'owned or obtained' by the agency.')").

<sup>&</sup>lt;sup>47</sup> *Id*.

<sup>&</sup>lt;sup>48</sup> *Id*.

<sup>&</sup>lt;sup>49</sup> *Id.* at 19 (emphasis added).

<sup>&</sup>lt;sup>50</sup> Provider's Reply Brief at 4 (Mar. 1, 2021).

<sup>&</sup>lt;sup>51</sup> Provider's FPP at 15.

<sup>&</sup>lt;sup>52</sup> *Id*. at 19.

<sup>&</sup>lt;sup>53</sup> *Id.* at 20-21.

<sup>&</sup>lt;sup>54</sup> 79 Fed. Reg. at 50317.

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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. 55

AdventHealth asserts "extenuating circumstances are moderating factors that make someone's actions excusable or less blameworthy," *i.e.*, "reasonable excuses for less than full compliance." AdventHealth contends this standard is "a subjective standard" that requires CMS to evaluate the extenuating circumstances that it has claimed. <sup>57</sup>

AdventHealth also asserts that "[t]he rulemaking record [for the <u>August 22, 2014 final rule</u>] shows that CMS was allowing providers to submit documentation of reasonable excuses to explain why they were not able to achieve full compliance." AdventHealth contends that "[t]he scope of CMS' equitable discretion to reverse payment penalties in LTCH QRP cases under this second standard of review is broad." According to AdventHealth's Final Position Paper, "when an appeal is filed with CMS after the penalty is imposed, 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." AdventHealth contends that, "[i]f CMS did not conclude that there was full compliance by [AdventHealth] with the LTCH QRP, then the evidence clearly supported a finding of 'extenuating circumstances' that required reversal of the payment penalty."

AdventHealth argues that its Request for Reconsideration was sufficient to establish its compliance with all the LTCH QRP reporting requirements for the reporting period at issue:

[P]rovided CMS with supporting documentation and evidence demonstrating "extenuating circumstances that affected noncompliance. . . . ." The Provider timely submitted all quality data through the [CDC] NHSN system, as reflected in the Provider's documentation submitted with the request for reconsideration. This documentation is proof of compliance with all LTCH QRP requirements during the reporting period. If there was any non-compliance, it was only because some of the boxes for monthly reporting plans were not checked in [the CDC] NHSN [system]. This was either a typo or a technical issue with the [CDC] NHSN [system]. <sup>62</sup>

AdventHealth maintains that, even if there were any potential noncompliance, CMS should have exercised its discretion and applied the "extenuating circumstances" standard because AdventHealth "submitted all required quality data to [the CDC] NHSN [system], even if the boxes for some of the

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<sup>55</sup> Provider's FPP at 21.
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<sup>&</sup>lt;sup>56</sup> *Id*.

<sup>57</sup> Id

<sup>&</sup>lt;sup>58</sup> *Id.* (citing to 79 Fed. Reg. at 50317).

<sup>&</sup>lt;sup>59</sup> Id.

<sup>&</sup>lt;sup>60</sup> *Id.* at 22 (citing to 79 Fed. Reg. at 50317).

<sup>&</sup>lt;sup>61</sup> *Id*.

<sup>&</sup>lt;sup>62</sup> *Id*.

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monthly reporting plans were not checked in [the CDC] NHSN [system] due to a typo or technical issue." AdventHealth maintains its situation is a "perfect example" of extenuating circumstances:

[T]his case is the perfect example of an extenuating circumstance that may have led CMS to believe that the Provider did not report their quality data on time, when in fact it did. All of the data were timely reported to [the CDC] NHSN [system] and available to CMS. Any issue with the monthly reporting plans does not change the fact that the data were there at the agency. The Provider has no control over the data once it is reported to [the CDC] NHSN [system]. 64

\* \* \* \*

At the reconsideration stage, CMS should have evaluated all of the Provider's evidence under both standards of review. However, nothing in the Reconsideration shows that CMS considered whether there were extenuating circumstances here. . . . CMS completely failed to 'articulate [a] rational connection between the facts found and the choice made' as required by the Supreme Court in *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962).<sup>65</sup>

AdventHealth concludes: "[b]ecause CMS failed to make any findings and conclusions regarding these extenuating circumstances, the [Board] should reverse the Reconsideration." 66

AdventHealth argues that there is another basis for extenuating circumstance that should have been considered by CMS in this case. Specifically, it contends that the CDC "NHSN system did not have adequate software to generate an alert or otherwise notify [it] that a systems error prevented the data from being transmitted to CMS."<sup>67</sup> AdventHealth explains that, although all of its data was submitted to [the CDC] NHSN [system] and accessible by CMS before the deadline, neither CMS nor the CDC provided any notice to AdventHealth that there was any issue with the data submission.<sup>68</sup> AdventHealth contends that the Board should reverse the 2 percentage point penalty because all required quality data was submitted by the applicable due dates, and satisfied the essential statutory purpose of the LTCH QRP, causing was no harm to the Medicare program, despite the typo or technical issue preventing its data from being transmitted from the CDC NHSN system to CMS.<sup>69</sup> AdventHealth further claims "another extenuating circumstance that affected noncompliance" was that the CDC NHSN system did not flag or notify AdventHealth that its quality data would *not* be transmitted to CMS.<sup>70</sup>

AdventHealth contends that CMS' September 11, 2019 Reconsideration decision disregarded the standards of review for the LTCH QRP reconsideration process, and was a one page form letter: 71

<sup>&</sup>lt;sup>63</sup> *Id*.

<sup>&</sup>lt;sup>64</sup> *Id.* at 23.

<sup>&</sup>lt;sup>65</sup> *Id* 

<sup>66</sup> Id. at 23-24.

<sup>&</sup>lt;sup>67</sup> *Id.* at 24.

<sup>&</sup>lt;sup>68</sup> *Id*.

<sup>&</sup>lt;sup>69</sup> *Id*.

<sup>&</sup>lt;sup>70</sup> *Id.* at 25.

<sup>&</sup>lt;sup>71</sup> Provider's FPP at 30.

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Although CMS states in the letter that it reviewed the Provider's reconsideration request, the Reconsideration includes no discussion of the Provider's arguments establishing proof of full compliance with the LTCH QRP for the FY 2020 payment determination and the Provider's evidence of extenuating circumstances. The Reconsideration only states that CMS 'decided to uphold the decision to grant the reduced FY 2020 APU.' The Reconsideration does not even mention or attempt to apply either of the two standards of review. In *PAM Squared* and *Landmark Hosp.*, the court held that the final agency decisions at issue were arbitrary and capricious when they did not apply the correct LTCH QRP reconsideration rules.<sup>72</sup>

AdventHealth contends that the CMS Reconsideration in this case suffered from the same defects as those in the final agency decisions at issue in *Pam Squared*<sup>73</sup> and *Landmark Hosp*. Thus, it believes that the Board must ensure CMS evaluated both aspects of the reconsideration standard for LTCH QRP appeals – compliance and extenuating circumstances – as adopted in the FY 2015 Final Rule. The compliance is the compliance of the reconsideration of the compliance and extenuating circumstances – as adopted in the compliance and extenuating circumstances – as adopted in the compliance of the compliance and extenuating circumstances – as adopted in the compliance and extenuating circumstances – as adopted in the complex circumstances – as adopted in the circumstances – as adopted in the complex circumstances – as adopted in the circumstances

AdventHealth maintains that "the Reconsideration here ignores the Provider's key arguments. . . . [and] does not discuss with any specificity the evidence that [it] submitted with its request for reconsideration." It believes that "[t]he CMS Reconsideration fails to meet the most basic requirements under the APA." Therefore, it maintains that the Board should overturn the Reconsideration as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."

Citing to the FY 2012 IPPS/LTCH PPS Final Rule, AdventHealth maintains that the purpose of the LTCH QRP is to improve quality of care and to promote more efficient delivery of healthcare to Medicare beneficiaries. Asserting that it timely submitted all of the required LTCH QRP data, it argues that: (1) the imposition of a 2 percentage point penalty is "inconsistent with the intent and goals of the LTCH" and (2) the imposition of a 2 percentage point penalty is precluded by the "doctrine of substantial compliance." AdventHealth elaborates on this argument as follows:

The 2% cut to all of the Provider's Medicare payments in FY 2020 has a significant negative impact on the hospital and its ability to treat patients effectively, at a time when LTCH payments from

<sup>&</sup>lt;sup>72</sup> *Id.* (citing *Landmark Hosp.* 442 F. Supp. 3d at 334; *Pam Squared* 436 F. Supp. 3d at 57-58).

<sup>&</sup>lt;sup>73</sup> Pam Squared, 436 F. Supp.3d at 54. AdventHealth asserts the U.S. District Court for the District of Columbia found that CMS got lost in its own labyrinth of Medicare regulations and granted summary judgment for Pam Squared and Landmark Hosp. of Salt Lake City and remanded the cases back to the Secretary. Provider's FPP at 12.

<sup>&</sup>lt;sup>74</sup> Landmark Hosp. of Salt Lake City, 442 F. Supp. 3d at 329.

<sup>&</sup>lt;sup>75</sup> Provider's FPP at 31.

<sup>&</sup>lt;sup>76</sup> *Id.* at 32.

<sup>&</sup>lt;sup>77</sup> *Id.* at 38.

<sup>&</sup>lt;sup>78</sup> *Id.* (citing 5 U.S.C. § 706(2)(A)).

<sup>&</sup>lt;sup>79</sup> *Id.* at 39 (citing to 76 Fed. Reg. 51476, 51743 (Aug. 18, 2011)).

<sup>&</sup>lt;sup>80</sup> *Id*.

<sup>&</sup>lt;sup>81</sup> *Id*.

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Medicare have already been drastically reduced. Therefore, applying the payment penalty when the Provider timely submitted all required quality data is contrary to the intent of the LTCH QRP.<sup>82</sup>

For these various reasons, AdventHealth requests that the Board reverse CMS' reconsideration decision (which upheld the 2 percentage point payment penalty) and award it interest pursuant to 42 U.S.C § 1395g(d).<sup>83</sup>

The Medicare Contractor contends that AdventHealth has not described any circumstances that could be considered "extenuating circumstances" which prohibited it from transmitting the data at issue to CMS. <sup>84</sup> The Medicare Contractor notes that AdventHealth admits in its Reconsideration Request that "an administrative error was made and a few of the monitoring plan boxes were inadvertently not checked . . . even though the data had been submitted." However, the Medicare Contractor explains:

The data that the Provider failed to submit timely are part of the LTCH Quality Reporting Program requirements. It was the Provider's failure to submit this data completely that resulted in the CMS determination of a 2 percentage-point reduction in the FY 2020 Annual Payment Update.

It is clear by the Provider's own admission that the data was incomplete, and there do not appear to be any extenuating circumstances demonstrated by the Provider.<sup>86</sup>

The Medicare Contractor continues, noting "[T]o the extent that Provider, begrudgingly, accepted that the fault lay with them, Provider still sought to pass the blame by arguing that it wasn't notified of its mistake, despite acknowledging no obligation by CMS or [the CDC] NHSN [system] to so notify. Provider's unwillingness to accept blame for the failure to check the appropriate monitoring plan boxes belies its request for extenuation." 87

Finally, the Medicare Contractor addresses AdventHealth's position that "the monthly plan boxes are not 'data' and that, as a result, its failure to check those boxes should be of no consequence." The Medicare Contractor contends that whether monthly plan boxes constitute "data" as defined in 42 U.S.C. § 1395ww(m)(5)(A) and (C) is irrelevant to CMS's determination of compliance with the LTCH QRP reporting requirements. He Medicare Contractor claims that, because the Secretary has prescribed the manner in which quality data is to be submitted to CMS, and that manner includes the checking/marking of appropriate monthly plan boxes, the Provider failed to satisfy the reporting requirements. Specifically, AdventHealth's failure to follow the Secretary's

<sup>82</sup> Id. at 39-40.

<sup>&</sup>lt;sup>83</sup> *Id.* at 13.

<sup>&</sup>lt;sup>84</sup> Medicare Contractor's Final Position Paper (hereinafter "Medicare Contractor's FPP") at 4-5 (Jan. 29, 2021).

<sup>&</sup>lt;sup>85</sup> *Id.* at 5.

<sup>&</sup>lt;sup>86</sup> *Id.* at 6.

<sup>&</sup>lt;sup>87</sup> Medicare Contractor's Post-Hearing Brief [corrected] at 4 (citing Hearing Transcript at 108-109) (June 1, 2021).

<sup>&</sup>lt;sup>88</sup> *Id*.

<sup>&</sup>lt;sup>89</sup> *Id*.

<sup>&</sup>lt;sup>90</sup> *Id*.

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specific directions for the submission of QRP data, prevented the data from being transmitted to CMS. Paccordingly, the Medicare Contractor asserts that the assessment of the LTCH QRP payment penalty should be upheld because "it was [AdventHealth's] failure to submit this [LTCH QRP] data completely that resulted in the CMS determination of a 2 percentage-point reduction in the FY2020 Annual Payment Update." Page 1872.

# **DISCUSSION, FINDINGS OF FACT. AND CONCLUSIONS OF LAW:**

The statute at 42 U.S.C. § 1395ww(m)(5)(C), requires LTCHs to report on the quality of their services "in a form and manner, and at a time, specified by the Secretary." The statute provides that a long-term care hospital that does not submit data in accordance with 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.<sup>94</sup>

The Board finds this case focuses on whether AdventHealth *properly* submitted to CMS certain CAUTI, CLABSI, VAE, and CDI quality data for the CY 2018 reporting period, as required under the LTCH QRP, in order to receive the full annual payment update for FY 2020. More specifically, the parties dispute whether AdventHealth *properly* submitted to CMS the requisite CAUTI, CLABSI and VAE measures for March and April 2018 and the CDI measure for May and June 2018.<sup>95</sup> The Board finds that AdventHealth failed to *properly* submit data at issue for the CAUTI, CLABSI, VAE, and CDI measures in the form, manner, and at the time specified by the Secretary.

AdventHealth 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.""<sup>96</sup> AdventHealth contends that it "met this first standard because it reported all required quality data by the applicable deadlines."<sup>97</sup> These deadlines were August 15, 2018 (for the first quarter of 2018) and November 15, 2018 (for the second quarter of 2018).<sup>98</sup>

The statute at 42 U.S.C. § 1395ww(m)(5)(C) establishes the standards for reporting under the LTCH QRP in effect for the CY 2018 reporting period and it requires LTCHs to report on the quality of their services "in a form and manner, and at a time, specified by the Secretary." CMS instructed LTCHs that the CAUTI, CLABSI, VAE, and CDI data measures must be submitted to CMS using the CDC NHSN system.<sup>99</sup> The website for the CDC NHSN system informed LTCHs

<sup>&</sup>lt;sup>91</sup> *Id.* at 4-5.

<sup>&</sup>lt;sup>92</sup> Medicare Contractor's FPP at 6.

<sup>&</sup>lt;sup>93</sup> 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)).

<sup>&</sup>lt;sup>94</sup> 1395ww(m)(5)(A); see also 42 C.F.R. § 412.560(b)(2).

<sup>&</sup>lt;sup>95</sup> See Ex. P-4 at 1.

<sup>&</sup>lt;sup>96</sup> Provider's FPP at 14 (citing 79 Fed. Reg. at 50317) (emphasis added).

<sup>97</sup> Id

<sup>&</sup>lt;sup>98</sup> *Id*.

<sup>&</sup>lt;sup>99</sup> 80 Fed. Reg. at 49751; 82 Fed. Reg. at 38454-56; 83 Fed. Reg. 41144, 41633 (Aug. 17, 2018) (stating "Data on LTCH QRP measures that are also collected by the CDC for other purposes are reported by LTCHs to the CDC through the NHSN, and the CDC then transmits the relevant data to CMS. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38454 through 38456) for the data collection and submission timeframes that we finalized for the LTCH QRP."). *See also* 79 Fed. Reg. at 50312 (stating "The LTCHQR Program, through the FY 2012, FY 2013, and FY 2014

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that monthly reporting plans *must* be created (and updated as relevant) to include surveillance of the CAUTI, CLABSI, VAE, and CDI outcome measures *in order for data associated with those outcome measure for the relevant month to be transmitted from the CDC NHSN system to CMS.* <sup>100</sup> Furthermore, "[m]onthly reporting plans must be created or updated to include CLABSI [CAUTI, VAE, CDI] surveillance in all locations from which reporting is required, i.e., CLABSI surveillance must be 'in-plan' for data to be shared with CMS."<sup>101</sup>

Pursuant to the reconsideration process prescribed at 42 C.F.R. § 412.560(d)(2)(viii) (Oct. 2019), LTCHs requesting reconsideration are required to submit all supporting documentation and evidence that "demonstrates compliance of the long-term care hospital with the LTCH QRP requirements." However, AdventHealth, in its reconsideration request, admits its error, stating "[o]ur hospital submitted 12 months of events to [the CDC] NHSN [system] and checked the appropriate monitoring plan boxes. However, it appears *an administrative error was made* and a few of the monitoring plan boxes were inadvertently *not checked* (CAUTI, CLABSI, VAE for Mar & Apr 2018 and CDI for May and Jun 2018) even though the data had been submitted." Accordingly, the Board finds that AdventHealth did *not* properly report its CAUTI, CLABSI, and VAE quality data to CMS for the first quarter of CY 2018, and its CDI quality measure to CMS for the second quarter of CY 2018, in a form and manner and at a time as specified by the Secretary. As such, there is no supporting evidence to demonstrate full compliance with all LTCH QRP reporting requirements during the reporting period as required by the regulation at § 412.560(d)(2)(vii) and in the relevant final rules. 103

The Board finds that AdventHealth's claim that monthly reporting plans "are not data subject to the 2 percent[age point] penalty" rings hollow. Whether monthly reporting plans are "data," or not, misses the point. 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 to CMS appropriately. The Board finds that AdventHealth acknowledges that, due to administrative error, the monthly reporting plan boxes were not properly checked/marked for the CAUTI, CLABSI, and VAE quality measures for the first quarter or CY 2018, and for the CDI quality measure for the second quarter of CY 2018. Accordingly, it is clear that AdventHealth failed to comply with prescribed "form and manner."

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).").

100 Operational Guidance for Long Term Care Hospitals to Report Central Line-Associated Bloodstream (CLABSI) Data to CDC's NHSN for the Purpose of Fulfilling CMS's Quality Reporting Requirements, 2 (Nov. 2014) (hereinafter "LTCH Operational Guidance to Report CLABSI Data to NHSN") (available at <a href="https://www.cdc.gov/nhsn/PDFs/CMS/LTCH-CLABSI-Guidance\_2015.pdf">https://www.cdc.gov/nhsn/PDFs/CMS/LTCH-CLABSI-Guidance\_2015.pdf</a>; Operational Guidance for Long Term Care Hospitals to Report Catheter-Associated Urinary Tract Infection (CAUTI) Data to CDC's NHSN for the Purpose of Fulfilling CMS's Quality Reporting Requirements, 2 (Nov. 2014) (available at <a href="https://www.cdc.gov/nhsn/PDFs/CMS/LTCH-CAUTI-Guidance\_2015.pdf">https://www.cdc.gov/nhsn/PDFs/CMS/LTCH-CAUTI-Guidance\_2015.pdf</a>; 101 LTCH Operational Guidance to Report CLABSI Data to NHSN at 2.

<sup>&</sup>lt;sup>102</sup> Ex. P-5 at 001 (emphasis added).

<sup>&</sup>lt;sup>103</sup> See supra note 99.

<sup>&</sup>lt;sup>104</sup> Provider's FPP at 16.

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The Board points out that, notwithstanding the admission in its reconsideration request, AdventHealth waivered during the hearing as to whether the unchecked/unmarked monthly reporting plan boxes was a result of an administrative error ("typo") or some other type of error ("system error"). When questioned if she "would ... accept that the most likely, given that you have no anecdotal or direct evidence of anybody at NHSN ever unchecking boxes and given that computers are not sentient, the most likely scenario is an administrative error led to the box being unchecked," AdventHealth's witness responded:

I wouldn't say that because I don't know. And to me, if the plan is not checked then wouldn't let me enter the data. So at some point, the plan was checked. It—was a typo on my part, sure. I'm human. Was it a computer glitch within [the CDC] NHSN [system]? Happens all the time with computer systems and data. It could be any of those scenarios. 105

During her testimony, the witness also agreed that the CDC NHSN system has certain requirements, such as checking/marking the appropriate boxes on the website, to ensure that the required data was transmitted to CMS from the CDC NHSN system, *and* that it was AdventHealth's responsibility to check/mark the appropriate boxes. <sup>106</sup> Further, in its request for reconsideration and its filings with the Board, AdventHealth acknowledges that the CDC NHSN system transmits data to CMS *according to the facility's monthly reporting plan*. <sup>107</sup> This testimony leads to only one conclusion: it is the facility's responsibility to check/mark the monthly reporting plan boxes and if the facility does properly not complete those plans to prompt the CDC NHSN system to transmit the data to CMS, then the CDC NHSN system has no way of knowing the facility wants/needs the data to be submitted to CMS. Accordingly, the Board finds that it is the LTCH's responsibility to properly complete the monthly reporting plan (including checking/marking the appropriate boxes) to prompt the CDC NHSN system to transmit the relevant underlying data to CMS and that AdventHealth failed to properly complete the monthly plans at issue, thereby causing the data for the months at issue *not* to be transmitted from the CDC NHSN system to CMS at the tolling of the relevant reporting deadlines.

AdventHealth asserts that two different court decisions "have treated data reported to one component of HHS as received by another component of HHS." Thus, based on these court cases, AdventHealth asserts "CMS possesses all required data from this Provider for the FY 2020 payment determination." The Board finds AdventHealth's argument (and the court cases cited in

 $<sup>^{105}</sup>$  Tr. at 106-107.

<sup>&</sup>lt;sup>106</sup> *Id.* at 109-110.

<sup>&</sup>lt;sup>107</sup> Ex. P-5 at 001 (copy of the Provider's August 7, 2019 reconsideration request stating: "it appears an administrative error was made and a few of the monitoring plan boxes were inadvertently not checked (CAUTI, CLABSI, VAE for Mar & Apr 2018 and CDI for May & Jun 2018) even though the data had been submitted. We believe this [*sic* is] why all data entered did not upload to CMS."); Provider's Post Hearing Brief at 20 (June 1, 2021) (stating: "The 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. CMS' guidance explains that the 'CDC submits the data to CMS on behalf of the facility, according to the facility's monthly reporting plan."" (emphasis omitted)). <sup>108</sup> Provider's Post-Hearing Brief at 24.

<sup>&</sup>lt;sup>109</sup> Provider's FPP at 18 (citing to *United States ex rel. Coyne v. Amgen, Inc.*, 229 F. Supp. 3d 159, 171 (E.D.N.Y. 2017) (concerning the False Claims Act); *In Def. of Animals v. Nat'l Institutes of Health*, 543 F. Supp. 2d. 70, 77 (D.D.C. 2008) (concerning the Freedom of Information Act).

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support) unpersuasive. The court cases cited related to the False Claims Act and the Freedom of Information Act<sup>110</sup> and did *not* concern quality data submissions that are required by statute to be submitted "in a form and manner, and at a time, specified by the Secretary."<sup>111</sup> For quality data submissions using the CDC NHSN system, the Secretary requires that the relevant boxes in the monthly reporting plan be checked to prompt the CDC NHSN system to transmit the associated underlying data from the CDC NHSN system to CMS. AdventHealth was aware of this requirement but failed to check/mark the relevant boxes in the monthly reporting plans at issue. As a result of the Provider's failure, CMS did not receive the required data at issue. The Provider's argument is akin to stating that the data was loaded into the online form but nobody pressed the "enter" or "save" button, as needed. This is a failure on the Provider's part to submit the data to CMS *in the form and manner* as required by the Secretary, not a failure of the CDC NHSN system or any non-CMS branch of HHS.

AdventHealth argues that, "[i]f CMS did not conclude that there was full compliance by the Provider with the [LTCHOR Program], then the evidence clearly supported a finding of 'extenuating circumstances' that required reversal of the payment penalty." However, the Board finds that the reconsideration process in place at 42 C.F.R. § 412.560(d) provides in paragraph (2)(vii) that an LTCHs reconsideration request "must contain . . . [a]ccompanying documentation that demonstrates compliance of the long-term care hospital with the LTCH QRP requirements."113 Similarly, the Board finds the 2015 Final Rule outlines what is required to be submitted by providers to CMS in order for CMS to review provider reconsideration requests and that CMS codified this process into 42 C.F.R. § 412.560(d) as part of the FY 2016 IPPS/LTCH Final Rule. However, it does not address the weight that CMS will give to the documentation submitted by providers. CMS made it clear in the FY 2015 Final Rule that it would not review any reconsideration requests that failed to provide the necessary documentation and evidence. Moreover, the regulation at 42 C.F.R. § 412.560(c) makes it clear that an LTCH must submit a request for an exemption or exception due to "extraordinary circumstances beyond the control of the [LTCH]" within 90 days of those circumstances occurring. 114 The Board recognizes that AdventHealth contends that the reconsideration process codified at § 412.560(d) requires that CMS reverse the initial finding of non-compliance if the reasons for requesting reconsideration are supported by documentation that demonstrates the LTCH's compliance with the quality reporting requirements. However, the Board finds that, although this may be true, as previously stated, AdventHealth failed to provide supporting documentation and evidence demonstrating full compliance with the LTCHQR Program requirements. Specifically, based on the record before it, it is clear that AdventHealth failed to check/mark the relevant boxes on the monthly reporting plans at issue for the CAUTI, CLABSI, and VAE quality outcome measures for the first and second quarter of CY 2018, and the CDI quality outcome measure for the second quarter of CY 2018, which resulted in the associated underlying data at issue not being transmitted from the CDC NHSN system to CMS. If those boxes were not properly checked/marked, then, compliance was not (and could not be) "full" since the data would not be transmitted/submitted to CMS.

<sup>&</sup>lt;sup>110</sup> See supra note 109.

<sup>&</sup>lt;sup>111</sup> 42 U.S.C. § 1395ww(m)(5)(C).

<sup>&</sup>lt;sup>112</sup> Provider's Post-Hearing Brief at 27.

<sup>113 (</sup>Emphasis added.)

<sup>114 (</sup>Emphasis added.)

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AdventHealth points to the discussion of the LTCH quality reporting reconsideration process in the preamble to the FY 2015 IPPS Final Rule and contends CMS should have found "extenuating circumstances" to excuse its failure to submit all the required data to CMS for a variety of reasons. First, the Provider states that it submitted all of the relevant data to NHSN, and the fact that the relevant data was not transmitted to CMS because not all of the monthly reporting plans were checked/marked by the Provider, is irrelevant. AdventHealth also asserts that the CDC NHSN system's software was inadequate because it did not notify or alert AdventHealth that the data submitted to the CDC NHSN system was not then transmitted to CMS and, therefore, did not prevent a penalty. As neither CMS nor the CDC NHSN system notified AdventHealth of the absence of the required data, prior to the deadline, AdventHealth claims that "extenuating circumstances" (as discussed in the preamble to the FY 2015 IPPS Final Rule) were present.

The Board disagrees with AdventHealth's position that it should be excused for its failure to comply with the LTCH QRP requirements. First, as AdventHealth acknowledged during the hearing, 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. The Board finds that AdventHealth *alone* has the responsibility for submitting the required data by the relevant quarterly deadline. AdventHealth does *not* dispute that CMS did not receive the following quality data *from the CDC NHSN system*: (1) its quality data for the CAUTI, CLABSI, and VAE outcome measures for the first *and* second quarters of CY 2018; and (2) its CDI outcome measure for the second quarter of CY 2018. AdventHealth 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, and also admitted that it failed to do so. The Board finds that AdventHealth admits that the required LTCHQR Program data was *not* timely reported *to CMS* and, thus, violated the LTCHQR Program reporting requirements.

Second, AdventHealth 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]."

<sup>115</sup> Provider's FPP at 25 (citing to 79 Fed. Reg. at 50317).

**Mr. Berends**: Okay. Can you point me to anything anywhere that requires or mandates that NHSN provide you with notification that the data is not going to be transmitted?

The Witness: I don't know that there is one.

\*\*\*\*

**Mr. Berends**: Understood. But you acknowledge that you're not aware of any requirement—**The Witness**: No.

**Mr. Berends**: --by NHSN to notify you that the data you submitted, the data you collected isn't going anywhere?

The Witness: Right.

Tr. at 108-109.

<sup>116</sup> Id. at 22.

<sup>&</sup>lt;sup>117</sup> *Id.* at 24.

<sup>&</sup>lt;sup>118</sup> *Id*.

<sup>&</sup>lt;sup>119</sup> AdventHealth's witness gave the following testimony during the hearing during cross-examination by the Medicare Contractor's representative, Mr. Berends:

<sup>&</sup>lt;sup>120</sup> 42 C.F.R. § 412.560(c). *See also* Ex. P-8 (June 8, 2020 print out of CMS website entitled "LTCH Quality Reporting Reconsideration and Exception & Extension" which refers to the "extraordinary circumstances beyond their control" standard and requires, as part of a reconsideration request the LTCH include "information supporting the LTCH belief

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Specifically, when the Secretary codified the processes for exceptions/extensions and reconsiderations into the LTCH QRP regulations (as explained above), the Secretary codified a narrower standard of "extraordinary circumstances beyond the control of the [LTCH]" as set forth in 42 C.F.R. § 412.560(c). This is consistent with the standard used elsewhere with other quality reporting programs<sup>121</sup> as well for extension of certain filing deadlines under Board processes. <sup>122</sup> Here, it is clear that AdventHealth'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. 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 CMS consideration is only triggered 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. 123 Here, neither review was triggered. First, AdventHealth did not timely request an exception/extension within 90 days of the triggering event (i.e., within 90 days of either August 15, 2018 or November 15, 2018 which are the reporting deadline for the first and second quarters of CY 2018 respectively). 124 Second, CMS did not consider (nor did AdventHealth raise) a systemic or regional issue in its reconsideration request.

Regardless, even if the standard were simply "extenuating circumstances" <sup>125</sup> and the Board were to have the authority to otherwise grant an exception/extension as part of the present Board appeal, <sup>126</sup> the evidence would not support a finding of "extenuating circumstances" affecting AdventHealth's non-compliance with the LTCHQR Program requirements. As discussed above, AdventHealth's attempts to demonstrate "extenuating circumstances" fell short as they failed to provide any basis which warrant a reversal of the 2 percentage point payment penalty. Accordingly, AdventHealth

that the non-compliance finding is error, or evidence of the impact of *extraordinary circumstances* that prevented timely submission of data" (emphasis added)).

<sup>&</sup>lt;sup>121</sup> 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)); skilled nursing facilities (42 C.F.R. §413.360(c)); ambulatory surgical centers (42 C.F.R. § 416.310(d)); hospital OPPS (42 C.F.R. §419.46(d)); home health agencies (42 C.F.R. §484.250(d)). 

<sup>122</sup> 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).

<sup>123</sup> It is unclear whether CMS *alone* has the authority to consider a exception/extension request due to "circumstances beyond the control of the [LTCH]" or justifiable excuse" or, 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.

124 The triggering event was AdventHealth's failure to properly complete the monthly reporting plans both for March and April 2018 by the reporting deadline for the first quarter of 2018 and for May and June of 2018 by the reporting deadline for the second quarter of 2018. 90 days from the reporting deadlines for the first and second quarters was November 13, 2018 and February 13, 2019, respectively. Indeed, AdventHealth did not explicitly make an exception/extension request in its August 7, 2019 reconsideration request.

<sup>&</sup>lt;sup>125</sup> 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 <a href="https://thelawdictionary.org/extenuating-circumstances/">https://thelawdictionary.org/extenuating-circumstances/</a> (last visited Sept. 23, 2023). <sup>126</sup> See supra note 123 and accompanying text.

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has 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.

The Board conducted an evidentiary hearing *de novo* and reached its own conclusions. As such, the Board will not address AdventHealth's remaining arguments related to the reconsideration stage and whether CMS failed to evaluate all of its evidence under both reconsideration standards of review.<sup>127</sup>

Based upon the testimony presented, the evidence admitted, and having considered the arguments presented in the context of Medicare law, regulations and guidance, the Board concludes that AdventHealth failed to fully comply with the LTCHQR Program requirements. Specifically, AdventHealth failed to *properly* submit data at issue to CMS in the form and *manner* and at a *time*, specified by the Secretary because it failed to check/mark all of the appropriate boxes in the monthly reporting plans at issue for the CAUTI, CLABSI, and VAE quality measures in the first and second quarters of CY 2018, and the CDI quality measure in the second quarter of CY 2018. Further, the Board finds that the evidence does not support a finding of extraordinary circumstance beyond its control (or even extenuating circumstances) affecting non-compliance that would potentially warrant considering 128 reversing the 2 percentage point payment penalty. The Board concludes that the payment penalty imposed by CMS under the LTCHQR Program to reduce AdventHealth's APU for FFY 2020 by 2 percentage points was proper.

# **DECISION:**

After considering Medicare law and regulations, arguments presented, and the evidence admitted, the Board finds that CMS properly reduced AdventHealth's APU for FY 2020 by 2 percentage points.

# **BOARD MEMBERS:**

Clayton J. Nix, Esq. Robert A. Evarts, Esq. Kevin D. Smith, C.P.A. Ratina Kelly, C.P.A.

### **FOR THE BOARD:**

9/27/2023

X Clayton J. Nix

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

<sup>&</sup>lt;sup>127</sup> See 42 C.F.R. § 405.1869(a), the Board has "the legal authority to fully resolve the matter in a hearing decision (as described in §§ 405.1842(f), 405.1867, and 405.1871 of this subpart)."

<sup>&</sup>lt;sup>128</sup> Per 42 C.F.R. § 412.560(c), "CMS *may* grant an exception or extension . . . ." (Emphasis added.)