# PROVIDER REIMBURSEMENT REVIEW BOARD DECISION

# HEARING ON THE RECORD 2023-D34

PROVIDER -DATE OF RECORD HEARING -Lubbock Heart Hospital LP June 2, 2022 PROVIDER NO. -FISCAL YEAR END -45-0876 2021 VS. **MEDICARE CONTRACTOR –** CASE NO. -Novitas Solutions, Inc. – (J-H) 21-0114 **INDEX** Page No. Statement of the Facts and Relevant Law...... 2 Discussion, Findings of Facts, and Conclusions of Law...... 6

Page 2 of 9 Case No. 21-0114

#### **ISSUE STATEMENT**

Whether, in connection with the hospital Inpatient Quality Reporting ("IQR") program, the Centers for Medicare and Medicaid Services' ("CMS") decision to reduce the Annual Percentage Update ("APU") to the Federal Fiscal Year ("FFY") 2021 Inpatient Prospective Payment System ("IPPS") for Lubbock Heart Hospital LP ("Provider" or "LHH") by one-fourth was correct?<sup>1</sup>

### **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' decision to reduce LHH's FFY 2021 IPPS APU by one-fourth, due to LHH's noncompliance with the hospital IQR program's validation requirements, was correct.

#### **INTRODUCTION**

LHH is an acute care hospital located in Lubbock, Texas.<sup>2</sup> The Medicare contractor<sup>3</sup> assigned to LHH for this appeal is Novitas Solutions, Inc. ("Medicare Contractor").

On May 28, 2020, CMS notified LHH that it failed to meet certain hospital IQR program requirements.<sup>4</sup> Specifically, CMS notified LHH that it "did not to meet the validation requirements for the clinical process measures" for the calendar year ("CY") 2019 reporting period, as required by federal law. LHH's failure to meet the validation requirements of the hospital IQR program resulted in CMS assessing a penalty for LHH's noncompliance; namely, CMS reduced LHH's FFY 2021 Inpatient Prospective Payment System ("IPPS") APU by one fourth. Following LHH's formal request that CMS reconsider its determination, CMS issued a July 13, 2020, reconsideration decision in which it upheld its finding of noncompliance and the resulting APU reduction penalty.

LHH timely appealed CMS' determination to the Board and met the jurisdictional requirements for a hearing. The Board approved a record hearing on June 2, 2022. LHH was represented by Nicole King of The Claro Group LLC. The Medicare Contractor was represented by Scott Berends, Esq. of Federal Specialized Services.

#### STATEMENT OF FACTS AND RELEVANT LAW

The Medicare program pays acute care hospitals for inpatient services under the IPPS, 8 which pays hospitals predetermined, standardized amounts per discharge, subject to certain payment

<sup>&</sup>lt;sup>1</sup> Provider's Final Position Paper ("Provider's FPP") at 2 (April 26, 2022).

 $<sup>^{2}</sup>$  Id.

<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 and relevant.

<sup>&</sup>lt;sup>4</sup> Exhibit P-2 at 1.

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

<sup>&</sup>lt;sup>6</sup> *Id*.at 3.

<sup>&</sup>lt;sup>7</sup> Exhibit P-4.

<sup>&</sup>lt;sup>8</sup> 42 U.S.C. § 1395ww(d); 42 C.F.R. Part 412. IPPS hospitals are often referred to as "subsection (d) hospitals."

Page 3 of 9 Case No. 21-0114

adjustments.<sup>9</sup> Hospitals receive an annual percentage increase in the standardized amount, known as the "market basket update," or APU, to account for increases in operating costs. <sup>10</sup>

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003<sup>11</sup> amended 42 U.S.C. § 1395ww(b)(3)(B) to establish the hospital IQR program that requires every hospital to submit quality of care data "in a form and manner, and at a time, specified by CMS." For fiscal years 2015 and beyond, CMS reduces the hospital's annual IPPS APU by one-fourth if a hospital fails to report the quality data required under the hospital IQR program. <sup>13</sup>

In order to meet the hospital IQR program requirements, IPPS hospitals must submit quality data as specified by the Secretary:

(II) Each subsection (d) hospital shall submit data on measures selected under this clause to the Secretary *in a form and manner, and at a time, specified by the Secretary* for purposes of this clause. The Secretary may require hospitals to submit data on measures that are not used for the determination of value-based incentive payments under subsection (o). <sup>14</sup>

At issue in this case are two quality measures relating to catheter-associated urinary tract infection ("CAUTI") and central line-associated blood stream infection ("CLABSI"). CMS established QualityNet<sup>15</sup> to facilitate the process of quality data submission for IPPS hospitals under the IQR program.<sup>16</sup> QualityNet is utilized for secure communications and healthcare quality data exchange between: quality improvement organizations, hospitals, physician offices, nursing homes, end stage renal disease networks and facilities, and data vendors.

Following submission of the requisite quality data for a given reporting year under the IQR Program, CMS selects certain hospitals to validate the quality data submitted as required by statute:

(XI) The Secretary shall establish a process to validate measures specified under this clause as appropriate. Such process shall include the auditing of a number of randomly selected hospitals sufficient to ensure validity of the reporting program under this

<sup>&</sup>lt;sup>9</sup> 42 C.F.R. Part 412.

<sup>&</sup>lt;sup>10</sup> 42 U.S.C. § 1395ww(b)(3). *See also* 42 C.F.R. §413.40(a)(3) (stating, in part: "Market basket index is CMS's projection of the annual percentage increase in hospital inpatient operating costs. The market basket index is a wage and price index that incorporates weighted indicators of changes in wages and prices that are representative of the mix of goods and services included in the most common categories of hospital inpatient operating costs...").

<sup>&</sup>lt;sup>11</sup> Pub. L. No. 108-173, 117 Stat. 2066 (2003).

<sup>&</sup>lt;sup>12</sup> *Id.* at § 501, 117 Stat. at 2290; 42 C.F.R. § 412.140(c)(1).

<sup>&</sup>lt;sup>13</sup> See 42 U.S.C. § 1395ww(b)(3)(B)(viii)(I); 42 C.F.R. § 412.64(d)(2)(i)(C).

<sup>&</sup>lt;sup>14</sup> 42 U.S.C. § 1395ww(b)(3)(B)(viii)(II) (emphasis added).

<sup>&</sup>lt;sup>15</sup> See <a href="http://www.qualitynet.org/">http://www.qualitynet.org/</a>.

<sup>&</sup>lt;sup>16</sup> See 69 Fed. Reg. 48916, 49078 (Aug. 11, 2004) (stating that a provider must submit their data to the Quality Improvement Organization ('QIO') Clinical Warehouse using the "CMS Abstraction & Reporting Tool (CART), the JCAHO Oryx Core Measures Performance Measurement System (PMS), or another third-party vendor" and that "[t]he QIO Clinical Warehouse will submit the data to CMS on behalf of the hospitals . . . . [t]hrough QualityNet Exchange").

Page 4 of 9 Case No. 21-0114

clause as a whole and shall provide a hospital with an opportunity to appeal the validation of measures reported by such hospital.<sup>17</sup>

The regulation at 42 C.F.R. § 412.140(d) sets forth the validation requirement under the hospital IQR Program, stating:

- (d) *Validation of Hospital IQR Program data*. CMS may validate one or more measures selected under section 1886(b)(3)(B)(viii) of the Act by reviewing patient charts submitted by selected participating hospitals.
- (1) Upon written request by CMS or its contractor, a hospital must submit to CMS a sample of patient charts that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the patient charts to CMS or its contractor within 30 days of the date identified on the written request.
- (2) (i) A hospital meets the chart-abstracted validation requirement with respect to a fiscal year if it achieves a 75-percent score, as determined by CMS.
- (ii) A hospital meets the eCQM validation requirement with respect to a fiscal year if it submits at least 75 percent of sampled eCQM measure medical records in a timely and complete manner, as determined by CMS.

Here, LHH failed to achieve a 75-percent score on the CAUTI and CLAPSI quality measures selected for chart-abstracted validation for the CY 2019 reporting period.

The parties have filed a Joint Stipulation of Facts, and have also agreed to the authenticity of, and entered into evidence, Stipulated Exhibits A through G. The Joint Stipulation of Facts states:

- 1. The Provider is required to comply with the requirements of the Hospital Inpatient Quality Reporting Program ("IQR") as outlined in 42 U.S.C. §1395ww(b)(3)(B)(viii). See Exhibit A.
- 2. Provider requirements and data specifications for the Inpatient Quality Reporting Program are outlined in Version 5.5a Specifications Manual for discharges 01/01/2019 06/30/2019. Healthcare-Associated Infection (HAI) measure data are collected by the Centers for Disease Control and Prevention (CDC) via the National Healthcare Safety Network (NHSN) tool. See Exhibit B.

<sup>&</sup>lt;sup>17</sup> 42 U.S.C. § 1395ww(b)(3)(B)(viii)(XI).

Page 5 of 9 Case No. 21-0114

3. CAUTI and CLABSI chart abstracted measures are included in the Hospital Inpatient Quality Reporting Program per 83 FR 41608 (August 17, 2018). See Exhibit C.

- 4. Provider is required to comply with validation requirements as outlined in the IQR Program FY20 Guide Fiscal Year 2021 Payment Determination/ Calendar Year 2019 Reporting Period, Section 10 "Meet Validation Requirements (If Hospital Is Selected for Validation)". See Exhibit D.
- 5. Provider submitted Request for Reconsideration Form, which stated a clerical error was made on the validation template. See Exhibit E.
- 6. The penalty for non-compliance is pursuant to 42 U.S.C. §1395ww(b)(3)(B)(viii) [See Exhibit A], which states:
- "...a subsection (d) hospital that does not submit, to the Secretary in accordance with this clause, data required to be submitted on measures selected under this clause with respect to such a fiscal year, the applicable percentage increase under clause (i) for such fiscal year shall be reduced by 2.0 percentage points (or, beginning with fiscal year 2015, by one- quarter of such applicable percentage increase (determined without regard to clause (ix), (xi), or (xii)))."

Provider agrees that the use of the "shall" rather than the word "may" is instructive that the intent of Congress was to impose the penalty for non-compliance with the reporting requirements with no discretion afforded to the Secretary except as described in 42 C.F.R. §419.46.

- 7. CMS may grant exemptions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred pursuant to 42 C.F.R. §419.46 (See Exhibit F) which states:
- (e) Exception. CMS may grant an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an exception as follows:
- (1) Upon request by the hospital. Specific requirements for submission of a request for an exception are available on the QualityNet Web site.
- (2) At the discretion of CMS. CMS may grant exceptions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred.

Page 6 of 9 Case No. 21-0114

> 8. The QualityNet Help Desk assists providers with technical issues, such as sending and receiving files in the QualityNet Secure Portal and QualityNet registration as stated in the "IQR Program FY20 Guide." See Exhibit G.

LHH admits it made a mistake when entering the location of attribute, as required in the IQR protocol:

> On July 24, 2019, [LHH's] Director of Quality entered validation templates [Exhibits P-12 and P-13] containing the incorrect location of attribute, assigning the secondary reviewer to review for accuracy per [LHH's] established review process.

Despite [LHH's] responses to all requests and instructions communicated by the QNet Helpdesk, the secondary reviewer's access into QualityNet was not resolved until the day of the template submission deadline of August 01, 2019 [Exhibit P14.27]. 18

The dispute in this appeal is whether LHH met the IQR program validation requirements related to the FFY 2021 hospital IQR Prospective Payment System APU determination.

# DISCUSSION, FINDINGS OF FACT, AND CONCLUSIONS OF LAW

In order to meet each of the hospital Inpatient QRP requirements, hospitals must submit quality data "in a form and manner, and at a time, specified by the Secretary" and, if selected, meet the chart-abstracted validation requirements.<sup>19</sup>

The hospital IQR program regulations permit CMS to grant exceptions to the reporting requirements in the event of extraordinary circumstances beyond the control of the provider. CMS may grant such an exception pursuant to 42 C.F.R. § 412.140(c)(2), which states:

- (2) Extraordinary circumstances exceptions. CMS may grant an exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the hospital. CMS may grant an exception as follows:
- (i) For circumstances not relating to the reporting of electronic clinical quality measure data, a hospital participating in the Hospital IQR Program that wishes to request an exception with respect to quality data reporting requirements must submit its request to CMS within 90 days of the date that the extraordinary circumstances occurred. For circumstances relating to the reporting of electronic clinical quality measures, a hospital participating in the Hospital IQR Program that wishes to request an exception must submit its request to CMS by April 1 following the end of the reporting calendar year in which the extraordinary circumstances occurred.

<sup>&</sup>lt;sup>18</sup> Provider's FPP at 4.

<sup>&</sup>lt;sup>19</sup> 42 U.S.C. § 1395ww(b)(3)(B)(viii)(II), (IX) (emphasis added).

Page 7 of 9 Case No. 21-0114

Specific requirements for submission of a request for an exception are available on QualityNet website.

(ii) CMS may grant an exception to one or more hospitals that have not requested an exception if CMS determines that a systemic problem with CMS data collection systems directly affected the ability of the hospital to submit data; or if CMS determines that an extraordinary circumstance has affected an entire region or locale.<sup>20</sup>

LHH asserts it made every attempt to ensure the accuracy and timeliness of the data submitted. Further, it claims that, by "implementing a secondary review" in the HAI monitoring and reporting process, it ensures that the data is accurately reported. In April 2019, LHH asserts that the secondary review enabled it to identify inaccuracies, make the correction, and achieve "accurately reported" data in a timely manner. However, LHH failed to identify who corrected those inaccuracies, raising questions as to whether the quality submission process is consistently followed.

LHH also claims that the QNet Helpdesk hindered its ability to make corrections which would have eliminated the data entry error that resulted in the below-target validation rate. LHH explains that on July 10, 2019, the secondary reviewer experienced difficulty with its login credentials when trying to access QNet. It contacted the QualityNet Helpdesk as instructed in the FY20 IQR Program Guide. LHH "attempted to resolve the QNet technical issues with the QualityNet helpdesk on several occasions, but the issue was not resolved." As explained in its Final Position Paper, LHH claims that, despite following all QNet Helpdesk instructions, the secondary reviewer's access into QualityNet was "not resolved until the day of the template submission deadline of August 1, 2019." However, LHH confirms the issue was resolved August 1, 2019, the day of the deadline, but fails to explain why its secondary reviewer did not log in *on August 1, 2019*, and correct the location of attribute, once the access issue was resolved.

LHH "does not dispute the material facts of this case," rather it asserts there were "extraordinary events that occurred outside of [its] control" which caused the deadline to be missed. LHH claims that the evidence "demonstrates [its] due diligence and extraordinary circumstance, [and that] these factors outside of [its] control…may qualify for exception as enumerated in 42 C.F.R. § 419.46."

The Medicare Contractor's position is that LHH could have submitted or corrected the data in question, but failed to do so. After reviewing LHH's "Quality Net Support Team Communications Timeline" and the supporting documentation at Exhibit P-14, the Medicare Contractor points out that this evidence focuses solely on resolving the secondary reviewer's technical problem of not being able to log into QNet. The Medicare Contractor also notes that LHH does not discuss any

<sup>&</sup>lt;sup>20</sup> The Board notes that the parties refer to the exception regulation at 42 C.F.R. § 419.46 in their Stipulation of Facts and briefs, however, this regulation is applicable to the Outpatient Hospital Quality Reporting Program.

<sup>&</sup>lt;sup>21</sup> Provider's FPP at 4.

<sup>&</sup>lt;sup>22</sup> Provider's FPP at 5.

<sup>&</sup>lt;sup>23</sup> Provider's FPP at 4. See also Exhibit P-22.

<sup>&</sup>lt;sup>24</sup> Provider's FPP at 4. See also Exhibits P-14.1 through P-14.27.

<sup>&</sup>lt;sup>25</sup> Provider's FPP at 4.

<sup>&</sup>lt;sup>26</sup> *Id.* at 5.

<sup>&</sup>lt;sup>27</sup> *Id.* at 5-6.

Page 8 of 9 Case No. 21-0114

attempt to utilize "an alternative method to verify the submitted information given the situation of the secondary reviewer's login difficulty." <sup>28</sup>

The Medicare Contractor notes that LHH did not make the same correction in April 2019 to its incorrect Critical Care Unit location entries when it learned in July 2019 that validation templates containing an incorrect location of attribute had been entered.<sup>29</sup> The Medicare Contractor argues this demonstrates that, "although the secondary reviewer lacked system access, the Director of Quality did have appropriate access, and, given the experience with location corrections three months earlier, could, and should have, sought alternative means to ensure the accuracy of the QNet entry."<sup>30</sup> It is the Medicare Contractor's position that LHH "allowed the unreviewed (incorrect) data to remain until after the submission deadline had passed. And, in doing so, disregarding [sic] the "best practice" of secondary review."<sup>31</sup>

The Medicare Contractor contends that LHH is at fault for the failure to submit accurate and timely data, and that "[LHH] fully admits that it was responsible for the incorrect data entry."<sup>32</sup> The Medicare Contractor claims the technical difficulties experienced by LHH "do not excuse [it] from its duty to submit accurate data in a timely manner,"<sup>33</sup> and the incorrect entry of data (and lack of correction) were *not* circumstances which are "extraordinary" or "outside of the provider's control."<sup>34</sup>

The Medicare Contractor's argument is essentially one of strict liability supported by the applicable statutory and regulatory language. The Statute requires the Secretary to establish a process to validate the hospital **IQR** measures<sup>35</sup> and, by LHH's own admission, it submitted erroneous data that it failed to correct *prior to* the submission deadline.<sup>36</sup>

The Board finds that the failure to accurately complete the quality measures data entry was fatal to LHH's successful compliance with the hospital IQR program requirements for its FY 2021 payment determination. The Statute is clear that all data shall be submitted "in a form and manner, and at a time, specified by the Secretary."<sup>37</sup> Further, CMS regulations state that "CMS may validate one or more measures"<sup>38</sup> and that, "[u]pon written request by CMS or its contractor, a hospital must submit to CMS a sample of patient charts that the hospital used for purposes of data submission under the program."<sup>39</sup>

The Board acknowledges that the technical difficulties experienced by LHH's secondary reviewer appear not to have been resolved until the day of the deadline, August 1, 2019.<sup>40</sup> However, the technical difficulties experienced by the secondary reviewer do not amount to an "extraordinary circumstance" such as a *systemic* problem with one of CMS' data collection systems and, again,

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28 Medicare Contractor's Final Position Paper ("Medicare Contractor's FPP") at 8 (May 18, 2022).
29 Id. See also Exhibits P-7 through P-10.
30 Id. at 9.
31 Id.
32 Id.
33 Id.
34 Id.
35 42 U.S.C. 1395ww(b)(3)(B)(viii)(XI).
36 Provider's FPP at 4.
37 42 U.S.C. § 1395ww(b)(3)(B)(viii) (2017) (emphasis added).
38 42 C.F.R. 412.140(d).
39 42 C.F.R. 412.140(d)(1).
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<sup>40</sup> See infra note 41.

Page 9 of 9 Case No. 21-0114

LHH to explain why its secondary reviewer did not log in *on that same day* (after her access issue was resolved on August 1, 2019), to correct the location of attribute.<sup>41</sup> In fact, there is no evidence in the record of a *systemic* problem with the quality data collection system which would have prevented LHH from properly submitting the required quality data within the required timeframe. Further, LHH demonstrated, in April of 2019, that its internal surveillance process was capable of identifying and correcting data inaccuracies.<sup>42</sup>

Based on the statute, regulations and guidance identified above, the Board finds it is not sufficient to simply submit data, rather, the submitted data must be accurate and capable of being verified, in order to meet the requirements of the hospital IQR program. The validation audit confirms that LHH failed to *accurately* report the required quality data "to the Secretary *in a form and manner, and at a time, specified by the Secretary.*" Accordingly, the Board concludes that LHH failed to meet the validation requirements of the hospital IQR program for the CY 2019 reporting period and, therefore, LHH is subject to a one-fourth reduction to its APU for FFY 2021, pursuant to 42 C.F.R. § 412.64(d)(2)(i)(C).

#### **DECISION AND ORDER**

After considering Medicare law and regulations, the arguments presented, and the evidence admitted, the Board finds that CMS' decision to reduce LHH's FFY 2021 hospital IQR PPS APU by one-fourth was correct.

## **BOARD MEMBERS PARTICIPATING:**

FOR THE BOARD:

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

9/26/2023

X Clayton J. Nix

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

<sup>&</sup>lt;sup>41</sup> The Board's review of the email correspondence with QNet Support suggests that the technical issue was resolved on July 30, 2019 and that the reviewer was then able to log-in at some point on or after 4:26 pm EDT on July 30, 2019. Ex. P- 14 at 14.26. It is unclear what happened on the remainder of July 30<sup>th</sup> and on the next day July 31<sup>st</sup> (no testimony was presented). Regardless, the Provider's FPP at 4 confirms that, two days later, as of August 1, 2019, it had been able to log in. *See also* 42 C.F.R. § 405.1871(a)(3) (stating: "The decision must include findings of fact and conclusions of law regarding the Board's jurisdiction over each specific matter at issue (see § 405.1840(c)(1)), and whether the provider carried *its burden of production of evidence and burden of proof by establishing*, *by a preponderance of the evidence*, that the provider is entitled to relief on the merits of the matter at issue." (emphasis added)).

<sup>&</sup>lt;sup>42</sup> Provider's FPP at 4 (stating "Lubbock Heart Hospital's internal Hospital Acquired Infections ("HAI") surveillance process of Identifying Hospital Acquired Events incorporates a second reviewer, which is recognized as best practice to achieve accurate data submissions [EXHIBIT P-6]. Implementing a secondary review is a critical element in the HAI monitoring and reporting process to ensure the accuracy of the data reported. This process has demonstrated its effectiveness during the CY Q1 reporting period, when it was identified that the location of attribute entered for both events in NHSN on February 7, 2019, that which was Critical Care Unit (CCU), was incorrectly entered as a non-CCU location [Exhibits P-7 and P-9]. After the secondary reviewer identified the inaccuracies, the HAI events were reviewed by the Infection Prevention Committee on May 30, 2019 [EXHIBIT P-11]. On April 12, 2019, the correct location of attribute was updated for both the CAUTI and CLABSI events in NHSN [EXHIBITS P-8 and P-10], achieving accurately reported data submission by the August 15, 2019 deadline [EXHIBIT P-16].").

<sup>43</sup> 42 U.S.C. § 1395ww(b)(3)(B)(viii) (emphasis added).