#### PROVIDER REIMBURSEMENT REVIEW BOARD DECISION

2024-D26

**PROVIDER** – Marshall Medical Center

**PROVIDER NO**. – 05-0254

vs.

**MEDICARE CONTRACTOR** – Noridian Healthcare Solutions c/o Cahaba Safeguard Administrators HEARING HELD – May 11, 2023

FISCAL YEAR-2021

**CASE NO.** – 21-0412

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DECISION

## **ISSUE STATEMENT:**

Whether the Centers for Medicare and Medicaid Services ("CMS") properly determined that the federal fiscal year ("FFY") 2021 payment update to the inpatient prospective payment system ("IPPS") for the hospital should be reduced by one fourth<sup>1</sup> because the hospital allegedly did not meet the quality data submission requirements for the Hospital Inpatient Quality Reporting program.<sup>2</sup>

# **DECISION**:

After considering Medicare law and regulations, the arguments presented, and the evidence admitted, the Provider Reimbursement Review Board ("Board") finds that CMS properly imposed the annual payment update ("APU") penalty, in accordance with 42 C.F.R. § 412.64(d)(2)(i)(C).

## **INTRODUCTION:**

Marshall Medical Center ("Marshall" or the "Provider") "is a general acute care hospital located in Placerville, California."<sup>3</sup> Marshall's designated Medicare contractor<sup>4</sup> is Noridian Healthcare Solutions c/o Cahaba Safeguard Administrators ("Medicare Contractor").

[BOARD MEMBER]: [....] Provider states the issue as follows: Whether CMS properly determined that the hospital's federal fiscal year 2021 hospital IPPS payment update should be reduced by 0.6 percent because the hospital allegedly did not meet the quality data submission requirements for the Hospital Inpatient Quality Reporting program. Mr. Roth, does that properly reflect the Provider's issue statement?

MR. ROTH: Yes, it does, Mr. Evarts.

<sup>3</sup> Provider's Final Position Paper (hereinafter "Provider's FPP") at 1.

<sup>4</sup> CMS's 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>1</sup> While Marshall's original issue statement asks whether the FFY 2021 hospital IPPS payment update should be reduced by six-tenths of a percent (0.6%), for clarity, the Board will use "one fourth" to conform to the language of 42 C.F.R. § 412.64(d)(2)(i)(C) (10-1-2019). The Market Basket Rate-of-Increase for FFY 2021 is two and four-tenths percent (2.4%). 85 Fed. Reg. 58432, 58798 (Sept. 18, 2020) ("FY 2021 Applicable Percentage Increases for the IPPS"). Thus, the Adjustment for Failure to Submit Quality Data under 42 U.S.C. § 1395ww(b)(3)(B)(viii) is one-fourth of 2.4% (*i.e.*, minus six-tenths of a percent (-0.6%)).

<sup>&</sup>lt;sup>2</sup> The Parties identified different issue statements for the matter to be heard by the Board. *See* Transcript (hereinafter "Tr.") at 7-8:

<sup>[</sup>BOARD MEMBER]: Thank you. The Medicare Contractor asserts the issue is whether the payment penalty imposed by CMS under the Hospital Inpatient Quality Reporting program to reduce the Provider's federal fiscal year 2021 annual payment update by one-fourth was proper. Mr. Bauers, does that properly reflect the Contractor's issue statement? MR. BAUERS: Yes, it does.

Marshall also raised the issue that because of the Medicare Contractor's decision, Marshall is excluded from participating in the FFY 2021 Hospital Value Based Purchasing Program ("HVBPP"). *See* Provider's Response to the Medicare Contractor's Final Position Paper ("Provider's Response" at 2 (Apr. 10, 2023). Because participation in HVBPP is relevant only in the context of the amount in controversy, and the Board does not find in favor of Marshall, the Board elects not to make any findings on the impact of Marshall's exclusion.

CMS reviews all Hospital Inpatient Quality Reporting ("IQR") Program requirements to make APU decisions. CMS notifies hospitals subject to Hospital IQR Program payment reductions in two (2) phases. Only Phase 2 is at issue in this appeal and it includes the following IQR Program requirements:

- Maintenance of an active QualityNet Security Administrator, regardless of whether the hospital submits data directly or uses a vendor
- Submission of aggregate initial patient population and sample size counts each quarter by the posted submission deadlines (Quarter [Q]4 2019)
- Submission of data for each required clinical process measure, including Perinatal Care (PC-01), each quarter by the posted submission deadlines (Q4 2019)
- Submission of Healthcare-Associated Infection (HAI) data to the National Healthcare Safety Network (NHSN) each quarter by the posted submission deadlines (Q4 2019)
- Submission of Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey data each quarter by the posted deadline (Q1 2019, Q2 2019, Q3 2019, and Q4 2019)
- Submission of data for at least four electronic clinical quality measures (eCQMs) for one self-selected quarter by the posted submission deadline (Q1 2019, Q2 2019, Q3 2019, or Q4 2019)
- Completion of the annual Data Accuracy and Completeness Acknowledgement (DACA) between April 1 and May 15, 2020
- Chart-Abstracted Data Validation: Achievement of a confidence interval validation score of 75 percent or greater (only for hospitals selected for this year's chart abstracted validation reviews)
- eCQM Data Validation: Timely and complete submission of at least 75 percent of the records CMS requested (only for hospitals selected for this year's eCQM validation reviews)<sup>5</sup>

To receive the full APU for FFY 2021 reimbursement under the Hospital IQR program, hospitals such as Marshall were required to submit data on certain quality measures during calendar year ("CY") 2019. By letter dated May 28, 2020, CMS notified Marshall that during the Phase 2 review, it was determined that Marshall failed to submit at least one quarter of at least four (4) electronic Clinical Quality Measures ("eCQM") data by the submission deadline for CY 2019 and, as a result, Marshall's FFY 2021 Inpatient Prospective Payment System ("IPPS") APU would be

<sup>&</sup>lt;sup>5</sup> Exhibit (hereinafter "Ex.") C-1 at 3 (CMS' Phase 2 APU Update Notification Letter (May 28, 2020)).

reduced by one fourth.<sup>6</sup> By letter dated June 11, 2020, Marshall sought reconsideration of the determination;<sup>7</sup> however, on July 13, 2020, CMS upheld its decision.<sup>8</sup> On December 23, 2020, Marshall timely appealed CMS's reconsideration decision to the Board, and met the jurisdictional requirements for a hearing before the Board.<sup>9</sup>

The Board conducted a live video hearing on May 11, 2023. Marshall was represented by Robert Roth, Esq. and Sven Collins, Esq. of Hooper, Lundy, & Bookman. The Medicare Contractor was represented by Joseph Bauers Esq., of Federal Specialized Services. At the hearing, the Board received testimony from Mr. Eric Schwagerus, a Clinical Informatics Analyst for Marshall.

# **STATEMENT OF RELEVANT FACTS:**

In September 2019, CMS gave notice on the QualityNet Secure Portal ("the Portal")<sup>10</sup> of a new navigation and submission process that would be used by IPPS hospitals for the submission of their CY 2019 IQR quality data by certain deadlines in 2020 for purposes of FFY 2021 reimbursement.<sup>11</sup> On November 20, 2019, CMS hosted a presentation, "Submitting CY 2019 eCQM Data Using CMS' Next Generation Hospital Quality Reporting System" which was attended by Marshall's IQR data submitter ("submitter").<sup>12</sup>

Marshall was required to submit data for at least four (4) eCQMs, for at least one (1) self-selected quarter of CY 2019, by the submission deadline of March 2, 2020 to satisfy the IQR Program requirements and receive a full FFY 2021 APU.<sup>13</sup> On February 24, 2020, Marshall's submitter uploaded the eCQMs for CY 2019 quality data into the Portal.<sup>14</sup> Later that day, Marshall's submitter ran a Program Credit Report in an attempt "to confirm that the data had been properly uploaded to the system and that there were no data errors; [however, the] Program Credit Report<sup>15</sup> showed there was "no data available" on the [P]ortal relating to the submission . . . of the Hospital's CY 2019 quality data."<sup>16</sup>

<sup>&</sup>lt;sup>6</sup> Ex. P-1 at 4 (CMS's Preliminary Decision re: audit of Marshall's Hospital Inpatient Quality Reporting ("IQR") Program data for FFY 2021, dated May 28, 2020).

<sup>&</sup>lt;sup>7</sup> Ex. P-16 (Marshall's Jun. 11, 2020 APU Reconsideration Request) (duplicates Ex. C-2).

<sup>&</sup>lt;sup>8</sup> Ex. P-2 at 2 (CMS final decision re: audit of Marshall's IQR Program data for FFY 2021, dated Jul. 13, 2020).

<sup>&</sup>lt;sup>9</sup> Ex. P-3 at 1 (Copy of Marshall's issue statement filed on Dec. 23, 2020). See also Provider's FPP at 1-2.

 <sup>&</sup>lt;sup>10</sup> See infra Statement of the Relevant Law at Subsection C (discussing submission requirements in more detail).
<sup>11</sup> See Ex. P-5. This exhibit is the eCQM Next Generation of Hospital Quality Reporting Navigation Guide, Fall 2019 (hereinafter "the 2019 QualityNet Update").

<sup>&</sup>lt;sup>12</sup> Ex. P-6 (CMS Presentation Transcript dated Nov. 20, 2019 entitled "Submitting CY 2019 eCQM Data Using

CMS' Next Generation Hospital Quality Reporting System"); Ex. P-25 at ¶ 4 (Declaration of Eric Schwagerus).

<sup>&</sup>lt;sup>13</sup> See infra Statement of the Relevant Law at Subsection B (explaining IQR Program Requirements in more detail). <sup>14</sup> Ex. P-25 at ¶ 7.

<sup>&</sup>lt;sup>15</sup> In response to Board questions during the Hearing, the witness testified that the "program credit report" he referred to is the interoperability program credit report. The witness clarified that there is a separate QR credit report. *See* Tr. at 50-51. "Once quality data has been submitted using the Portal, the submitter can confirm that the submission is complete and has been accepted by CMS by obtaining a Program Credit Report from the Portal. For each clinical quality measure that an IPPS hospital is required to submit for the IQR program, the Program Credit Report shows the submission status, including when it was last updated." Provider's FPP at 5.

<sup>&</sup>lt;sup>16</sup> Ex. P-25 at ¶ 7.

On February 27, 2020, Marshall's submitter contacted a QualityNet Service Desk representative to determine why the Program Credit Report did not reflect the February 24, 2020 submission.<sup>17</sup> The QualityNet Service Desk representative confirmed their conversation in an email stating:

Today you called to inquire about a QualityNet Submission Issue you are having with the eCQM data. I advised the Program Credit Report will only provide how uploaded data applies toward program credit. I advised [*sic* you] will want to track the status and validation of EHR Patient files through the eCQM tab. Files – Production – shows matching batch ID and an excel spreadsheet to advise of any errors.<sup>18</sup>

Also on February 27, 2020, Marshall's submitter "checked the batch ID and did not find any errors listed."<sup>19</sup> Marshall's submitter, based on his conversation with the QualityNet Service Desk representative, assumed the system had not yet been updated to reflect his February 24, 2020 submission.<sup>20</sup>

On March 2, 2020 (the deadline for the submission of its CY 2019 IQR and PI Program quality data), Marshall's submitter once again "checked the Hospital Quality Reporting section of the CMS website."<sup>21</sup> This time, he found that Marshall had received a passing score of sixty-eight (68) for the PI Program for the CY 2019 hospital quality data for purposes of the FFY 2021 IPPS update.<sup>22</sup> However, the witness states that its submission was still showing as incomplete:

When I rechecked the Hospital's PI Program Credit Report later on March 2, 2020, the Report inexplicably still indicated there was "no data available" for purposes of compliance with IQR and PI Program requirements for FFY 2021 and the Hospital's PI Attestation Report indicated the Hospital's submission was "Incomplete."<sup>23</sup>

Later, on March 2, 2020, Marshall's submitter called the QualityNet Service Desk noting that it "had received a passing score for the PI Program and . . . expected a similar passing score for the IQR program."<sup>24</sup> On that same day, the QualityNet Service Desk sent an email response stating:

At this time, we do not have an ETA when the PI Submission Summary reports will be corrected with the Sub-Status reflecting your passing score. It is said it will not be until after the deadline,

<sup>&</sup>lt;sup>17</sup> Ex. P-25 at ¶ 8.

<sup>&</sup>lt;sup>18</sup> Ex. P-9 (Feb. 27, 2020 email from QualityNet Service Center concerning Case CS0801461 Ticket). *See also* Ex. P-25 at ¶ 8.

<sup>&</sup>lt;sup>19</sup> Ex. P-25 at ¶ 8.

<sup>&</sup>lt;sup>20</sup> Id. See also Provider's FPP at 8.

<sup>&</sup>lt;sup>21</sup> *Id.* at ¶ 9.

<sup>&</sup>lt;sup>22</sup> Ex. P-10 (screenshot of the Hospital Quality Report showing score of 68 for Quality Data for PI Program for FFY 2021). See also Ex. P-25 at ¶ 9.

<sup>&</sup>lt;sup>23</sup> Ex. P-25 at ¶ 10.

<sup>&</sup>lt;sup>24</sup> Id. See also Provider's FPP at 8-9; Ex. P-11 (copy of the CMS Report for Incident INC0155659).

until then we ask that you hold onto the report and the screenshot of your completed Objectives with the passing score. This will be all the proof you need at this time.

I am going to create an incident in your name and attach it to the parent incident. You will receive a notification that this case is closed and another that a new incident was opened in its place. Please use this new incident number in all future correspondence.<sup>25</sup>

At this point, Marshall's submitter testifies that he believed that the hospital had met the submission requirements for *both* the PI Program and the IQR Program based on the QualityNet Service Desk representative's March 2, 2020 email and the representative not indicating any additional steps were needed to submit quality data for the IQR Program.<sup>26</sup>

On March 17, 2020, the QualityNet Service Desk sent Marshall's submitter an email stating:

Thank you for contacting the QualityNet Helpdesk in regards to the Promoting Interoperability Attestation Summary Report Objective Sub-Status showing incomplete.

A fix was deployed into production last night and the report is now showing completed for the Objective Sub-Status.<sup>27</sup>

On April 21, 2020, Marshall filed an Extraordinary Circumstance Exception ("ECE") requesting an extension for the IQR eCQM submission.<sup>28</sup> Marshall provided the following justification for the submission restart date:

Already submitted eCQM files through Qnet, screen shot attached. Apparantly [*sic*] it didn't get counted for IQR though so could resubmit any time.<sup>29</sup>

In addition, Marshall provided the following reasons for requesting the extension:

Requesting extension for IQR eCQM submission. eCQMs for 2Q 2019 already submitted but only got counted towards Promoting Interoperability and not IQR. Could submit again any time.<sup>30</sup>

<sup>&</sup>lt;sup>25</sup> Ex. P-12 (the QualityNet Service Center Mar. 2, 2020, 8:11 P.M. EST email for HQR Case CS0804773). *See also* Ex. P-25 at ¶ 10.

<sup>&</sup>lt;sup>26</sup> Ex. P-25 at ¶ 11.

<sup>&</sup>lt;sup>27</sup> Ex. P-13 (Mar. 17, 2020 email from the QualityNet Helpdesk to Eric Schwagerus at Marshall).

 <sup>&</sup>lt;sup>28</sup> Ex. P-14 (Apr. 21, 2020 Extraordinary Circumstances Exceptions (ECE) Request Form completed by Marshall).
<sup>29</sup> Id. at 2 of 7.

<sup>&</sup>lt;sup>30</sup> *Id.* Marshall provided a screen shot at Ex. P-14 of what Marshall refers to as the "IQR eCQM submission." The Board notes that the referenced screen shot is entitled "Promoting Interoperability." Pages 5-6 of this exhibit show a page with the header "Promoting Interoperability" which shows Electronic Clinical Quality Measures (eCQMs) for each quarter of 2019, some with measurements.

In a letter dated May 18, 2020, CMS denied the ECE request, explaining that the hospital IQR Program is a *separate* program from the PI Program, and that the PI Program has a separate hardship exception process.<sup>31</sup>

CMS then notified Marshall in a letter dated May 28, 2020 that Marshall did not meet the Hospital IQR Program requirements impacting FFY 2021 and that, as a result, its FFY 2021 IPPS APU would be reduced by one fourth.<sup>32</sup>

On, June 11, 2020, the Hospital submitted to CMS a "CMS Quality Reporting Program APU Reconsideration Request Form" requesting a reconsideration of CMS's May 18, 2020 decision (the "APU Reconsideration Request").<sup>33</sup> Marshall's reason for requesting reconsideration was:

We believe we should receive the full APU because we submitted the eCQM files through the Qnet new HQR site using the slide deck instruction from the 11/20/2019 webinar Submitting CY 2019 eCQM Data Using CMS' Next Generation Hospital Quality Reporting system on 02/21/2019. Slide 42 led us to believe that this new submission portal allowed us to submit once for both PI and IOR. The Program Credit report did not report MMC complete submission status though so we submitted help desk ticket CS0804773. On 03/02/2020 the help desk replied: ... "At this time, we do not have an ETA when the Submission Summary report will be corrected with the Sub-Status reflecting your passing score. It is said it will not be until after the deadline, until then, we ask that you hold onto the report and screenshot of your completed Objectives with the passing score. This will be all the proof you need at this time." We therefore took no further action. Screenshots and copy of the help desk communication attached. Thank you for the reconsideration.<sup>34</sup>

Slide 42 referenced in the APU Reconsideration Request bears the title "Program Credit Report Interface – Promoting Interoperability Program Example."<sup>35</sup> It shows a sample Program Credit Report for Promoting Operability on one side, and on the other side includes the following note:

NOTE: Meeting the Hospital IQR Program eCQM requirement also satisfies the CQM electronic requirement for the Promoting

<sup>&</sup>lt;sup>31</sup> Ex P-15 (duplicates Ex. C-1). See also Provider's FPP at 10-11.

<sup>&</sup>lt;sup>32</sup> Ex. P-1.

<sup>&</sup>lt;sup>33</sup> Exs. P-16 and C-2 are the CMS Quality Reporting Program APU Reconsideration Request Form dated Jun. 11, 2020 and submitted by Marshall. However, the version that is Ex. P-16 also includes screenshots (an "Upload History" showing a batch file uploaded Feb. 21, 2019; the Promoting Interoperability Objectives which is also in the record as Ex. P-10; the Nov. 20, 2019 Submitting CY 2019 eCQM Data slide deck which is also in the record as Ex. P-6; a copy of the help desk communication dated Feb. 27, 2020 between the QualityNetService Center and Eric Schwagerus, which is also in the record as Ex. P-9; and a copy of the help desk communication dated Mar. 2, 2020 between the QualityNetService Center and Eric Schwagerus, which is also in the record as Ex. P-16 (emphasis added).

<sup>&</sup>lt;sup>35</sup> *Id.* at 51. The Board notes that this page of the exhibit is the Slide 42 that is also shown in Ex. P-6.

Interoperability Program for EHs and Critical Access Hospitals *except* the outpatient measure ED-3, National Quality Form (NQF) #496.

In this example, the PI Program requirement has been fulfilled, but the Hospital IQR program requirements remain unfulfilled if an additional measure was not successfully reported.<sup>36</sup>

The transcript of the webinar, with respect to Slide 42, states in pertinent part,

In this example, the Program Credit Report is specific to the Promoting Interoperability Program. *Be sure to export the Promoting Interoperability and the Hospital IQR Report to ensure the eCQM reporting requirement is fulfilled for <u>each</u> program.* This report interface shows the ED-3 measure was successfully reported. As a reminder, ED-3, as a measure, does not have aligned credit with the Hospital IQR Program. Submitters need to make sure to report on an additional eCQM to ensure they met the minimum reporting requirements.<sup>37</sup>

On July 13, 2020 CMS upheld the decision to reduce Marshall's FY 2021 APU citing failure to meet the requirements set forth in 42 C.F.R. Part 412, Subpart H and of the FY 2021 Hospital IQR Final Rule found at 83 Federal Register 41144.<sup>38</sup> Specifically, "CMS's decision was based on noncompliance with the following Hospital IQR Program requirement(s): Submission of Electronic Clinical Measures (eCQMs) data – 2019 - Annual."<sup>39</sup>

On September 3, 2020, Marshall spoke with a CMS contractor representative regarding the alleged submission failure and the contractor representative replied in an email dated September 9, 2020.<sup>40</sup> The email explained:

- 1. The "[t]he <u>production</u> submission [Marshall] referenced was for CY 2018 Q3 submissions uploaded 2/21/2019 not CY 2019 as you originally stated"<sup>41</sup>;
- 2. "[W]hat [Marshall] submitted for CY 2019 eCQM submissions was to the <u>test</u> portion of the HQR System"<sup>42</sup>; and

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

 <sup>&</sup>lt;sup>37</sup> Ex. P-6 at 7-8 (emphasis added) (CMS Presentation Transcript dated Nov. 20, 2019 entitled "Submitting CY 2019 eCQM Data Using CMS' Next Generation Hospital Quality Reporting System"). Specifically, the example shows measures AMI-8a, ED-3, STK-3, and STK-5 as "submitted" and another measure, STK-10 with no submission status.
<sup>38</sup> Ex. P-2.

<sup>&</sup>lt;sup>39</sup> Id.

<sup>&</sup>lt;sup>40</sup> Provider's FPP at 12 (indicating that Marshall had a call with representatives from the Health Services Advisory Group ("HSAG"), a CMS contractor that provides assistive administrative services to providers related to CMS quality programs). *See also* Ex. P-17.

<sup>&</sup>lt;sup>41</sup> Ex. P-17 at 2.

<sup>&</sup>lt;sup>42</sup> *Id.* at 3.

3. "[P]roduction data was not received by the [Hospital Quality Reporting ("HQR")] system by the 3/2/20 submission deadline for CY 2019 eCQM reporting to the Hospital IQR and the Medicare portion of the Medicare and Medicaid Promoting Interoperability Program."<sup>43</sup>

On December 7, 2020, in response to Marshall's counsel's request to administratively resolve the matter, a CMS representative further explained that CMS decided to uphold its original decision during reconsideration because:

CMS found that Marshall did not meet the Phase 2 FY 2021 Hospital IOR Program requirement to submit eCOM data. The November 20, 2019, presentation, "Submitting CY 2019 eCQM Data Using CMS' Next Generation Hospital Quality Reporting System," explains that while submitting eCOM data for the Hospital IOR Program will fulfill requirements for the PI Program, the reverse is not true and the presentation offers an example of this scenario. The presentation further advises providers to export and review of their PCRs for both programs in totality to ensure proper reporting of eCQMs according to each specified program requirement. In addition, the help desk ticket referenced by Marshall (ticket CS0804773) pertained specifically to its submission of PI Program data and not its submission of Hospital IOR Program eCOM data. Finally, Marshall submitted an FY 2021 Extraordinary Circumstance Exception (ECE) request for an extension for IQR eCQM submission, stating that second quarter 2019 eCQMs were submitted but only counted towards the PI Program and not the Hospital IQR Program. CMS denied Marshall's ECE request, stating in the decision letter: "Please note the Hospital IQR Program is a separate program from the Promoting Interoperability Program...."44

From December 11, 2020 through April 19, 2021, additional correspondence transpired between counsel for Marshall and CMS, whereby Marshall – through counsel – attempted to avoid Board appellate proceedings and challenge the APU and reconsideration decision, and CMS indicated that nothing further could be done.<sup>45</sup> Marshall filed the instant appeal with the Board on December 23, 2020.<sup>46</sup>

<sup>&</sup>lt;sup>43</sup> *Id.* at 4.

<sup>&</sup>lt;sup>44</sup> Ex. P-19 at 1 (emphasis added) (email exchange dated Nov. 30, 2020 and Dec. 7 2020, between Marshall's representative (Mr. Roth) and Mses. Moody-Williams and Kerr of CMS).

<sup>&</sup>lt;sup>45</sup>See Ex. P-22 (an email exchange inclusive of Ex. P-19 and including further email exchanges between Mr. Roth and Ms. Kerr of CMS (with Ms. Moody-Williams copied) dated Dec. 7, 2020, Dec. 11, 2020, Jan. 6, 2021, Jan. 21, 2021, Feb. 18, 2021, Apr. 12, 2021, and Apr. 19, 2021).

<sup>&</sup>lt;sup>46</sup> See Ex. P-4 at 2 (email exchange between the PRRB and the Parties attaching information on the instant case).

# **STATEMENT OF RELEVANT LAW:**

## A. Burden of Proof and Standard of Review

A Board decision must include findings of fact and conclusions of law that "the provider carried its burden of production of evidence and burden of proof by establishing, by a preponderance of the evidence, that the provider is entitled to relief on the merits of the matter at issue."<sup>47</sup> Additionally, "[a] decision by the Board shall be based upon the record made at such hearing, which shall include the evidence considered by the [Medicare contractor] and such other evidence as may be obtained or received by the Board, and shall be supported by substantial evidence when the record is viewed as a whole."<sup>48</sup> In *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 230 (1938), the U.S. Supreme Court held, "[s]ubstantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion."<sup>49</sup> Accordingly, in an appeal before the Board, a provider must prove by a preponderance of substantial, relevant evidence that it is entitled to the relief sought.

# B. CMS Hospital Inpatient Quality Reporting Program

Section 501(b) of the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA") of 2003 amended 42 U.S.C. § 1395ww(b)(3)(B) to establish the Hospital Inpatient Quality Reporting ("IQR") Program.<sup>50</sup> The IQR Program allows CMS to pay hospitals that successfully report designated quality measures a higher APU.<sup>51</sup> The CMS Hospital IQR Program Phase 2 review for FFY 2021 required that hospitals submit data for at least four (4) electronic Clinical Quality Measures ("eCQMs") for at least one (1) self-selected quarter of CY 2019, by the submission deadline of March 2, 2020.<sup>52</sup>

42 U.S.C. § 1395ww(b)(3)(B) requires each hospital to submit quality of care data "...in a *form and manner, and at a time*, specified by the Secretary."<sup>53</sup>

<sup>&</sup>lt;sup>47</sup> 42 C.F.R. § 405.1871(a)(3) (as of Oct. 1, 2020).

<sup>&</sup>lt;sup>48</sup> 42 U.S.C. § 139500(d). This statutory provision also confirms: "[t]he Board shall have the power to affirm, modify, or reverse a final determination of the fiscal intermediary with respect to a cost report and to make any other revisions on matters covered by such cost report (including revisions adverse to the provider of services) even though such matters were not considered by the intermediary in making such final determination." *But also see* 42 C.F.R. § 405.1869(a).

<sup>&</sup>lt;sup>49</sup> See also Pomona Valley Hosp. Med. Ctr. v. Becerra, 82 F.4th 1252, 1258-59 (D.C. Cir. 2023).

<sup>&</sup>lt;sup>50</sup> Pub. L. 108-173, § 501(b), 117 Stat. 2066, 2289 (2003).

<sup>&</sup>lt;sup>51</sup> "Hospital Inpatient Quality Reporting Program", available at <u>https://www.cms.gov/medicare/quality/initiatives/</u> <u>hospital-quality-initiative/inpatient-reporting-program</u> (last updated Dec. 27, 2023) (last accessed Jul. 10, 2024). <sup>52</sup> 83 Fed. Reg. 41144 at 41150 (Aug. 17, 2018) (stating: "[ ... ] for the CY 2019 reporting period/FY 2021 payment determination, we are: (1) Requiring the same eCQM reporting requirements that were adopted for the CY 2018 reporting period/FY 2020 payment determination (82 FR 38355 through 38361), such that hospitals submit one, self-selected calendar quarter of 2019 data for 4 eCQMs in the Hospital IQR Program measure set; and (2) requiring that hospitals use the 2015 Edition certification criteria for CEHRT. These changes are in alignment with changes or current established policies under the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs).").

<sup>&</sup>lt;sup>53</sup> (Emphasis added.)

The Hospital IQR program was expanded by § 5001(a) of the Deficit Reduction Act of 2005 so that for fiscal years 2015 and beyond, a hospital that fails to report the required quality data under the IQR program is penalized by reducing the hospital's IPPS market basket percentage increase for the relevant year by one-fourth.<sup>54</sup> Specifically,

[i]n the case of a "subsection (d) hospital," as defined under section 1886(d)(1)(B) of the Act, that does not submit quality data on a quarterly basis to CMS, in the form and manner specified by CMS, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals is reduced -

\*\*\*\*

(C) For fiscal year 2015 and subsequent fiscal years, by one-fourth.55

## C. CMS QualityNet

The *form and manner* in which a hospital is to submit quality data is the QualityNet Secure Portal. CMS established QualityNet to facilitate of the process of quality data submission for by IPPS hospitals under the IQR Program.<sup>56</sup> CMS QualityNet reporting instructions are posted on the QualityNet Secure Portal ("the Portal").<sup>57</sup> QualityNet is used "for secure communications and healthcare quality data exchange between: quality improvement organizations ("QIOs"), hospitals, physician offices, nursing homes, end stage renal disease networks and facilities, and data vendors."<sup>58</sup>

### D. CMS's Promoting Interoperability Program

CMS's Promoting Interoperability ("PI") Program<sup>59</sup> encourages hospitals to adopt, implement, upgrade, and demonstrate meaningful use of certified electronic health record technology ("CEHRT").<sup>60</sup> Hospitals participating in the PI Program are also required to submit quality of care data annually.<sup>61</sup> Hospitals that are eligible to participate in the PI Program must

 <sup>&</sup>lt;sup>54</sup> Pub. L. 109-171, § 5001(a), 120 Stat. 4, 28 (2006). See also 42 C.F.R. § 412.64(d)(2)(i)(C) (as of Oct. 1, 2019).
<sup>55</sup> 42 C.F.R. § 412.64(d)(2)(i)(C) (as of Oct. 1, 2019).

<sup>&</sup>lt;sup>56</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"). <sup>57</sup> See 42 C.F.R. § 412.140(a) (as of Oct. 1, 2019). See also Ex. P-5, Ex. P-6; <u>https://qualitynet.cms.gov/</u> inpatient/igr (formerly qualitynet.org) (last accessed Jul. 17, 2024).

<sup>&</sup>lt;sup>58</sup> "About QualityNet" at <u>https://qualitynet.cms.gov</u> (last accessed Jul. 17, 2024).

<sup>&</sup>lt;sup>59</sup> Formerly known as the Electronic Health Record ("EHR") Incentive Programs. *See* "Promoting Interoperability Programs" at <u>https://www.cms.gov/medicare/regulations-guidance/promoting-interoperability-programs</u> (last modified 07/01/2024) (last accessed Jul. 8, 2024).

<sup>&</sup>lt;sup>60</sup> See "Promoting Interoperability Programs" at <u>https://www.cms.gov/medicare/regulations-guidance/promoting-interoperability-programs</u> (last modified Jul. 1, 2024) (last accessed Jul. 8, 2024).

<sup>&</sup>lt;sup>61</sup> 42 U.S.C. §1395ww(n)(3)(A)(iii).

successfully demonstrate meaningful use of their certified EHR technology each year to avoid a downward payment adjustment.<sup>62</sup>

A hospital can satisfy both the IQR and PI programs using the same quality data. Specifically, "*[s]uccessfully meeting the Hospital IQR Program eCQM requirement* also fulfills the CQM electronic reporting requirement for the [PI Program]."<sup>63</sup> As discussed *infra*. meeting the IQR program requirements may be used to satisfy the PI program requirements, but not the reverse.

# E. Exception Process

A hospital may be granted an exception or extension to the Hospital IQR Program requirements when certain extraordinary circumstances exist.<sup>64</sup> The deadline for submitting the eCQM-related extraordinary circumstances exception for the CY 2019 reporting period was April 1, 2020.<sup>65</sup> The IQR extraordinary circumstances exception process is as follows:<sup>66</sup>

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

 $<sup>^{62}</sup>$  See 85 Fed. Reg. 58432, 58798 (Sept. 18, 2020). For example, if an eligible hospital does not demonstrate meaningful use, reduction of the annual market basket update otherwise applicable to IPPS hospitals for FFY 2021 was minus one and eight-tenths percent (-1.8%) ("the PI Program Penalty"). Thus, a hospital that does *not* demonstrate meaningful use *and* does *not* submit the required quality data would have its update reduced by 2.4% (1.8% + 0.6%).

<sup>&</sup>lt;sup>63</sup> Ex. P-7 at 8 (emphasis added) (the "CY 2019 eCQM Reporting Tips and Tools for the Hospital IQR and Promoting Interoperability ("PI") Programs," Questions and Answers, dated Jan. 15, 2020).

<sup>&</sup>lt;sup>64</sup> See 42 C.F.R. § 412.140(c)(2) (10-1-2019). See also Ex. P-6 at 9.

<sup>&</sup>lt;sup>65</sup> See 42 C.F.R. § 412.140(c)(2)(i) (10-1-2019). See also Ex. P-6 at 9.

<sup>&</sup>lt;sup>66</sup> The Board notes that "the Hospital IQR Program is a separate program from the Promoting Interoperability Program (formerly known as the Electronic Health Records Incentive Program). The Medicare Promoting Interoperability Program has a separate hardship exception process." Ex. P-15 at 2.

(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>67</sup>

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

#### A. Form, Manner, and Time

To find in favor of Marshall (*i.e.*, to find that the one-fourth APU reduction does *not* apply), we must find that Marshall submitted the Hospital IQR program quality data in the "*form and manner, and at a time, specified by CMS*."<sup>68</sup> As we have established, the quality data required by 42 U.S.C. § 1395ww(b)(3)(B) are collected through the Portal (form and manner), and CMS notifies providers of the due dates of the reports (time). Hospitals (including Marshall) were required to submit CY 2019 data by March 2, 2020 to receive a full FFY 2021 APU.<sup>69</sup> Each year, information on the form and manner and time are published by CMS.<sup>70</sup>

### 1. Form and Manner

### a. <u>Submission to Test Site</u>

In September 2019, CMS gave notice on the Portal of a new navigation and submission process that IPPS hospital would use for the submissions of their CY 2019 IQR quality data by certain deadlines in 2020 for purposes of FFY 2021 reimbursement.<sup>71</sup> Under this new process, when a submitter enters the Portal to submit data, the default setting automatically causes the data to be submitted to an area of the Portal known as the "test" production site. The purpose of this default is to allow the submitter to test for errors and validate that the data is complete and ready for submission to the actual production site.<sup>72</sup> If a submitter wants to submit data to the actual production site (as opposed to the test production site), the submitter must select "production" from the drop-down menu in the Portal.<sup>73</sup> Once quality data has been submitted using the Portal,

<sup>70</sup> See "Fiscal Year 2021 Hospital Inpatient Quality Reporting Program Guide" at 7 (available at

<sup>&</sup>lt;sup>67</sup> 42 C.F.R. § 412.140(c)(2) (as of Oct. 1, 2019).

<sup>&</sup>lt;sup>68</sup> 42 C.F.R. § 412.140(c)(1) (as of Oct. 1, 2019).

<sup>&</sup>lt;sup>69</sup> See supra Subsection B of the Statement of the Relevant Law.

https://qualitynet.cms.gov/files/5dcaecef2963f6001fc622ab?filename=IQR\_FY\_2021\_Prog\_Gde\_Oct2019.pdf) (last accessed Jul. 19, 2024). The Board notes that neither party presented this publicly-available document as evidence.

<sup>&</sup>lt;sup>71</sup> See Ex. P-5 at 2 (copy of "eCQM Next Generation of Hospital Quality Reporting Navigation Guide, Fall 2019"). <sup>72</sup> See Ex. P-6 at 12 (copy of the "Submitting CY 2019 eCQM Data Using CMS' Next Generation Hospital Quality Reporting System, Presentation Transcript, Nov. 20, 2019") (stating: "Next question: We are going to submit quarter four of 2019 data. Can we start sending test files of just one month worth of data to test for errors? [Response:] The answer to that is yes. If you would like to test just one month to validate your file format and to validate you are getting expected results you are anticipating, it is okay for you to go ahead and test with one month of those files."). <sup>73</sup> See Ex. P-6 at 5 (stating: "[T]he system defaults to test, as shown on the slide. If you want to submit production files, use the drop-down menu to select production.").

the submitter can confirm that the submission is complete and has been accepted by CMS by obtaining a Program Credit Report from the Portal.<sup>74</sup>

In a September 9, 2020 email to Marshall, the HSAG explains how the submitter could have become aware of the problem, and how the error could have been corrected at the time of submission, explaining:

As we discussed on the call, you mentioned that you generated the Program Credit report, but it was blank. That would be correct, because *production data was not received by the HQR system by the 3/2/2020 submission deadline for CY 2019* eCQM reporting to the Hospital IQR and the Medicare portion of the Medicare and Medicaid Promoting Interoperability Program. As it outlines in the slide deck from the 11/20/19 webinar, *had you gone on to review the eCQM Submission Accuracy tab* you would have been able to check where the QRDA I files were processed (test versus production) and how they were processed (accepted versus rejected). At that point, you could have resubmitted the files to the production portion of HQR, re-checked the production portion of the Upload History tab, the production portion of the eCQM Submission Accuracy tab and generated the Program Credit report for confirmation of successful data submission by the deadline.<sup>75</sup>

Indeed, the November 20, 2019 webinar, attended by Marshall's submitter, includes *both* screen shots of successful file uploads *and* processing status notifications.<sup>76</sup>

In its final position paper and at the hearing, Marshall admitted that it submitted its PI Program data *to the <u>test portion</u>* of the site and not to the production portion of the site.<sup>77</sup> As noted by the HSAG, Marshall also had tools available to confirm/verify whether it had made a successful IQR submission.<sup>78</sup> The Board finds submission of Marshall's quality data to the *PI Program <u>test</u> site* 

<sup>&</sup>lt;sup>74</sup> Ex. P-6 at 9.

<sup>&</sup>lt;sup>75</sup> Ex. P-17 at 4.

<sup>&</sup>lt;sup>76</sup> Ex. P-16 at 35-36. *See also* Ex. P-6 at 6 (transcript of webinar stating: "The Files Upload History UI, or user interface, displays the following details for test and production QRDA I file submission: batch file name, batch ID, file size, upload date, identifies who uploaded the batch file, status of the hospital's submission, and provides the ability to export the errors for this specified batch of QRDA I files. Once the status shows 'Ready,' users are able to download a report of errors. Other statuses available are 'Processing' and 'Deleted.' 'Processing' indicates that the submitted batch of QRDA I files is still in progress at that moment in time. The 'Deleted' status maybe displayed when the complete batch is deleted.").

<sup>&</sup>lt;sup>77</sup> Provider's FPP at 12 (stating: "While it is true that the Hospital's CY 2019 quality data submission was uploaded only to the PI Program 'test' site (the data was not uploaded to the PI Program 'production' site) ....").

<sup>&</sup>lt;sup>78</sup> During the time at issue, Marshall's witness was aware the he could run verification or credit reports for *both* the PI *and* IQR programs to confirm Marshall's submission was accepted for both programs; however, he apparently chose not do so for the IQR program prior to the submission deadline at issue based on, in whole or in part, the erroneous assumption (as discussed *infra*) that meeting the PI requirements would satisfy the IQR requirements. *See* Tr. at 50-54, 56, 62-63.

does not meet the requirement to report its IQR Program data to the *IQR production site*, and thus, does not meet the "form and manner" requirement of the IQR Program.

### b. Submission for the PI Program

Marshall asserts that, "[o]nce CMS gave [Marshall] a passing score for its CY 2019 quality data submission for FY 2021 PI Program purposes, CMS was required to have also given [Marshall] a passing score for its CY 2019 quality data submission for FFY 2021 IQR Program purposes."<sup>79</sup> Marshall contends that the quality data it "submitted to meet the PI Program requirements can also be used to meet IQR Program quality data submission requirements."<sup>80</sup> Marshall believes that it was allowed to submit data once for the PI Program to meet the requirements of both the PI Program and the IQR Program.<sup>81</sup> Marshall asserts that its submitter "reasonably believed that the Hospital had met the FFY 2021 quality data submission requirements by the March 2, 2020 deadline for both the PI and IQR Programs."<sup>82</sup>

In support of its position, Marshall relies on various CMS-sponsored webinars. First, in a November 20, 2019 webinar, entitled "Submitting CY 2019 eCQM Data Using CMS' Next Generation Hospital Quality Reporting System," CMS, through its support contractor, advised that "[h]ospitals participating in the Hospital IQR Program are required to report on four (4) of the fifteen (15) available eCQMs and one self-selected quarter of calendar year 2019 data by the March 2, 2020 submission deadline."<sup>83</sup> Marshall points to language that states that "[*m*]eeting the Hospital IQR Program eCQM requirement also satisfies the CQM electronic reporting requirement for the Medicare Promoting Interoperability Program for Eligible Hospitals (EHs) and critical access hospitals (CAHs) except outpatient measure ED-3, National Quality Forum (NQF) #0496."<sup>84</sup> We described this webinar – specifically Slide 42 – in the section titled "Statement of Relevant Facts" above.

In a January 15, 2020 webinar, entitled "CY 2019 eCQM Reporting Tips and Tools for the Hospital IQR and Promoting Interoperability Programs," Marshall emphasizes that the CMS contractor reiterated that "[s]uccessfully *meeting the Hospital IQR Program eCQM requirement also fulfills the CQM electronic reporting requirement for the Medicare Promoting Interoperability Program* with one submission."<sup>85</sup>

In yet another webinar on February 11, 2020, entitled "Question and Answer Session: CY 2019 eCQM Reporting for the Hospital IQR and Promoting Interoperability Programs," the CMS

<sup>&</sup>lt;sup>79</sup> Provider's FPP at 12.

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

<sup>&</sup>lt;sup>81</sup> Ex. P-16 at 2 (stating: "We believe we should receive the full APU because we submitted the eCQM files through the Qnet new HQR site.... Slide 42 led us to believe that this new submission portal allowed us to submit once for both PI and IQR.").

<sup>&</sup>lt;sup>82</sup> Provider's FPP at 10.

<sup>&</sup>lt;sup>83</sup> Ex. P-6 at 3.

<sup>&</sup>lt;sup>84</sup> Ex. P-16 at 19, 51. This message is also repeated in the presentation transcript of the "Question and Answer Session: CY 2019 eCQM Reporting for the Hospital IQR and Promoting Interoperability Programs" dated Feb. 11, 2020 located at Ex. P-8 at 3.

<sup>&</sup>lt;sup>85</sup> Ex. P-7 at 8, Question 18 (emphasis added).

contractor stated: "[p]lease remember that *meeting the Hospital IQR Program eCQM requirement also satisfies the CQM electronic reporting requirement for the Medicare Promoting Interoperability Program* for eligible hospitals and critical access hospitals."<sup>86</sup>

Marshall also relies on the QualityNet Service desk email dated March 2, 2020,<sup>88</sup> to support its contention that it met the FFY 2021 quality data submission requirements by the March 2, 2020 deadline for *both* the PI and IQR Programs. The Board finds that the email specifically refers to Marshall's submission of PI Program data and *not* its submission of IQR Program eCQM data. To be clear, the email states: "At this time, we do not have an ETA when the *PI Submission Summary reports* will be corrected with the Sub-Status reflecting your passing score."<sup>89</sup> The March 17, 2020 follow up email from the QualityNet Service desk representative also confirmed this stating: "Thank you for contacting the QualityNet Helpdesk in regards to the *Promoting Interoperability Attestation Summary Report Objective Sub-Status* showing incomplete."<sup>90</sup> Marshall may have met the quality data submission requirements by the deadline for the *PI Program*.

The Board is also unconvinced by Marshall's argument that, once CMS gave it a passing score for its CY 2019 quality data submission for FFY 2021 PI Program purposes, CMS was required to *also* give it a passing score for its CY 2019 quality data submission for FFY 2021 IQR Program purposes. The IQR Program is a separate program from the PI Program. Nowhere in the program guidance does it state that CMS is required to give a passing score to a provider for the IQR Program *automatically* if it meets the requirements for the PI Program. The guidance lists *separate requirements* for uploading PI Program quality data versus IQR Program quality data. Therefore, CMS was not required to give a passing score to Marshall for its IQR Program simply because Marshall received a passing score for its PI Program.

The Board finds that, although the IQR Program and PI Program may use certain shared sets of electronic clinical quality measures<sup>91</sup> to meet data submission requirements for both IQR Program

<sup>&</sup>lt;sup>86</sup> Ex. P-8 at 4 (emphasis added) (transcript from the referenced Feb. 11, 2020 question and answer session).

<sup>&</sup>lt;sup>87</sup> Ex. P-19 at 2 (emphasis added).

<sup>&</sup>lt;sup>88</sup> Ex. P-12.

<sup>&</sup>lt;sup>89</sup> Id. (emphasis added).

<sup>&</sup>lt;sup>90</sup> Ex. P-13 (emphasis added).

<sup>&</sup>lt;sup>91</sup> Ex. P-7 at 13 (stating: "The Hospital IQR and Promoting Interoperability Programs both require the reporting of a shared set of electronic clinical quality measures along with additional measures that are specific to each respective program."); Ex. P-16 at Slide 42. *See also* 85 Fed. Reg. 58432, 58936 (Sept. 18, 2020) (stating: "In recent years, we have also improved alignment between Hospital IQR Program's reporting requirements and other quality programs, such as the Promoting Interoperability (PI) program. For example the Hospital IQR Program and Promoting Interoperability

and PI Program, the statute and regulation requires that quality data be submitted in the form and manner specified by CMS. In its November 20, 2019, January 15, 2020, and February 11, 2020 guidance/trainings, CMS makes clear that meeting the Hospital IQR Program eCQM requirement satisfies the PI Program reporting requirement. However, CMS has not indicated or confirmed the reverse, *i.e.*, that meeting the PI Program reporting requirement satisfies the IQR Program requirement.

Indeed, the Portal to which Marshall submitted its quality data was not only the *test Portal*, it was the Portal for the *PI Program*. Also, again, as noted by the HSAG, Marshall also had tools available to confirm/verify whether it had made a successful IQR submission. The Board finds that, to meet the IQR Program reporting requirements, the IQR data must be submitted to the IQR Program site; Marshall failed to do so.

## c. <u>CMS accepted its CY 2018 quality data as sufficient for both the PI and IQR Programs.</u>

Marshall further proffers that CMS accepted its CY 2018 quality data "as sufficient for both the PI and IQR Programs" when its submitter "downloaded CY 2018 quality data only to the PI Program site, using the Pre-Submission Validation Application tool."<sup>92</sup> Marshall asserts this shows "that quality data submitted to meet PI Program requirements can also be used to meet IQR Program quality data submission requirements."<sup>93</sup>

In an email dated September 9, 2020, a CMS contractor advised Marshall that its CY 2018 data was uploaded to the "production" site while its CY 2019 data was uploaded to the "test" site and not to production.<sup>94</sup> The Board finds that Marshall's FFY 2021 data was not submitted using the same process which Marshall used for its FFY 2020 submission. As a result, Marshall did not meet the requirements of the IQR Program for FFY 2021.

# d. <u>CMS acted arbitrarily and capriciously.</u>

Marshall asserts that CMS knowingly based its determination that Marshall did not meet the FFY 2021 IQR program requirements on incorrect data.<sup>95</sup> Marshall asserts that this reliance on incorrect CY 2019 data deprived Marshall of its full FFY 2021 IPPS payment update when at the

Program now have the same eCQMs and data submission requirements. We will continue to look across all quality programs to identify areas for further streamlining and opportunities to reduce any remaining duplication."). There is a list of fifteen (15) eCQMs, from which a hospital must choose a minimum of four (4) to submit by March 2, 2020 to fulfil the Hospital IQR Program eCQM requirement. *See* CMS Publication "Fiscal Year 2021 Hospital Inpatient Quality Reporting Program Guide Fiscal Year 2021 Payment Determination/Calendar Year 2019 Reporting Period" (available at: https://qualitynet.cms.gov/files/5dcaecef2963f6001fc622ab?filename=IQR\_FY\_2021\_Prog\_Gde\_Oct2019.pdf (last accessed Jul. 25, 2024)). Although the reported eCQMs can be the same, the PI Program must report other aspects. *See* 42 C.F.R. § 495.24.

<sup>&</sup>lt;sup>92</sup> Provider's FPP at 13.

<sup>&</sup>lt;sup>93</sup> *Id.* at 15.

<sup>&</sup>lt;sup>94</sup> Ex. P-17.

<sup>&</sup>lt;sup>95</sup> Provider's Response at 6.

time, the agency had the correct data which showed that Marshall met IQR Program requirements for purposes of the FFY 2021 update.<sup>96</sup>

What Marshall's argument fails to address is, regardless of whether CMS had the correct data within the agency, Marshall did not submit that quality of care data in a form and manner, and at a time, specified by the Secretary. Based on the statue, regulations, and guidance identified above, the Board finds it is not sufficient to simply submit data, rather, the data must be submitted in a form and manner specified by the Secretary, as required by 42 U.S.C. § 1395ww(b)(3)(B).

2. <u>Time</u>

March 2, 2020 was the deadline for the submission of CY 2019 IQR and PI Program quality data.<sup>97</sup> On February 24, 2020, Marshall's submitter uploaded the eCQMs for CY 2019 quality data into the Portal.<sup>98</sup> The Board finds that Marshall met the deadline with respect to the PI Program quality data. However, because Marshall's upload was to the PI Program and *not* to the IQR Program, the Board agrees with CMS and finds that Marshall did not meet the time requirement for submission of IQR Program quality data.

## B. CMS's Promoting Interoperability Program

Hospitals that are eligible to participate in the PI Program must successfully demonstrate meaningful use of their certified EHR technology each year to avoid a downward payment adjustment.<sup>99</sup> Whether Marshall submitted quality of care data sufficient to meet the requirements to be a "meaningful user of EHR" is not an issue in this appeal. Accordingly, the Board will not address whether Marshall is a "meaningful user." The Board has described this program only to the degree it is relevant with respect to Marshall's submission of eCQMs and not to address whether Marshall meets the requirements of the PI Program.

### C. Exception and Extension Requirements.

### 1. The "Extraordinary Circumstances" Standard

A hospital may request exceptions or extensions to the eCQM reporting requirements in extraordinary circumstances *beyond the control of the hospital.*<sup>100</sup> The QualityNet web site provides examples of extraordinary circumstances, including "infrastructure challenges (a hospital is in an area without sufficient Internet access) or unforeseen circumstances, such as vendor issues outside of the hospital's control (including a vendor product losing

<sup>&</sup>lt;sup>96</sup> Id.

<sup>&</sup>lt;sup>97</sup> See Ex. P-7 at 3-4.

<sup>&</sup>lt;sup>98</sup> Ex. P-25 at ¶ 7.

<sup>&</sup>lt;sup>99</sup> See 85 Fed. Reg. 58432, 58798 (Sept. 18, 2020). For example, if an eligible hospital does not demonstrate meaningful use, reduction of the annual market basket update otherwise applicable to IPPS hospitals ("the PI Program Penalty") for FFY 2021 was minus one and eight tenths percent (-1.8%). See also the definition of "Meaningful EHR user" at 42 C.F.R. § 495.4.

<sup>&</sup>lt;sup>100</sup> See Statement of the Relevant Law at Subsection E.

certification)."<sup>101</sup> Marshall's basis for the ECE is that the eCQMs "only got counted towards Promoting Interoperability and not IQR."<sup>102</sup> The Board finds that Marshall's reason does not meet the criteria under the ECE policy. Marshall's failure to properly complete its submission to the IQC site is not a qualifying extraordinary circumstance beyond Marshall's control.

## 2. Extension/Exception Request Due by April 1, 2020

Because Marshall's ECE request was based on circumstances relating to the reporting of electronic clinical quality measures, its ECE request was due to CMS by April 1 following the end of the reporting calendar year (*i.e.*, the deadline for submitting the eCQM-related extraordinary circumstances exception for the CY 2019 reporting period was April 1, 2020). The Board finds that Marshall, in submitting its request on April 21, 2020, failed to timely request an ECE.

### 3. Systemic Problem or Regional Impact

The Board finds that there was no evidence presented to warrant a finding that there was a systemic problem with CMS' data collection systems that directly affected the ability of Marshall to submit data, or that an extraordinary circumstance affected the entire region or locale.

\* \* \* \* \*

For the reasons stated above, the Board concludes that Marshall has failed to meet its burden of production of evidence and burden of proof under 42 C.F.R. § 405.1871(a)(3) and that CMS correctly denied Marshall's April 21, 2020 ECE request.

### **DECISION**:

After considering Medicare law and regulations, the arguments presented, and the evidence admitted the Board finds that CMS properly imposed the APU penalty, in accordance with 42 C.F.R. 412.64(d)(2)(i)(C).

**Board Members Participating:** 

Clayton J. Nix, Esq. Kevin D. Smith, CPA Ratina Kelly, CPA Nicole E. Musgrave, Esq. For the Board:

8/23/2024

X Clayton J. Nix

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

<sup>&</sup>lt;sup>101</sup> CMS "Extraordinary Circumstances Exceptions (ECE) Policy" (available at <u>https://qualitynet.cms.gov/inpatient/</u> <u>iqr/participation#tab3</u> (last accessed Jul. 19, 2024)). With respect to eCQM-Related ECEs, this webpage includes a link to a PDF document dated Mar. 1, 2017 entitled "ECE Policy Clarification Questions and Answers." <sup>102</sup> Ex. P-14.