PROVIDER REIMBURSEMENT REVIEW BOARD
On the Record

2025-D39

PROVIDER –
Hazard ARH Regional Medical Center

PROVIDER NO. –
18-0029

vs.

MEDICARE CONTRACTOR –
CGS Administrators (J-15)

HEARING DATE –
September 25, 2023

FEDERAL/ FISCAL YEARS –
09/30/2018
12/31/2018
FFY 2019

CASE NOS. –
18-1545, 18-1669, 18-1802

INDEX

ISSUE STATEMENT:

Whether the Provider timely reported influenza vaccination data to the Centers for Medicare & Medicaid ("CMS") consistent with the legal standards in 42 C.F.R §§ 412.140(e), 412.434, and 419.46(g), and whether the penalties imposed by CMS were proper?[1]

DECISION:

After considering Medicare law and regulations, the arguments presented, and the evidence admitted, the Provider Reimbursement Review Board ("Board" or "PRRB") finds the Provider failed to timely report influenza vaccination data for healthcare personnel to CMS consistent with the legal standards in 42 C.F.R §§ 412.140, 412.434, and 419.46, and the penalties imposed by CMS were proper.

INTRODUCTION AND PROCEDURAL HISTORY:

Hazard ARH Regional Medical Center ("Hazard" or "Provider"), located in Hazard, KY, is a Medicare certified acute care hospital that also provides outpatient services, and operates an inpatient psychiatric facility ("IPF").[2] Hazard is part of Appalachian Regional Healthcare ("ARH") and ARH consists of more than 10 hospitals.[3] The Provider's assigned Medicare Administrative Contractor[4] is CGS Administrators, LLC – J15 (the "Medicare Contractor").

PRRB Case Number 18-1545 – FY 2018 Inpatient Psychiatric Facility QRP:

On September 11, 2017, CMS notified Hazard that it had failed to meet the Inpatient Psychiatric Facility Quality Reporting Program ("IPF QRP") requirements for FY 2018. As a result of its failure to meet the IPF QRP requirements, Hazard's FY 2018 Inpatient Psychiatric Facility Prospective Payment System ("IPF PPS") Annual Payment Update ("APU") was reduced by two percentage points.[5] Specifically, CMS notified Hazard that the two-percentage point reduction in its FY 2018 APU was because it did not submit NHSN HCP (National Healthcare Safety Network Healthcare Personnel) data as required by federal law. Following Hazard's formal request for reconsideration, CMS upheld its decision to impose a two-percentage point reduction in its APU on February 5, 2018.[6]

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[1] *Order of the Administrator* at 2 (Mar. 10, 2023). The Board notes that the regulations cited in the Administrator's Order relate to "reconsiderations and appeals of Hospital IQR Program decisions" (42 C.F.R. § 412.40(e)), "Reconsideration and appeals procedures of Inpatient Psychiatric Facilities Quality Reporting (IPFQR)" (42 C.F.R. § 412.434), and "Reconsiderations and appeals of Hospital OQR Program decisions" (42 C.F.R. § 419.46(g). These regulations are specific to reconsideration and appeals of QR program decisions. The Board also notes that at the time Hazard requested reconsideration of CMS' decisions in 2017, the reconsideration and appeals provision was located at 42 C.F.R. § 419.46(f) and was subsequently relocated to 42 C.F.R. § 412.46(g).

[2] Transcript (hereinafter "Tr.") at 15.

[3] *Id.* at 58-59.

[4] 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 relevant law may refer to FIs and MACs interchangeably, and the Board will use the term "Medicare contractor" to refer to both FIs and MACs as appropriate and relevant.

[5] Case No. ("CN") 18-1545, Exhibit (hereinafter "Ex.") at C-1. Given the overlapping nature of the exhibits and position papers in these cases, all citations are to CN 18-1545, unless otherwise noted.

[6] CN 18-1545, Ex. C-3.

PRRB Case Number 18-1669 – CY 2018 Outpatient QRP:

On November 3, 2017, CMS notified Hazard that its CY 2018 Outpatient Prospective Payment System ("OPPS") APU would be reduced by two percentage points due to Hazard's failure to meet the requirements of the Outpatient Quality Reporting Program ("Outpatient QRP").[7] Specifically, CMS notified Hazard that the two-percentage point reduction in its CY 2018 Outpatient Prospective Payment System APU was because it "did not submit flu data to NHSN."[8] Following Hazard's formal request that CMS reconsider its determination, CMS upheld the payment reduction on May 31, 2018.[9]

PRRB Case Number 18-1802 – FY 2019 Inpatient QRP:

On March 8, 2018 the Medicare Contractor notified Hazard that its FY 2019 Inpatient Prospective Payment System ("IPPS") APU would be reduced by one fourth due to Hazard's failure to meet the requirements of the Inpatient Quality Reporting Program ("Inpatient QRP").[10] Specifically, the Medicare Contractor notified Hazard that the one fourth reduction in its FY 2019 IPPS APU was due to the fact that it failed to "[s]ubmit Influenza Vaccination Coverage Among Healthcare Personnel (HCP) data annually to NHSN by the posted submission deadline."[11] Following Hazard's formal request that CMS reconsider its determination, CMS issued a May 15, 2018 reconsideration decision in which it upheld the payment reduction.[12]

Consolidated Cases:

Hazard timely appealed all three CMS determinations individually to the Board and met the jurisdictional requirements for a hearing in all cases. The three cases were consolidated for hearing, and the Board held a video hearing on June 25, 2020. On March 24, 2021, the Board issued a decision addressing the consolidated cases in PRRB Decision 2021-D14 finding that CMS' reduction to the APU was proper.

Hazard sought review of the Board's decision in the U.S. District Court for the Eastern District of Kentucky.[13] Hazard's complaint states:

> This is an appeal from a decision of the Provider Reimbursement Review Board (PRRB) which applied the wrong section of its regulation […] while also improperly assigning the wrong burden of proof to the hospital and, in the absence of proof from the government, based its decision on its own speculations.[14]

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[7] CN 18-1669, Ex. C-1 at 1.
[8] *Id.* at 2.
[9] CN 18-1669, Ex. C-2. CMS' reconsideration decision incorrectly refers to CY 2017, however, the Provider has clarified the CY in dispute is 2018. *See* CN 18-1669, Provider's Final Position Paper (Sept. 13, 2019) at 3.
[10] CN 18-1802, Ex. C-1 at 8.
[11] *Id.* at 9.
[12] CN 18-1802, Ex. C-2.
[13] *Appalachian Regional Healthcare, Inc. v. Becerra*, 5:21-cv-00138 (E.D. Ky. May 20, 2021).
[14] Complaint (hereinafter "Compl.") at 2 – 3, *Appalachian Regional Healthcare, Inc. v. Becerra*, Civil Action No. 5:21-cv-138-CHB (E.D. Ky. May 20, 2021).

The Joint Motion for Voluntary Remand filed by the parties with the Court states "Remand is appropriate in this case, as it will permit the [A]gency to reconsider the Plaintiff's claims consistent with the legal standards articulated in 42 C.F.R §§ 412.140(e), 412.434, and 419.46(g)."[15] By order dated August 26, 2021, the U.S. District Court remanded this case to the agency.[16] On March 10, 2023, the CMS Administrator remanded these cases to the Board pursuant to the U.S. District Court order.[17] The Administrator ordered:

> THAT the case is remanded to the Provider Reimbursement Review Board; and
>
> THAT the March 24, 2021, final decision of the Board in Case Nos. 18-1545, 18-1669, and 18-1802 is to be reconsidered in light of the court remand; and
>
> THAT the Board will reconsider whether the Plaintiff timely reported influenza vaccination data to the Centers for Medicare and Medicaid Services consistent with the legal standards articulated in 42 C.F.R §§ 412.140(e), 412.434, and 419.46(g); and
>
> THAT the Board will determine whether the penalties imposed by CMS in Case Nos. 18-1545, 18-1669, and 18-1802 were proper; and
>
> THAT the Board's decision will be subject to review as provided under section 1878 of the Social Security Act and 42 C.F.R. §§ 405.1801, *et seq*.[18]

The Board reopened all three cases, providing both parties the opportunity to file additional briefing. Only the Provider filed an additional brief.[19] The Board issued a Notice of Hearing on the Record on September 25, 2023. The Provider was represented by Stephen R. Price, Sr., Esq. of Wyatt, Tarrant & Combs, LLP. The Medicare Contractor was represented by Joe Bauers, Esq. of Federal Specialized Services.

STATEMENT OF RELEVANT LAW:[20]

The Provider maintains that there is one data set at issue in each of the three cases before the Board - Influenza Vaccination Coverage among Healthcare Personnel for the 2016-2017 influenza season.[21] CMS has reduced payment to the Provider under three separate quality data reporting programs based upon the Provider's failure to timely submit this data set.[22] The applicable law related to each quality data reporting program is set forth below.

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[15] Joint Motion for Voluntary Remand at 2, *Appalachian Regional Healthcare Inc. v. Becerra*, Civil Action No. 5:21-cv-138-CHB (E.D. Ky. Aug. 20, 2021).
[16] Order Granting Remand, *Appalachian Regional Healthcare Inc. v. Becerra*, Civil Action No. 5:21-cv-138-CHB (E.D. Ky. Aug. 26, 2021).
[17] Appalachian Regional Healthcare Inc., Mar. 10, 2023, Centers for Medicare & Medicaid Services, *Order of the Administrator*.
[18] *Order of the Administrator* at 2. In PRRB Decision 2021-D14 the Board relied on "'exception' and 'extraordinary circumstances' provisions in 42 C.F.R. § 419.46(d) (2018) and 42 C.F.R. § 412.140(c)(2)." Compl. at ¶28 *Appalachian Regional Healthcare, Inc. v. Becerra*, Civil Action No. 5:21-cv-138-CHB (E.D. Ky. May 20, 2021).
[19] Provider's Brief on Remand was filed July 5, 2023.
[20] The Board notes these are the applicable laws in effect at the relevant times in the subject appeals.
[21] CN 18-1545, Provider's Final Position Paper (Jan. 17, 2020) at 4.
[22] *Id.*

A. Inpatient Psychiatric Facility Quality Reporting Program (as it relates to Case No. 18-1545)

42 U.S.C. § 1395ww(s)(4) (effective Dec. 13, 2016), states, in pertinent part:

> **(4) Quality reporting**
>
> **(A) Reduction in update for failure to report**
>
> **(i) In general**
>
> Under the system described in paragraph (1), for rate year 2014 and each subsequent rate year, in the case of a psychiatric hospital or psychiatric unit that does not submit data to the Secretary *in accordance with subparagraph (C) with respect to such a rate year*, any annual update to a standard Federal rate for discharges for the hospital during the rate year, and after application of paragraph (2), *shall be reduced by 2 percentage points.*
>
> **(ii) Special rule**
>
> The application of this subparagraph may result in such annual update being less than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.
>
> ***
>
> **(C) Submission of quality data**
>
> For rate year 2014 and each subsequent rate year, each psychiatric hospital and psychiatric unit shall submit to the Secretary data on [the required] quality measures specified under subparagraph (D). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.[23]

42 C.F.R. § 412.434 (effective Oct. 1, 2012) states, in relevant part:

> (a) An inpatient psychiatric facility may request reconsideration of a decision by CMS that the inpatient psychiatric facility has not met the requirements of the IPFQR Program for a particular fiscal year. An inpatient psychiatric facility must submit a reconsideration request to CMS no later than 30 days from the date

[23] (Bold emphasis in original and italics and underline emphasis added.)

> identified on the IPFQR Program Annual Payment Update Notification Letter provided to the inpatient psychiatric facility.
>
> (b) A reconsideration request must contain the following information:
>
> > (1) The inpatient psychiatric facility's CMS Certification Number (CCN);
> >
> > (2) The name of the inpatient psychiatric facility;
> >
> > (3) Contact information for the inpatient psychiatric facility's chief executive officer and QualityNet system administrator, including each individual's name, email address, telephone number, and physical mailing address;
> >
> > (4) A summary of the reason(s), as set forth in the IPFQR Program Annual Payment Update Notification Letter, that CMS concluded the inpatient psychiatric facility did not meet the requirements of the IPFQR Program;
> >
> > (5) A detailed explanation of why the inpatient psychiatric facility believes that it complied with the requirements of the IPFQR Program for the applicable fiscal year; and
> >
> > (6) Any evidence that supports the inpatient psychiatric facility's reconsideration request, such as emails and other documents.
>
> (c) An inpatient psychiatric facility that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board under part 405, subpart R of this chapter.

B. Outpatient Quality Reporting Program (as it relates to Case No. 18-1669)

42 U.S.C. § 1395l(t)(17)(A)(i) (effective Dec. 18, 2015) provides, in pertinent part:

> (17) Quality reporting
>
> > (A) Reduction in update for failure to report
> >
> > > (i) in general
> > >
> > > For purposes of paragraph (3)(C)(iv) for 2009 and each subsequent year, in the case of a subsection (d) hospital (as defined in section 1395ww(d)(1)(B) of this title) that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures

> selected under this paragraph with respect to such a year, the OPD fee schedule increase factor under paragraph (3)(C)(iv) for such year shall be reduced by 2.0 percentage points.

42 C.F.R. § 419.46 (effective January 1, 2017) states, in pertinent part:

> (c) ***Submission of Hospital OQR Program data.***
>
> > (1) General rule. Except as provided in paragraph (d) of this section, hospitals that participate in the Hospital OQR Program must submit to CMS data on measures selected under section 1833(t)(17)(C) of the Act in a form and manner, and at a time, specified by CMS.
>
> ***
>
> (d) ***Exemption.*** CMS may grant an extension or exemption of 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 extension or exemption as follows:
>
> > (1) ***Upon request by the hospital***. Specific requirements for submission of a request for an extension or exemption are available on the QualityNet Web site.
> >
> > (2) ***At the discretion of CMS***. CMS may grant extensions or exemptions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred.
>
> ***
>
> (f) ***Reconsiderations and appeals of Hospital OQR Program decisions***.
>
> > (1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital OQR Program for a particular fiscal year. Except as provided in paragraph (d) of this section, a hospital must submit a reconsideration request to CMS via the QualityNet Web site, no later than the first business day on or after March 17 of the affected payment year as determined using the date the request was mailed or submitted to CMS.
> >
> > (2) A reconsideration request must contain the following information:
> >
> > (i) The hospital's CMS Certification Number (CCN);

> (ii) The name of the hospital;
>
> (iii) The CMS–identified reason for not meeting the requirements of the affected payment year's Hospital OQR Program as provided in any CMS notification to the hospital;
>
> (iv) The hospital's basis for requesting reconsideration. The hospital must identify its specific reason(s) for believing it should not be subject to the reduced annual payment update;
>
> (v) The hospital-designated personnel contact information, including name, email address, telephone number, and mailing address (must include physical mailing address, not just a post office box);
>
> (vi) The hospital-designated personnel's signature;
>
> (vii) A copy of all materials that the hospital submitted to comply with the requirements of the affected Hospital OQR Program payment determination year; and
>
> (viii) If the hospital is requesting reconsideration on the basis that CMS determined it did not meet the affected payment determination year's validation requirement set forth in paragraph (e)(1) of this section, the hospital must provide a written justification for each appealed data element classified during the validation process as a mismatch. Only data elements that affect a hospital's validation score are eligible to be reconsidered.

C. Inpatient Quality Reporting Program (as it relates to Case No. 18-1802)

42 C.F.R. § 412.64(d)(2)(i) (effective Oct. 1, 2016) provides, in pertinent part:

> (2)(i) In 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.

42 C.F.R. 412.140 (effective Oct. 1, 2016) states, in pertinent part:

> (c) Submission and validation of Hospital IQR Program data.

(1) General rule. Except as provided in paragraph (c)(2) of this section, subsection (d) hospitals that participate in the Hospital IQR Program must submit to CMS data on measures selected under section 1886(b)(3)(B)(viii) of the Act in a form and manner, and at a time, specified by CMS. A hospital must begin submitting data on the first day of the quarter following the date that the hospital submits a completed Notice of Participation form under paragraph (a)(3) of this section.

(2) Exception. Upon request by a hospital, CMS may grant an extension or exemption of one or more data submission deadlines in the event of extraordinary circumstances beyond the control of the hospital. Specific requirements for submission of a request for an extension or exemption are available on QualityNet.org.

***

(e) Reconsiderations and appeals of Hospital IQR Program decisions.

(1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital IQR Program for a particular fiscal year. Except as provided in paragraph (c)(2) of this section, a hospital must submit a reconsideration request to CMS no later than 30 days from the date identified on the Hospital Inpatient Quality Reporting Program Annual Payment Update Notification Letter provided to the hospital.

(2) A reconsideration request must contain the following information:

(i) The hospital's CMS Certification Number (CCN);

(ii) The name of the hospital;

(iii) Contact information for the hospital's chief executive officer and QualityNet system administrator, including each individual's name, e-mail address, telephone number, and physical mailing address;

(iv) A summary of the reason(s), as set forth in the Hospital Inpatient Quality Reporting Program Annual Payment Update Notification Letter, that CMS concluded the hospital did not meet the requirements of the Hospital IQR Program;

(v) A detailed explanation of why the hospital believes that it complied with the requirements of the Hospital IQR Program for the applicable fiscal year;

> (vi) Any evidence that supports the hospital's reconsideration request, including copies of patient charts, e-mails and other documents; and
>
> (vii) If the hospital has requested reconsideration on the basis that CMS concluded it did not meet the validation requirement set forth in paragraph (d) of this section, the reconsideration request must contain the following additional information:
>
> > (A) A copy of each patient chart that the hospital timely submitted to CMS or its contractor in response to a request made under paragraph (d)(1) of this section; and
> >
> > (B) A detailed explanation identifying which data the hospital believes was improperly validated by CMS and why the hospital believes that such data are correct.

SUMMARY OF PROVIDER'S POSITION:

In its Remand Brief, Hazard contends that it requested reconsideration under 42 C.F.R. § 419.46(g); 42 C.F.R. § 412.140(e); and 42 C.F.R. § 412.434, and that it is improper for the Board to apply the extraordinary circumstances standards set forth in 42 C.F.R. § 412.140(c)(2) and the 2018 version of 42 C.F.R. § 419.46(d).[24] Hazard avers that, in accord with 42 C.F.R. § 419.46(g)(2), it has "identified the specific reasons that it should not be subject to a reduced annual payment update" and has explained why it believes it has "complied with the Hospital IRP and the IPFQWR Program," as required under 42 C.F.R. § 412.140(e) and 42 C.F.R. § 412.434.[25]

Specifically, Hazard argues it "complied with all substantive APU requirements and its personnel were all vaccinated as required," however, Hazard was not able to timely enter all data showing its personnel were vaccinated "because the government website stopped accepting that data ten hours before the announced 11:59 p.m. deadline."[26] Hazard explains that its Infection Disease Coordinator resigned from employment in March 2017, and they had difficulty acquiring the security card necessary to enter the quality data.[27] Hazard finally obtained a new security card on May 15, 2017, which was also the deadline for reporting the required data.[28] When it tried to enter the data on the due date, "the system would not accept the 2016-2017 data, but would only accept data for the next time period."[29]

Hazard claims that the system would not accept the required data on the due date, and that "contemporaneous communications attesting to this fact" have been produced.[30] Hazard alleges that the Medicare Contractor did not offer any proof that the system was working properly on the

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[24] Provider's Brief on Remand (hereinafter "Provider's Brief") at 6-7 (Jul. 5, 2023).
[25] *Id.* at 7.
[26] *Id.* at 1.
[27] *Id.* at 2.
[28] *Id.*
[29] *Id.*
[30] *Id.* at 3.

due date, and that CMS has stated reports of data processing errors will be thoroughly researched.[31] Citing the 2006 IPPS Final Rule at 71 Fed. Reg. 47870 (Aug. 18, 2006), Hazard also argues there is no evidence CMS researched any data processing and communication errors.[32] Hazard claims the burden is on CMS to show the system was functioning properly as CMS has sole access to information regarding the system, and the Board erred in finding no evidence of system failure.[33] To support this argument, Hazard states that "[t]he Ninth Circuit has said it is 'arbitrary and capricious for CMS to make an error that essentially prevented proper submission of data and then penalize a hospital for not presenting the data.'" [34]

Hazard asserts it requested reconsideration under 42 C.F.R. § 419.46(g), 42 C.F.R. § 412.140(e), and 42 C.F.R. § 412.434[35], but the Board previously, in PRRB Decision 2021-D14, applied the wrong regulatory subsections to evaluate the evidence.[36] Hazard claims the specific reason it should not be subject to a payment penalty is "its personnel had been vaccinated as required and Hazard ARH had the data available…but was prevented from uploading the data due to a malfunction which caused the agency website to shut down early."[37]

Hazard argues the record in these cases is "full of" extenuating circumstances, listing them as follows:

1. The event that precipitated Hazard's difficulties was the resignation of Hazard's Infection Disease Coordinator…[and] no one remaining at Hazard had authorized access to NHSN.

2. …Hazard appointed its Interim Director of Nursing . . . as the acting IDC… [and she] was advised that she would need to register with SAMS in order to get access to NHSN and submit the requisite quality data…

3. Hazard was diligent in immediately initiating the multi-step process of getting SAMS/NHSN authorization for [its Interim Director of Nursing]… However, Hazard…was informed that it would take six to eight weeks to obtain a "grid" card…which meant that, even with their diligence, delivery of [the Interim Director of Nursing's] grid card would potentially occur almost a week *after* the May 15th submission deadline.

4. [Th]e SAMS Helpdesk confirmed on May 8, 2017 that a "grid" card was being sent to [the Interim Director of Nursing].

5. [T]he record suggests that the "grid" card was, in fact, delivered…no later than May 15th [to her home in Montana].

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[31] *Id.*
[32] *Id.* at 4.
[33] *Id.*
[34] *Id.* at 5, quoting *PAMC Ltd. v. Sebelius*, 747 F.3d 1214, 1219 (9th Cir., 2014).
[35] *Id.* at 7.
[36] *Id.* at 6-7.
[37] *Id.* at 7.

6. The IDC position apparently was renamed the Infection Control Coordinator ("ICC"). On April 26, 2017, Hazard hired [employee] as ICC and Hazard immediately initiated the SAMS registration process for [the ICC]… [but] received the same notice…that it could take six to eight weeks to obtain the "grid" card.

7. On May 15, 2017…a Hazard employee e-mailed the NHSN Helpdesk [and asked]:…Is there any way to FAX this info to you or be given a temporary generic pass code?

8. The NHSN Helpdesk replied back roughly 20 minutes later, "Unfortunately you must have an active SIMS account and grid card to access the NHSN application."

9. After [the Interim Director of Nursing] receive the grid card on the afternoon of May 15, 2017, she attempted to log into the NHSN system multiple times…[the ICC]…was able to sign into the NHSN system around 4:54 p.m. MST. However, he stated that "We are past the deadline it seems, it only allows 2017 data now."[38]

Based upon the foregoing, Hazard contends that "[t]he only evidence in this case was that the hospital made it only to find the finish line had been taken down ten hours early"[39] And that a "chain of extenuating circumstances justif[ies] relief here."[40]

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."[41] Additionally, "[a] decision by the Board . . . shall be supported by substantial evidence when the record is viewed as a whole."[42] In *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (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."

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[38] *Id.* at 10-11. The following is presented for background information. The SAMS portal requires multi-factor authentication. *See* User Guide for CDC's SAMS Partner Portal, Version 2.0, updated 10/1/2021, available at https://auth.cdc.gov/sams/SAMSUserGuide.pdf (accessed 06/23/2025). One option for a second factor authentication is the physical Entrust grid card referenced in this case. "The grid card is a paper-based card that can be printed from a PDF file and contains a grid of rows and columns consisting of numbers and characters. As part of the MFA process, users are presented with a coordinate challenge and must respond with the information in the corresponding cells from the unique card that they possess." Rohan Ramesh, Grid Cards: Multi-factor authentication without the technical overhead, Nov. 1, 2022, available at https://www.entrust.com/blog/2022/11/grid-cards-multi-factor-authentication-without-the-technical-overhead (accessed 06/23/2025).
[39] *Id.* at 12.
[40] *Id.*
[41] 42 C.F.R. § 405.1871(a)(3).
[42] 42 U.S.C. 1395oo(d).

DISCUSSION:

In the instant consolidated matters, CMS has reduced payment to the Provider under three separate quality data reporting programs based upon the Provider's failure to timely submit one particular data set – Influenza Vaccination Coverage among Healthcare Personnel for the 2016-2017 influenza season.[43]

The applicable legal standards require the submission of certain documentation to CMS along with the provider's request for reconsideration in each of the three quality reporting programs. Specifically, inpatient psychiatric facilities are required to submit a "detailed explanation of why the inpatient psychiatric facility believes that it complied" with program requirements,[44] and "[a]ny evidence that supports the inpatient psychiatric facility's reconsideration request, such as emails and other documents."[45] A hospital outpatient department is required to provide the "specific reason(s) for believing it should not be subject" to the payment penalty as well as "[a] copy of all materials that the hospital submitted to comply with the requirements of the affected Hospital OQR Program payment determination year."[46] Inpatient hospitals are required to submit "[a] detailed explanation of why the hospital believes that it complied" with program reporting requirements, and also "[a]ny evidence that supports the hospital's reconsideration request, including copies of patient charts, e-mails and other documents."[47]

Hazard concedes it timely "submitted all its quality data to satisfy the relevant Prospective Payment System annual payment updates ***except*** the final data set showing that staff had received required vaccinations for influenza for the 2016-2017 influenza season."[48] Hazard explains that its staff did not have the ability to enter this final data set until the due date of May 15, 2017 because of staff changeover and "difficulty acquiring a new 'Grid' security card."[49] Hazard alleges that when it attempted to enter the final data set, an error on the part of the system resulted in the final data set not being accepted by the system.[50] Later, after the due date, the Provider was able to enter the missing data set and it was accepted for "historical purposes."[51]

Hazard offered witness testimony[52] and affidavits of employees[53] stating Hazard had difficulty getting into the NHSN system, and once it was able to get into NHSN that it was not able to upload the data. Hazard concludes it was not able to upload the required data set because "the

[43] Case No. 18-1545, Provider's Final Position Paper at 4.
[44] 42 C.F.R. § 412.434(b)(5).
[45] 42 C.F.R. § 412.434(b)(6).
[46] 42 C.F.R. § 419.46(f). The Board notes that section (f), as effective from Jan. 1, 2017 to Dec. 31, 2017, is the one quoted here. The Provider refers to 42 C.F.R. § 419.46(g) in their arguments, however, section (g) did not relate to "reconsiderations and appeals" until the version of the regulation that became effective Jan. 1, 2021.
[47] 42 C.F.R. § 412.140(e).
[48] Provider's Brief at 1-2. Emphasis added.
[49] *Id.* at 2.
[50] *Id.*
[51] *Id.*
[52] Tr. at 36-38.
[53] Case No. 18-1545, Ex. P-3 and Ex. P-4.

site closed ahead of time."[54] Hazard alleges that NHSN was not working and "it appeared as though the site was busy perhaps from too much traffic…."[55]

Hazard cites to *Pomona Valley Hosp. Med. Ctr. V. Azar, 2020 WL 5816486 (D.D.C. 2020)* and argues the burden is on CMS to show that the NHSN website was functioning.[56] However, the Board notes Hazard's witness stated an employee was able to get into the website on the due date, but was not able to input the data at that time.[57] Additionally, the facts in this case are distinguished from the *Pomona Valley* case. Here, the Provider is in complete possession of the data set to be uploaded into a data system which will then send the data to CMS. In *Pomona Valley*, CMS and the Social Security Administration are the sole possessors of a data set that the providers seek to obtain to verify payment accuracy. The factual circumstances are quite different.

Hazard also cites to 71 Fed. Reg. 47870, 48040-41 (Aug. 18, 2006), arguing there is no evidence CMS researched the alleged data processing and communication errors which were reported to CMS in an e-mail on May 15, 2017.[58] The Federal Register states in relevant part:

> *Comment:* One commenter requested that hospitals not be held responsible when data processing and communication errors, under the control of CMS or that occur as a result of actions of its contractors, cause a failure in validation.
>
> *Response:* When a hospital reports data processing and communication errors, the errors are thoroughly researched. CMS has not held a hospital responsible for data processing and communication errors that were clearly under the control of CMS or its contractors. However, CMS does hold the hospital responsible for its own errors in data processing and communication. If the error is by the hospital's contracted vendor, the hospital is held responsible….

The Board notes that the Federal Register comment contains no mention of a burden on CMS to prove the data system was working, but rather simply states CMS will research reports of errors and that CMS has not held a hospital responsible for errors under CMS control. Additionally, other than self-proclaiming emails and affadavits, Hazard has produced no evidence demonstrating that their inability to upload the data was through no fault of their own (e.g., user error). There is no documentary evidence (such as screenshots or the like) to show exactly what was encountered during the employees' attempts to upload the data. There is no documentary evidence, such as communications with other facilities which corroborate that they, too, experienced issues with the NHSN system on May 15, 2017.[59] In the absence of such documentary support, the Board cannot reasonably conclude that heavy server traffic on the NHSN system caused it to shut down prior to the 11:59pm deadline, thus preventing Hazard

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[54] Provider's Brief at 3.
[55] CN 18-1545, P-4 at ¶ 5.
[56] Provider's Brief at 4.
[57] Tr. at 37.
[58] *See* Case No. 18-1545, Provider's Final Position Paper at 7-8; Case No. 18-1545, Ex. P-8; Provider's Brief at 4.
[59] Tr. at 83: 3-7.

from uploading the data, as suggested by the Hazard employee.[60] In fact, Hazard admits that no other hospitals in the ARH system experienced issues with uploading the HCP Influenza Vaccine data.[61] Thus, Hazard has failed in its efforts to shift the burden of production (i.e., going forward)[62] to CMS to prove that the issues encountered by Hazard on May 15, 2017 were under the control of NHSN or CMS.

The Board further notes that, in an email to NHSN regarding the errors sent on May 15, 2017, the Provider's employee stated: "Hello, we are trying to enter in the data for Q3 & Q4 2016 for ***LTAC*** facilities, but it doesn't have Q4 available for us to enter."[63] Hazard is not an LTAC (long-term acute care, also known as long term care hospital ("LTCH")), nor are the quality programs at issue LTCH quality programs. Indeed, the response from NHSN focused on reports and data for the "CMS Long Term Care Hospital Quality Reporting Program,"[64] not IPPS QRP or IPF QRP or OPPS QRP. The question posed to NHSN identified "LTAC" and therefore would seem to have misled the help desk analyst. The Board also notes that the response from NHSN stated "[w]e have been unable to followup with this question because . . . none of the users for this org ID19129 have recently generated new data sets."[65] It would appear research was attempted, but NSHN was unable to find data for the org ID in the LTCH system.

Finally, Hazard contends that only certain regulatory provisions, particularly, the reconsideration request requirements, be applied to its appeal. Hazard believes that by meeting the elements of the reconsideration request requirements through claims of substantial compliance, it should be immune from penalty. However, fulfilling the reconsideration request requirements set forth in 42 C.F.R. §§ 410.140(e), 412.434(a)-(b), or 419.46(f)(1)-(2) (as codified in 2017, currently (g) after 2021), to be reviewed by CMS is not synonymous with meeting its burdens of production and proof by a preponderance of the substantial evidence before the Board.[66] In the instant appeal, even if the Board concludes as a matter of law that Hazard met the procedural requirements of 42 C.F.R. §§ 410.140(e), 412.434(a)-(b), or 419.46(f)(1)-(2) (currently (g)), that does not equate to a conclusion of law that Hazard met the requirements of 42 C.F.R. § 410.140(c)(1), 42 U.S.C. § 1395ww(s)(4)(C) or 42 C.F.R. § 419.46(c)(1), which all required the submission of the HCP Influenza Vaccination data "in a form and manner, and at a time, specified by CMS [or the Secretary]."

FINDINGS OF FACT AND CONCLUSIONS OF LAW:

Medicare pays hospitals for various settings of care under the prospective payment system and provides financial incentives for participation in quality reporting programs, which include

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[60] Ex. P-4 at ¶¶ 5, 6, and 7.
[61] Tr. at 82:23-25 and 83:1-2.
[62] *See Bruner v. Off. Of Pers. Mgmt.*, 996 F.2d 290, 293 (Fed. Cir. 1993) ("The burden of production, also called the burden of going forward, is initially upon the person with the burden of proof, and generally requires the production of sufficient evidence to support a finding in favor of that person. *E.g., Greenwich Collieries*, 990 F.2d at 735. The burden of production then shifts to the other party, who must, in turn, produce enough evidence to raise a question of material fact. *Texas Department of Community Affairs v. Burdine*, 450 U.S. 248, 255 & n. 8 101 S.Ct. 1089, 1094 & n.8, 67 L.Ed.2d 207 (1981)."
[63] Ex. P-8 at 2 (Bold and italics emphasis added). *See also* Ex. P-4 at ¶ 9.
[64] *Id.* at 1.
[65] *Id.*
[66] The Board notes that the subsection 42 C.F.R. § 419.46(f)(1)-(2), as codified in 2017, was recodified to subsection (g) after 2021. *See* footnotes 1 and 47, above.

requirements for compliant quality data reporting for each respective program. Quality reporting programs include, but are not limited to, Inpatient QRP, Outpatient QRP, and IPF QRP. On deadlines set by CMS and published on CMS' designated websites, quality reporting program participants are required to electronically submit defined quality data sets via each quality reporting programs' specified website/portal. One particular data set is for Healthcare Personnel (HCP) Influenza Vaccination Measures. Quality reporting program participants that fail to meet the respective program requirements are subject to reductions in their annual payment updates—two-percentage point reductions for IPF QRP and Outpatient QRP noncompliance and reduction by one-fourth for Inpatient QRP noncompliance.

Quality reporting program participants may request an exception to or extension of data submission deadlines in extraordinary circumstances outside of the control of the participant. Specific regulatory instructions have been cited supra. Information on extension requests is available on QualityNet.org. If CMS determines that a quality reporting program participant failed to meet program requirements for an applicable calendar or fiscal year, the participant may also request reconsideration within 30 days of the date on Inpatient QRP and IPF QRP APU Notification Letters and no later than the first business day on or after March 17 of the affected payment year for Outpatient QRP, in accordance with the regulations. A participant dissatisfied with a reconsideration decision may file an appeal with the Board.

Hazard ARH Regional Medical Center was a participant in the Inpatient QRP, IPF QRP, and Outpatient QRP. It is undisputed that Healthcare Personnel (HCP) Influenza Vaccination Measure data sets for Inpatient QRP, Outpatient QRP, and IPF QRP for October 1, 2016 – March 31, 2017, were due on May 15, 2017. On March 10, 2017, Hazard's Infectious Disease Coordinator who was responsible for the hospital's quality data reporting resigned. The Chief Clinical Nursing Officer (at that time) assumed the duties of the role on March 13, 2017, and on that same day, initiated the registration process with NHSN in order to access the system.[67] On or about April 26, 2017, Hazard initiated the registration process for the new hire for the position, and was "informed that it could take six to eight weeks to obtain the 'grid' card" for NHSN system access.[68] Basing the calculation on the April 26, 2017 date, six to eight weeks would fall between June 7 and June 21, 2017. Noting that those dates would fall after the deadline for the HCP data submission, the Board notes that Hazard could have requested an exception or exemption (as allowed by law at that time) for the inpatient or outpatient data. At that time, there was no regulatory provision regarding exception or exemption requests for inpatient psychiatric data submissions. However, per the hearing testimony, Hazard's witness did not request any extension or exemption, in view of the delays in registration. The witness had no knowledge of any requests being made by anyone else at ARH, either.[69]

On the morning of May 8, 2017, Hazard followed up regarding the status of the two employees' NHSN access and received an email including instructions for resolution, which noted "there was a discrepancy with her address…users was going to re-register with the correct address."[70] That same day, at 12:09pm, Hazard received notification that it had not yet submitted the Healthcare Personnel (HCP) Influenza Vaccination Measure data sets that were due within one-

[67] Ex. P-3 at ¶¶ 3-4 and 6-9. *See also* Ex. P-2 at 1-6.
[68] *Id*. at ¶ 13.
[69] Tr. at 42:20-25 and 43:1-3.
[70] Ex. P-2 at 8.

week on May 15, 2017, at 11:59pm (PST). Later that day, Hazard had completed the re-registration and the SAMS Helpdesk notified Hazard that the "paperwork had been received and approved," but the grid card was needed before they "could access the account which should be received within 10 business days."[71] Again, an extension or exemption could have been requested at this time, in view of the fact that 10 business days from May 8th would be after the May 15th deadline, but no request was made.

At 10:55am on the deadline date of May 15, 2017, Hazard contacted NHSN via email inquiring about other options to submit the HCP Influenza data because they had not received the grid cards to access the system. Hazard's representative stated:

> I understand an extension is not normally given – but we are out of options to meet the deadline without this card. Is there any way to FAX this info to you or be given a temporary generic pass code? ***We are open to your directions***. Please feel free to contact me by email or cell phone.[72]

Less than 30 minutes later, a NHSN representative promptly responded to the email copying both of the Hazard employees who were awaiting their grid cards. The email stated:

> Unfortunately you must have an active SAMS account and grid card to access the NHSN application. ***You may consider reaching out to another facility who has SAMS access to help in the interim.*** Please advise should you have more questions going forward. ***Please direct all extension request[s] directly to CMS.*** Thank you[.][73]

Hazard ***did not*** submit an extension request ***directly to CMS*** as instructed by the NHSN representative in its email.[74] Further, the Board notes that, upon receipt of the email indicating Hazard had not yet submitted the required data, which it received on May 8th, that email was forwarded (also on May 8th) to another employee at ARH, with the Subject, "FW: Medicare Payment at Risk: HCP Influenza Vaccination is May 15, 2017." In a response to that forwarded email, less than an hour later, the other ARH employee copied both employees who were in need of grid cards, stating "If you need help let me know and I can get us some."[75] The record does not provide any evidence to show that this offer was accepted at that time, or at any time leading up to the May 15th deadline.

Around 2:45pm MST on May 15, 2017, Hazard's employee's previously arranged flight from Kentucky arrived in Montana (her home state). Upon arriving at her home, she discovered that the grid card had been mailed to her home address instead of the work address. She made multiple attempts to sign on to the website, with the grid card, but could not log in.[76] She contacted the new Infection Control Coordinator (also awaiting a grid card), and from about 2:45pm MST to 4:54pm EST, the two employees made repeated attempts to submit the data to

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[71] Ex. P-3 at ¶¶ 14-16. *See also* Ex. P-2 at 9-11.
[72] Ex. P-5 (emphasis added).
[73] Ex. P-6 (emphasis added). See also Tr. at 32.
[74] Tr. at 42-43.
[75] Ex. P-2 at 9-10.
[76] Tr. at 33-35.

no avail. The Infection Control Coordinator successfully logged in around 4:54pm, however he informed the other employee that he was unable to submit the data as the options were limited to 2017 data, not the October 1, 2016 – March 31, 2017 data set that was due on that day.[77]

The Infection Control Coordinator emailed NHSN at 4:53pm on May 15th, informing them of the issues Hazard was experiencing, but referring to "LTAC" facility data submission, specifically that the system indicated that there was nothing for Hazard to complete despite there being hours left to complete the submission.[78] It is unclear whether Hazard was accessing the appropriate modules within NHSN for proper data submission, and there is no evidence in the record (such as screenshots) to show what modules were at issue. Again, at this time, still hours before the deadline, no Hazard representatives submitted an extension request ***directly to CMS as they had been instructed at 11:16am***.

No other ARH facilities experienced difficulties submitting data sets on May 15, 2017. Hazard did not inquire nor was it informed of other facilities experiencing NHSN data submission issues on May 15, 2017.[79] Hazard eventually uploaded the October 1, 2016 – March 31, 2017 HCP Influenza Vaccination Measure in or about July or August of 2017.[80]

The regulations at 42 C.F.R. § 410.140(c)(1), 42 U.S.C. § 1395ww(s)(4)(C), and 42 C.F.R. § 419.46(c)(1), respectively, require that inpatient hospitals, inpatient psychiatric facilities, and hospital outpatient departments each submit data on quality measures in a form and manner, and at a time, specified by the Secretary. Hazard failed to comply with the submission requirements for the HCP Influenza Vaccination Measure data sets for the October 1, 2016 – March 31, 2017 reporting period on or before the May 15, 2017 deadline. Hazard could have requested an exception pursuant to 42 C.F.R. § 412.140(c)(2) or an exemption pursuant to 42 C.F.R. § 419.46(d) for any extraordinary circumstances. Hazard made no such request(s) despite having staffing issues and advance notice that it would be running up against the deadline for data reporting and risking the possibility of inability to access the data system in time.

While Hazard claims it has demonstrated that "CMS or its contractor caused the error in the data submission process that kept the data from being timely submitted,"[81] the Board disagrees. The Board finds that Hazard has not provided supporting evidence demonstrating full compliance with the data reporting requirements for the data set at issue as required by 42 C.F.R §§ 412.140(e), 412.434, and 419.46(g). The Board concludes that Hazard failed to fully comply with Inpatient, Outpatient and IPF Quality Reporting Program requirements to submit data in a form and manner, and at a *time*, specified by the Secretary. Further, as noted *supra*, the Board finds that the simple fact that Hazard filed three reconsideration requests, with the necessary elements required for the filings does not make it immune from penalty. Pursuant to 42 C.F.R. § 405.1871(a)(3), Hazard had the burdens of production and proof in this matter, and in order to shift the burden to CMS to show that it or NHSN was responsible for system issues on May 15, 2017, Hazard must first have produced sufficient evidence to support a finding in its favor. Hazard failed to do so. Based on the foregoing, CMS properly imposed the penalties in accordance with law.

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[77] Ex. P-4 at ¶¶ 7-10.
[78] Ex. P-8 at 2. See also Ex. P-4 at ¶ 9.
[79] Tr. at 82:22-25 and 83:1-7.
[80] *Id.* at 44-45 and 124-125.
[81] Provider's Brief at 5.

DECISION AND ORDER:

After considering Medicare law and regulations, the arguments presented, and the evidence admitted, the Board finds that the Provider did not timely report influenza vaccination data to CMS consistent with the legal standards articulated in 42 C.F.R. §§ 412.140, 412.434, and 419.46, and that CMS properly imposed the penalties in Case Nos. 18-1545, 18-1669, and 18-1802.

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FOR THE BOARD:

7/9/2025

X Kevin D. Smith, CPA

Kevin D. Smith, CPA
Board Chair
Signed by: Kevin D. Smith -A