

PROVIDER REIMBURSEMENT REVIEW BOARD DECISION

2021-D14

PROVIDER –
Hazard ARH Regional Medical Center

VIDEO HEARING DATE –
June 25, 2020

PROVIDER NO. –
18-0029

YEARS –
Fiscal Year 2018
Calendar Year 2018
Fiscal Year 2019

vs.

MEDICARE CONTRACTOR –
CGS Administrators, LLC – J15

CASE NOS. –
18-1545
18-1669
18-1802

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ISSUE STATEMENT:

1. For Case No. 18-1545, whether CMS' decision to reduce the Provider's Fiscal Year ("FY") 2018 Inpatient Psychiatric Facility Prospective Payment System annual payment update ("APU") by 2 percentage points was proper?¹
2. For Case No. 18-1669, whether CMS' decision to reduce the Provider's Calendar Year ("CY") 2018 Outpatient Prospective Payment System APU by 2 percentage points was proper?²
3. For Case No. 18-1802:
 - a. Whether CMS' decision to reduce the Provider's FY 2019 hospital Inpatient Quality Reporting Prospective Payment System APU by one-quarter was correct; and³
 - b. Whether CMS' decision to exclude the Provider from participating in a hospital value based purchasing program for FY 2019 was proper?⁴

DECISION:

After considering Medicare law and regulations, arguments presented, and the evidence admitted, the Provider Reimbursement Review Board ("Board") finds:

1. In all three cases, the Centers for Medicare and Medicaid Services' ("CMS") reduction to the APU for Hazard ARH Regional Medical Center ("Hazard" or "Provider") was proper; and
2. It was proper for CMS to exclude Hazard from participating in the hospital value based purchasing program for FY 2019.

INTRODUCTION:

Hazard is a hospital located in Hazard, Kentucky that operates both an acute care hospital, a long term acute care hospital, and an inpatient psychiatric facility.⁵ Hazard is appealing three separate CMS determinations for which it requested a consolidated hearing. Hazard's designated Medicare contractor⁶ is CGS Administrators, LLC – J15 ("Medicare Contractor"). Hazard is part of Appalachian Regional Healthcare ("ARH") and ARH consists of more than 10 hospitals.⁷

¹ Transcript ("Tr.") at 5-6.

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ *Id.* at 15.

⁶ The term "Medicare contractor" refers to fiscal intermediary or Medicare administrative contractor as relevant.

⁷ Tr. at 58-59.

On September 11, 2017, CMS notified Hazard that it had failed to meet the Inpatient Psychiatric Facility (“IPF”) Quality Reporting Program (“QRP”) requirements for FY 2018. As a result of its failure to meet the IPF QRP requirements, Hazard’s FY 2018 Prospective Payment System APU was reduced by two percentage points.⁸ Specifically, CMS notified Hazard that the 2 percent reduction in its FY 2018 APU was due to the fact that it failed to timely submit quality data as required by federal law. Following Hazard’s formal request for reconsideration, CMS upheld its decision to impose a 2 percent reduction in its APU on February 5, 2018.⁹

On November 3, 2017, CMS notified Hazard that its CY 2018 Outpatient Prospective Payment System APU would be reduced by two percentage points due to Hazard’s failure to meet the requirements of the Outpatient Quality Reporting Program (“OQRP”).¹⁰ Specifically, CMS notified Hazard that the 2 percent reduction in its CY 2018 Outpatient Prospective Payment System APU was due to the fact that it failed to timely submit quality data as required by federal law. Following Hazard’s formal request that CMS reconsider its determination, CMS upheld the payment reduction on May 31, 2018.¹¹

On March 8, 2018 the Medicare Contractor notified Hazard that its FY 2019 Inpatient Prospective Payment System (“IPPS”) APU would be reduced by one quarter due to Hazard’s failure to meet the requirements of the Inpatient QR Program.¹² Specifically, the Medicare Contractor notified Hazard that the one quarter reduction in its FY 2019 IPPS APU was due to the fact that it failed to timely submit quality data as required by federal law. 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.¹³

Hazard has timely appealed all three CMS determinations to the Board and met the jurisdictional requirements for a hearing. These three cases were consolidated for hearing, and the Board held a video hearing on June 25, 2020. 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 FACTS AND RELEVANT LAW:

There is one data set at issue in all three cases before the Board - Influenza Vaccination Coverage among Healthcare Personnel for the 2016-2017 influenza season.¹⁴ 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.¹⁵

⁸ Case No. (“CN”) 18-1545, Exhibit 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.

⁹ CN 18-1545, Exhibit C-3.

¹⁰ CN 18-1669, Exhibit C-1.

¹¹ CN 18-1669, Exhibit 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 Final Position Paper (Sept. 13, 2019) at 3.

¹² CN 18-1802, Exhibit C-1.

¹³ CN 18-1802, Exhibit C-2.

¹⁴ CN 18-1545, Provider Final Position Paper (Jan. 17, 2020) at 4.

¹⁵ *Id.*

A. Case No. 18-1545 – FY 2018 IPF-QRP

Section 124 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 implemented the IPF Prospective Payment System, which is a per diem prospective payment system for inpatient hospital services furnished by psychiatric hospitals.¹⁶ The IPF Prospective Payment System was phased-in over a three (3) year period, starting with cost reporting periods beginning on or after January 1, 2005.¹⁷ Since Congress did not specify a methodology for updating the payment rates under the IPF Prospective Payment System, the Secretary adopted an annual update methodology based on the approach used in other hospital prospective payment systems, with the first update to the IPF Prospective Payment System scheduled for July 1, 2006.¹⁸

As part of the Patient Protection and Affordable Care Act of 2010, Congress required the Secretary to implement the IPF QRP starting with the FY 2014 payment determination.¹⁹ Specifically, 42 U.S.C. § 1395ww(s)(4) ties receipt of a facility's full APU each year to participation in the applicable QRP and requires that, for FY 2014 and each subsequent fiscal year, the Secretary reduce the APU by two percentage points for any inpatient psychiatric facility that does not comply with the quality data submission requirements for that fiscal year.²⁰ Section 1395ww(s)(4) also requires psychiatric facilities to submit their quality data "in a form and manner, and at a time, specified by the Secretary."²¹ In the final rule published on August 6, 2014, CMS announced the IPF QRP requirement for inpatient psychiatric hospitals to report data for the "influenza vaccination coverage among healthcare personnel" ("Influenza Vaccine Data") quality measure, beginning with the FY 2017 payment determination.²²

The reporting period for Influenza Vaccine Data for the FY 2018 payment determination was October 1, 2016 through March 31, 2017.²³ May 15, 2017 was the deadline for the Influenza Vaccine Data to be submitted through the CDC's National Healthcare Safety Network ("NHSN").²⁴ Once entered into NHSN, the data is sent to CMS.²⁵ The 2014 final rule also directed participants to the QualityNet web site for access to a manual containing directions regarding the form, manner, and timing of the data submission for the IPF QRP quality measures.²⁶ NHSN also provides a number of resources on its website, including Frequently

¹⁶ Pub. L. No. 106-113, Appendix F, 113 Stat. 1501A-321, 1501A-332 (1999).

¹⁷ 69 Fed. Reg. 66921, 66964-67 (Nov. 15, 2004); 42 C.F.R. § 412.426(a).

¹⁸ 69 Fed. Reg. at 66966.

¹⁹ Pub. L. No. 111-148, 124 Stat. 119, 483-84, 952-54 (2010) (revising 42 U.S.C. § 1395ww(s)(4)). *See also* 77 Fed. Reg. 53257, 53644-45 (Aug. 31, 2012).

²⁰ *Id.*

²¹ 42 U.S.C. § 1395ww(s)(4)(C). *See also* 42 C.F.R. § 412.424(d)(1)(vi)(A).

²² 79 Fed. Reg. 45937, 45968-70 (Aug. 6, 2014).

²³ Inpatient Psychiatric Facility Quality Reporting Program Manual at 7, 32 (Version 2.1, June 7, 2016) (*available at* <https://qualitynet.cms.gov/ipf/ipfqr/resources>)

²⁴ *Id.* at 30, 32.

²⁵ CMS Quality Reporting Programs Frequently Asked Questions (Last reviewed March 30, 2015) (*available at* https://www.cdc.gov/nhsn/faqs/cms/faq_cms_hai.html#q8).

²⁶ 79 Fed. Reg. at 45976. *See also* 77 Fed. Reg. at 53654-55.

Asked Questions (“FAQs”) for CMS quality reporting programs²⁷ and an Enrollment and Set-Up Checklist for Inpatient Psychiatric Facilities.²⁸

The 2 percentage point reduction to the APU penalty imposed by CMS impacts payment to the Provider for FY 2018 as determined under the IPF Prospective Payment System.

B. Case No. 18-1669 – CY 2018 Outpatient QRP

Medicare pays hospitals for outpatient services under the Outpatient Prospective Payment System.²⁹ CMS provides financial incentives to hospitals that report quality data for multiple settings of care if hospitals comply with reporting requirements “in a form and manner, and at a time, specified by the Secretary[.]”³⁰ For hospitals’ outpatient care, quality data is reported through the Outpatient QRP. The Outpatient QRP requirements are communicated to hospitals through multiple sources, including Federal Register notices/rulemakings, regulations and the QualityNet website.³¹ Failure to submit quality data as required results in a 2 percentage point reduction in the hospital outpatient department (“OPD”) fee schedule increase factor.³²

The data reporting requirements for the CY 2018 Outpatient Prospective Payment System payment determinations were finalized in the CY 2015 OPSS Final Rule.³³ The finalized reporting requirements include “OP–27: Influenza Vaccination Coverage among Healthcare Personnel.”³⁴

The Outpatient QR Program regulations permit CMS to grant exceptions to 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.”³⁵

C. Case No. 18-1802 – FY 2019 Inpatient QRP

The Medicare program pays acute care hospitals for inpatient services under the IPPS,³⁶ whereby the Medicare program pays hospitals predetermined, standardized amounts per discharge, subject to certain payment adjustments.³⁷ Hospitals receive an annual percentage increase in the standardized amount, known as the “market basket update,” or APU, to account for increases in operating costs.³⁸

²⁷ (Last reviewed March 30, 2015) (available at https://www.cdc.gov/nhsn/faqs/cms/faq_cms_hai.html).

²⁸ (Last revised April, 2015) (available at <https://www.cdc.gov/nhsn/PDFs/IPFs/IPF-Enrollment-Checklist.pdf>).

²⁹ 42 U.S.C. § 1395l(t).

³⁰ 42 U.S.C. § 1395l(t)(17)(B).

³¹ See <http://www.qualitynet.org>.

³² 42 U.S.C. § 1395l(t)(17)(A)(i).

³³ 79 Fed. Reg. 66770, 66956 (Nov. 10, 2014).

³⁴ *Id.*

³⁵ 42 C.F.R. § 419.46(d) (2018).

³⁶ 42 U.S.C. § 1395ww(d); 42 C.F.R. Part 412. IPPS hospitals are often referred to as “subsection (d) hospitals.”

³⁷ 42 C.F.R. Part 412.

³⁸ 42 U.S.C. § 1395ww(b)(3). See also 42 C.F.R. § 413.40(a)(3) (“Market basket index is CMS’s projection of the annual percentage increase in hospital inpatient operating costs. The market basket index is a wage and price index

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003³⁹ amended 42 U.S.C. § 1395ww(b)(3)(B) to establish the Inpatient QRP that requires every hospital to submit quality of care data “in a form and manner, and at a time, specified by CMS.”⁴⁰ For fiscal years 2015 and beyond, CMS reduces the hospital’s annual IPPS APU by one-fourth if a hospital fails to report the quality data required under the Inpatient QRP.⁴¹

In order to meet each of the hospital Inpatient QRP requirements, hospitals must submit quality data in a specified format:

(II) Each subsection (d) hospital shall submit data on measures selected under this clause to the Secretary *in a form and manner, and at a time, specified by the Secretary* for purposes of this clause. The Secretary may require hospitals to submit data on measures that are not used for the determination of value-based incentive payments under subsection (o).⁴²

Inpatient QRP regulations permit CMS to grant exceptions to Program reporting requirements in the event of extraordinary circumstances beyond the control of the provider. CMS may grant such an exception, even if not requested, if it “determines that a systemic problem with CMS data collection systems directly affected the ability of the hospital to submit data”⁴³

DISCUSSION, FINDINGS OF FACT AND CONCLUSIONS OF LAW:

The facts in these cases are not in dispute. Hazard concedes that it failed to submit Influenza Vaccination Data for the 2016-2017 influenza season into NHSN by the reporting deadline of May 15, 2017. Significantly, the May 15, 2017 date was the reporting deadline of this data for three different quality reporting program requirements (*i.e.*, the non-submission of this data impacted three different quality reporting programs).

Hazard claims that it is being penalized for a CMS error, or the error of a CMS contractor.⁴⁴ In support of its position, Hazard cites to *PAMC, Ltd. v. Sebelius*.⁴⁵ Specifically, Hazard states it *attempted* to timely submit the required data, but was unable to do so because of a NHSN system failure. Specifically, Hazard alleges the NHSN reporting website closed ten hours before the cut-off time for data submission and that the website would not accept the data.⁴⁶ In support of this allegation, Hazard has offered affidavits⁴⁷ and testimony⁴⁸ from Hazard employees

that incorporates weighted indicators of changes in wages and prices that are representative of the mix of goods and services included in the most common categories of hospital inpatient operating costs”).

³⁹ Pub. L. No. 108-173, 117 Stat. 2066 (2003).

⁴⁰ *Id.* at § 501, 117 Stat. at 2290; 42 C.F.R. § 412.140(c)(1).

⁴¹ See 42 U.S.C. § 1395ww(b)(3)(B)(viii)(I); 42 C.F.R. § 412.64(d)(2)(i)(C).

⁴² 42 U.S.C. § 1395ww(b)(3)(B)(viii) (emphasis added).

⁴³ 42 C.F.R. § 412.140(c)(2).

⁴⁴ CN 18-1545, Provider Final Position Paper at 4-5.

⁴⁵ 747 F.3d 1214, 1219 (9th Cir. 2014) (copy at CN 18-1545, Exhibit P-10).

⁴⁶ CN 18-1545, Provider Final Position Paper at 1.

⁴⁷ CN 18-1545, Exhibits P-3 and P-4.

⁴⁸ Tr. at 34-38.

explaining the attempts made to submit the required data on the due date of May 15, 2017. Hazard also offers copies of text messages between its employees discussing these attempts to upload the data.⁴⁹ Hazard concludes “[i]t was *only* because of an error by CMS or its contractor that the NHSN site did not remain operational in order for the Provider to upload the data.”⁵⁰

Submission of data to CMS required Hazard to have an authorized user with the necessary credentials to submit the data, and to follow other procedures as required in order to use the NHSN system. Hazard explains it did not have an authorized user with the necessary credentials to submit the data *until the afternoon of the day the data was due*.⁵¹

Consistent with the statutory provisions governing each of the quality reporting programs at issue, the Secretary specified the “*form and manner, and . . . time*” by which the Influenza Vaccination Coverage Data was required to be submitted for the APU determinations under appeal. The data was required to be entered into NHSN by the May 15, 2017 deadline so that it could be submitted to CMS. The Board recognizes Hazard’s argument regarding CMS’ ability to grant exceptions to QRP requirements. In support of its position, Hazard cited to 42 C.F.R. § 419.46(d) (2018)⁵² which addresses exemptions under the Outpatient QRP as follows:

(d) *Exception.* CMS may grant an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS’ data collection systems directly or indirectly affects data submission. CMS may grant an exception as follows:

(1) *Upon request by the hospital.* Specific requirements for submission of a request for an exception are available on the QualityNet Web site.⁵³

(2) *At the discretion of CMS.* CMS may grant exceptions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred.⁵⁴

⁴⁹ CN 18-1545, Exhibit P-4 at Exhibit C. *See also* Tr. at 36-37.

⁵⁰ CN 18-1545, Provider Final Position Paper at 10 (emphasis added).

⁵¹ Tr. at 33.

⁵² Tr. at 12-13.

⁵³ *See* CMS Quality Program Extraordinary Circumstances Exceptions Request Form (dated April 2019) (*available at*: <https://qualitynet.cms.gov/inpatient/hvbp/participation#tab6>).

⁵⁴ As noted in the FY 2017 IPPS Final Rule, a provider may submit an “extraordinary circumstance exception request” using the form posted on the QualityNet Web site for the Inpatient and Outpatient QRPs as well as the IPF-QRP. CMS stated that this exception is “intend[ed] to provide relief only for hospitals whose ability to accurately or timely submit all of their claims (from which readmission measures data are derived) has been negatively impacted as a direct result of experiencing a significant disaster or other extraordinary circumstance beyond the control of the hospital.” 81 Fed. Reg. 56762, 56977 (Aug. 22, 2016); 82 Fed. Reg. 37990, 38001 (Aug. 14, 2017). *See also* 80 Fed. Reg. 49326, 49542-49543 (Aug. 17, 2015).

However, there is no evidence in the record of *extraordinary* circumstances beyond Hazard's control that caused the failure to submit the data, much less any evidence that Hazard submitted a request for an extraordinary circumstances exception.⁵⁵ To be sure, Hazard encountered difficulties in getting SAMS⁵⁶ authorization for the two new employees that Hazard hired and the Board is sympathetic with Hazard in this regard. However, upon close review of the record, the Board finds that Hazard's failure to follow up and plan for the May 15, 2017 submission deadline set itself up for the difficulties that it experienced when it unsuccessfully attempted to submit the requisite quality data on the afternoon of the May 15, 2017. In this regard, the Board makes the following factual findings:

1. The event that precipitated Hazard's difficulties was the resignation of Hazard's Infectious Disease Coordinator ("IDC") on March 10, 2017. The employee who resigned was Ms. Reynolds and she historically was responsible for submitting quality data.⁵⁷ Prior to Ms. Reynolds' departure on March 10, 2017, no one at Hazard other than Ms. Reynolds had authorized access to NHSN for Hazard.⁵⁸ Accordingly, after Ms. Reynolds' departure, no one remaining at Hazard had authorized access to NHSN.
2. On March 13, 2017, Hazard appointed its Interim Director of Nursing, Ms. Parker, as the Acting IDC until someone could be hired to fill the IDC position.⁵⁹ Significantly, Ms. Parker was a consultant or contract employee based out of Montana, and every three weeks she commuted back and forth from her home in Montana to Kentucky to work at Hazard.⁶⁰ When Ms. Reynolds resigned on March 10, 2017, the requisite quality data was not yet ready for submission to NHSN.⁶¹ To this end, Ms. Parker was advised that she would need to register with SAMS in order to get access to NHSN and submit the requisite quality data through NHSN.⁶²
3. Hazard was diligent in immediately initiating the multi-step process of getting SAMS/NHSN authorization for Ms. Parker and, on March 27, 2017, submitted the last piece of required information to NHSN (the Identify Verification Request form).⁶³ However, Hazard admits that it was informed that it would take six to eight weeks to obtain a "grid" card for login to NHSN, which is necessary to upload the quality data.⁶⁴ Significantly, six to eight weeks from March 27, 2017 is roughly in the range of May 7th to May 21st, which meant that, even with their diligence, delivery of Ms. Parker's grid card would potentially occur almost a week *after* the May 15th submission deadline.

⁵⁵ See Tr. at 42-43, 66, 161, 176-77 (Hazard witnesses confirming that they did not recall anyone from Hazard contacting CMS for, or otherwise discussing the pursuit of, an extension).

⁵⁶ Secure Access Management Services ("SAMS") is a federal information technology system that gives authorized personnel secure access to the NHSN website. See <https://www.cdc.gov/nhsn/sams/about-sams.html>.

⁵⁷ Exhibit P-3 at ¶¶ 4-5.

⁵⁸ Tr. at 57-58.

⁵⁹ Exhibit P-3 at ¶ 4.

⁶⁰ Tr. at 26-27.

⁶¹ *Id.* at 23.

⁶² *Id.* at 24.

⁶³ Exhibit P-3 at ¶ 12 and Exhibit F.

⁶⁴ *Id.* at ¶ 13.

4. Notwithstanding the upcoming submission deadline and the fact that, under normal procedure, the grid card could potentially come *after* the submission deadline, Ms. Parker apparently waited until May 8, 2017 to follow up on the status of her requested “grid” card.⁶⁵ Based on this follow up, the SAMS Helpdesk confirmed on May 8, 2017 that a “grid” card was being sent to Ms. Parker and that she “should receive” the grid card “within 10 business days,” *i.e.*, by Monday, May 23, 2017, which is well after the May 15, 2017 submission deadline.⁶⁶ Ms. Parker admits that, on May 8th when she made her inquiry with the SAMS Helpdesk, she was in Kentucky working at Hazard’s facility⁶⁷ and that she had not confirmed *where* the grid card was being sent.⁶⁸ Notwithstanding, she planned to fly back to Montana the morning of May 15th, the date when the submission was due, and admitted that the May 15th return date was selected to allow her to submit the requisite data on the May 15th submission deadline date, presumably, *if by chance*, her “grid” card had been already been delivered to her home in Montana ahead close of the quoted within-10-business-days delivery time frame.⁶⁹
5. Based on the May 8th response from the SAMS Helpdesk, the record suggests that the “grid” card was, in fact, delivered to Ms. Parker sometime between May 8th and 15th, but no later than May 15th, as she arrived back in Montana at 2:45 pm Mountain Standard Time (“MST”) on May 15, 2017 and found the “grid” card was sitting in her home mailbox.⁷⁰ As previously noted, Ms. Parker was unsure where the “grid” card was being sent and stated that her receipt of the “grid” card at her home was how she learned *where* the “grid” card was actually being sent.⁷¹
6. On May 8, 2017, Ms. Parker received notification from the Medicare program that the requisite data had not yet been submitted (the “At Risk Letter”).⁷² This notice was sent via email and confirmed that: (a) the submission deadline was Monday, May 15, 2017, at 11:59 pm Pacific Standard Time (“PST”); (b) hospitals that do not “meet the criteria for the IQR Program are at risk of having their annual payment reduced by one-fourth of the applicable market basket update”; (c) it “encouraged” facilities to submit the requisite data “well before the deadline to allow for transmission from CDS to CMS to be timely reflected on data submission reports”; (d) “[i]f you have questions” to contact the NHSN Help Desk at nhsn@cdc.gov; and (e) questions regarding the Hospital IQR Program could be submitted through a portal at <https://cms-ip.custhelp.com> or by calling the Hospital Inpatient Value, Incentives, and Quality Reporting (“VIQR”) Outreach Education Support Contractor at two specified telephone numbers weekdays from 8 a.m. to 8 p.m. Eastern Time.⁷³ Ms. Parker asserts that it was “by chance” that this notification

⁶⁵ *Id.* at ¶ 14 and Exhibit G.

⁶⁶ Exhibit P-3 at ¶ 16 and Exhibit I. Ten business days from Monday, May 8, 2017 was Monday May 22, 2017.

⁶⁷ Tr. at 29.

⁶⁸ *Id.* at 30.

⁶⁹ *Id.* at 29.

⁷⁰ *Id.* at 33.

⁷¹ *Id.* at 34.

⁷² Exhibit P-3 at ¶ 14; Tr. at 28-29.

⁷³ Exhibit P-3 at Exhibit H.

arrived on the same day that she made her inquiry to SAMS regarding the status of her “grid” card.⁷⁴

7. The CEO of Hazard also received this “At Risk Letter” notification on May 10, 2017.⁷⁵
8. The IDC position apparently was renamed the Infection Control Coordinator (“ICC”). On April 26, 2017, Hazard hired Mr. Hensley as ICC and Hazard immediately initiated the SAMS registration process for Mr. Hensley.⁷⁶ Hazard received the same notice that Ms. Parker received when she undertook NHSN registration, *i.e.*, that it could take six to eight weeks to obtain the “grid” card.⁷⁷ Significantly, six to eight weeks from April 26, 2017 is well past the May 15, 2017 submission deadline. As a result, it is clear that Hazard could not rely on the newly-hired ICC for submitting the requisite data by the May 15, 2017 submission deadline and needed to plan for an alternate means of submission. The record suggests that Hazard was going to rely *solely* on Ms. Parker being able to submit the requisite data by the May 15, 2017 submission deadline, notwithstanding the fact that she too could potentially not receive the “grid” card in time to meet the May 15, 2017 submission deadline.
9. Hazard waited until May 15, 2017 (the submission deadline date) to seek assistance from the NHSN Helpdesk and inquire about potential alternative ways for submitting the requisite quality data. Specifically, on May 15, 2017 at 10:55 am Eastern Standard Time (“EST”) while Ms. Parker was on travel back to Montana, a Hazard employee emailed the NHSN Helpdesk:

[W]e are contacting the NHSN Help Desk for information and support needed in process [*sic*] of how to submit the “influenza vaccination data” for the time period of Oct 1, 2016 through March 31, 2017.

We HAVE this data ready to submit via NHSN but due to turn over in our Infection Control Coordinator – we do NOT have the SAMS card/information to be able to submit. We HAVE applied for this card/information but do NOT have [*sic* it] at this time. We do anticipate the arrival of the card by the end of this week.

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.⁷⁸

10. The NHSN Helpdesk replied back roughly 20 minutes later at 11:16 am EST: “Unfortunately you must have an active SAMS account and grid card to access the

⁷⁴ Tr. at 28.

⁷⁵ Exhibit P-3 at Exhibit J.

⁷⁶ Exhibit P-4 at ¶ 3.

⁷⁷ Exhibit P-3 at ¶ 13.

⁷⁸ *Id.* at Exhibit J.

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 [sic] to CMS. Thank you.”⁷⁹

Notwithstanding this instruction, Hazard did *not* attempt to contact CMS about an extension request or learn more about the extension process or try to get more information regarding this option.⁸⁰ Similarly, Hazard did not explore the suggested option of reaching out to another ARH facility which had SAMS access to help in the interim.⁸¹ Rather, Hazard appeared to continue to put all its eggs in one basket and try to work through Ms. Parker and hope her grid card was waiting for her at her home in Montana.⁸²

11. After Ms. Parker received the grid card on the afternoon of May 15, 2017, she attempted to log into the NHSN system multiple times from her home in Montana. As a result of her difficulties accessing the system, she telephoned Mr. Hensley (the newly-hired ICC) who was at the Hazard facility in Kentucky and also texted with him. During this telephone call, she gave Mr. Hensley information on her username, password and grid card to allow him to attempt to sign in using his computer in Kentucky. He encountered some difficulties due to traffic on the system (presumably other facilities entering data to meet the May 15, 2017 submission deadline) but was able to sign into the NHSN system around 4:54 pm MST.⁸³ However, he stated that “We are past the deadline it seems, it only allows for 2017 data now. I emailed their support to try and figure out why.”⁸⁴ The referenced email was sent to the NHSN Helpdesk and 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. The facility is Hazard ARH in Hazard, Kentucky, Facility ID 19129. It says that there is nothing for us to complete, yet it’s still business hours on the 15th which is the deadline?”⁸⁵
12. There are multiple steps before the NHSN system will allow a provider to enter raw data for a month. In particular, for each reporting month, a provider has to first complete a monthly reporting plan to indicate the quality measures for which the provider will be submitting data for that month so that the system can create pathways to process the data on each quality measure when it is later submitted (*i.e.*, the system has to know that influenza vaccination data as opposed to data on another quality measure is being submitted so that it can know where to route that information).⁸⁶ Ms. Parker claimed that, prior to Ms. Reynolds’ leaving on March 13, 2017, Ms. Reynolds had assured her that the needed monthly plans for the quality data at issue in this case had been entered on or prior to March 13, 2017.⁸⁷ However, Ms. Parker had no evidence of that fact other than her recollection and she relied on Mr. Hensley’s description of what he was seeing

⁷⁹ *Id.*

⁸⁰ Tr. at 42-43, 66, 160-161, 177.

⁸¹ *See id.* at 67-68.

⁸² *See id.* at 160-161.

⁸³ Exhibit P-3 at ¶¶ 20-26.

⁸⁴ *Id.* at Exhibit K.

⁸⁵ *Id.* at Exhibit L.

⁸⁶ Tr. at 76-78.

⁸⁷ *Id.* at 78.

in the NHSN system and apparently did not ask Mr. Hensley to confirm whether a monthly plan had in fact been entered consistent with her recollection from March 2017.⁸⁸ Indeed, Ms. Parker had not had a grid card prior to the March-May 2017 application and, prior to May 15, 2017, had neither logged into the NHSN portal nor received any training on how to use the system.⁸⁹ Only after specific inquiry by the Board did Mr. Hensley discuss the import of the monthly plans or his alleged actions relating to them during his *first* log into the NHSN system. In particular, during the Board's inquiry, he acknowledged that the NHSN web page where raw data is entered is different from the NHSN web page or tab where monthly plans are created; *but then claimed* that, on May 15, 2015, in addition to the NHSN web page where raw data is entered, he did visit the NHSN web page where monthly plans are created and attempt to add a monthly reporting plan for the influenza vaccine.⁹⁰ However, the Board questions the credibility of his claim and testimony surrounding the monthly plans because, prior to May 15, 2017, Mr. Hensley had never signed onto NHSN⁹¹ and Mr. Hensley's testimony does not match the documentary evidence in this case. Specifically, his text to Ms. Parker on May 15, 2017⁹² and his email to NHSN on May 15, 2017⁹³ only refer to the NHSN web page where raw data entry is performed and do not discuss or reference any issues related to monthly data plans which are a prerequisite to entering any raw data. Based on the above, the Board must find that there is insufficient evidence to confirm that: (a) the requisite monthly plan had been previously entered by Ms. Reynolds; (b) on May 15, 2017, Mr. Hensley visited the NHSN web page where monthly plans are displayed to confirm that the requisite monthly plans were not visible and whether Mr. Hensley then attempted to unsuccessfully create the requisite monthly plans. Accordingly, the Board must conclude that the lack of the requisite monthly plans was the reason Mr. Hensley was not seeing a function to allow him to enter the raw data that was due to be submitted on May 15, 2017.⁹⁴

13. None of the other 10+ ARH hospitals/facilities had issues with submitting their influenza vaccine data.⁹⁵ There did not appear to be any communication from NHSN, CDC, or CMS about communication errors or system errors occurring on May 15, 2017.⁹⁶

Based on the above findings, the Board concludes that there was no evidence submitted of any systemic problem with the NHSN system that caused Hazard's failure to timely submit the

⁸⁸ *Id.*

⁸⁹ *Id.* at 41-42, 74-75.

⁹⁰ *Id.* at 150-54.

⁹¹ *Id.* at 114. Mr. Hensley did assert that he had received some training on NHSN prior to May 15, 2017 and was aware of monthly plans. *Id.* at 156.

⁹² Exhibit P-3 at Exhibit K.

⁹³ *Id.* at Exhibit L.

⁹⁴ Tr. at 151 (where Mr. Hensley testified that "I was unable to see really anything but that future data set point. So, I couldn't see past data options or anything. So, any past data options.").

⁹⁵ *Id.* at 82-83.

⁹⁶ *Id.* at 120-21.

Influenza Vaccination Coverage Data in a timely manner and that Hazard was at fault for its failure to timely submit said data.⁹⁷

42 U.S.C. § 1395ww(o) established the hospital value-based purchasing (“VBP”) program and it is implemented through the regulations at 42 C.F.R. § 412.160 *et seq.* Essentially, the Hospital VBP program rewards acute care hospitals with incentive payments for the quality of care provided in the inpatient hospital setting. This program adjusts payments to hospitals under the IPPS based on the quality of care they deliver. Significantly, if a hospital fails to meet the requirements for the FY 2019 Inpatient QRP is not eligible for inclusion in the FY 2019 VBP Program.⁹⁸ Given that Hazard failed to submit the Influenza Vaccination Coverage Data required by the Inpatient QRP, the Board must necessarily find that Hazard failed to qualify for inclusion in the Hospital VBP Program.⁹⁹

In summary, based on the statute, regulations and guidance identified above, the Board finds no evidence of system failure or error on the part of CMS or its contractor that contributed in any manner to Hazard’s failure to timely submit its Influenza Vaccination Data through NHSN. In the absence of such evidence, the Board must find the failure to timely submit the Influenza Vaccination Data resulted in Hazard’s non-compliance with the IQR, IPFQR, and OQR program requirements for its FY 2018, CY 2018, and FY 2019 payment determinations. Furthermore, these failures disqualified Hazard for the Hospital VBP Program for FY 2019. CMS’ payment determinations in these three cases are, therefore, affirmed. The Statute is clear that all data shall be submitted “in a form and manner, and at a time, specified by the Secretary,” and that Hazard failed to comply with this requirement.

⁹⁷ Moreover, the Board notes that 42 C.F.R. § 419.46(g)(1) suggests that, in order for the Board to review a claim of extraordinary circumstances, CMS must first render a decision on the alleged extraordinary circumstances as part of a reconsideration request:

(1) *A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital OQR Program in paragraph (b) of this section for a particular calendar year. Except as provided in paragraph (e) of this section, a hospital must submit a reconsideration request to CMS via the QualityNet website, no later than March 17, or if March 17 falls on a nonwork day, on the first day after March 17 which is not a nonwork day as defined in paragraph (d)(2) of this section, of the affected payment year as determined using the date the request was mailed or submitted to CMS. . . .*

(3) *A hospital that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board under part 405, subpart R, of this chapter.*

(emphasis added). Here, CMS’ denials of the reconsideration requests in the three cases do not address or discuss extraordinary circumstances. *See* CN 18-1545, Exhibit C-3; CN 18-1669, Exhibit C-2; 18-1802, Exhibit C-2. Accordingly, the Board has questions whether the Board would have the authority to review the claim of extraordinary circumstances at this late date. However, the Board need not resolve these concerns since the record is clear that there are no extraordinary circumstances.

⁹⁸ *See* 42 C.F.R. § 412.60 (defining hospital for purposes of participation in the hospital VBP program with respect to a fiscal year as one that is not subject to a payment reduction under the Inpatient QRP for that fiscal year). *See also* CN 18-1802, Exhibit C-3 (FY 2019 VBP final determination for Hazard (July 27, 2018)).

⁹⁹ The Board also notes that, similar to the Hospital IQR Program, CMS allows providers to request an exception for “extraordinary circumstances” in the Hospital VBP Program using the form on the QualityNet Web site. *See* 81 Fed. Reg. at 56977; *supra* note 54 (providing link to the form on the QualityNet Web site). However, there is no evidence that Hazard requested such an exception.

DECISION AND ORDER:

After considering Medicare law and regulations, arguments presented, and the evidence admitted, the Board finds:

1. In all three cases, the CMS' reduction to the APU for Hazard was proper; and
2. It was proper for CMS to exclude Hazard from participating in the hospital value based purchasing program for FY 2019.

BOARD MEMBERS PARTICIPATING:

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Susan Turner, Esq.

FOR THE BOARD:

3/24/2021

X Clayton J. Nix

Clayton J. Nix, Esq.
Chair
Signed by: Clayton J. Nix -A