PROVIDER REIMBURSEMENT REVIEW BOARD DECISION

2023-D26

PROVIDER –
Brazosport Regional Health System

VIDEO HEARING DATE –
March 17, 2021

PROVIDER NO. –
45-0072

YEAR –
Fiscal Year 09/30/2020

vs.

MEDICARE CONTRACTOR –
Novitas Solutions, Inc. – J-H

CASE NO. – 20-0230

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ISSUE STATEMENT

Whether the Provider complied with the Affordable Care Act ("ACA")[1] Inpatient Rehabilitation Facility ("IRF") Quality Reporting Program ("QRP") requirements for submission of quality data for the period at issue and, therefore, is not subject to a 2 percentage point reduction to its Medicare annual payment update ("APU") for fiscal year ("FY") 2020.[2]

DECISION

After considering Medicare law and regulations, arguments presented, and the evidence admitted, the Provider Reimbursement Review Board ("Board") finds that the 2 percentage point reduction of the Medicare APU for FY 2020 for Brazosport Regional Health System ("Brazosport" or "Provider") was proper.

INTRODUCTION

Brazosport is an acute care hospital (that includes an IRF as a sub-unit) located in Lake Jackson, Texas.[3] Brazosport's designated Medicare contractor[4] is Novitas Solutions, Inc. (the "Medicare Contractor").

By letter dated July 9, 2019, the Medicare Contractor notified Brazosport that the Centers for Medicare and Medicaid Services ("CMS") determined that Medicare payment for Brazosport's IRF sub-unit would be reduced by 2 percentage points for FY 2020 for failure to meet the quality reporting requirements pursuant to the Affordable Care Act § 3004 because Brazosport either failed to submit the required data to the Centers for Disease Control and Prevention ("CDC") National Healthcare Safety Network ("NSHN") system and/or failed to submit the required quality measures that are to be submitted to the CMS Quality Improvement Evaluation System ("QIES") system.[5] More specifically, the record shows that quality reporting period relevant to FY 2020 was calendar year ("CY") 2018 and that CMS assessed the penalty because Brazosport failed to properly and timely submit:

(1) The third quarter of CY 2018 data for NQF #1716 facility-wide inpatient hospital onset methicillin-resistant Staphylococcus aureus ("MRSA") for the third quarter CY 2018 (July 2018 – September 2018); and

(2) NQF #1717 facility-wide inpatient hospital onset Clostridium difficile infection ("CDI") Outcome Measure for the third and fourth quarter of CY 2018 (July 2018 – September 2018 and October 2018 – December 2018).[6]

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[1] Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (2010).
[2] Medicare Contractor's Final Position Paper (hereinafter, "Medicare Contractor's FPP") at 3.
[3] *Id.* at 2.
[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 term "Medicare contractor" refers to both FIs and MACs as appropriate.
[5] Exhibit C-1.
[6] Exhibit C-3.

Brazosport requested reconsideration of CMS' determination and submitted additional materials supporting its request on July 22, 2019.[7] On reconsideration, by letter dated September 11, 2019, CMS upheld the decision to reduce the APU for Medicare payments for FY 2020 by two (2) percentage points.[8]

Brazosport timely appealed to the Board and met the jurisdictional requirements for a hearing. The Board held a video hearing on March 17, 2021. Brazosport was represented by Tamara Rice of Brazosport. The Medicare Contractor was represented by Bianca Smith, Esq., and Joe Bauers, Esq., of Federal Specialized Services.

STATEMENT OF FACTS AND RELEVANT LAW

The Medicare program pays an IRF for services under the IRF prospective payment system ("IRF PPS"). Under IRF PPS, the Medicare program pays an IRF predetermined, standardized amounts per discharge, subject to certain payment adjustments. The standardized IRF PPS payment amounts are increased each year by a "market basket update" (or Annual Payment Update, "APU") to account for increases in operating costs.

ACA § 3004(b) amended 42 U.S.C. § 1395ww(j) to establish the IRF QRP at subsection (j)(7). As a result of this amendment, § 1395ww(j)(7)(C) requires each IRF to submit certain quality of care data "in a form and manner, and at a time, specified by the Secretary." Further, § 1395ww(j)(7)(A)(I) specifies that an IRF that fails to report the quality data required under the IRF QRP is subject to a 2 percent reduction to its APU.

The regulation governing IRF QRP data submission is located at 42 C.F.R. § 412.634 and states, in pertinent part:

> (b) *Submission Requirements and Payment Impact.*
>
> (1) IRFs must submit to CMS data on measures specified under section 1886(j)(7)(D), 1899B(c)(1), 1899B(d)(1) of the Act, and standardized patient assessment data required under section 1899B(b)(1) of the Act, as applicable. **Such data must be submitted in the form and manner, and at a time, specified by CMS**.[9]
>
> * * * *
>
> (f) *Data Completion Thresholds*. (1) IRFs must meet or exceed two separate data completeness thresholds: One threshold set at 95 percent for completion of required quality measures data and standardized patient assessment data collected using the IRF-PAI submitted through the CMS designated data submission system;

[7] Exhibit C-2.
[8] Exhibit C-3.
[9] 42 C.F.R. § 412.634(b)(1); 83 Fed. Reg. 38514, 38573 (Aug. 6, 2018) (emphasis added).

> and **a second threshold set at 100 percent for measures data collected and submitted using the CDC NHSN**.
>
> (2) These thresholds (95 percent for completion of required quality measures data and standardized patient assessment data on the IRF-PAI; 100 percent for CDC NHSN data) will apply to all measures and standardized patient assessment data requirements adopted into the IRF QRP.
>
> (3) An IRF must meet or exceed both thresholds to avoid receiving a 2 percentage point reduction to their annual payment update for a given fiscal year, beginning with FY 2016 and for all subsequent payment updates.[10]

In adopting quality data measures collected through the CDC NHSN system, the Secretary confirmed that the substantive aspects of the quality reporting process had been adopted through appropriate notice and comment rulemaking:

> *Comment*: One commenter had concerns about measures that are collected via the CDC's NHSN system, noting that more data is collected through NHSN than is required for the quality measure, and that those reporting processes are not subject to rulemaking and may add additional reporting burdens.
>
> *Response*: When we propose to adopt a quality measure that is collected and submitted to CMS via the CDC's NHSN, we make certain that the proposed rule provides a detailed description of the measure, and we address and respond to public comments on the reporting burden related to the measure. **In addition, we make certain that the measure specifications and protocols for the measure are posted on the CDC's NHSN Web site, the CMS Web site, and the NQF Web site, as applicable, and available for public scrutiny and comment, <u>including details related to the procedures for using NHSN for data submission</u> and information on definitions, numerator data, denominator data, data analysis, and measure specifications for the proposed measure**. Because of this, we believe that the substantive aspects of the reporting processes are subject to rulemaking.[11]

The record includes at Exhibit C-4 a copy of guidance that CMS issued in April 2018 entitled "Guidance for Reporting Data Into The [CDC's NHSN]."[12] This guidance included the

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[10] 42 C.F.R. § 412.634(f) (emphasis added).
[11] 80 Fed. Reg. 47036, 47087 (Aug. 6, 2015) (bold and underline emphasis added and italics emphasis in original).
[12] Also available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Downloads/IRF-CDC-Submission-Guidance-2018.pdf (last accessed July 14, 2023). *See also*

following general instruction on submitting data to CMS using the CDC NHSN and confirms that a monthly reporting plan must be complete in order to transmit data from CDC NHSN to CMS for the relevant month:

> Reporting of the NHSN CAUTI Outcome Measure (NQF #0138), the NHSN Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716), and the NHSN Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717) data ***are required***. For these quality measures, the reporting period consists of the four quarters in a given CY, with the fourth quarter's data to be submitted by May 15 of the subsequent year. ***To fulfill the CMS IRF QRP requirements***, *each facility's data* for the NHSN CAUTI Outcome Measure (NQF#0138), the NHSN Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716), and the NHSN Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717) ***must be entered into the CDC's NHSN*** no later than 135 days after the end of the reporting quarter. In other words, for first quarter (Q1) data (January 1–March 31) to be shared with CMS, data must be entered into NHSN by August 15.
>
> ***CDC submits the data to CMS on behalf of the facility, according to the facility's monthly reporting plan***. Data submitted to CDC more than 135 days after the end of the reporting quarter, such as data submitted to the CDC NHSN after August 15, for Q1, of that same CY will not be provided to CMS and will not be considered for the purpose of compliance determination.
>
> IRFs are able to review data submitted to CMS on their behalf through the "Analysis – Reports" function within NHSN. More information regarding the location and interpretation of these reports can be found on the CDC Web site: https://www.cdc.gov/nhsn/ps-analysisresources/reference-guides.html.
>
> ****
>
> For more information on data collection time frames and data submission deadlines the IRF Quality Reporting Data Submission Deadlines Web site, available in the Downloads section at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-QualityReporting/IRF-Quality-Reporting-Data-Submission-Deadlines.html.[13]

https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Archives.

[13] (Emphasis added apart from website addresses.)

The April 2018 guidance emphasizes the need to complete the monthly reporting plan with each quality measure for each location:

> ***NHSN CAUTI Outcome Measure (NQF #0138) Reporting***
>
> For reporting data on the NHSN CAUTI Outcome Measure (NQF #0138) under the IRF QRP, IRFs must adhere to the definitions and reporting requirements for CAUTIs as specified in CDC's NHSN Patient Safety Component Manual, available at https://www.cdc.gov/nhsn/pdfs/pscmanual/7psccauticurrent.pdf
>
> These requirements include reporting denominator data (patient days, and urinary catheter days) by location, as well as CAUTIs (event data), to NHSN each month. Monthly denominator data must be reported on CAUTIs regardless of whether an infection occurred in the IRF. Monthly reporting plans must be created or updated to include CAUTI surveillance in all locations that require reporting (i.e., surveillance must be "in-plan"). All required data fields in the numerator and the denominator, including the "no events" field for any month during which no CAUTIs were identified, must be submitted to NHSN. More information on how to report zero CAUTI events for a month is available at https://www.cdc.gov/nhsn/PDFs/CMS/how-to-report-NoEvents-CLAB-CAU.pdf.
>
> ***NHSN Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) Reporting***
>
> For reporting data on the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure under the IRF QRP, IRFs must adhere to the definitions and reporting requirements for this measure as specified in the CDC's *NHSN Healthcare Personnel Safety Component Protocol*, available at https://www.cdc.gov/nhsn/pdfs/hps-manual/vaccination/hpsflu-vaccine-protocol.pdf.
>
> To report Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) data, the NHSN *Healthcare Personnel Safety* (HPS) Component must be activated. An HPS Component Reporting Plan (see pages 2-1 and 4-2 of *Healthcare Personnel Safety Component Protocol*) must be completed for every month that data are entered into NHSN; however, for Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) reporting, once the "Influenza Vaccination Summary" box is checked on one monthly reporting plan, the system will auto-check

that same box on every monthly reporting plan throughout the entire NHSN-defined influenza season (defined as the 12 months from July 1–June 30). . . .

NHSN Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716) and NHSN Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717) Reporting

For reporting data on the NHSN Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716) and the NHSN Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717) under the IRF QRP, IRFs must adhere to the definitions and reporting requirements for MRSA Bacteremia and CDI as specified in CDC's NHSN *Multidrug-Resistant Organism (MDRO) and Clostridium difficile Infection (CDI) Module Protocol*, available at www.cdc.gov/nhsn/pdfs/pscmanual/12pscmdro_cdadcurrent.pdf.

These requirements include reporting data through Laboratory-Identified (LabID) Event forms and the MDRO denominator data form (patient days and admissions) to the NHSN at the facility-wide inpatient level on a monthly basis. Numerator data (i.e., all qualifying LabID specimens) will be reported using the *Laboratory-identified MDRO or CDI event form*.

For additional guidance on reporting these measures, please refer to https://www.cdc.gov/nhsn/inpatient-rehab/cdiff-mrsa/index.html.

General NHSN Reporting

To report data for the IRF QRP through CDC's NHSN, the IRF must be enrolled in the NHSN. Enrollment steps are outlined in the NHSN Facility Administrator Enrollment Guide available at www.cdc.gov/nhsn/pdfs/gen-support/facilityadminenrollmentguidecurrent.pdf. The information in the rest of this chapter supplements information available to the IRFs through the NHSN *Facility Administrator Enrollment Guide*.

Reminder: IRFs can be enrolled in NHSN as Acute Care Hospital units designated as IRFs OR as freestanding Inpatient Rehabilitation Facilities If your IRF is not enrolled in NHSN as a separate facility, and instead is currently submitting data as part of an acute-care hospital, i.e., as an acute care hospital unit designated as an IRF, it must have its own unique IRF CCN. If you have

> questions or need assistance, please contact IRFCoverage@cms.hhs.gov
>
> If your IRF is a freestanding inpatient rehabilitation facility and is not currently enrolled in NHSN as a separate facility, it will have to be enrolled in NHSN as a separate facility with a unique orgID that is identified as an IRF. If you have questions or need assistance, please contact the CDC NHSN Help Desk at nhsn@cdc.gov.[14]

Finally, the April 2018 guidance includes the following tips in its "Basic Steps to . . . Data Submission":

> 8. Use one of the following two NHSN Monthly checklists depending on the type of IRF to ensure complete reporting.
>
>   - NHSN Monthly Checklist for Acute Care Hospital units designated as Inpatient Rehabilitation Facilities reporting to the CMS IRF IQR Program: https://www.cdc.gov/nhsn/pdfs/cms/IRFs-acute-Monthly-Checklist-CMS-IQR.pdf.
>
>   - NHSN Monthly Checklist for Freestanding Inpatient Rehabilitation Facilities reporting to CMS IRF QRP: https://www.cdc.gov/nhsn/pdfs/cms/IRFs-freestandMonthly-Checklist-CMS-IQR.pdf.
>
> 9. **The locations must also be added to the monthly reporting plan** under the device-associated module section **for each month** you plan on submitting the NHSN CAUTI Outcome Measure (NQF #0138) to CMS. After adding the location, please remember to check the "CAUTI" box to ensure that the data will be appropriately sent to CMS.
>
> 10. The FacWideIN location must also be selected **in the Monthly Reporting Plan** for both LabID MRSA Blood Only Specimens and LabID *C. difficile* All Specimens to meet the LabID Event reporting requirements.

The Medicare Contractor explains that to comply with the CDC NHSN data submission requirements, IRFs must report quality data for each month of each quarter through the CDC NHSN. Additionally, IRFs need to take certain steps in order to ensure that data entered into the CDC NHSN system is transmitted to CMS by the applicable deadline. First, an IRF located within an acute care hospital must be included on the acute care hospital's monthly reporting plan ***for each month*** for which it is required to submit quality data. Second, the IRF must ensure

[14] (Underline emphasis added apart from website and email addresses.)

that ***each*** monthly reporting plan identifies the specific type of quality outcome measure for which the IRF intends to track and report quality data to CMS using the CDC NHSN system (*e.g.*, CAUTI outcome measure). If it is properly completed for a particular month prior to the relevant reporting deadline for that month, the monthly reporting plan will prompt the CDC NHSN system to then transmit the quality data associated with the outcome measures listed on that monthly reporting plan ***and*** *in accordance with the location identified on that monthly reporting plan* (here, the location relevant to this appeal that had to be listed on the monthly reporting plans at issue was the Brazosport IRF sub-unit). Accordingly, consistent with the monthly reporting plan completed for each month, the IRF must then enter the required quality data to report the number of infection events; including if no events occurred during that month. Quarterly, on the day after each reporting deadline, the CDC NHSN system transmits the data submitted by the IRF to CMS where the data is transmitted *according to the relevant monthly reporting plans properly and timely completed for the 3 months in that quarter*. The transmitted data is then reviewed to determine if the IRF's required data entries were complete and correct. This review determines whether an IRF has complied with the IRF QRP data reporting requirements. Every submission deadline, the CDC queries the CDC NHSN system to generate a list of non-compliant facilities and the reasons (if any) for that non-compliance.[15]

Brazosport's deadline for submitting the CY 2018 third quarter IRF data was February 15, 2019, and the deadline for submitting the CY 2018 fourth quarter IRF data was May 15, 2019.[16] CMS determined that:

- Brazosport's IRF sub-unit failed to submit the required data to the CDC NHSN; and/or
- Brazosport's IRF sub-unit failed to submit the required quality measures that are to be submitted to the CMS QIES system.[17]

More specifically, CMS determined that Brazosport failed to properly and timely submit: (1) the quality data for NQF #1716 facility-wide inpatient hospital onset MRSA for the third quarter CY 2018 (*i.e.*, for July 2018 – September 2018); and (2) NQF #1717 facility-wide inpatient hospital onset CDI Outcome Measures for the third *and* fourth quarters of CY 2018 (*i.e.*, for July 2018 – September 2018 and October 2018 – December 2018).[18]

Brazosport disagrees with CMS' findings and contends that they timely submitted all of the required MDRO and CDI Monthly Denominator Forms and Event Reports for the time periods referenced by CMS as being non-compliant.[19] In support of its position, Brazosport includes, in Exhibit P-3, copies of certain MDRO and CDI reports from the CDC NHSN for July through December 2018. Further, at the hearing, Brazosport's witness testified that she believed that, for the CY 2018 reporting period: (1) Brazosport's monthly reporting plan *processes* ensured that quality data is submitted timely; (2) along with alerts provided by the CDC NHSN dashboard, Brazosport's *processes* ensured timely submission; and (3) the paperwork included in Exhibit

[15] Medicare Contractor's FPP at 6.
[16] Provider's Final Position Paper (hereinafter "Provider's FPP") at 1.
[17] Exhibit C-1.
[18] Exhibit C-3.
[19] Provider's FPP at 1.

P-3 confirms that the quality data at issue was, in fact, timely submitted.[20] Brazosport's witness testified that:

> On the dashboard for NHSN you get alerts, and it tells you if the data has been submitted for that month or not. So, all of my current plans are created at the beginning of the year. So, when I -- I have one for January, I have one for February, and so on and so forth, you can't put in a reporting plan past the month of March unless you've done the annual survey. So, NHSN has its own set of alerts and queries on the dashboard that lets you know whether or not your data has been entered. But, also, I have a process of my data . . . . I'd print the patients' charts, I review it for HAI and get all of the necessary relative information that's needed to enter it into CMS. Once it is entered into CMS -- NHSN, I write the event numbers on the papers and then I am able to file those away into my binder…. Which would be the forms that are in our exhibit. They indicate the date it was submitted.[21]

Brazosport recognizes that the various CDC NHSN reports that it has entered into the record for this case show *only* the date the report was printed from the CDC NHSN system and not the last modified date. However, Brazosport asserts that the CDC NHSN system does not have the capability to show the submission or last modified dates and that, when it inquired with the CDC NHSN whether it was possible to verify submission dates, it was informed that capability did not yet exist.[22] Notwithstanding, Brazosport asserts that it has provided "proof" of its compliance and, as a result, the burden of proof has shifted to CMS:

> At no time during the course of this appeal have the representatives of CMS provided actual copies or proof of the purported deficient data as stated in their correspondence with BRHS they have only provided a narrative statement of the deficiency in the correspondence. [Brazosport] has provided actual report proof of compliance, submitted at multiple stages during the course of this appeal.[23]

Finally, Brazosport generically alleges that "the NHSN reporting system frequently experiences errors and glitches that effect data retrieval and/or viewing."[24] In support, Brazosport included, with its post-hearing submission, the Post-Hearing ("PH") Exhibit P-8 as an example of a purported technical issue within the CDC NHSN system, regarding an issue reported to users on March 15, 2021 regarding reported data that "may appear to be missing or unsaved" when it is not missing/unsaved and directing users experiencing these issues to contact NHSN.[25] However, this is not related to this case nor did it occur during the time period at issue. Brazosport has not

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[20] Tr. at 18-20, 32.
[21] Tr. at 32-33.
[22] Provider's Responsive Brief; Tr. at 34-35.
[23] Provider's Post-Hearing Brief at 1 (May 29, 2021).
[24] *Id.* at 2.
[25] Post Hearing (hereinafter, "PH") Exhibit P-8 (CDC Email regarding NSHN Application, dated Mar. 15, 2021).

presented any evidence or testimony to suggest that such errors or glitches occurred in connection with the quality data submissions at issue.

DISCUSSION, FINDINGS OF FACT, AND CONCLUSIONS OF LAW

This case focuses on whether Brazosport met the IRF QRP reporting requirements for FY 2020. Brazosport claims it timely filed all data for the third and fourth quarters of CY 2018.[26] However, the CDC's "non-reporter files" for the third and fourth quarters of CY 2018 reflect that, as of the time of the deadlines, Brazosport had not reported either the CDI quality data at issue for the third and fourth quarters or the MRSA quality data for the fourth quarter.[27]

At hearing, Brazosport claimed that it should not be penalized because it reported all data at issue by the appropriate deadlines.[28] Furthermore, Brazosport's witness testified she had been completing and submitting the hospital and IRF monthly reporting plans for several years without issue. As noted in the testimony of Brazosport's witness, quality outcome measures (*e.g.*, the CDI quality outcome measure) must be timely identified and included as "in-plan" on the relevant monthly reporting plan, to ensure data associated with those quality outcome measures are transmitted from the CDC NHSN system to CMS:

> *MS. SMITH*: So, more specifically about the monthly reporting plan, what's the difference between in-plan and out-of-plan?
>
> *THE WITNESS*: If it's in-plan it's required to be reported. If it's out-of-plan then it's not required.
>
> *MS. SMITH*: So, could you say that if it's in-plan that means that it's indicated on the monthly reporting plan and that information gets sent to CMS?
>
> *THE WITNESS*: Yes.
>
> *MS. SMITH*: And, if it's out-of-plan it's not on the monthly reporting plan and that won't go to CMS, right?
>
> *THE WITNESS*: Correct.[29]

The line listing for the monthly reporting plans, provided by Brazosport's Post-Hearing Brief, helps to clarify what errors resulted in the failed submission. More importantly, as noted from the testimony above, when a quality outcome measure (*e.g.*, the CDI quality outcome measure) is included in the Monthly Reporting Plan, it then prompts the CDC NHSN system to send to CMS any data associated with that quality outcome measure for the month covered by the Monthly

[26] Provider's Post-Hearing Brief at 2.
[27] Medicare Contractor's FPP at 7.
[28] Tr. at 39-40.
[29] Tr. at 26-27.

Reporting Plan. Thus, proper reporting requires both the data to be present and timely (as dictated and reported within Post-Hearing Exhibit P-5); ***and*** the relevant quality outcome measure to be included as in-plan in the monthly reporting plan for the relevant month (line listings in Post-Hearing Exhibit P-4), again in time for the reporting deadline.[30]

At the end of the hearing, the Board exercised its discretion to request additional documents from Brazosport, on a post-hearing basis, as the record and testimony at hearing failed to identify the reason for data submission failure. In response to this request, Brazosport submitted the following post-hearing ("PH") exhibits:

PH Exhibit P-1 – NSHN 3rd and 4th Quarter Summary Reports – pages 1-2
PH Exhibit P-2 – Analysis Report from MAC Exhibit C-4, page 3 (Output Report)
PH Exhibit P-3 – "How to View the Create & Modify Dates within NHSN" – pages 4-7
PH Exhibit P-4 – NHSN Line Listing – Plan – pages 8-13
PH Exhibit P-5 – NHSN Line Listing for all Summary Data Listing – pages 14-21
PH Exhibit P-6 – NHSN Email detailing "double entry," dated October 11, 2018 – page 22-23
PH Exhibit P-7 – NHSN Email detailing "data entry validation" availability, dated May 20, 2020 – pages 24-25
PH Exhibit P-8 – NHSN Email detailing "data/application error," dated March 15, 2021 – pages 26-27
PH Exhibit P-9 – NHSN Monthly Reporting Plans, July 2018 – December 2018 – pages 28-39
PH Exhibit P-10 – NHSN Line Listing for All Infection Events, Q3 & Q4 2018 – page 40

As noted earlier, the deadline for submitting to CMS the third quarter data for CY 2018 was February 15, 2019 and the deadline for submitting to CMS the fourth quarter data for CY 2018 was May 15, 2019 ("4.5 months or 135 days following the end of each CY quarter").[31] PH Exhibit P-4 shows the Monthly Reporting Plan Line Listing, and includes applicable events reported for Brazosport and the IRF sub-unit location at issue,[32] as well as MRSA and *C. Difficile* infection events, for each specific reporting month.[33] This monthly plan line listing indicates that, for some of the months, the monthly reporting plan and associated data were created and updated timely. For example, on page 9 (the second page of PH Exhibit P-4), the first line is an example of an in-plan event, that was created on May 17, 2018, and modified on December 10, 2018, for the "2018M07" reporting plan year and month, July 2018.[34]

However, on Page 9, in the line listing for monthly reporting plans, is an entry (the penultimate line on this page) for "2018M08" month, August 2018, which was modified on September 20, 2019, suggesting that the data for that month was late (*i.e.*, the data was uploaded *after* the February 15, 2019 submission deadline). Scattered throughout PH Exhibit P-4 are a number of other line listing monthly reporting plan examples that reflect a similar pattern, some with modified dates before the due date, and some with modified dates *well past the reporting deadlines*. For example, at page 13, on the third line from the bottom of the page, the

[30] (Italics emphasis added).
[31] Exhibit C-4 at 4.
[32] IRF is noted as location 5555 on these Line Listings.
[33] Exhibit P-4.
[34] Exhibit P-4, at 9 (page number reflects the full set of Exhibits).

"2018M12" item had a submission deadline of May 15, 2019; however, this item was last modified well beyond that deadline on September 20, 2019. All of these examples pertain to third and fourth quarters of CY 2018 and document that the last modification was *well after the submission deadline.*

Brazosport reaffirms its belief that its witness "testified to the completeness of the data and provided hard-copy evidence of compliance."[35] Brazosport again asserts that it:

> [S]ubmitted the ***MDRO and CDI Monthly Denominator Forms***, and ***Event Reports*** (when an event was reported), the evidence of compliance, for the six months comprising the third and fourth quarters of 2018. Both outcome measures were reported, specific to the IRF, each of the six months in question. These reports were submitted at appeal and presented at the PRRB Hearing on March 17, 2021. NHSN stated that they currently do not have reporting available to demonstrate and/or print reports showing submission/validation dates of reporting. . . . The evidence provided by BRHS clearly demonstrates complete and compliant reporting of the data in question.[36]

The requested printouts of the monthly reporting plans from the CDC NHSN system for third and fourth quarters from CY 2018 were provided in PH Exhibit P-9. The printouts indicate monthly reporting plans from July 2018 through December 2018 and show an access/print date of March 17, 2021.[37] However, the printouts do not include any dates to establish *when* these documents were created (*i.e*., last modified in the CDC NHSN system). The Board further reviewed PH Exhibit P-4, which shows the line listing report for monthly reporting plans, including creation and modification dates. The process to generate/create this report is explained in PH Exhibit P-3. In particular, page 6 of this exhibit specifically explains how the instructions provided by the CDC NHSN system can be used to determine *when* monthly reporting plans, events, procedures, and summary data were first entered or last modified within NHSN, as well as the user who created or modified the record.[38] However, Brazosport failed to include in the record printouts of the monthly reporting plans at issue showing *when* they were last modified.

Similarly, PH Exhibit P-5 (which shows the specific event data that is actually being reported to CMS) has the same date created and modified columns and shows incidences of both on time and late data, specifically in August 2018, as well. Here, lines include data that was both created and modified after the due dates, specifically, the final line on PH Exhibit P-5, at Page 16, shows Rehab data for the location at issue (5555), and indicates that this data for "2018M08," August 2018, was entered in September 2019, well beyond the due date of February 2019.[39]

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[35] Provider's Post-Hearing Brief at 2.
[36] *Id* (emphasis in original).
[37] PH Exhibit P-9.
[38] PH Exhibit P-3 at 6.
[39] PH Exhibit P-5 at 16.

Based on the record before it, the Board is unable to confirm that the monthly reporting plan was properly and timely completed in the CDC NHSN, that the underlying data was timely entered into the CDC NHSN, and the CDC NHSN "swept" that data per the relevant monthly reporting plans. In particular, the data and monthly reporting plan reports from the CDC NHSN submitted by Brazosport with their Post-Hearing Brief suggest that the monthly reporting plans at issue and associated data were *not* timely completed. Further, simply entering the data into the CDC NHSN system (as shown in PH Exhibit P-5) is insufficient to satisfy the reporting requirements, because the data must be entered prior to the submission deadline and, similarly, the monthly reporting plans for the applicable months must have been properly completed and in place as a final step in the reporting process *prior to the applicable reporting deadline*, in order to prompt the CDC NHNS to transmit the underlying data from the CDC NHSN *to CMS* at the expiration of the reporting deadline.

The Board recognizes that Brazosport's post-hearing submission includes, as PH Exhibit P-8, an email from NHSN dated March 15, 2021, regarding an issue that users may have then been "currently experiencing." However, as noted by the Medicare Contractor:

> This appears to be a ***generic*** email sent to all providers and it indicates that *if a specific provider is experiencing technical issues to email NHSN*. Nowhere does this email indicate that this Provider experienced this specific issue. Additionally, it states that once you email NHSN, "NHSN staff will confirm that your data has been received by our data base administrators and provider additional instruction." This appears to contradict a previous email where an NHSN contractor stated there was no way to verify data.[40]

The October 2018 email guidance that Ms. Guerra received from the CDC NHSN on double MRSA entry was submitted as PH Exhibit P-6. The CDC NHSN guidance specifically addressed the requirement that MRSA outcome measure must be listed as "in plan" on the monthly reporting plan by stating: "[i]f you have selected to monitor MRSA bacteremia LabID events *on your monthly reporting plan* . . . . "[41] While Brazosport submitted some documentation that suggests it included MRSA or CDI outcome measures on the monthly reporting plans for the third and fourth quarters of CY 2018,[42] the Board is unable to confirm that those monthly reporting plans were properly completed, and in effect, *prior to the applicable reporting deadlines*. Moreover, there are a number of discrepancies indicating that the underlying data associated with those plans was entered late, *i.e.,* ***after*** the applicable reporting deadlines.

Specifically, at the hearing, the Board requested that Brazosport submit, post-hearing, any CASPER/QIES reports or validation reports available to the Provider about NHSN data submission to CMS, and "whether – to what extent those system (inaudible) during the time at

[40] Medicare Contractor's Post-Hearing Brief at 8 (emphasis added).
[41] PH Exhibit P-6 at 22 (emphasis added).
[42] The previous discussion regarding data in Exhibit P-5 indicates the LabID events were present for all the relevant location data (5555), but not timely in every instance.

issue provided validation error or verification reports about NHSN data submitted to CMS."[43] Brazosport included as PH Exhibit P-7 an email exchange with the CDC NHSN inquiring whether "a report . . . can be ran on a given time frame that shows the date and time data was entered and transmitted" and receiving a response "[n]ot as [*sic* at] this time."[44] However, the CDC NHSN guidance in the record confirms that:

1. Brazosport is able to generate reports to confirm what was transmitted to CMS from the CDC NHSN system as showing in the following excerpt from CDC NSHN guidance dated April 2018:

> CDC submits the data to CMS on behalf of the facility, according to the facility's monthly reporting plan. Data submitted to CDC more than 135 days after the end of the reporting quarter, such as data submitted to the CDC NHSN after August 15, for Q1, of that same CY will not be provided to CMS and will not be considered for the purpose of compliance determination.
>
> IRFs are able to review data submitted to CMS on their behalf through the "Analysis – Reports" function within NHSN. More information regarding the location and interpretation of these reports can be found on the CDC Web site: https://www.cdc.gove/nhsn/ps-analysis-resources/reference-guides.html.[45]

2. As previously discussed, Brazosport is able to generate CDC NHSN reports that show "when monthly reporting plan, event, procedure, and summary data were first entered (createDate) or last modified (modifyDate) within NHSN" and "[t]he user in a facility who created and modified the record can also be determined in these reports."[46] The specific CDC NHSN instructions to generate these reports are included at PH Exhibit P-3 and are dated January 2020.

Based on the above, the Board finds the Provider has failed to demonstrate that it did, in fact, submit its IRF QRP data concerning MRSA and CDI for the months in question "in a form, manner and time, specified by the Secretary."[47] From the information provided, the Board is able to identify the presumed cause of the noted quality reporting deficiencies. However, the fact that they only occurred in two months demonstrates that the Provider knows, and has employed, the proper methodology for quality data submission. However, it just failed to do so for the months in question.

These circumstances compel CMS to impose the 2 percentage point reduction to Brazosport's FY 2020 Medicare APU. 42 U.S.C. § 1395ww(j)(7)(A)(i) clearly states:

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[43] Tr. at 102.
[44] PH Exhibit P-7 at 24.
[45] PH Exhibit P-2 (a one-page excerpt from Exhibit C-4).
[46] PH Exhibit P-3.
[47] 42 C.F.R. § 412.634(b)(1); 83 FR 38514, 38573 (Aug. 6, 2018).

> For purposes of fiscal year 2014 and each subsequent fiscal year, in the case of a rehabilitation facility that does not submit data to the Secretary *in accordance with subparagraphs (C) and (F) with respect to such a fiscal year*, after determining the increase factor described in paragraph (3)(C), and after application of clauses (ii) and (iii) of paragraph (3), the Secretary ***shall*** *reduce* such increase factor for payments for discharges occurring during such fiscal year *by 2 percentage points*.[48]

The use of the "shall" rather than the word "may" demonstrates that Congress mandated the imposition of the penalty for non-compliance with the reporting requirements.

The Board recognizes that, in the preamble to the FY 2015 IRF PPS Final Rule published on August 6, 2014, CMS stated that, for reconsiderations relevant to FY 2016 and beyond IRF payments:

> We may reverse our initial finding of noncompliance if: (1) The IRF provides adequate proof of full compliance with all IRF QRP reporting requirements during the reporting period; or (2) the IRF provides adequate proof of a valid or justifiable excuse for noncompliance if the IRF was not able to comply with the requirements during the reporting period.[49]

However, the preamble discussion is unclear whether CMS alone has the authority to consider a "justifiable excuse" and this language was not incorporated into the governing regulation at 42 C.F.R. § 412.634.

The Board need not resolve this issue as it is clear from the record that Brazosport did not have a "justifiable excuse" and simply failed to include the MRSA and CDI measures on the monthly reporting plans for the third and fourth quarters of CY 2018. This failure resulted in the quality data associated with those measures not being transmitted in a complete manner to CMS for those months. Brazosport's submitted support[50] clearly indicates that changes were made to the data *after the reporting deadlines* for certain line items suggesting that some or all of the requisite data for the months at issue was not timely entered into CDC NHSN (again data entry into the CDC NHSN system alone is not sufficient to satisfy Brazosport's reporting obligations). Finally, the Board notes that its decision in this case is consistent with its decisions in similar cases where the provider failed to complete the required monthly reporting plan which resulted in certain quality data not being transmitted to CMS.[51]

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[48] (Emphasis added.)
[49] 79 Fed. Reg. 45872, 45919 (Aug. 6, 2014).
[50] Exhibits P-4, P-5.
[51] *See, e.g., Westchester Gen. Hosp. v. First Coast Serv. Options*, PRRB Dec. No. 2018-D24 (Feb. 12, 2018), *declined review*, CMS Adm'r (Mar. 20, 2018); *Conway Reg. Rehab. Hosp. v. Novitas Solutions, Inc.*, PRRB Dec. No. 2018-D42 (June 28, 2018), *declined review*, CMS Adm'r (Aug. 2, 2018).

Consequently, the Board finds that Brazosport failed to properly update certain elements of its infection data, and failed to properly configure its MRPs for the months at issue, resulting in incomplete submission to CMS. Thus, Brazosport did not submit the IRF QRP data in a form and manner, and at a time, specified by CMS.

DECISION

After considering Medicare law and regulations, arguments presented, and the evidence admitted, the Board finds that the 2 percent reduction of Brazosport's APU for FY 2020 was proper.

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FOR THE BOARD:

8/10/2023

X Clayton J. Nix

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Chair
Signed by: PIV