PROVIDER REIMBURSEMENT REVIEW BOARD DECISION

2024-D22

PROVIDER– Community Stroke and Rehabilitation Center

Provider No.: 15-3045

vs.

MEDICARE CONTRACTOR – WPS Government Health Administrators HEARING DATE – September 14, 2023

Federal Fiscal Year – 2022

Case No. – 22-0953

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ISSUE STATEMENT

Whether the Community Stroke and Rehabilitation Center ("Community Stroke" or "Provider") should be subject to a two (2) percentage point reduction to its federal fiscal year 2022 inpatient rehabilitation facility annual payment update ("APU") for failure to meet the Inpatient Rehabilitation Facility ("IRF") Quality Reporting Program ("QRP") requirements in accordance with 42 C.F.R. § 412.634(f).¹

DECISION

After considering Medicare law and regulations, the arguments and testimony presented, and the evidence admitted, the Provider Reimbursement Review Board ("Board") finds that the two (2) percentage point reduction of Community Stroke's Medicare APU for FY 2022 was proper.

INTRODUCTION

Community Stroke is an IRF located in Crown Point, Indiana.² Community Stroke's designated Medicare contractor³ is WPS Government Health Administrators (the "Medicare Contractor"). Swingtech Consulting, Inc. ("Swingtech") is a company used by the Centers for Medicare and Medicare Services ("CMS") to provide certain data analytic and technical support needed for Post-Acute Care ("PAC") QRPs.⁴

In order to receive the full APU for FY 2022 reimbursement under the IRF prospective payment system, IRFs such as Community Stroke were required to submit data on certain quality measures during calendar year ("CY") 2020. By letter dated July 1, 2021, the Medicare Contractor notified Community Stroke that it failed to submit the required data and/or submit the required quality measures⁵ and, as a result, its Medicare APU would be reduced by two (2) percentage points for FY 2022.⁶ Community Stroke sought reconsideration of that determination by letter dated July 12, 2021,⁷ but on September 21, 2021, CMS upheld its decision.⁸ On March 17, 2022, Community Stroke timely appealed that decision and has met the jurisdictional requirements for a hearing before the Board.

The Board held a video hearing on September 14, 2023. Community Stroke was represented by Michael Grubbs, Esq. of Barnes & Thornburg, LLP. The Medicare Contractor was represented by Scott Berends, Esq. of Federal Specialized Services.

¹ Transcript of Proceedings (hereinafter "Tr.") at 5 (Sept. 14, 2023).

² Medicare Contractor's Final Position Paper (hereinafter "Medicare Contractor's FPP") at 2 (Jul. 13, 2023).

³ 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.

⁴ Exhibit (hereinafter "Ex.") P-3 at COMM000006.

⁵ Ex. P-10.

⁶ Id.

⁷ Ex. P-11.

⁸ Ex. C-2. *See also* Ex. P-13.

STATEMENT OF RELEVANT FACTS

Community Stroke states that it was accepted for participation in the Medicare Program and assigned CMS Certification Number ("CCN") 15-0185 by CMS on September 30, 2019. Later, on October 25, 2019, CMS notified Community Stroke that Community Stroke's CCN had been terminated and replaced by CCN 15-3045 effective August 31, 2019.⁹ The CCN format in the letters from CMS *included a hyphen* [xx-xxx]. The October 25, 2019 letter noted that the original CCN (15-0185) was incorrect because it was applicable to an acute care hospital, while the replacement CCN (15-3045) was the correct one for a rehabilitation hospital.¹⁰

CMS requires providers to collect data on certain quality measures on an annual or quarterly basis (*e.g.*, the third and fourth quarters of CY 2020) and to report the data in the next year, or quarter, based on published submission deadlines (*e.g.*, February 15, 2021 and May 17, 2021) to be eligible for an APU in the following year (*e.g.*, FY 2022).¹¹ Community Stroke was required to submit data on the following quality measures for the third and fourth quarters of calendar year 2020 (respectively, "Q3 CY 2020", "Q4 CY 2020", and "CY 2020"):

- 1. "NQF #1038 NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure Q3 and Q4", hereinafter the "CAUTI outcome measure";
- "NQF #0431 Influenza Vaccination Coverage Among Healthcare Personnel Season 2020/2021 – Annual", hereinafter the "flu vaccination outcome measure"; and
- 3. "NQF #1717 Facility-wide Inpatient Hospital-onset Clostridium difficile Infection Outcome Measure Q3 and Q4", hereinafter the "CDI outcome measure."¹²

Community Stroke states that it reported both Q3 CY 2020 and Q4 CY 2020 CAUTI and CDI data on February 11, 2021 – prior to the respective February 15, 2021 and May 17, 2021 deadlines¹³ – but using the superseded CCN 15-0185, *including the hyphen*.¹⁴

⁹ Provider's Final Position Paper (hereinafter, "Provider's FPP") at 2 (June 16, 2023). *See also* Exs. P-1, Ex. P-2. ¹⁰ Ex. P-2 at COMM000003.

¹¹ See Inpatient Rehabilitation Facility Quality Reporting Program Data Collection & Final Submission Deadlines for the FY 2022 IRF QRP *available at* <u>https://www.cms.gov/files/document/irf-qrp-data-collection-and-final-submission-deadlines-fy-2022-irf-qrp.pdf</u> (accessed June 13, 2024).

¹² Ex. C-2. *See also* Medicare Contractor's FPP at 8.

¹³ "Inpatient Rehabilitation Facility Quality Reporting Program Data Collection & Final Submission Deadlines for the FY 2022 IRF QRP," *available at* <u>https://www.cms.gov/files/document/irf-qrp-data-collection-and-final-</u> <u>submission-deadlines-fy-2022-irf-qrp.pdf</u> (accessed May 24, 2024). Final submission deadlines for the FY 2022 IRF QRP CAUTI and CDI measures were February 15, 2021 for July 1 – September 30, 2020 (Q3 CY 2020) and May 17, 2021 for October 1 – December 31, 2020 (Q4 CY 2020). Data from January 1, 2020 through June 30, 2020 (Q1-Q2) were not required for that fiscal year, and the parties stipulated to that during the hearing. *See* Tr. at 51. *See also* Medicare Contractor's FPP at 8.

¹⁴ Provider's FPP at 2; *see also* P-4. The Board notes that Community Stroke also states that it "reported 2020/2021 Healthcare Personnel Influenza Vaccination data under CCN 15-0185 before the May 17, 2021 deadline"; however, the submitted Ex. P-5 is inconclusive as to *when* it was submitted. Provider's FPP at 2.

The Medicare Contractor asserts that on February 8, 2021, Swingtech sent an email notice to Community Stroke indicating that data was missing and/or underreported for Q3 CY 2020.¹⁵ Community Stroke asserts that it did not receive this email.¹⁶

On May 3, 2021, Community Stroke received notice from Swingtech that, as of April 16, 2021, the Provider had not submitted its Q4 2020 data on the CAUTI, CDIFF and flu vaccination outcome measures.¹⁷ This notice from the Swingtech Help Desk Team to Community Stroke's Operational Assistant twice listed Community Stroke's CCN as "153045" *without the hyphen*.¹⁸ Community Stroke finalized the entry of its Q4 CY 2020 data into the CDC NHSN system prior to the May 17, 2021 deadline – under CCN 15-3045 *including the hyphen*.¹⁹ However, as recognized by Community Stroke, CMS did not receive that data because the list of IRF CCNs for which CMS requests data upon expiration of the relevant deadline does not contain hyphens.²⁰

On July 1, 2021, the Medicare Contractor notified Community Stroke that the APU for its FY 2022 Medicare payments would be reduced by two (2) percentage points because it failed to submit the required data to the CDC NHSN system and/or the required quality measures to the CMS Quality Improvement Evaluation System.²¹ Then, on July 12, 2021, Community Stroke submitted a request for reconsideration of that determination and noted that it had updated NHSN with the correct CCN "153045" (*i.e.*, the CCN without the hyphen).²² Finally, on September 21, 2021, CMS upheld its decision and specifically identified Community Stroke's noncompliance as the failure to submit Q3 and Q4 data on the CAUTI and CDIFF outcome measure and the annual data on the flu vaccination outcome measure.²³ The Board notes that all the correspondence referenced in this paragraph (including the Community Stroke's request for reconsideration) uses CCN "153045" *without the hyphen*.

In the interim, on August 4, 2021, Swingtech emailed Community Stroke regarding quality data for a period not at issue in this case, but nonetheless relevant to Community Stroke's struggle to identify the CCN hyphen issue. Specifically, Swingtech's email (1) notified Community Stroke that as of July 16, 2021, there were no data for the first quarter of calendar year 2021 ("Q1 CY 2021") relating to either the CAUTI or CDF outcome measures; and (2) reminded Community Stroke of the upcoming August 16, 2021 submission deadline for the Q1 CY 2021 data on those measures.²⁴ Following receipt, Community Stroke sent several *internal* emails questioning why it was receiving this notice.²⁵ However, it was not until October 6, 2021 (after the deadline for

¹⁵ Ex. C-1 at C-0003.

¹⁶ Tr. at 113.

¹⁷ Provider's FPP at 3; Ex. P-7.

¹⁸ Ex. C-1 at C-0004; Ex. P-7.

¹⁹ Provider's FPP at 3. *See also infra* note 20; Tr. at 25-29; Ex. P-8 at COMM000253 – 57 (screenshots from NHSN showing summaries of the Q4 CY 2020 data with an "as of" date of July 12, 2021).

²⁰ Tr. at 10 (CDC NHSN "get[s] a list from CMS and that's the list [*sic* that] says send us the data for these CCN's [*sic*]. We now know that the list that CMS [*sic*] does not have the hyphen in it. So, whenever, FY of 2022 deduction was determined by CMS as far as they knew, there had – no data had ever been reported under either of those hyphenated CCNs, and so that's why when CMS saw no data, they issued the reduction.")

²¹ Ex. P-10.

²² Ex. P-11.

²³ Ex. P-13.

²⁴ Ex. P-22 at Ex. L, COMM000393.

²⁵ *Id.* at COMM000390 – 93.

Q1 CY 2021), that Community Stroke sought any *external* assistance. Specifically, on October 6, 2021, via email, Community Stroke sought assistance from the Swingtech QRP Help Desk regarding QRP data not reported for Q1 CY 2021 and the emails appear to have included certain attachments.²⁶ However, as noted in the hearing, the October 6, 2021 email was sent to the wrong email address, "QPRHelp@swingtech.com," rather than "<u>QRPHelp@swingtech.com</u>," which is the correct email address, per the original August 4, 2021 email.²⁷

Community Stroke corresponded with Swingtech's QRP Help Desk on November 15, 2021, the due date for the second quarter of calendar year 2021 ("Q2 CY 2021") QRP data.²⁸ Evidence presented shows that Community Stroke updated its reporting at that time to reflect the six (6)-digit CCN "153045" *without the hyphen.*²⁹

The parties do not dispute the foregoing facts;³⁰ however, the parties disagree with: (1) whether these facts give rise to a failure on Community Stroke's part to meet the IRF QRP requirements and, thus, the two (2) percentage point reduction to its federal fiscal year ("FY") 2022 APU; and (2) if so, whether Community Stroke should be excused for its failure to submit quality data based on a systemic problem with one of CMS's data collection systems.

STATEMENT OF RELEVANT LAW

Under the IRF prospective payment system ("IRF PPS"), the Medicare program pays an IRF predetermined, standardized amounts per discharge, subject to certain payment adjustments.³¹ The standardized IRF PPS payment amounts are increased each year by a "market basket update" (also referred to as "Annual Payment Update" or "APU") to account for increases in operating costs.³²

Section 3004(b)(2) of the Patient Protection and Affordable Care Act amended 42 U.S.C. 1395ww(j) to establish the IRF QRP.³³ As a result, each IRF is required to submit certain quality data "in a form and matter, and at a time, specified by the Secretary."³⁴ Specifically –

(b) *Submission Requirements*. (1) IRFs must submit to CMS data on measures specified under section 1886(j)(7)(D), 1899B(c)(1),

²⁶ Ex. P-17. The Board notes that in these emails the Swingtech QRP Help Desk uses CCN "153045" *without the hyphen* while the NHSN documents attached by Community Stroke to prove timely submission reflect CCN "15-3045" *including the hyphen*.

²⁷ Tr. at 109-110.

²⁸ Ex. P-18.

²⁹ See Community Stroke internal emails (Ex. P-18), witness testimony (Tr. at 85), and NHSN CMS Report run on November 15, 2021 (Ex. P-19).

³⁰ The Board notes that the Provider's FPP at 2 – 3 and Medicare Contractor's FPP at 8 – 9 recite congruous facts. ³¹ See 42 C.F.R. § 412.624 (2019). See also 42 U.S.C. § 1395ww(j); 42 C.F.R. §§ 412.600 – 412.634. The term "rehabilitation facility" as used in 42 U.S.C. § 1395ww(j) refers to inpatient hospital services of a rehabilitation hospital or a rehabilitation unit.

 $^{^{32}}$ See 42 U.S.C. § 1395ww(j)(3). The "market basket update" is also referred to as the "annual percentage update," or APU.

³³ The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 at 369 (2010).

³⁴ *Id.* at § 3004(b)(2); *see also* 42 U.S.C. § 1395ww(j)(7)(C).

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and 1899B(d)(1) of the [Social Security] Act, and standardized patient assessment data required under section 1899B(b)(1) of the [Social Security] Act, as applicable. Such data must be submitted in the form and manner, and at a time, specified by CMS.³⁵

An IRF that fails to report the quality data required under the IRF QRP is subject to a two (2) percentage point reduction to its APU.³⁶ The data completion thresholds set by CMS for IRF quality reporting are as follows:

(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; 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.³⁷

The quality data required by 42 U.S.C. § 1395ww(j) are collected through the Centers for Disease Control and Prevention ("CDC") National Healthcare Safety Network ("NHSN") system.³⁸ In adopting quality measures that are collected and submitted to CMS via the CDC's NHSN, 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.

³⁵ 42 C.F.R. § 412.634(b)(1) (2019) (bold emphasis added and italics in original).

³⁶ 42 C.F.R. § 412.624(c)(4)(i) (Oct. 1, 2018 – Sept. 30, 2022) ("In the case of an IRF that is paid under the prospective payment system specified in § 412.1(a)(3) that does not submit quality data to CMS in accordance with § 412.634, the applicable increase factor [...] is reduced by 2 percentage points."); *see also* 42 U.S.C. § 1395ww(j)(7)(A)(i).

³⁷ 42 C.F.R. § 412.634(f) (2019) (bold emphasis added and italics in original).

³⁸ 42 C.F.R. § 412.634(f)(1) (2019).

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, including details related to the procedures for using NHSN for data submission 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.³⁹

An IRF may be granted an exception or extension to the previously mentioned reporting requirements when certain extraordinary circumstances exist. The IRF QRP disaster/extraordinary circumstances waiver and appeals process is as follows:

(c) *Exception and Extension Requirements*. (1) An IRF may request and CMS may grant exceptions or extensions to the measures data or standardized patient assessment data reporting requirements, for one or more quarters, when there are **certain extraordinary circumstances beyond the control of the IRF**.

(2) An **IRF must request an exception or extension within 90 days** of the date that the extraordinary circumstances occurred.

(3) Exception and extension requests must be submitted to CMS from the IRF by sending an email to IRFQRPReconsiderations@cms.hhs.gov containing all of the following information:

(i) IRF CMS Certification Number (CCN).

(ii) IRF Business Name.

(iii) IRF Business Address.

(iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address. (The address must be a physical address, not a post office box.)

(v) IRF's reason for requesting the exception or extension.

³⁹ 80 Fed. Reg. 47036, 47087 (Aug. 6, 2015) (bold and underline emphasis added and italics in original).

(vi) Evidence of the impact of extraordinary circumstances, including, but not limited to, photographs, newspaper, and other media articles.

(vii) Date when the IRF believes it will be able to again submit IRF QRP data and a justification for the proposed date.

(4) CMS may grant exceptions or extensions to IRFs without a request if it is determined that one or more of the following has occurred:

(i) An extraordinary circumstance affects an entire region or locale.

(ii) A systemic problem with one of CMS's data collection systems directly affected the ability of an IRF to submit data.

(5) Email is the only form of submission that will be accepted. Any reconsideration requests received through another channel will not be considered as a valid exception or extension request.⁴⁰

DISCUSSION, FINDINGS OF FACT, AND CONCLUSIONS OF LAW

A. Form, Manner, and Time.

To find in favor of Community Stroke (*i.e.*, to find that the two (2) percentage point reduction does not apply), there must be a finding that Community Stroke submitted both the IRF-PAI data and the data on the relevant quality measures in the form and manner, and at a time, specified by CMS.⁴¹ Here, the IRF-PAI data requirements are not at issue; thus, the focus of the instant appeal is the CDC NHSN IRF-QRP quality data requirements.⁴² As previously stated, the quality data required by 42 U.S.C. § 1395ww(j) are collected through the CDC NHSN system for transmission to CMS (form and manner), and CMS notifies providers of the due dates of the reports (time). Each year, information on the form, manner and time are published by CMS on its website.⁴³

1. Use of the Incorrect CCN for Q3 CY 2020 Quality Data Submissions

The parties' dispute over the Q3 CY 2020 data submission revolves around the change of CCN from the original acute care provider CCN to the IRF CCN that occurred prior to QRP deadlines.⁴⁴ Community Stroke received notice of the updated CCN ("153045"), dated October

⁴⁰ 42 C.F.R. § 412.634(c) (2019) (bold emphasis added and italics in original). The Federal Register in which this exception process was adopted refers to it as "the IRF/QRP disaster/extraordinary circumstances waiver and appeals processes". 78 Fed. Reg. 47860, 47920 (Aug. 6, 2013).

⁴¹ 42 C.F.R. § 412.634(b)(1).

⁴² Ex. C-2.

⁴³ See, e.g., "Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP) Data Submission Deadlines" *available at* <u>https://www.cms.gov/medicare/quality/inpatient-rehabilitation-facility/irf-quality-reporting-data-submission-deadlines</u> (accessed May 24, 2024) (publishing the submission deadlines and resources on the form and manner requirements).

⁴⁴ Medicare Contractor's FPP at 9-12.

25, 2019, almost sixteen (16) months prior to the Q3 CY 2020 reporting deadline.⁴⁵ Nonetheless, Community Stroke did not update its CCN in NHSN until May 14, 2021, well after that reporting deadline.⁴⁶

Significantly, due to the COVID-19 pandemic, quality reporting was initially suspended and, as a result, Q3 CY 2020 was the first period when Community Stroke was required to submit quality data.⁴⁷ Yet, Community Stroke submitted the data on February 11, 2021, *using the prior and incorrect CCN* (specifically as "15-0185" *including the hyphen*),⁴⁸ regardless of having received the updated CCN in October, 2019. The Board finds that Community Stroke failed to input the correct CCN and, thus, failed to submit the Q3 CY 2020 data in the manner and form prescribed by CMS.^{49,50} In making this finding, the Board notes that Community Stroke admits that it had the responsibility to update its CCN listed in the NHSN system but failed to promptly do so when it received its new CCN October 2019.⁵¹

2. <u>Q4 CY 2020 Quality Data Submissions and the Hyphen Hypothesis</u>

The parties' dispute over the Q4 CY 2020 data submission revolves around the fact that, while Community Stroke updated NHSN with the correct CCN prior to the submission data for Q4 CY 2020, it entered that CCN incorrectly with a hyphen between the second and third digits.⁵² Community Stroke explains that it initially "entered the Q4 CY 2020 QRP data under the wrong CCN" and asserts that "*before the due date*, CMS's software automatically transferred [that] data and all data previously submitted under the wrong CCN to the correct CCN when the Provider edited its CCN to the correct number."⁵³ Nonetheless, CMS did not receive the data from the CDC NHSN system due to the incorrect use of the hyphen between the second and third digits of the six (6)-digit CCN.⁵⁴

Community Stroke states that, up until November 15, 2021, it had been entering the CCN in the NHSN system with a hyphen between the first two (2) digits and the last four (4) digits.⁵⁵ On November 15, 2021, the due date for the Q2 CY 2021 QRP data, Community Stroke corresponded with Swingtech, a contractor helpdesk for QRP reporting.⁵⁶ Community Stroke internal emails,⁵⁷

⁵⁶ Ex. P-18.

⁴⁵ Ex. P-2.

⁴⁶ Tr. at 29-31.

⁴⁷ Ex. P-4; Tr. at 23-24, 136.

⁴⁸ Provider's FPP at 7. *See also* Ex. P-4.

⁴⁹ Not only did Community Stroke enter the incorrect CCN, it also failed to correctly enter that CCN because it still included a hyphen. Tr. at 29-31. However, for Q3 CY 2020 this is only a secondary issue.

⁵⁰ Although not conclusive, there is evidence that Swingtech sent an outreach notification on February 8, 2021 prior to the Q3 CY 2020 reporting deadline of February 15, 2021, to alert Community Stroke of the upcoming deadline and either of the missing data or under-reported data. *See* Ex. C-1. Whether Swingtech sent, in fact, this notification does not impact the Board's finding.

⁵¹ Tr. at 21-31.

⁵² Tr. at 29-31.

⁵³ Provider's FPP at 6.

⁵⁴ Ex. C-2; Tr. at 29-31; Ex. P-18.

⁵⁵ Tr. at 85-90.

⁵⁷ Id.

witness testimony,⁵⁸ and a November 15, 2021 NHSN CMS Report,⁵⁹ all show that the CCN was updated to the six (6) digits of the CCN *without the hyphen* on November 15, 2021, and at that time, Community Stroke determined the hyphen was the issue that was causing the reporting failures (hereinafter referred to as the "hyphen hypothesis").⁶⁰ Witness testimony showed that Community Stroke's reporters entered the CCN with a hyphen because the system allowed it,⁶¹ and asserted that there had been no prior notice nor QRP guidance to enter the CCN without a hyphen.⁶² The witness testimony suggests that Community Stroke's reporters referenced NHSN guidance in entering the CCN. However, Community Stroke did not produce for the record any of the NHSN guidance materials relied upon to demonstrate the lack of guidance regarding how to enter the CCN.⁶³ Further, that characterization conflicts with the guidance in effect during the time period at issue and still publicly available, as discussed *infra*.

CMS provides many resources to providers on how to properly submit quality data using the CDC NHSN system, including how to change or update your CCN.^{64,65} Additionally, and specific to Community Stroke, on May 3, 2021, the Swingtech Help Desk Team sent an email – that twice listed Community Stroke's CCN as "153045" (*i.e.*, *without a hyphen*)⁶⁶ – to Community Stroke's Operational Assistant. On May 4, 2021, the Operational Assistant forwarded the email to Community Stroke's Quality Manager, Control Coordinator and Patient Advocate ("Quality Manager").⁶⁷ On May 11, 2021, the Quality Manager then forwarded Swingtech's correspondence

⁶¹ *Id.* at 17.

https://www.cdc.gov/nhsn/pdfs/cms/Changing-CCN-within-NHSN.pdf (last visited Sept. 15, 2023); "CMS certified IRF Locations within Acute Care, Critical Access, and Long Term Acute Care Hospitals" (January 2021) available at https://www.cdc.gov/nhsn/pdfs/irf/updating-irf-locations-within-nhsn.pdf (last visited May 31, 2024); "DIALYSIS COMPONENT How to ADD and EDIT Facility CMS Certification Number (CCN) within NHSN" available at https://www.cdc.gov/nhsn/pdfs/dialysis/dialysis-change-ccn.pdf (Feb. 2021) (last visited May 31, 2024); "LONG-TERM CARE FACILITY (LTCF) How to ADD and EDIT Facility CMS Certification Number (CCN) within NHSN" (Apr. 2020) available at https://www.cdc.gov/nhsn/pdfs/ltc/ccn-guidance-508.pdf (last visited May 31). ⁶⁵ The CDC NHSN weblink at https://www.cdc.gov/nhsn/pdfs/cms/Changing-CCN-within-NHSN.pdf is referenced in other NHSN publications and guidance and has been active at least since December 2017 as it is referenced in the NHSN Newsletter, Vol 12, Issue 4 at 14 (Dec. 2017) (referenced in the context of ensuring your CCN is entered into NHSN and stating "Specific guidance on adding/updating the facility CCN and CCN effective date within NHSN can be found here: www.cdc.gov/nhsn/pdfs/cms/changing-ccn-within-nhsn.pdf."); id. at 10 (similarly including reference to weblink). See also "CMS certified IRF Locations within Acute Care, Critical Access, and Long-Term Acute Care Hospitals: Location Mapping" (Jan. 2021) (available at: https://www.cdc.gov/nhsn/pdfs/irf/Updating-IRF-locations-within-NHSN.pdf (last visited: June 3, 2024)) (all examples to illustrate data entry in NHSN have no hyphens); "NHSN CHECKLIST FOR HCP REPORTING TO CMS HOSPITAL, IRF and LTCH QUALITY REPORTING PROGRAMS" (Sept. 2021) available at https://www.cdc.gov/nhsn/pdfs/cms/hcp-monthly-checklistcms-508.pdf (last visited May 31, 2024).

⁶⁷ Ex. P-6.

⁵⁸ Tr. at 85.

⁵⁹ Ex. P-19.

⁶⁰ Tr. at 85-90. The Board characterizes Community Stroke's assertion that on November 21, 2021, their use of the hyphenated CCN in NHSN entries caused reporting failures as the "hyphen hypothesis."

⁶² *Id.* at 90 and 91. *See also* Ex. P-20.

⁶³ Tr. at 52-53, 61-62.

⁶⁴ Examples of CDC materials before or from the time period at issue providing instruction on entry of a provider's CCN and give an example of a CCN entry without using a hyphen (e.g., "9999999" or "123456") include: "Changing a CMS Certification Number within NHSN" (Mar. 2020) *available at*

⁶⁶ Ex. C-1 at 3.

on to the one staffer at Community Stroke with the ability to change the "basic facility info" in NHSN.⁶⁸ The foregoing all took place *prior to* the Q4 CY 2020 deadline of May 17, 2021.

However, as discussed *infra*, the evidence demonstrates that the first instance of Community Stroke reaching out to a help desk for assistance is an October 6, 2021 email from the Quality Manager to Swingtech regarding Q1 CY 2021 data.⁶⁹ Indeed, the Board is perplexed why Community Stroke did not reach out sooner to the Swingtech QRP Helpdesk after receiving multiple deficiency notices, as discussed *supra*. The response from Swingtech advised that Swingtech does not have up-to-date information on data submission and for questions on verification reports to contact NHSN HelpDesk.⁷⁰ The Board would like to emphasize that this was over three (3) months after Community Stroke had been informed that their Q3 and Q4 CY 2020 QRP data was insufficient and Community Stroke would be penalized with the two (2) percentage point reduction to its FY 2022 APU, *long after this outreach would have been relevant to the data in question*.

The Medicare Contractor's position is that, regardless of whether Community Stroke updated the data to the correct CCN (form and manner) prior to the Q4 CY 2020 deadline (time), Community Stroke acknowledged it reported Q3 CY 2020 data under the incorrect CCN (form and manner), and so it remains in violation of the reporting requirements; therefore, the two (2) percentage point reduction should be upheld.⁷¹

The Board agrees with the Medicare Contractor on this point and finds that in submitting data under the incorrect CCN for Q3 CY 2020, Community Stroke failed to submit data on measures *in the form and manner, and at a time, specified by CMS*. Because *both* Q3 and Q4 CY 2020 data were required to meet the requirement for FY 2022, the Board finds Community Stroke's argument that it corrected the CCN for Q4 CY 2020 to be irrelevant in the outcome of this dispute.

B. Data Completion Thresholds.

To comply with the IRF QRP requirements, Community Stroke must show that it met or exceeded *both* a ninety-five percent (95%) data completeness threshold 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," *and* a one hundred percent (100%) data completeness threshold for "measures data collected and submitted using the CDC NHSN."⁷² Again, the IRF-PAI is not at issue in this case.

For the reasons expressed in "Form, Manner, and Time," *supra* at pages 8 - 10, the Board finds that, in submitting data under the incorrect CCN for Q3 CY 2020, Community Stroke failed to meet the one hundred percent (100%) data completeness threshold for measures data collected and submitted using the CDC NHSN. And again, because *both* Q3 and Q4 CY 2020 data were

⁶⁸ Tr. at 73. *See also* Ex. P-7.

⁶⁹ Ex. P-17 at COMM000295 –96.

⁷⁰ *Id.* at COMM000294.

⁷¹ Medicare Contractor's FPP at 18. *See also* Tr. at 13-14; Medicare Contractor's Post Hearing Brief at 1 (Oct. 30, 2023).

⁷² See 42 C.F.R. § 412.634(f) (2019).

required to meet the requirement for FY 2022, the Board finds Community Stroke's argument that it corrected the CCN for Q4 CY 2020 to be inconsequential.

C. Exception and Extension Requirements.

As set forth more fully in "Statement of Relevant Law," *supra* at pages 5-8, an IRF may request exceptions or extensions to the measures data or standardized patient assessment data reporting requirements in extraordinary circumstances beyond the control of the IRF.⁷³ CMS, on its own accord, "may grant exceptions or extensions to IRFs without a request if ... [a]n extraordinary circumstance affects an entire region or locale" and/or a "systemic problem with one of CMS's data collection systems directly affected the ability of an IRF to submit data."⁷⁴ Within ninety (90) days of the occurrence of an extraordinary circumstance beyond the control of the IRF, an IRF must request an exception or extension by sending an email to CMS that includes certain pertinent information.⁷⁵ Reconsideration requests are only accepted by email.⁷⁶

Regarding the Q3 CY 2020 data, Community Stroke argues:

The NHSN QRP data collection system's failure to notify an IRF it has submitted QRP data under an inactive acute care CCN constitutes a "systemic problem with one of CMS's data collection systems" that affected the Provider's ability to file its CY 2020 Q3 QRP data before the February due date. Accordingly, the Provider requests that the Board grant an exception to the February 15, 2021 deadline pursuant to 42 C.F.R. § 412.634(c)(4)(ii).⁷⁷

Community Stroke further argues that the NHSN's system's ability to allow for a seven (7) character CCN without generating an error message also represents a systemic problem and the Board should grant Community Stroke and exception for its failure to meet the deadlines.⁷⁸

Community Stroke's plea to the Board to "grant an exception to the February 15, 2021 deadline pursuant to 42 C.F.R. § 412.634(c)(4)(ii)" is misplaced. CMS requires exceptions based on the occurrence of extraordinary circumstances to be made by sending an email to CMS within ninety (90) days of the occurrence of the extraordinary circumstances. The record does not reflect an assertion of any extraordinary circumstance. In the same way, the Board finds no evidence in the record to show such an exception request was properly submitted by sending an email to CMS within the required time. Accordingly, an analysis of whether the alleged system problems were extraordinary circumstances is unnecessary for resolving the issues currently before the Board.

The open question is whether either the NHSN QRP data collection system's failure to notify an IRF it has submitted QRP data under an inactive acute care CCN or the NHSN's system's ability

⁷³ See 42 C.F.R. § 412.634(c)(1) (2019).

⁷⁴ 42 C.F.R. § 412.634(c)(4) (2019).

⁷⁵ See 42 C.F.R. § 412.634(c)(1) - (3)(2019).

⁷⁶ 42 C.F.R. § 412.634(c)(5) (2019).

⁷⁷ Provider's Responsive Position Paper at 2-3 (Aug. 15, 2023); see also 42 C.F.R. § 412.634(c)(4)(ii) (2019).

⁷⁸ Provider's Post Hearing Brief at 4-5 (Oct. 30, 2023).

to allow for a seven (7) character CCN constitute a *systemic problem* for which CMS should have granted an exception. The Board notes that CMS differentiates the processes for *extraordinary events* and *systemic problems*. An exception or extension for an *extraordinary event* may be requested by providers *or* initiated by CMS:

[W]e finalized a policy that *allowed us to grant waivers (which we are now calling exceptions or extensions) to IRFs that have not requested them if we determine that an extraordinary circumstance*, such as an act of nature, affects an entire region or locale. We stated that if this determination was made, we will communicate this decision through routine communication channels to IRFs and vendors....⁷⁹

In contrast, an exception or extension for a *systemic problem* may *only* be initiated by and communicated by CMS:

We also proposed, for the FY 2017 adjustments to the IRF PPS annual increase factor and subsequent year increase factors, that we may grant an exception or extension to IRFs *if we determine* that a systemic problem with one of our data collection systems directly affected the ability of the IRF to submit data. Because we do not anticipate that these types of systemic errors will happen often, we do not anticipate granting an exception or extension on this proposed basis frequently. We proposed that *if we make the determination* to grant an exception or extension, *we will communicate this decision* through routine communication channels to IRFs and vendors, including, but not limited to, issuing memos, emails, and notices on the CMS Web site at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html.⁸⁰

⁷⁹ 79 Fed. Reg. 45872, 45920 (Aug. 6, 2014) (emphasis added); see also 78 Fed. Reg. at 47920 (Aug. 6, 2013). An IRF must provide "[e]vidence of the impact of extraordinary circumstances, including, but not limited to, photographs, newspaper, and other media articles." 42 C.F.R. § 412.634(c)(3)(vi) (2019). It is clear from the preamble discussion in the Federal Register from which this regulation was adopted that CMS's intent was to offer leniency "when providers are unable to submit quality data due to the occurrence of extraordinary circumstances beyond their control (for example, natural or man-made disasters)." 78 Fed. Reg. at 47920 (Aug. 6, 2013). A "disaster" is a "catastrophe which causes damages of sufficient severity and magnitude to partially or completely destroy or delay access to medical records and associated documentation." *Id.* Examples include "hurricanes, tornadoes, earthquakes, volcanic eruptions, fires, mudslides, snowstorms, and tsunamis" and "terrorist attacks, bombings, floods caused by man-made actions, civil disorders, and explosions." *Id.*

⁸⁰ 79 Fed. Reg. at 45920 (Aug. 6, 2014) (emphasis added). *Compare* 42 C.F.R. § 412.433(f) (Where CMS may grant an exception in the event of extraordinary circumstances beyond the control of an inpatient psychiatric facility ("IPF"), "such as when an act of nature affects an entire region or locale or a *systemic problem with one of CMS's data collection systems directly or indirectly affects data submission*. CMS may grant an exception as follows: (1) *Upon request by the IPF*. (2) At the discretion of CMS. CMS may grant exceptions to IPFs that have not requested them when CMS determines that an extraordinary circumstance has occurred" (emphasis added)).

The Board finds no evidence in the record to show that CMS determined that the NHSN QRP data collection system's failure to notify an IRF it submitted QRP data under an inactive acute care CCN was a systemic problem. Likewise, the Board finds no evidence in the record to show that the NHSN's system's ability to allow for a seven (7) character CCN (*i.e.*, a CCN *including a hyphen*) without generating an error message was a systemic problem. If such evidence exists, Community Stroke failed to produce it.

When Community Stroke introduced the "hyphen hypothesis" regarding the Q4 CY 2020 (and Q1 CY 2021) data at the hearing, the Medicare Contractor again emphasized the Q3 CY 2020 data being submitted under the wrong CCN is all that is required for the two (2) percentage point reduction penalty, and any discussion of the hyphen hypothesis is a problem specific to the provider and not a systemic problem.⁸¹

The Board, therefore, finds that Community Stroke's ability to file its Q3 CY 2020 QRP data was not affected by any systemic problem with CMS's data collection systems, but instead was a provider-specific failure, and as such, no exception applies.

However sympathetic the Board may be to Community Stroke's struggle with the unclear hyphen issue, the Board does not have discretion to provide equitable relief; CMS has rejected the idea of leniency based on "good-faith effort to comply."⁸² Sympathy in this regard is better sought from the appropriate quality reporting programs ("QRPs") office.⁸³

The Board also observes that the Medicare Contractor and Swingtech both missed the opportunity to educate the provider on proper entry of the CCN in the reports and to explain where that guidance is located.⁸⁴ The Board takes notice that the letters in Exhibits P-1 and P-2 are drafted by the Principal Program Representative for Non-Long Term Care Certification & Enforcement Branch of CMS, and that they are misleading in including the hyphen. The Board is also aware of CDC NHSN guidance on entering CCNs and that it gives examples and screen shots of correct CCN entries without the hyphen, but does not explicitly state to not include the

⁸² In the preamble to the final rule, 84 Fed. Reg. 39054, 39164-65 (Aug. 8, 2019), the Secretary states: *Comment:* Some commenters suggested that CMS provide flexibility in its application of the IRF QRP payment penalty for IRFs who make a good-faith effort to comply and submit quality reporting data.

⁸¹ See Medicare Contractor's Post Hearing Brief at 2; see also Tr. at 14.

Response: We interpret the commenter's suggestion that we take into consideration case by case exceptions and apply leniency for providers have attempted but failed to submit their quality reporting data for the IRF QRP. We are unable to provide flexibility with respect to the 2 percent payment penalty; as noted previously, section 1886(j)(7) of the Act requires the Secretary to reduce the annual increase factor for IRFs that fail to comply with the quality data submission requirements. While we did not seek comment on flexibilities on which the penalty is applied, we note that we have provided flexibility where the failure of the IRF to comply with the requirements of the IRF QRP stemmed from circumstances beyond its control. For example, we have finalized policies that grant exceptions or extensions for IRFs if we determine that a systemic problem with one of our data collection systems affected the ability of IRFs to submit data (79 FR 45920). We have also adopted policies (78 FR 47920) that allow us to grant exceptions or extensions to an IRF if it has experienced an extraordinary circumstance beyond its control.

 ⁸³ See Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP) Help <u>https://www.cms.gov/medicare/quality/inpatient-rehabilitation-facility/irf-quality-reporting-help</u> (last modified 4/10/2024) (Accessed May 31, 2024).
 ⁸⁴ See supra notes 64, 65.

hyphen.⁸⁵ Community Stroke's witness states that it referenced CDC NHSN guidance when entering the CCN, incorrectly with a hyphen; however, Community Stroke failed to include that guidance in the record.⁸⁶ Again, while the Board may be sympathetic to Community Stroke's struggle with the hyphen issue, the Board does not have discretion to provide equitable relief.

In summary, as described above, the Board finds that, per 42 C.F.R. § 405.1871(a)(3), Community Stroke has not "carried its burden of production of evidence and burden of proof by establishing, by a preponderance of the evidence, that [it] is entitled to relief on the merits of the matter at issue."

DECISION

After considering Medicare law and regulations, the arguments and testimony presented, and the evidence admitted, the Board finds that the two (2) percentage point reduction of Community Stroke's Medicare APU for FY 2022 was proper.

BOARD MEMBERS:

Clayton J. Nix, Esq. Kevin D. Smith, CPA Ratina Kelly, CPA Nicole E. Musgrave, Esq.

FOR THE BOARD:

7/22/2024



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

⁸⁵ See supra notes 64, 65. But see Tr. at 91, "MR. GRUBBS: And to date, as you prepared for this hearing, is there any guidance anywhere that's available in the NHSN system that says don't use the hyphen when you're entering in CCN? THE WITNESS: No, it does not." See generally Exs. C-4, C-5.
⁸⁶ Tr. at 52-53, 61-62.