PROVIDER REIMBURSEMENT REVIEW BOARD
DECISION
Hearing on the Record
2025-D49

PROVIDER –
Landmark Hospital of Savannah, LLC

RECORD HEARING DATE –
January 30, 2024

PROVIDER NO. –
11-2018

FEDERAL FISCAL YEAR –
2017

vs.

MEDICARE CONTRACTOR –
Palmetto GBA, LLC

CASE NUMBER –
21-1677

INDEX

ISSUE STATEMENT

Whether the payment penalty that the Centers for Medicare and Medicaid Services ("CMS") imposed under the Long-Term Care Hospital Quality Reporting Program ("LTCH QRP") to reduce Landmark Hospital of Savannah, LLC's ("Savannah" or "Provider") payment update for Fiscal Year ("FY") 2017 by 2 percentage points was proper?[1]

DECISION

After considering the Medicare law and regulations, the arguments presented and the evidence submitted,[2] and consistent with the District Court's remand in *Landmark Hosp. of Salt Lake City & Landmark Hosp. of Savannah v. Azar,* 442 F. Supp. 3d 327 (D.D.C. 2020) ("*Landmark*"), the Provider Reimbursement Review Board ("Board") has reviewed the record, the applicable regulations, and additional CMS guidance and as set forth below, the Board finds the Provider failed to ***properly*** submit the Healthcare Personnel influenza vaccination measure data at issue in the form, manner and at the time, specified by CMS.

The Board acknowledges that its original decision cited and relied upon the incorrect subsection of the regulation and applied the incorrect standard of review, but, as set forth below, concludes that the application of the correct regulation and standard of review does not alter its finding that CMS properly assessed the 2 percentage point APU penalty due to the Savannah's failure to submit the HCP influenza vaccination summary data measure in the time, form and manner specified by CMS.

INTRODUCTION AND PROCEDURAL HISTORY

Landmark Hospital of Savannah, LLC is "a Medicare certified long-term care hospital ("LTCH") located in Savannah, Georgia."[3] The Provider's assigned Medicare administrative contractor[4] is Palmetto GBA, LLC (the "Medicare Contractor").

To receive the full APU for FY 2017 reimbursement under the LTCH QRP, participating hospitals were required to submit data on certain quality measures during calendar year ("CY") 2015.[5]

By letter dated July 15, 2016, the MAC issued a *Notification of Non-Compliance with Required Long-Term Care Hospital (LTCHs) Quality Reporting Program (QRP) Measurement Data*.[6] The noncompliance cited was Savannah's failure to submit required quality data through the

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[1] Stipulations at ¶ 3 (Nov. 14, 2023).
[2] Any arguments or evidence, whether or not specifically referenced or discussed herein, were considered by the Board in the deliberations of this appeal.
[3] Stipulations at ¶ 1 (Nov. 14, 2023).
[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 know as Medicare administrative contractors ("MACs"). The relevant law may refer to FIs and MACs interchangeably, and the Board will use the term "Medicare contractor" to refer to both FIs and MACs, as appropriate and relevant.
[5] *See* 42 U.S.C. § 1395ww(m)(5)(A)(i).
[6] Exhibit (hereinafter "Ex.") P-2.

Center for Disease Control and Prevention's ("CDC") National Healthcare Safety Network ("NHSN") and/or via CMS' Quality Improvement Evaluation System ("QIES"). As a result, Savannah's FY 2017 Annual Payment Update ("APU") was subject to a 2-percentage point reduction.[7]

On August 15, 2016, Savannah requested reconsideration of CMS' noncompliance finding and the 2-percentage point APU reduction.[8] On September 22, 2016, CMS notified Savannah that the July 15, 2016 Notice of Noncompliance would be upheld ("Original Reconsideration").[9] On September 27, 2016, the MAC issued a letter notifying the Provider of the same.[10]

On March 16, 2017, Savannah appealed the Original Reconsideration to the Board.[11] The Board held a hearing on the matter on October 2, 2017,[12] and on February 26, 2019, issued Board Decision 2019-D17 affirming the 2-percentage point reduction to Savannah's FY 2017 APU.[13]

On April 26, 2019, Savannah sought judicial review of the Board's decision from the U.S. District Court for the District of Columbia ("D.C. District Court") resulting in *Landmark Hosp. of Salt Lake City & Landmark Hosp. of Savannah v. Azar,* 442 F. Supp. 3d 327 (D.D.C. Mar. 2, 2020) ("*Landmark*").[14] In *Landmark*, the D.C. District Court determined that the Board relied on the incorrect regulations to affirm CMS' reconsideration decision and concluded that a remand was appropriate "so the Secretary can direct a new review" under 42 C.F.R. § 412.560(d) instead of subsection (c).[15]

Following remand from the District Court, CMS reviewed the matter once more, and on March 11, 2021, issued a second reconsideration determination notifying Savannah that it upheld the decision that Savannah failed to meet LTCH quality reporting program ("QRP") requirements during the data reporting period for calendar year 2015 ("CY 2015") and, as a result, was subject to a 2 percentage point reduction to its FFY 2017 APU ("Second Reconsideration Determination").[16]

On September 7, 2021, Savannah timely appealed CMS' March 11, 2021 Second Reconsideration Determination to the Board and met the jurisdictional requirements for a hearing.

On January 30, 2024, the Board issued a Notice of Hearing on the Record and closed the record on March 1, 2024. The Provider was represented by Jason M. Healy, Esq. of The Law Offices of Jason M. Healy, PLLC. The Medicare Contractor was represented by Joseph J. Bauers, Esq. of Federal Specialized Services, LLC.

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[7] *Id.* at P0016.
[8] Ex. P-3.
[9] Ex. P-4 at P0076.
[10] *Id.* at P077.
[11] Ex. P-1.
[12] Ex. P-15 (Hearing Transcript).
[13] Ex. P-16.
[14] Stipulations at ¶ 20 (Nov. 14, 2023). *See also* Ex. P-20.
[15] *Landmark* at 335, 333.
[16] Ex. P-14 at P0118-0119.

Accordingly, this matter is ripe for consideration, particularly, reviewing Savannah's appeal of CMS' Original and Second Reconsideration Determinations (collectively "Reconsideration Determinations")[17] under 42 C.F.R. § 412.560(d).

STATEMENT OF FACTS AND RELEVANT LAW

A. Relevant Factual Background

LTCH QRP payment determinations for FY 2017 were based upon the timely submission of quality data collected during CY 2015 (January 1, 2015, through December 31, 2015), with the exception of the quality measure for Influenza Vaccination Coverage among Healthcare Personnel NQF #0431 ("HCP Flu Vaccination"), for which the data collection period was October 1, 2015 through March 31, 2016. The related submission deadline for the HCP Flu Vaccination measure was May 15, 2016.[18] CMS determined that Savannah failed to submit its HCP Flu Vaccination data by the May 15, 2016, submission deadline.[19]

By email, on May 3, 2016, Savannah acknowledged receipt of a NHSN notification from the week prior that its HCP Flu Vaccination data was incomplete and reached out to NHSN to inquire as to what was missing because there were no alerts or error messages on the portal.[20] On May 5, 2016, NHSN informed Savannah that although the HCP Flu Vaccination data had been entered on March 30, 2016, Savannah's "CCN still needs to be entered in NHSN in order for the data to be transmitted to CMS. To do so, please follow the instructions below:…"[21] Shortly thereafter, Savannah "***entered 11-0218 instead of 11-2018***"[22] and followed up with NHSN to confirm that they had met the reporting requirements.[23] On May 6, 2016, NHSN responded, "[I]t ***appears*** that you have now added your CCN. ***No further action is required on your part regarding these data.***"[24]

On May 10, 2016, Savannah received a second email notification that as of April 29, 2016, it had not submitted complete 2015/2016 HCP Flu Vaccination Summary Data (along with four other data measures for Q4).[25] Savannah immediately responded to the notification informing NHSN that, on May 5, 2016, corrective action had been taken and that they were under the impression that everything was properly submitted.[26] On May 13, 2016, NHSN responded:

> The summary data "looks" complete however, I can't say for sure

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[17] Savannah's arguments in both appeals of the Reconsideration Determinations are substantively the same. Accordingly, where the Board renders findings in reference to either of the Reconsiderations, it shall apply to the other, unless otherwise distinguished.
[18] Ex. P-8 at P0090 - 91.
[19] Stipulations at ¶¶ 7, 8, 9.
[20] Ex. P-5 at P0080.
[21] *Id*. at P0079.
[22] Savannah's Preliminary Position Paper (hereinafter, "Provider's PPP") at 42 (emphasis added).
[23] Ex. P-5 at P0079.
[24] *Id*. (emphasis added).
[25] Ex. P-6 at P0083-84.
[26] *Id*. at P0083.

> until you generate new data sets. Select Analysis from the menu located on the left-hand side of the NHSN home screen. From here, select Generate Data Sets and then click the "Generate New" button.
>
> After you have done this we can use the Analysis Output Options to create a CMS report that shows what Healthcare Personnel Influenza Vaccination data will be sent to CMS on behalf of your facility.[27]

Savannah again followed up to confirm the data had been properly entered into NHSN stating, "I did as instructed below and it looks like the report to CMS is accurate, if you please check it again to be sure I would appreciate it, thank you for your help!"[28] Shortly thereafter, NHSN's public health analyst responded, "***You're good to go***!"[29]

As previously stated, the deadline for the submission of HCP Flu Vaccination data was May 15, 2016, and on July 15, 2016, CMS issued a Notification of Non-Compliance.[30] Within two (2) business days, on July 19, 2016, Savannah discovered that the CCN had been entered incorrectly and immediately corrected it.[31]

B. Relevant Applicable Law

1. Burden of Proof and Standard of Review

A Board decision must include findings of fact and conclusions of law that "the provider carried its burden of production of evidence and burden of proof by establishing, by a preponderance of the evidence, that the provider is entitled to relief on the merits of the matter at issue."[32] Additionally, "[a] decision by the Board shall be based upon the record made at such hearing, which shall include the evidence considered by the [Medicare contractor] and such other evidence as may be obtained or received by the Board, and shall be supported by substantial evidence when the record is viewed as a whole."[33] In *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 230 (1938), the U.S. Supreme Court held, "[s]ubstantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion."[34] Accordingly, in an appeal before the Board, a provider must prove by a preponderance of substantial, relevant evidence that it is entitled to the relief sought. Further, the

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[27] *Id*. at P0082.
[28] *Id*.
[29] *Id*.
[30] Ex. P-2.
[31] Ex. P-7 (July 19, 2016 internal email with the subject line: "screen shot confirming correction of CCN").
[32] 42 C.F.R. § 405.1871(a)(3) (as of Oct. 1, 2014).
[33] 42 U.S.C. § 1395oo(d). This statutory provision also confirms: "[t]he Board shall have the power to affirm, modify, or reverse a final determination of the fiscal intermediary with respect to a cost report and to make any other revisions on matters covered by such cost report (including revisions adverse to the provider of services) even though such matters were not considered by the intermediary in making such final determination." *See also* 42 C.F.R. § 405.1869(a).
[34] *See also Pomona Valley Hosp. Med. Ctr. v. Becerra*, 82 F.4th 1252, 1258-59 (D.C. Cir. 2023).

"Board shall afford great weight to interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS."[35]

2. Requirements under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

Contrary to the parties' stipulation that CMS reconsiderations for FY 2017 payment determinations are governed in part by the FY 2015 IPPS/LTCH PPS Final Rule,[36] the FY 2015 LTCH IPPS Final Rule was superseded by the FY 2016 IPPS Final Rule that codified the reconsideration and appeals process "for the FY 2017 Payment Determination and Subsequent Years."[37] Accordingly, the October 1, 2015 version[38] of the regulations set forth in 42 C.F.R. § 412.560 that were in effect on August 15, 2016 (the date of Savannah's initial reconsideration request), apply to this appeal on remand as they fully address the reconsideration process at that time, *discussed infra*.[39] Here, it is important to acknowledge that the October 1, 2019 version[40] of 42 C.F.R. § 412.560(d)(2) that was in effect on March 11, 2021 (the date of CMS' Second Reconsideration Determination) is substantively unchanged as it relates to reconsideration request requirements. Thus, specific to the issues in this appeal on remand, the regulation provides in pertinent parts:

42 C.F.R. § 412.560 (October 1, 2015)[41]

> (b) *Submission of data requirements and payment impact.*
>
> > (1) Except as provided in paragraph (c) of this section, a long-term care hospital must submit to CMS data on measures specified under sections 1886(m)(5)(D), 1899B(c)(1), and 1899B(d)(1) of the Act, as applicable, in a form and manner, and at a time, specified by CMS.
> >
> > (2) A long-term care hospital that does not submit data in accordance with sections 1886(m)(5)(C) and 1886(m)(5)(F) of the Act with respect to a given fiscal year will have its annual update to the standard Federal rate for discharges for the long-term care hospital during the fiscal year reduced by 2 percentage points.

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[35] 42 C.F.R. § 405.1867.
[36] Stipulations at ¶13.
[37] 80 Fed. Reg. 49326, 49755-56 (Aug. 17, 2015) (Section C (Long-Term Care Hospital Quality Reporting Program (LTCH QRP) at (13) and (14) of the preamble codified these provisions and the headers make clear that this codification was effective "for the FY 2017 Payment Determination and Subsequent Years").
[38] Effective October 1, 2015 to September 30, 2016.
[39] For FY 2017 payment determinations and subsequent years, the FY 2016 IPPS/LTCH PPS Final Rule codified the LTCH QRP procedure for requesting reconsideration of a noncompliance decision. *See* 80 Fed. Reg. 49326, 49755-56, 49769-70. *See* further discussion, *infra*.; *see also See Landmark* at 334 (where the District Court states, "When CMS codified its rule from Volume 79 of the Federal Register at 42 C.F.R. § 412.560, the "extenuating circumstances" language in the preamble did not carry over. It is unclear why.").
[40] Effective October 1, 2019 to September 30, 2023.
[41] This is the version of the regulation in effect on May 15, 2016 (the deadline for the data submission).

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(d) Reconsiderations of noncompliance decisions—

(1) Written notification of noncompliance decision. CMS will send a long-term care hospital written notification of a decision of noncompliance with the quality data reporting requirements for a particular fiscal year. CMS also will use the Quality Improvement and Evaluation system (QIES) Assessment Submission and Processing (ASAP) System to provide notification of noncompliance to the long-term care hospital.

(2) Request for reconsideration of noncompliance decision. A long-term care hospital may request a reconsideration of CMS' decision of noncompliance no later than 30 calendar days from the date of the written notification of noncompliance. The reconsideration request by the long-term care hospital must be submitted to CMS via email and must contain the following information:

(i) The CCN for the long-term care hospital.

(ii) The business name of the long-term care hospital.

(iii) The business address of the long-term care hospital.

(iv) Contact information for the long-term care hospital's chief executive officer or designated personnel, including each individual's name, title, email address, telephone number, and physical mailing address. (The physical address may not be a post office box.)

(v) CMS's identified reason(s) for the noncompliance decision from the written notification of noncompliance.

(vi) The reason for requesting reconsideration of CMS' noncompliance decision.

(vii) Accompanying documentation that demonstrates compliance of the long-term care hospital with the quality reporting requirements.

> This documentation must be submitted electronically at the same time as the reconsideration request as an attachment to the email. Any reconsideration request that fails to provide sufficient evidence of compliance will not be reviewed.
>
> (3) CMS decision on reconsideration request. CMS will notify the long-term care hospital, in writing, of its final decision regarding any reconsideration request. CMS also will use the QIES ASAP System to provide notice of its final decision on the reconsideration request.
>
> (e) Appeals of reconsideration requests. A long-term care 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.

Additional Guidance

In addition to its governing statutes and codified regulations, CMS publishes certain Medicare program requirements through various sub-regulatory mechanisms and materials on the CMS website, in program instruction or guidance manuals, transmittal letters, and the like.

The CMS LTCH Quality Reporting Manual, Chapter 5 (October 2015) provided an overview and guidance for data submission to NHSN, stating, in pertinent parts, as follows:

> **5.1 Overview…**
>
> **Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) Reporting**
>
> For reporting of data on the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure under the LTCH QRP, LTCHs ***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 http://www.cdc.gov/nhsn/PDFs/HPS-manual/vaccination/HPS-flu-vaccine-protocol.pdf.
>
> ***
>
> To report data for the LTCH QRP through CDC's NHSN, the LTCH must be enrolled in the NHSN. Enrollment steps are outlined in the *NHSN Facility Administrator Enrollment Guide*

> available at: http://www.cdc.gov/nhsn/PDFs/FacilityAdminEnrollmentGuideCurrent.pdf. The information in the rest of this chapter supplements information available to the LTCHs through the *NHSN Facility Administrator Enrollment Guide*.
>
> **If your LTCH is already enrolled as an LTCH in the NHSN, please do the following:**
>
> 1) ***Confirm that your CMS Certification Number (CCN) is <u>correctly</u> entered on the Facility Information screen.***
>
> ***
>
> **5.3 Basic Steps to NHSN Enrollment and Data Submission…**
>
> 3. Register for the NHSN, which includes accepting the NHSN Rules of Behavior and providing your contact information at http://nhsn.cdc.gov/RegistrationForm/index. If you use an identifier other than your CCN during the enrollment process, you will have to enter your CCN on NHSN's Facility Information screen after your facility is enrolled ***to ensure that the appropriate data are shared with CMS.***
>
> ***
>
> **5.4 Additional Tips and Hints…**
>
> - Locate your facility's CCN or relevant identifier code.
>
> ***
>
> - ***LTCHs do not need to confer rights to CMS. CDC submits data to CMS on behalf of the LTCH***.[42]

The Operational Guidance for reporting HCP Flu Vaccination data states, in pertinent parts:

> The NHSN protocol provides guidance for healthcare facilities to report HCP influenza vaccination summary data from October 1 (or when the vaccine became available) through March 31, which

[42] *See* pgs. 5-7, 5-8, 5-10, 5-12, 5-13 of *CMS LTCH Quality Reporting Manual, Chapter 5: Guidance For The Reporting Of Data Into The Centers For Disease Control And Prevention's National Healthcare Safety Network ("LTCH QR Manual"),* available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/LTCH-QRP-Manual-V-300-FINAL.zip (last accessed Sept. 25, 2025) (bold italics added). The Board notes that, at the time of this decision, the CDC website archives are not available, thus the hyperlink cited at 5.1 is not available.

> includes all influenza vaccinations administered during the influenza season at the facility or elsewhere . . . .
>
> ***
>
> HCP influenza vaccination summary reporting in NHSN consists of a single data entry screen per influenza season, so each time a user enters data for a particular influenza season, all previously [entered] data for that season will be overwritten . . . . For the purpose of fulfilling CMS quality reporting measurements reporting requirements, this summary report will only be submitted once to CMS. The summary report must be entered by May 15 for data to be shared with CMS.
>
> HCP influenza vaccination summary data submitted to NHSN by May 15 will be reported by CDC to CMS for each long term care hospital CMS Certification umber (CCN). CDC will share all in-plan HCP influenza vaccination summary data with CMS. CDC will provide a HCP influenza vaccination percentage for each reporting long term care hospital CCN.[43]

The FAQs for HCP Flu Vaccination data reporting provide:

> **Q23. I entered my HCP influenza vaccination summary data into NHSN. How can I confirm that my data were entered correctly and will be shared with CMS?**
>
> One way to confirm data entry is to login to the Healthcare Personnel Safety Component and then choose your facility. Next, go to Vaccination Summary on the left-hand navigation bar, click

[43]Ex. P-16 (PRRB Dec. 2019-D7) at P0208 – P0209, *citing Operational Guidance for Long Term Care Hospitals* to Report Healthcare Personnel (HCP) Influenza Vaccination Data to CDC's National Healthcare Safety Network (NHSN) for the Purpose of Fulfilling CMS's Long-Term Care Hospital Quality Reporting (LTCHQR) Program Requirements* ("Operational Guidance"), *available as* Ex. I-2 to Medicare Administrative Contractor Post-Hearing Brief for Case Nos. 17-1223 and 17-1266 (Nov. 16, 2017), *explaining,* at 14:

> The Board requested that the MAC submit a corrected Exhibit I-2, a quick reference guide, to its Savanna [sic] Final Position Paper as the original exhibit was published after the time period covering the LTCH QRP reporting period in question. The MAC was unable to find a quick reference guide for the time period in question as CMS, apparently, previously maintained individual guidance for each reporting measurement.
>
> The MAC offers this revised Exhibit I-2 as documentation of CMS' operational guidance, which was made available to Savanna [sic] at the time its Influenza data was required to be reported. While the substitute Exhibit I-2 does not cover all LTCH QRP measurements, it does cover the one measurement at issue in the Savanna [sic] appeal; Influenza data.

> on Annual Vaccination Flu Summary, then Find. For Summary Data Type, choose the Influenza Vaccination Summary, and in the Flu Season drop-down box, choose the influenza season you would like to verify. ***Facilities should also confirm that the correct CCN is entered into NHSN.*** Facilities can also run a report that will show when data were first entered and last modified in the NHSN application. For instructions on running this report, please see: Create dates for influenza QRG (cdc.gov).[44]

DISCUSSION, FINDINGS OF FACT, AND CONCLUSIONS OF LAW

To satisfy LTCH quality reporting program requirements related to the FFY 2017 payment update determination, LTCHs were required to submit all required data measures, including the HCP Flu Vaccination summary data measure, via NHSN by May 15, 2016.[45] Pursuant to 42 C.F.R. § 412.560(b)(1) and (2) (2015), failure to submit the data in the correct form and manner, and at the correct time results in a two (2) percentage point reduction to an LTCH's APU. Accordingly, this case focuses on the parties' dispute as to whether Savannah ***properly*** submitted to CMS the requisite data on the Healthcare Personnel influenza vaccination measure for October 2015 through March 2016, *i.e.*, the dispute as to whether the Healthcare Personnel influenza vaccination measure data at issue was submitted "in a form and manner, and at a time, specified by the CMS," as required by 42 C.F.R. § 412.560(b) (2015).[46]

Savannah admits that it transposed the numbers in its CCN when entering the data into NHSN.[47] However, in its original appeal and in the appeal of CMS' Second Reconsideration Determination, Savannah contends it is entitled to reversal of the 2 percentage-point payment penalty because: 1) the CMS reconsideration decision failed to follow the reconsideration process "established in the regulation and preamble to the FY 2015 Final Rule"[48], 2) any perceived noncompliance was mitigated by extenuating circumstances,[49] 3) the reconsideration's conclusory findings failed to specifically address Savannah's arguments, rendering it arbitrary and capricious;[50] and 4) enforcing the penalty is contrary to the LTCH QRP's intent.[51] The Board addresses Savannah's arguments as follows:

A. Whether Savannah submitted the 2015/2016 HCP Flu Vaccination Summary Data measure as specified by CMS in accordance with law.

In its preliminary position paper, Savannah argues:

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[44] *See HCP Influenza Summary Reporting FAQs, available at:* https://www.cdc.gov/nhsn/faqs/vaccination/faq-influenza-vaccination-summary-reporting.html (last accessed Sept. 25, 2025).
[45] Ex. P-8 at P0090 – 0091.
[46] *See also* Ex. C-7 at C0050.
[47] Provider's PPP at 12-13. *See also* Ex. P-7.
[48] Provider's PPP at 28-29 and 41-53.
[49] *Id.* at 53-57 and 65-68.
[50] *Id.* at 73-89.
[51] *Id.* at 89-90.

> This is not a case where the provider did not report its *quality data* to the CDC and CMS. Savannah submitted the actual data for the quality measure at issue. The district court agreed. Thus, the transposed CCN digits are the only explanation as to why CMS believes Savannah did not report all data. CCNs are not data subject to the 2 percent penalty. The statute is clear that the reduction in payment is only for a hospital that does not submit "data on quality measures." 42 U.S.C. § 1395ww(m)(5)(A),(C).[52]

Savannah later states, "the district court has already determined that Savannah timely reported its data to the NHSN, but there was a typographical error to the Provider's CCN."[53] Savannah suggests that CMS could have viewed the vaccination data in the NHSN system even though the data did not transmit to CMS.[54] Savannah claims there was no way it could have known that the CCN entered with vaccination data was incorrect,[55] and that its CCN was entered correctly "into NHSN for this reporting period in general."[56] Savannah also contends that "transmission of quality data from NHSN to CMS is not relevant for purposes of determining compliance with the [Quality Reporting Program]."[57] Savannah argues that "data reported to one component of HHS" should be treated "as received by another component of [the same agency]."[58]

In its reliance on certain parts of the District Court's *Landmark* decision, Savannah overlooks that fact that, although the District Court deemed the transposition of numbers in the CCN a "typo," it did not conclude that Savannah complied with the requirements of 42 C.F.R. § 412.560(b), nor did it conclude that Savannah should not be subject to the 2-percentage point reduction in its APU. In addition to the commentary favorable to Savannah in *Landmark,* the District Court also stated:

> Landmark might fare better under the correct standards. ***It might not***. Perhaps the different circumstances in Savannah and Salt Lake City will lead to different outcomes. "It is not the Court's role to guide the agency through its own regulations. ***Nor should it hypothesize how the correct regulation might alter the Board's analysis***." *PAM Squared*, 436 F.Supp.3d at 60. All the Court can say with certainty is that "the Board's reasoning came about by reviewing the CMS reconsideration through the tainted lens of the wrong regulation." *Id.* And that, at the very least, cannot stand.[59]

Further, in its reliance on *PAM Squared*,[60] Savannah overlooks the Court's following holding:

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[52] *Id.* at 50; *see also* 41 – 43.
[53] *Id.* at 66.
[54] *Id.* at 43.
[55] *Id.* at 44.
[56] *Id.* at 46.
[57] *Id.* at 52.
[58] *Id.* at 51.
[59] *Landmark* at 335.
[60] *PAM Squared At Texarkana, LLC v. Azar,* 436 F. Supp. 3d, 52 (D.D.C. 2020).

> What then is the proper remedy? PAM Squared argues that the Court should not remand to the agency. [*citation omitted*]. Instead, it should reverse the PRRB's decision and "declare that Plaintiff is entitled to the full Medicare Annual Payment Update for FY 2017." *[citation omitted]*. The hospital contends that a remand is unnecessary where "there is not the slightest uncertainty as to the outcome of an agency proceeding." *[citation omitted]*. But here the Court has more than the "the slightest uncertainty" about the agency's decision on remand. ***Perhaps the typo does justify the full two-percent penalty. But perhaps, now applying the proper standard, the Board will come to a different conclusion***. The appropriate remedy here is to remand the case to the agency. *[citation omitted]*.[61]

Accordingly, it is clear that in neither of the foregoing cases did the District Court hold that typographical errors render providers immune from the imposition of penalties for failure to submit relevant data as specified by CMS for purposes of the relevant quality reporting programs. Therefore, based on the Court's remand, the Board now reconsiders whether Savannah met the requirements of 42 C.F.R. § 412.560(b)—did Savannah submit the 2015/2016 HCP Flu Vaccination data measure to CMS in a form and manner, and at a time, specified by CMS? Here, as well as in other cases where Landmark has made errors it characterizes as typos in its data entry, the answer is, "No."

Despite what some, including Savannah, characterize as minutiae, paying attention to detail and verifying that the correct CCN has been entered into NHSN is of grave significance. In a transmittal issued by CMS ***as early as October 12, 2007***, CMS discussed the importance of the CCN stating, "The CCN continues to serve a critical role in verifying that a provider has been Medicare certified and for what type of services. This number is used throughout the various components of CMS, and maintaining this number is integral to CMS' business operations."[62] The transmittal made certain updates to the State Operations Manual, Chapter 2 – The Certification Process. Section 2779A1 of the Manual stated, "The CCN for providers and suppliers paid under Part A have 6 digits. The first 2 digits identify the State in which the provider is located. The last 4 digits identify the type of facility."[63] The State Code for Georgia is 11.[64] The Manual indicates that providers are assigned the last four digits of the CCN sequentially from blocks of numbers based on facility type.[65] For long-term hospitals, the block of numbers is 2000 – 2299, while the block of numbers from 0001 – 0879 is for short-term (General & Specialty) hospitals.[66] Thus, Landmark Hospital of Savannah, LLC, was assigned CCN 11-2018, as it was a long-term care hospital located in the State of Georgia.

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[61] *Id.* at 61.
[62] *CMS Manual System, Transmittal 29, Change Request 5490* (Oct. 12, 2007) at 3.
[63] *Id.* at 7.
[64] *Id.*
[65] *Id.* at 8.
[66] *Id.*

As early as October 2015, the LTCH QRP Manual stated that "LTCHs ***must adhere to the definitions and reporting requirements*** for this measure ***as specified*** in the CDC's NHSN *Healthcare Personnel Safety Component Protocol,*"[67] which includes the annual HCP Flu Vaccination summary data. A general principle of data entry is that it requires accuracy and attention to detail.[68] "Common mistakes like typographical errors can compromise data integrity."[69] Specific to NHSN, the CDC's NHSN Data Validation page states, "**Data Accuracy**: NHSN depends on precise data from healthcare facilities to achieve its surveillance goals and ensure accurate reporting of facility outcomes."[70] Thus, data entry quality control measures must be implemented to prevent errors and ensure accuracy of the input.

What seems to be lost upon Savannah (and other providers in similar situations where they have failed to timely verify their manual data entries) is that NHSN is an internet-based software platform that heavily relies on the specific, accurate, and complete input of data in order to generate reliable occupational exposure surveillance reporting, particularly where healthcare personnel may be the source of the virus or suffer occupational exposure to it.[71] The technical structure or format and specificity of the input are crucial for proper identification, monitoring, reporting of occupational infectious disease exposures, and implementing preventive practices among healthcare personnel.[72] What may seem like a minute detail or hyper-technical data entry requirement is essential to produce ***valid*** data reports on which numerous entities, including the facilities and CMS, rely for the aforementioned efforts.[73]

Unfortunately for Savannah, the devil is in the details. By transposing the numbers in the CCN and ***entering 11-0218 instead of 11-2018 and not double-checking to ensure that the CCN was entered correctly at that time,*** the HCP flu vaccination summary data it submitted was not associated with Landmark Hospital of Savannah, LLC's CCN 11-2018. Thus, for Savannah's proper CCN, no HCP influenza vaccination percentage/data was reported by the CDC to CMS. And, if by some chance the data was transmitted to CMS, it was attributed to a short-term general or specialty hospital in Georgia assigned CCN 11-0218 (if any). Either way, if a short-term facility exists with that CCN, CMS could not be expected to know the data was not related to that facility, and if no short-term facility exists with that CCN, it is unreasonable to expect CMS to guess as to which facility that data might be related.

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[67] CMS LTCH Quality Reporting Program Manual, Chapter 5 at 5-7.

[68] One can simply conduct an internet search on the term "general principles of data entry" and the recurring theme is that the integrity of the data is contingent upon the accuracy of the input. *See e.g.*, *The Ultimate Guide to Data Entry: Efficiency, Accuracy, and Best Practices* at https://medium.com/@supermoneymake/the-ultimate-guide-to-data-entry-efficiency-accuracy-and-best-practices-6a3c5bf2dcc5 (last accessed Sept. 25, 2025).

[69] *Id.*

[70] *See NHSN Data Validation* available at https://www.cdc.gov/nhsn/validation/index.html (last accessed Sept. 25, 2025).

[71] The NHSN's *About NHSN* page on its website states, "NHSN provides facilities, health departments, tracking system, states, regions, and the nation with data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate healthcare-associated infections." *See* https://www.cdc.gov/nhsn/about-nhsn/index.html (last accessed Sept. 25, 2025).

[72] *See id.* The common concept of "garbage in, garbage out" comes to mind where inaccurate or incomplete data entries caused by human error (garbage in) will undoubtedly result in flawed results reporting (garbage out), which, in this arena, could be detrimental to patient safety.

[73] *Id.*; *see also Healthcare Personnel Safety Component (HPS)* at https://www.cdc.gov/nhsn/hps/index.html (last accessed Sept. 25, 2025).

Providers, including Savannah, have long been placed on notice of the significance of using the correct CCN across the CMS universe, including in quality reporting programs. As it directly relates to the LTCH QRP HCP Flu Vaccination summary data reporting, the LTCH QRP Manual (2015) and Operational Guidance clearly instructed that LTCHs:

1) Must use the NHSN database and adhere to the NSHN HCP Safety Component Protocol reporting requirements;[74]
2) Should confirm that their CCN "is correctly entered on the Facility Information screen….to ensure that the appropriate data are shared with CMS"; and [75]
3) LTCHs do not confer [their NHSN] rights to CMS for their data submission.[76] LTCHs manually enter the HCP Flu Vaccination summary data into NHSN, and then the CDC reports all of data to CMS on behalf each reporting LTCH CCN providing CMS with an HCP influenza vaccination percentage ***"for each reporting LTCH CCN***."[77]

Accordingly, Savannah's arguments that CMS could have viewed the data and that the transmission of the data from the CDC's NSHN to CMS is not relevant to LTCH QRP compliance are not persuasive in this appeal.[78] If Savannah takes issue with how CMS receives or accesses and reviews quality reporting data, it has had and continues to have the opportunity to avail itself of the public comments process or lobbying or whatever contacts it can make with CMS to present its proposed methods. However, at present, the CDC—a distinct government agency who owns the NHSN—provides CMS with an HCP influenza vaccination percentage ***for each reporting LTCH CCN*** for purposes of the LTCH QRP. And the issue before the Board is whether Savannah complied with the LTCH QRP's data submission requirements in the form, manner, and time mandated by CMS.

As for Savannah's reliance on *Coyne*[79] and *In Defense of Animals*[80] to support its argument that "CMS possessed all the required data from Savannah…before the reporting deadlines[,]"[81] such reliance is misplaced.[82] *Coyne* is an Eastern District of New York case, which has no binding precedent on the Board even if it were analogous or persuasive, which it is not. In *Coyne*, Coyne attempted to overcome the False Claims Act's ("FCA") public disclosure bar to his *qui tam* claims arguing that the documents that formed the basis of his complaint against a drug manufacturer were not publicly disclosed.[83] However, the documents had been produced by the FDA in response to his own FOIA Request (which rendered them publicly disclosed) before he initiated his *qui tam* complaint.[84] The court held that Coyne could not claim that he was the

[74] LTCH QRP Manual at 5-7.
[75] *Id.* at 5-8, 5-10.
[76] *Id.* at 5-13.
[77] Operational Guidance at 2.
[78] *See* Provider's PPP at 43, 52.
[79] *United States ex rel. Coyne v. Amgen, Inc*., 229 F. Supp. 3d 159 (E.D.N.Y. 2017).
[80] *In Def. of Animals v. Nat'l Institutes of Health*, 543 F. Supp. 2d. 70 (D.D.C. 2008).
[81] Provider's PPP at 51.
[82] *Id.* at 39-40, 51.
[83] *See generally, Coyne* at 169 – 171.
[84] *Coyne* at 171.

original source of information that had been deemed publicly disclosed.[85] To support its argument, Savannah relies on the court's statement that "Coyne cannot plausibly allege that disclosure to the FDA was somehow not disclosure to CMS, so as to avoid the conclusion that the NHT data was, in fact, publicly disclosed."[86] However, this was not a holding that a disclosure of information to one government agency equates to disclosure to another agency. The court's statement disposed of Coyne's allegation that the drug manufacturer concealed information from CMS by not making a separate disclosure of the same information provided to the FDA. Here, the court's statement connected the dots—the drug manufacturer disclosed information to the FDA, the FDA approved certain medications based on the disclosed information, and CMS relied upon the FDA's approved use of the drug in its reimbursement determinations. Thus, Coyne's claim that the drug manufacturer hid information from CMS (that it gave to the FDA) failed, and he could not extend that argument to negate the fact that the information had been publicly disclosed.[87] The context in *Coyne*—the FCA's public disclosure bar—is not applicable to the instant matter.

Next, although D.C. Circuit Court decisions are binding upon the Board, *In Def. of Animals* does not address the issue before the Board. In *In Def of Animals*, the animal rights organization submitted a FOIA request to the National Institutes of Health ("NIH"), which was withheld resulting in litigation to obtain the requested information. The issue before the Court was whether the documents constituted "agency records" for purposes of FOIA requests. In its analysis, the Court reviewed the "agency records" criteria—1) whether the agency created or obtained requested the documents and 2) whether the agency controlled the documents at the time of the FOIA request.[88] The Court held that because the NIH owned the facility, required a third-party contractor to maintain records at the facility to which NIH had access, and owned the subjects of the records (chimpanzees), the documents subject of the FOIA request were created or obtained by NIH and thus, "agency records."[89] To support its argument, Savannah cites to the Court's statement, "the D.C. Circuit has made clear that records need not be generated by an agency, or in the actual possession of an agency, for the records to be considered 'owned or obtained' by an agency."[90] However, this holding is inapplicable to the instant case as it is specific to what constitutes an agency record strictly for the purposes of a FOIA request.

Further, to support its argument, Savannah quotes *PAM Squared*'s dicta, "In other words, PAM Squared had indeed submitted the data to one arm of the Department of Health and Human Services, NHSN, but NHSN never sent the data to another arm of the Department because of the typo."[91] However, as previously stated, the Court went on to state, "Perhaps the typo does justify the full two-percent penalty."[92] Accordingly, the Court did not hold that submission of data to one component of HHS equates to the submission of the same to another distinct agency within the Department.

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[85] *Id.* at 171, 174.
[86] *Coyne* at 171; *see also* Provider's PPP at 51.
[87] *Id*. at 171.
[88] *In Def. Animals* at 76 – 78.
[89] *Id.* at 77.
[90] *Id.*; *see also* Provider's PPP at 51.
[91] Provider's PPP at 50.
[92] *Pam Squared* at 61.

Savannah also claims there was no way it could have known that the CCN entered with vaccination data was incorrect,[93] and that its CCN was entered correctly "into NHSN for this reporting period in general."[94] However, Savannah's reaction to the July 15, 2016 Notice of Noncompliance counters its own argument—on the same day that it received the Notice, Savannah corrected the CCN.[95] Accordingly, Savannah's argument fails as its reactive attention to detail proves that there was a way it could have known the CCN was entered incorrectly—they could have checked themselves.

Furthermore, the record demonstrates that between the last week of April 2016 and May 13, 2016, Savannah received at least two (2) notices regarding its HCP Influenza Vaccination data being incomplete. Particularly, on May 5, 2016, NHSN informed Savannah that although the HCP Flu Vaccination data had been entered on March 30, 2016, Savannah's "***CCN still needs to be entered in NHSN in order for the data to be transmitted to CMS***. To do so, please follow the instructions below:…"[96] Shortly thereafter, Savannah's employee "***entered 11-0218 instead of 11-2018***"[97] and instead of checking themselves or having another team member verify the entry, she requested that NHSN "check everything and make sure I am okay on all of this so I meet the mandatory reporting requirements?"[98] The NHSN employee responded, "I logged into your facility in NSHN (Org ID 44502), and it ***appears*** that you have now added your CCN. No further action is required on your part regarding these data."[99] Five (5) days later on May 10, 2016, Savannah received another notification that its HCP Influenza Vaccination data was incomplete.[100] Savannah's employee communicated with NHSN who stated, "The summary data 'looks' complete however, I can't say for sure until you generate new data sets...[and] use the Analysis Output Options to create a CMS report that shows what Healthcare Personnel Influenza Vaccination data will be sent to CMS on behalf of your facility."[101] Savannah's employee ran the reports as instructed, but she still did not check if the CCN was entered correctly.[102] Instead, the employee informed the NHSN representative that "it looks like the report to CMS is accurate, if you [could] please check it again to be sure I would appreciate it, thank you for your help!"[103] The NHSN employee responded, "You're good to go!"[104]

Savannah contends that neither the "NHSN module nor the NHSN representative made Savannah aware of the error in the CCN."[105] However, reporting guidance instructs LTCHs to verify that their CCNs have been entered correctly[106] Furthermore, although Savannah relied on

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[93] Provider's PPP at 44.
[94] *Id.* at 46.
[95] *See Id.* at 14, 43; *see also* Ex. P-7.
[96] Ex. P-5 at P0079.
[97] Provider's PPP at 42 (emphasis added).
[98] Ex. P-5 at P0079.
[99] *Id.* (emphasis added).
[100] Ex. P-6 at P0083.
[101] *Id.* at P0082.
[102] *Id*.
[103] *Id.*
[104] *Id.*
[105] Provider's PPP at 44, 68-69.
[106] *See* Ex. P-16 (PRRB Dec. 2019-D17) at P0211 - P0212:

the NSHN representative to check the accuracy of the submission and then relied on the their responses instead of verifying it themselves, it is well-established that one cannot wholeheartedly rely on a government agency employee's advice provided via email, particularly when the advice is not endorsed by the agency or when the advice is erroneous.[107] Further, the NSHN representative had no way of telling that the CCN was correct – at best, they could verify it had been input. No mention of the actual CCN was made in the Savannah employee's emails.

Finally, despite citing to SSA § 1886(m)(5)(C) and acknowledging that "Providers must submit data for the selected measures in the form, manner, and time specified by the Secretary[,]"[108] Savannah goes on to argue that that the CDC created an unnecessary extra step in NHSN for the transmission of data to CMS[109] and that "[t]he transmission of quality data from NHSN to CMS is not relevant for purposes of determining compliance with the QRP."[110] This argument simply fails. As previously stated, a Board appeal is not the appropriate forum to request equitable relief from penalty-based policy arguments about technical requirements. Savannah has researched both the Social Security Act and 42 C.F.R. § 412.560, which amplifies the Act, and understands that the law requires that LTCHs submit to CMS data on measures specified under the Act "in a form and manner, and at a time, specified by CMS."[111] And although Savannah argues, that "[t]he only issue in this case relates to the transmission of this data from one HHS component, the CDC, to another component, CMS[,]"[112] in an effort to diminish the fact that its own CCN error caused a failed transmission, Savannah is correct—that is the only issue. The record demonstrates that Savannah did not verify the accuracy of the CCN entry on May 5, 2016, or at any time after that date prior to May 15, 2016, which caused the failed transmission of the data from the CDC's NHSN to CMS. Further, the record demonstrates that in reaction to the Notice

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> NHSN had guidance dated July 2015 posted on a webpage entitled "CMS Requirements" that instructs providers such as LTCHs on how to add or correct their CCN in the NSHN system and reminds providers to double and triple check that they entered the CCN correctly:
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> Enter the new CCN and Effective Date in the appropriate boxes . . . . *Make sure to double check that the new* CCN and Effective Date *are correct!* . . . Click the Close button to close the Edit CCN Records pop up to return to the Edit Facility Information page. *Then verify that the new* CCN and effective date *are correctly listed.*

Citing NHSN Guidance entitled "Adding/Correcting a CMS Certification Number within NHSN" dated July 2015. (Footnotes omitted.) The Board notes that the CDC has historically published operational guidance documents upon mandating new reporting requirements and routinely reviews and updates them to reflect the changes as applicable. Unfortunately, at the time of this decision, the CDC website archives are not available, thus the hyperlink cited in Ex. P-16 as https://www.cdc.gov/NHSN/pdfs/CMS/Changing-CCN-within-NHSN.pdf provides the version last reviewed September 2022 rather than the cited July 2015 version.

[107] *See, e.g., Vernal Enters., Inc. v. Fed. Commc'ns Comm'n,* 355 F.3d 650, 660-661 (D.C. Cir. 2004) ("We recently reaffirmed our well-established view that an agency is not bound by the actions of its staff if the agency has not endorsed those actions. *See Cmty. Care Found. v. Thompson,* 318 F.3d 219, 227 (D.C. Cir. 2003) (citing *Amor Family Broad. Group v. FCC,* 918 F.2d 960 (D.C. Cir. 1990)). *See also Jelks v. FCC,* 146 F.3d 878, 881 (D.C. Cir.1998); *MacLeod v. ICC,* 54 F.3d 888, 891 (D.C. Cir. 1995)").

[108] Provider's PPP at 21.

[109] *Id.* at 39.

[110] *Id*. at 52.

[111] *See* Ex. P-12 (where Savannah located the version of 42 C.F.R. 412.560 in effect as of August 25, 2017).

[112] Provider's PPP at 49.

of Noncompliance, Savannah quickly identified the error, the same efforts which should have been made prior to the deadline to prevent the failure.

Based on the foregoing, the Board need not go further in determining whether Savannah submitted 2015/2016 HCP Influenza Vaccination Summary Data as specified by CMS in accordance with law, i.e., "***in the form and manner, and at a time, specified by CMS.***" The Board finds that it did not.

B. Whether the CMS reconsideration decision failed to follow the reconsideration process established in the regulation and/or the preamble to the FY 2015 Final LTCH IPPS Rule.

Now, we move on to the evaluation of the matter under 42 C.F.R. § 412.560(d) as directed by the District Court,[113] and Savannah's contention with CMS' Second Reconsideration Determination issued via email on March 21, 2021, which states, in pertinent part:

> On remand, CMS has carefully reviewed your reconsideration request along with the supporting documentation you submitted along with your reconsideration request and the information in connection with the administrative proceeding before the PRRB and the federal district court proceeding. Based on this review, CMS has decided to uphold its determination of noncompliance and the imposition of a 2% Medicare reimbursement penalty. This determination is based on CMS's finding that your LTCH failed to submit the required QRP data in the correct form and manner as required by statute. 42 U.S.C. §§ 1395ww(m)(5)(A) and (C). Specifically, your LTCH failed to submit data to HHS for the 2015 calendar year impacting the FY 2017 payment determination. Landmark Hospital of Savannah failed to submit to HHS healthcare personnel influenza vaccination data by the May 15, 2016 submission deadline as required.
>
> CMS has also determined that your reconsideration request did not provide a valid or justifiable excuse for non-compliance. Specifically, the facts your LTCH presented do not demonstrate the existence of extraordinary or extenuating circumstances that would excuse your LTCH's failure to comply with the QRP requirements. The facts you provided demonstrate a failure to report the required data in the correct form and manner as required by statute, ***not a mere clerical error or a technical error with the data reporting system.***[114]

To support its argument that CMS failed to follow the reconsideration process and again failed to employ the correct standard of review, Savannah relies on the preamble to the FY 2015 Final

[113] *See Landmark* at 332-333.
[114] Ex. P-14 at 118 - 119 (emphasis added).

Rule, which states that a provider's request for reconsideration must include evidence demonstrating: 1) full compliance with all LTCH QR Program reporting requirements during the reporting period; or 2) extenuating circumstances that affected noncompliance if the LTCH was not able to comply with the requirements during the reporting period. Savannah asserts that it met both reconsideration request requirements which entitles them to exemption from the two percentage-point reduction APU penalty.[115]

As previously addressed above in the *Relevant Applicable Law* Section, the ***codified*** regulation[116] at 42 C.F.R. § 412.560(d) fully addressed the reconsideration process in effect on August 15, 2016, when Savannah requested reconsideration. Specifically, 42 C.F.R. § 412.560(d)(2)(vi) and (vii) state that a provider's reconsideration request must state the reason for the request and include documentation substantiating compliance with the program requirements. Thus, although superseded, the reconsideration request requirements of the 2015 Final Rule were fully encompassed in 42 C.F.R. § 412.560(d)(2)(vi) and (vii)—a provider may include, in its stated reasons—***any*** reasons or circumstances *including those it claims are extenuating*—that effectuated noncompliance, ***and*** it is required to submit documentation demonstrating compliance (because with the codification of the regulation, both are required for a reconsideration request).

However, nothing in regulation states or implies that the mere submission of a reconsideration request stating reasons and providing documentation will automatically absolve a provider of a noncompliance reduction penalty—such does not guarantee that CMS will decide in a provider's favor. Upon submission of the reconsideration request, CMS evaluates the reason(s) and documentation to determine whether a reduction penalty for noncompliance should be reversed or upheld. Furthermore, fulfilling the procedural reconsideration request requirements to be reviewed by CMS is not synonymous with meeting its burdens of production and proof by a preponderance of the substantial evidence before the Board. In the instant appeal, even if the Board concludes, as a matter of law, that Savannah met the procedural requirements of 42 C.F.R. § 412.560(d)(2)(vi) and (vii) (it provided its reasons and documentation that it believed demonstrated compliance), that does not equate to a conclusion of law that Savannah indeed met the requirements of 42 C.F.R. § 412.560(b)(1), which requires the submission of data on the specified measures "in a form and manner, and at a time, specified by CMS [or the Secretary]" to avoid a two percentage-point APU reduction.

But before we delve further into whether CMS' Reconsideration Determinations should be reversed, we will address Savannah's argument that, in the Second Reconsideration Determination, CMS again conflated the standards of review under 42 C.F.R. § 412.560(c)(4) (Exception and Extension Request Requirements) and 42 C.F.R. § 412.560(d) (Reconsiderations of Noncompliance Decisions)—even after the District Court remanded the matter for consideration under ***42 C.F.R. § 412.560(d)***.[117]

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[115] Provider's PPP at 91.
[116] *See Landmark* at 334 (where the District Court states, "When CMS codified its rule from Volume 79 of the Federal Register at 42 C.F.R. § 412.560, the "extenuating circumstances" language in the preamble did not carry over. It is unclear why.").
[117] Provider's PPP at 57, 91.

In the March 21, 2021 Reconsideration Determination, CMS stated, in pertinent part:

> CMS has also determined that your reconsideration request did not provide a ***valid or justifiable excuse*** *for non-compliance*. Specifically, the facts your LTCH presented do not demonstrate the existence of ***extraordinary or extenuating circumstances*** that would excuse your LTCH's failure to comply with the QRP requirements. The facts you provided demonstrate a failure to report the required data in the correct form and manner as required by statute, ***not a mere clerical error or a technical error with the data reporting system.***[118]

Here, Savannah's argument has ***some merit.*** Instead of focusing solely on the all-encompassing language set forth in the reconsideration provision of 42 C.F.R. § 412.560(d) (the reconsideration request by the long-term care hospital must contain the reason for requesting reconsideration of CMS' noncompliance decision) or even what has been deemed the "extenuating circumstances standard" (the second prong of the 2015 Final Rule commentary),[119] CMS attempted to cover all its bases. However, in doing so, is this fatal to CMS' Reconsideration Determination? In this instance, it is not. CMS reviewed the facts as presented to determine whether entering the wrong CCN is:

1) A valid or justifiable excuse for noncompliance, or
2) A demonstration of the existence of an extraordinary circumstance, or
3) A demonstration of the existence of an extenuating circumstance,

CMS' determination still considered the latter, even if it did not have to consider the former two "standards" (applicable or not) in the instant matter.[120] It is not unfathomable that the same set of facts could result in a finding that such facts do not meet either of the three "standards" under any review (applicable or not). Nonetheless, CMS's kitchen sink approach included a review of the "extenuating circumstances standard" invoked by Savannah.

Savannah asserts that the reconsideration process review of evidence demonstrating "extenuating circumstances" is an *equitable standard* and that it need only establish "moderating factors that make someone's actions excusable or less blameworthy" and need only be "reasonable excuses for less than full compliance."[121] Savannah also asserts that the FY 2015 IPPS Final Rule at 79 Fed. Reg. 50317 confirms that "CMS was allowing providers to submit documentation of reasonable excuses to explain why they were not able to achieve full compliance."[122] Quoting the Black's Law Dictionary (11th ed. 2019), the District Court in *Landmark,* on which Savannah relies in its PPP,[123] stated that "extenuating" is a "'fact or situation that does not justify or excuse

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[118] Ex. P-14 at P0119 (emphasis added).
[119] *See* 79 Fed. Reg. at 50317.
[120] The "valid or justifiable excuse for noncompliance" commentary is referenced in the FY 2015 IRF PPS Final Rule (and possible other QRP final rule sections). The "extraordinary circumstances" review applies to an LTCH's request for an exception or extension under 42 C.F.R. § 412.560(c).
[121] Provider's PPP at 53-54.
[122] *Id* at 54.
[123] *Id*. at 56.

a wrongful act or offence but that reduces the degree of culpability.'"[124]

CMS' Second Reconsideration Determination stated, "[t]he facts you provided demonstrate a failure to report the required data in the correct form and manner as required by statute, not a mere clerical error or a technical error with the data reporting system."[125] As discussed *supra*, the record demonstrates that LTCH QRP guidance materials have long instructed LTCHs to confirm that their manually input CCN "is correctly entered on the Facility Information screen….to ensure that the appropriate data are shared with CMS."[126] The record clearly demonstrates that on May 5, 2016, Savannah entered the wrong CCN, which Savannah does not dispute, which resulted in a failed transmission of its HCP Influenza Vaccination Summary Data—because Savannah did not verify the accuracy of the data input between May 5, 2016 and May 15, 2016. The record demonstrates that instead of internal verification, Savannah relied on an NHSN representative to verify the accuracy of its submission. And as previously stated, the record shows that only *after* receiving the Notice of Noncompliance, Savannah corrected the CCN on the Facility Information screen within two (2) business days.[127]

Accordingly, Savannah's errors 1) do not demonstrate full compliance with LTCH QRP requirements and 2) do not reduce its degree of culpability for failing to submit the data to CMS in the form, manner, or time specified by law. Thus, Savannah's extenuating circumstances that it cites as its reason for its noncompliance and its underlying rationale for seeking reconsideration were not ignored by CMS, they simply were not deemed as exculpatory for overturning the initial noncompliance decision.

Further, Savannah's argument that CMS' Reconsideration Decisions are arbitrary and capricious because they make conclusory statements and do not respond to its arguments is unpersuasive. To support its argument, Savannah cites a host of U.S. Supreme Court, D.C. Circuit Court, and D.C. District Court cases that collectively held that an agency decision must demonstrate a consideration of the relevant facts and provide an explanation of its rationale for its decision.[128] Savannah, however, overlooks that even in one of its cited cases, the U.S. Supreme Court stated, "We will, however, 'uphold a decision of less than ideal clarity ***if the agency's path may reasonably be discerned***.' [citations omitted]"[129] Additionally, Savannah overlooks the D.C. Circuit's holding that:

> A "fundamental" requirement of administrative law is that an agency "set forth its reasons" for decision; an agency's failure to do so constitutes arbitrary and capricious agency action. [citations omitted]. That fundamental requirement is codified in section 6(d) of the APA, 5 U.S.C. § 555(e). Section 6(d) [of the APA] mandates that whenever an agency denies 'a written application, petition, or other request of an interested person made in

[124] *Landmark* at 334.
[125] Ex. P-14 at P0119.
[126] LTCH QRP Manual at 5-8, 5-10.
[127] Ex. P-7.
[128] *See* Provider's PPP at 74-75.
[129] *Motor Vehicle Manufacturers Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43, 103 S. Ct. 2856, 2867, 77 L. Ed. 2d 443 (1983) (citations omitted). Emphasis added.

> connection with any agency proceeding,' the agency must provide "***a brief statement of the grounds for denial***," unless the denial is "self-explanatory."
>
> ***
>
> Although nothing more than a "brief statement" is necessary, the core requirement is that the agency explain "why it chose to do what it did." [citations omitted][130]

Thus, nothing in the APA nor in common law requires that CMS respond to Savannah's arguments, but they require that CMS issue a decision from which a reviewing court can discern the rationale for the action taken. As stated above, in its Second Reconsideration Determination, CMS stated:

> Specifically, the facts your LTCH presented do not demonstrate the existence of extraordinary or extenuating circumstances that would excuse your LTCH's failure to comply with the QRP requirements. The facts you provided demonstrate a failure to report the required data in the correct form and manner as required by statute, not a mere clerical error or a technical error with the data reporting system.[131]

Upon review, the question of why CMS denied Savannah's reconsideration request can be answered: The clerical or technical errors with the data reporting system claimed by Savannah did not demonstrate the existence of an extenuating circumstance as asserted. CMS' "brief statement" explains why it chose to do what it did.

C. Whether 2-percentage point APU reduction for FY 2017 is contrary to the intent of the LTCH QRP?

Finally, Savannah argues that applying the payment penalty is contrary to the intent of the LTCH QRP.[132] As stated by Savannah in its PPP:

> According to CMS, the purpose of the LTCH QRP is "to promote higher quality and more efficient health care for Medicare beneficiaries . . . ." FY 2012 IPPS/LTCH PPS Final Rule, 76 Fed. Reg. 51476, 51743 (Aug. 18, 2011). CMS uses the LTCH QRP to "efficiently collect information on valid, reliable, and relevant measures of quality and to share this information with the public, as provided under section 1886(m)(5)(E) of the Act." Id. at 51744.

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[130] *Tourus Recs., Inc. v. Drug Enf't Admin.*, 259 F.3d 731, 737 (D.C. Cir. 2001) (emphasis added).
[131] Ex. P-14 at P0119; *cf. Tourus* at 737 (where the Court held that the letter at issue therein did not meet the APA standard because "[t]he letter says nothing other than that the 'Affidavit of Indigency you submitted in lieu of a cost bond is not adequately supported.'").
[132] Provider's PPP at 89-90.

> CMS hopes to "achieve a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement." Id. at 51750.[133]

The Board notes that, where Savannah failed to submit the HCP Influenza Vaccination Summary Data in the form, manner, and time specified by CMS, including following the technical data entry requirements of the CDC's NHSN to ensure that the data was transmitted to CMS, Savannah, as a participant in the LTCH QRP, negatively impacted CMS' ability to effectuate the purpose of the program. Accordingly, applying the payment reduction as a penalty for these actions is not contrary to the intent of the LTCH QRP as averred by Savannah.

Savannah also contends that the doctrine of substantial compliance precludes application of any payment penalties.[134] The doctrine of substantial compliance is inapplicable in this case and the cases cited by Savannah are unpersuasive – one is specific to Internal Revenue Service regulations, the other, relative to CMS, is not analogous to the issues in this case as the analysis therein focuses on the interpretation and usage of the phrase "substantial compliance" throughout the Medicare Part A and Part D statutes.[135] As previously discussed *supra*, Savannah acknowledges that the Social Security Act itself mandates that LTCHs submit data in the form, manner, and time specified by CMS. Accordingly, Savannah's argument that it substantially complied fails.

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Based on the foregoing, the Board finds:

1) Savannah failed to submit the HCP Influenza Vaccination Summary Data as specified by CMS in violation of 42 C.F.R. § 412.560(b)(1);

2) CMS' Reconsideration Decisions should not be reversed because Savannah did not meet the requirements of 42 C.F.R. § 412.560(b)(1). Specifically, Savannah did not fully comply with the FY 2017 LTCH QRP program requirements and its reasons for its noncompliance, represented as extenuating circumstances, do not warrant reversal of the penalty as a typographical error resulting from a failure to implement and execute an internal data entry quality control measure prior to the May 15, 2016 deadline does not reduce Savannah's culpability in its noncompliance;

3) CMS' March 11, 2021 Reconsideration Determination meets the requirements of Section 6(d) of the APA; and

4) The payment penalty is not contrary to the intent of the LTCH QRP.

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[133] *Id.*
[134] *Id.* at 90.
[135] In *Fox Ins. Co. v. Centers for Medicare & Medicaid Servs.*, 715 F.3d 1211, 1221 (9th Cir. 2013) ("The term should have the same meaning under both Parts.").

DECISION

After considering the Medicare law and regulations, the arguments presented and the evidence submitted, and consistent with the District Court's remand in *Landmark Hosp. of Salt Lake City & Landmark Hosp. of Savannah v. Azar,* 442 F. Supp. 3d 327 (D.D.C. 2020), the Board has reviewed the record, the applicable regulations, and additional CMS guidance and as set forth below, the Board finds the Provider failed to ***properly*** submit the Healthcare Personnel influenza vaccination measure data at issue in the form, manner and at the time, specified by CMS.

The Board acknowledges that its original decision cited and relied upon the incorrect subsection of the regulation and applied the incorrect standard of review, but, as set forth below, concludes that the application of the correct regulation and standard of review does not alter its finding that CMS properly assessed the 2 percentage point APU penalty due to the Savannah's failure to submit the HCP influenza vaccination summary data measure in the time, form and manner specified by CMS.

BOARD MEMBERS PARTICIPATING:

Kevin Smith, CPA
Ratina Kelly, CPA
Nicole E. Musgrave, Esq.
Shakeba DuBose, Esq.

FOR THE BOARD:

9/30/2025

X Kevin D. Smith, CPA

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