PROVIDER REIMBURSEMENT REVIEW BOARD
DECISION

2026-D05

PROVIDER –
Landmark Hospital of Salt Lake City, LLC

RECORD HEARING DATE –
January 30, 2024

PROVIDER NO. –
46-2006

FISCAL YEAR –
FFY 2017

vs.

MEDICARE CONTRACTOR –
Noridian Healthcare Solutions, LLC

CASE NUMBER –
21-1678

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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 Salt Lake City, LLC's ("Salt Lake" or "Provider") Annual Payment Update ("APU") for Fiscal Year ("FY") 2017 by two (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 in this decision, the Board finds the Provider failed to prove that it ***properly*** submitted the Catheter-Associated Urinary Tract Infection ("CAUTI") and Central Line-Associated Bloodstream Infection ("CLABSI") data measures for calendar year ("CY") 2015 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 in this decision, 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 Salt Lake's failure to submit the CAUTI and CLABSI data measures in the time, form and manner specified by CMS.

INTRODUCTION AND PROCEDURAL HISTORY

Landmark Hospital of Salt Lake City, LLC is "a Medicare certified long-term care hospital ("LTCH") located in Murray, Utah."[3] The Provider's assigned Medicare Administrative Contractor[4] is Noridian Healthcare Solutions, 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]

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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.
[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).

By letter dated July 7, 2016, CMS notified Salt Lake that it "did not meet one or more of the [LTCH QRP] requirements for Fiscal Year (FY) 2017" and that it would be subject to "a 2-percentage point reduction in the FY 2017 Annual Payment Update."[6] The noncompliance was cited as Salt Lake's failure to submit all of the required months of complete CAUTI and CLABSI data.[7]

On August 18, 2016, Salt Lake requested reconsideration of CMS' noncompliance finding and the 2-percentage point APU reduction.[8] On September 22, 2016, CMS notified Salt Lake that the July 7, 2016 Notice of Noncompliance would be upheld ("Original Reconsideration Determination") stating, "Our records indicate that this LTCH did not provide evidence that it submitted required quality data during the required timeframes."[9] On September 23, 2016, the MAC issued a letter notifying the Provider of the same.[10]

On March 20, 2017, Salt Lake appealed the Original Reconsideration Determination to the Board.[11] The Board held a hearing on the matter on October 2, 2017,[12] and on February 26, 2019, issued PRRB Decision 2019-D16 affirming the 2-percentage point reduction to Salt Lake's FY 2017 APU.[13]

On April 26, 2019, Salt Lake 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. 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 "[s]o 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 Salt Lake that it 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 FY 2017 APU ("Second Reconsideration Determination").[16] Particularly, CMS found that Salt Lake's noncompliance resulted from incomplete CAUTI data submissions for June, July, and August 2015, and for incomplete CLABSI data submissions for June and July 2015.[17]

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[6] Exhibit (hereinafter "Ex.") P-2 at P0015.
[7] *Id.*
[8] Ex. P-3.
[9] Ex. P-4 at P0052.
[10] *Id*. at P0053.
[11] Ex. P-1.
[12] Ex. P-11 (Hearing Transcript).
[13] Ex. P-12.
[14] Stipulations at ¶ 19 (*See also* Ex. P-27).
[15] *See Landmark* at 335.
[16] Ex. P-10 at P0099-0100.
[17] *Id*. at P0100.

On September 7, 2021, Salt Lake 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.

Accordingly, this matter is ripe for consideration, particularly, reviewing Salt Lake's appeal of CMS' Original and Second Reconsideration Determinations (collectively "Reconsideration Determinations")[18] 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 on the timely submission of quality data collected during CY 2015 (January 1, 2015, through December 31, 2015).[19] For LTCH QRP data submissions, CMS requires providers, including LTCHs, to utilize the Centers for Disease Control and Prevention's ("CDC") National Healthcare Safety Network ("NHSN"). LTCH QRP instructions and deadlines for data submission have historically been posted on CMS' LTCH QRP website. For FY 2017 payment determinations under the LTCH QRP, the collection timeframe and final submission deadlines for required outcome measures, including CAUTI and CLABSI data, were originally set and revised as follows: [20]

Data Collection Timeframe	**Final Submission Deadlines**	**REVISED Submission Deadlines[21]**
Q1: January 1 – March 31, 2015	May 15, 2015	February 15, 2016
Q2: April 1 – June 30, 2015	August 15, 2015	February 15, 2016
Q3: July 1 – September 30, 2015	November 15, 2015	February 15, 2016
Q4: October 1 – December 31, 2015	May 15, 2016	May 15, 2015 (No Change)

On August 3, 2015 at 14:19PM, Salt Lake created its Monthly Reporting Plan for June 2015 using the "WARD_LTCH" location and "WARD_LTAC" location type, indicating that it would

[18] Salt Lake'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 Reconsideration Determinations, it shall apply to the other unless otherwise distinguished.
[19] Ex. P-5 at P0055-0056.
[20] *Id.* at P0056.
[21] On December 11, 2015, CMS announced the extension of the NHSN data submission deadlines. See Ex. P-5 at P-0057 ("CMS has made the decision to extend the NHSN data submission deadline for LTCH providers until February 15, 2016, for Calendar Year 2015 Quarters 1, 2, & 3 for FY2017 payment determination. Facilities are encouraged to review their Q1, Q2, and Q3 data within NHSN to ensure completeness. Facilities may add or update data from 2015 Q1, Q2, and Q3 within NHSN until the February 15, 2016 submission deadline. This extension also applies to the submission deadlines for assessment data for the quality reporting program. The revised deadlines can be reviewed on the LTCH Quality Reporting Data Submission Deadlines page.")

be reporting on CAUTI ("utiPlan") and CLABSI ("bsiPlan").[22] On August 3, 2015 at 14:36PM, Salt Lake created/entered summary data for CAUTI and CLABSI for the month of June 2015, using the "WARD_LTCH" location and "WARD_LTAC" location type.[23] On August 24, 2015 at 12:39PM, Salt Lake created its Monthly Reporting Plan for July 2015 using the same parameters as used for creating the June plan.[24] On August 24. 2015 at 12:39PM, Salt Lake created/entered summary data for CAUTI and CLABSI for the month of July 2015, using the same location and location types.[25] On August 24, 2015 at 13:07PM, Salt Lake created/entered a patient CLABSI event that occurred on July 18, 2015 (counting for the month of July) using location "WARD_LTCH."[26] On October 6, 2015 at 8:38AM, Salt Lake created its Monthly Reporting Plan for August 2015 using the same parameters as used for the June and July reporting plans. [27] On October 6, 2015 at 10:03AM, using the same location and location type as used for June and July, Salt Lake created/entered summary data for CAUTI and CLABSI for the month of August 2015.[28]

By contrast, on August 3, 2015, when entering data for June 2015 on the *Denominators for Intensive Care Unit (ICU)/Other Locations (not NICU or SCA)* form in NHSN (hereinafter "Denominators Form"), Salt Lake used "N/A – UNIT" in the mandatory field for the Location Code.[29] For June 2015, Salt Lake checked the boxes for CAUTI and CLABSI indicating that there were no reportable events for both measures.[30] On August 24, 2015, when entering data on the Denominator Form for July 2015, Salt Lake again used "N/A – UNIT" in the mandatory field for the Location Code when reporting that there were no reportable CAUTI events in July 2015.[31]

As previously stated, the deadline for the submission of Q2 (April – June 2015) data measures was August 15, 2015, and it was extended to February 15, 2016. The deadline for submission of Q3 (July – September) data measures was November 15, 2015, and it was also extended to February 15, 2016.

On July 7, 2016, CMS notified Salt Lake that it failed to submit "all required months of complete" CAUTI and CLABSI data and that it would be subject to the 2 percentage point reduction in its APU for FY 2017.[32] After receiving the noncompliance notice, Salt Lake contacted the HCIS – Post Acute Care Help Desk and learned that their CAUTI data for June and July 2015, and their CLABSI data for June and August 2015 was incomplete despite their entries

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[22] *See* Ex. P-8 at P0067.
[23] *Id.* at P0068 (where User 127324 entered 810 "numpatdays" for both CAUTI and CLABSI event types and entered 314 and 602 "numddays" for CAUTI and CLABSI, respectively).
[24] *Id.* at P0067.
[25] *Id.* at P0068 (where User 127324 entered 723 "numpatdays" for both event types and entered 240 and 520 "numddays" for CAUTI and CLABSI, respectively).
[26] *Id.* at P0069.
[27] *Id.* at P0067.
[28] *Id.* at P0068 (where User 127324 entered 701 "numpatdays" for both event types and entered 202 and 526 "numddays" for CAUTI and CLABSI, respectively).
[29] *See* Ex. P-3 at P0033 (where Salt Lake submitted various reports with its Reconsideration Request. The Denominator Form for the month of June 2015 was saved on August 3, 2015, as indicated in the footer on the page.)
[30] *Id*. (where the "X" indicates "Report No Events").
[31] *See* Ex P-3 at P0037.
[32] Ex. P-2 at P0015; *see also* Ex. P-10 at P0100.

for the measures.[33] During their investigation of the missing data, Salt Lake downloaded several NHSN reports focusing on the monthly reporting plans that were previously re-entered before the submission deadlines (in response to a pre-deadline incomplete submission notification from NHSN).[34] After investigating and attempting to find any errors in their submissions and concluding that "Everything, the data was correct" because they were "unable to find a reason for the errors that we received on NHSN[,]" Salt Lake filed a reconsideration request with CMS.[35] Thereafter, the events set forth in the *Introduction and Procedural History* section, *supra,* ensued.

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."[36] 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."[37] 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."[38] 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 "Board shall afford great weight to interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS."[39]

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,[40] the FY 2015 LTCH IPPS Final Rule was superseded by the FY 2016 IPPS Final Rule that codified the reconsideration and appeals

[33] *See* Stipulations at ¶8.
[34] *See* P-11 at P0130 (Original Hearing Transcript ("Tr.") at 76:8-25).
[35] *Id.* at P0131 (Tr. 77-78).
[36] 42 C.F.R. § 405.1871(a)(3) (as of Oct. 1, 2014).
[37] 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).
[38] *See also Pomona Valley Hosp. Med. Ctr. v. Becerra*, 82 F.4th 1252, 1258-59 (D.C. Cir. 2023).
[39] 42 C.F.R. § 405.1867.
[40] Stipulations at ¶12.

process "for the FY 2017 Payment Determination and Subsequent Years."[41] Accordingly, the October 1, 2015 version[42] of regulations set forth in 42 C.F.R. § 412.560 that were in effect on August 18, 2016 (the date of Salt Lake's initial reconsideration request), apply to this appeal on remand as they fully address the reconsideration process at that time, *discussed infra*.[43] Here, it is important to acknowledge that the October 1, 2019 version[44] 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 applicable regulation provides in pertinent parts:

42 C.F.R. § 412.560 (October 1, 2015)[45]

> (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.[46]
> >
> > (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.
>
> ***
>
> (d) Reconsiderations of noncompliance decisions—
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> > (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

[41] 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").
[42] Effective October 1, 2015 to September 30, 2016.
[43] For FY 2017 payment determinations and subsequent years, the FY 2016 IPPS/LTCH PPS Final Rule codified the LTCH QRP the 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.").
[44] Effective October 1, 2019 to September 30, 2023.
[45] This is the version of the regulation in effect on May 15, 2016 (the deadline for the data submission).
[46] *See also* 80 Fed. Reg. 49326, 49729 – 48730 (Aug. 17, 2015) (where the Secretary instructed LTCHs that the data on the CAUTI and CLABSI data measures was adopted "for the FY 2014 payment determination and subsequent years").

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.

As early as November 2014, CMS issued Operational Guidance[47] for reporting CAUTI data to the CDC's NHSN for QRP compliance, which states in pertinent parts:

> After enrollment is complete ***[LTCHs] should map each of their inpatient locations to the appropriate CDC-defined location type***.
>
> NHSN users reporting CAUTI data to the system must adhere to the definitions and reporting requirements for CAUTIs as specified in the NHSN Patient Safety Component Protocol Manual http://www.cdc.gov/nhsn/LTACH/CAUTI/index.html. ***This includes reporting of denominator data (patient days and urinary catheter days)[.]…CAUTI data must be reported from each patient care location in which facilities are required to monitor and report CAUTIs.***
>
> LTCHs must report CAUTI and ***associated denominator data*** for infections that occur on or after October 1, 2012 ***from all inpatient locations.***
>
> Monthly reporting plans must be created or updated to include CAUTI ***surveillance in all locations*** from which reporting is required, i.e., CAUTI surveillance must be "in-plan" for data to be shared with CMS. All data fields required for both numerator and ***denominator data collection must be submitted to NHSN***, including the "no events" field for any month during which no CAUTI events were identified. Data must be reported to NHSN by means of manual data entry into the NHSN web-based application or via file imports using the Clinical Document Architecture (CDA) file format for numerator ***and denominator***

[47] *See Operational Guidance for Long Term Care Hospitals* to Report Catheter-Associated Urinary Tract Infection (CAUTI) Data to CDC's NHSN for the Purpose of Fulfilling CMS's Quality Reporting Requirements* located at https://www.cdc.gov/nhsn/PDFs/CMS/LTCH-CAUTI-Guidance_2015.pdf (last accessed Dec. 9, 2025).

> ***data*** (resources available at http://www.cdc.gov/nhsn/CDA/index.html).
>
> CDC/NHSN requires that data be submitted on a monthly basis and strongly encourages healthcare facilities to enter each month's data within 30 days of the end of the month in which it is collected (e.g., all March data should be entered by April 30) so it has the greatest impact on infection prevention activities. However, for purposes of fulfilling CMS quality measurement reporting requirements, each facility's data must be entered into NHSN no later than 1 ½ months after the end of the reporting quarter. In other words, Q1 (January/February/March) data must be entered into NHSN by May 15, Q2 must be entered by August 15, Q3 must be entered by November 15, and Q4 must be entered by February 15 for data to be shared with CMS.
>
> CAUTI data submitted to NHSN by hospitals that participate in the Long Term Care Hospital Quality Program will be reported by CDC to CMS for each hospital. CDC will share all in-plan CAUTI data ***from locations that are required to report CAUTIs (all inpatient locations for LTCHs).*** CDC will provide hospital-specific CAUTI standardized infection ratios (SIR) for each reporting hospital by CMS Certification Number (CCN).[48]

Guidance, also from November, 2014, for the CLABSI measure provides the same instructions and requirements.[49]

The CMS LTCH Quality Reporting Manual (October 2015) provides in pertinent parts:

> **5.1 Overview…**
>
> In the event that no patients have the infection or event of interest during the reporting period, ***the LTCH is required to submit monthly denominator counts*** (i.e., device days and patient days) along with the "no event" indicators to CDC's NHSN.
>
> ***
>
> LTCH providers must enter a monthly reporting plan, event (numerator), and summary data (denominator) for each quality measure for each month.

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[48] *Id.* at 1-3.

[49] *See Operational Guidance for Long Term Care Hospitals* to Report Central Line-Associated Bloodstream Infection (CLABSI) Data to CDC's NHSN for the Purpose of Fulfilling CMS's Quality Reporting Requirements* (emphasis added) available at: https://www.cdc.gov/nhsn/PDFs/CMS/LTCH-CLABSI-Guidance_2015.pdf (last accessed Dec. 9, 2025).

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NHSN CAUTI Outcome Measure (NQF #0138) and NHSN CLABSI Outcome Measure (NQF #0139) Reporting

For reporting of data on the NHSN CAUTI Outcome Measure (NQF #0138) and the NHSN CLABSI Outcome Measure (NQF #0139) under the LTCH QRP, LTCHs must adhere to the definitions and reporting requirements for CAUTIs and CLABSIs as specified in CDC's *NHSN Patient Safety Component Manual*, available at: http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf and http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf.

These requirements include reporting of denominator data (patient days, urinary catheter days, and central line days) ***by location***, as well as CAUTIs and CLABSIs (event data), to NHSN each month. Monthly denominator data must be reported on CAUTIs and CLABSIs, regardless of whether an infection occurred in the LTCH. Monthly reporting plans must be created or updated to include CAUTI and CLABSI ***surveillance in all locations that require reporting*** (i.e., surveillance must be "in-plan"). ***All required data fields in*** the numerator and ***the denominator***, including the "no events" field for any month during which no CAUTIs or CLABSIs were identified, ***must be submitted to NHSN***.

5.3 Basic Steps to NHSN Enrollment and Data Submission

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8. ***All patient care units will need to be added as location(s) and mapped in NHSN in advance by a facility user***. They must also be added to the monthly reporting plan under the device-associated module section for each month you plan on submitting the NHSN CAUTI Outcome Measure (NQF #0138), the NHSN CLABSI Outcome Measure (NQF #0139), and the NHSN VAE Outcome Measure data to CMS. After adding the location, please remember to check the "CAUTI," "CLABSI," and "VAE" boxes to ensure that the data will be appropriately sent to CMS.

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14. To report data, use the Denominators for Intensive Care Unit/Other Locations form, which can be found here: http://www.cdc.gov/nhsn/forms/57.118_DenominatorICU_BLANK.pdf. Instructions for filling out the form are available here: http://www.cdc.gov/nhsn/forms/instr/57_118.pdf

15. If no CAUTI, CLABSI, or VAE events were identified for the month, the "Report No Events" box must be checked for the appropriate surveillance type on the Denominator for "Intensive Care Unit/Other Locations" screen within the NHSN application.[50]

As it relates to mapping patient care locations as directed in Step 8 above, as early as 2006, the CDC had published the NHSN Patient Safety Component Protocol ("NHSN PSCP") and had included instructions for the completion of the Denominator Form, which requires the entry of "the location code of the unit where you collect the data."[51] The NSHN PSCP sets forth the definitions of key terms including:

Location	The specific patient care area in which a patient is assigned while receiving care in the healthcare facility. See also NHSN Location.
NHSN location	A CDC-defined designation given to a patient care area housing patients who have similar disease conditions or who are receiving care for similar medical or surgical specialties. ***Each facility location that is monitored is "mapped" to one CDC Location.*** The specific NHSN Location code is determined by the type of patients cared for in that area. That is, if 80% of patients are of a certain type (e.g., pediatric patients with

[50] *See* p. 5-3, 5-4, 5-6 to 5-7, 5-11 of the *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 for download at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/LTCH-QRP-Manual-V-300-FINAL.zip (last accessed December 9, 2025) (bold italics added).

[51] *See The National Healthcare Safety Network (NHSN) Patient Safety Component Protocol* (hereinafter NHSN PSCP) (May 17, 2006) at 42, available at: https://www.dhcs.ca.gov/provgovpart/initiatives/nqi/Documents/CDCPSProtocols.pdf (last accessed Dec. 9, 2025).

> orthopedic problems) then that area is designated as that type of location (in this case, an Inpatient Pediatric Orthopedic Ward).[52]

Relative to CLABSI, the 2006 NHSN PSCP also stated, "**Denominator Data**: Denominator data that are collected differ according to the location of the patients being monitored."[53] Relative to CAUTI it stated, "The data are collected separately for each of the locations monitored."[54]

The CDC has regularly published *The CDC Locations and Descriptions and Instructions for Mapping Patient Care Locations* ("CDC Locations & Descriptions Guide")[55] guidance that defines the CDC Location Labels and CDC Location Codes for all facility types and locations. The guidance provides that for a facility such as Salt Lake, the CDC Location Label is "Long Term Acute Care Ward" and that the CDC Location Code is "IN:ACUTE:WARD:LTAC," which it describes as a "Hospital area for the evaluation and treatment of patients suffering medically complex conditions or who have suffered recent catastrophic illness or injury and require an extended stay in an acute care environment."[56]

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 2015 required data measures, including the CAUTI and CLABSI data measures, via NHSN by the extended deadline of February 15, 2016 for Q1, Q2, and Q3, and by the original deadline of May 15, 2016 for Q4.[57] 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 Salt Lake ***properly*** submitted to CMS all of the required data for CAUTI and CLABSI for Q2 and Q3 of 2015 "in a form and manner, and at a time, specified by CMS," as required by 42 C.F.R. § 412.560(b)(1) (2015).

Salt Lake argues that all data was timely reported, including the CAUTI and CLABSI measures[58] but "a technical issue with the monthly reporting plans is the only explanation as to why CMS believes Salt Lake City did not report all data."[59] Salt Lake claims that similar to the facts in *PAM Squared at Texarkana, LLC v. Azar*, 436 F. Supp. 3d 52 (D.D.C. Jan. 22, 2020)("PAM Squared"), all data was entered and "a technical issue with the monthly reporting plan must have developed *after* Salt Lake City timely created its monthly reporting plans and reported its quality

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[52] *Id.* at 66-67. (Emphasis added.)
[53] *Id.* at 7.
[54] *Id*. at 23.
[55] Available at: https://www.cdc.gov/nhsn/pdfs/pscmanual/15locationsdescriptions_current.pdf (last accessed Dec. 9, 2025). At this time, the January 2025 version is published on the CDC's website and the archive is unavailable.
[56] *Id.* at 15-30 (January 2025 version).
[57] Ex. P-5 at P0056.
[58] *See e.g*., Salt Lake's Preliminary Position Paper (hereinafter Salt Lake's "PPP") at 29-32 (May 5, 2022); *see also* Ex. P-11 at 137 (Tr. 101-104).
[59] Salt Lake's PPP at 35.

data" which resulted in failure of the data to transmit from the NHSN system to its ultimate destination.[60] Additionally, Salt Lake argues that the monthly reporting plans are an "unnecessary extra step" in the data reporting process, are a "regulatory trap," and are not required by statute and that NHSN sending the data to CMS is "not relevant" for a compliance determination.[61]

Further, Salt Lake alleges that there must have been a problem with the NHSN system as it failed to provide notification that data could not be transmitted to CMS.[62] Salt Lake claims it ran several data validation reports prior to the data reporting deadline.[63] Salt Lake avers that coding errors and other shortcomings of the NHSN system have prevented data from showing as complete to providers.[64] To demonstrate technical issues acknowledged by NHSN, Salt Lake points to numerous e-mails that it received from NSHN over time.[65] However, the Board notes that for FY 2017, CMS determined over 400 LTCHs successfully met the LTCH QRP reporting requirements.[66]

The MAC simply argues that Salt Lake should be subject to the APU penalty because CMS' Second Reconsideration Determination upheld the noncompliance and "[t]his shows that the Provider has not presented evidence that the data in question was complete, timely submitted, and properly follow CMS's instructions" to run CMS output reports prior to the quarterly deadlines.[67]

In its original decision, the Board focused on the monthly reporting plans finding that:

> The record contains no evidence that the Provider's CAUTI and CLASBI reporting plans were input timely and no evidence of a printed validation report on or before the February 15, 2016 data submission deadline for quarters 2 and 3 of CY 2015.
>
> The Provider argued that the evidence it submitted "confirm that [the Provider] submitted all event data for all quality measures prior to the applicable reporting deadlines. Specifically, the 'createDate' column in each report shows that the DQM entered the quality data prior to the submission deadlines." The Board's review of the Provider's evidence shows the original "createDates" for the June, July and August 2015 quality measures at issue in this case were prior to the submission deadline. However, these

[60] *Id.* at 36-37.
[61] *Id.* at 38-40.
[62] *Id.* at 68-69.
[63] *Id.* at 69-70.
[64] *Id.* at 70-71.
[65] *Id.* at 71-72; *see also* Ex. P-9.
[66] *See LTCHs That Successfully Met QRP Reporting Requirements for APU FY 2017* available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/LTCH_FY2017APU_Compliant_List_October-2016.pdf (last accessed December 9, 2025). The Board notes that the list of LTCHs which successfully met the Reporting Requirements for APU FY 2017 include other Landmark providers, such as Joplin and Columbia, which are presumably related to Salt Lake.
[67] MAC's PPP at 9 (Aug. 18, 2022); *see also* MAC's FPP at 7 (Dec. 20, 2023).

> "createDates" simply reflect the dates on which the admittedly incomplete data was initially input into NHSN. The record contains no documentary evidence to show when the missing reporting plans for June, July and August 2015 were input into NHSN. In fact, the monthly reporting plan documentation submitted by the Provider for June, July, and August 2015 shows a modify date of August 8, 2016, well after the February 15, 2016 deadline. In light of the Provider's admission that the originally submitted data did not include all the reporting requirements the Board rejects the Provider's "createDates" argument. [footnotes omitted].[68]

In regard to what the Board deemed an admission by Salt Lake, the Board quoted Provider's Post-Hearing Brief at 21, which stated:

> On February 9, 2016, the DQM received a notification email from NHSN stating that Salt Lake City had incomplete data for the CAUTI (NQF #0138) outcome measure for June and July 2015, and for the CLABSI (NQF #0139) outcome measure for June and August 2015. The DQM logged onto the NHSN website and did see error messages stating that the Provider was missing the reporting plans for those months, despite the DQM's belief that it had been entered into the system. The DQM reentered reporting plans for the CAUTI (NQF #0138) outcome measure for June and July 2015, and for the CLABSI (NQF #0139) outcome measure for June and August 2015, and saved the information to the data registry." (internal citations omitted)).[69]

Thus, in its prior decision, the Board took the foregoing as an admission that the monthly reporting plans were not properly submitted.

In its Preliminary Position Paper, Salt Lake reiterates its argument that "The reports confirm that Salt Lake City submitted all event data for all quality measures prior to the applicable reporting deadlines. Specifically, the "createDate" column in each report shows that the DQM entered the quality data prior to the submission deadlines."[70] Salt Lake goes on to explain that the August 8, 2016 "modify date" in the reports were a result of Salt Lake's investigation of the issue in preparation for its August 18, 2016 reconsideration request.[71]

At this juncture on remand, the Board acknowledges that prior questions or concerns surrounding whether modifications were made to the CAUTI and CLABSI data entries on August 8, 2016, or whether the June, July, and August 2015 monthly reporting plans themselves were properly completed, may not be *entirely dispositive* of the issue of whether Salt Lake met the FY 2017

[68] See Ex. C-2 at P0191-0192 (PRRB Decision 2019-D16).
[69] *Id.* at 192 (Footnote 31 of PRRB Decision 2019-D16).
[70] Salt Lake's PPP at 33 (internal citations omitted).
[71] *Id.*

LTCH QRP requirements under these particular circumstances and based on more definitive evidence in the record.

Accordingly, we address the issue as follows:

1. ***Whether Salt Lake submitted the Q2 and Q3 CAUTI and CLABSI data measures as specified by CMS in accordance with law.***

Throughout its appeal of its FY 2017 APU penalty, Salt Lake has maintained that it correctly entered the data associated with the monthly reporting plans for June, July, and August of 2015, and that NHSN errors led to the failed transmission of its data. Salt Lake's Corporate Dir., Quality, Patient Safety & Standards ("Corp. Director") even testified (in response to whether the reporting plans were reviewed to determine what went wrong after receiving the notice of noncompliance):

> A: Yeah. There's a lot of different pieces to the NHSN system, a lot of different reports that have to be put in, so we, as part of our process -- *and this is what we do for our validation prior to, so one week prior to any deadline* our hospitals go in and we look at our reporting plans, *we look at our denominator data*, we look at our line listing, we look at our SIR reports so that we can exactly on all different angles that everything is there and corrected. So that was part of the process that the director of quality did is to actually go through each one of those reports to see if it was-- anything that was an error that she could identify.
>
> Q: Um-hum. And what was found?
>
> A: Everything, the data was correct, and [the Director of Quality Management] was unable to find a reason for the errors that we received on NHSN.[72]

Salt Lake also maintains that, despite the August 8, 2016 modification dates indicated on the reports,[73] none of the data entries were entered or altered by Salt Lake after the initial entries were made in February 2016 to meet the respective deadlines:

> Q: [Mr. Healy] Okay. Can you confirm that no data were entered or changed on August 6, 2016, for these quality measures?
>
> A: [Ms. Blake] It was not. Going back to our original timeframe back in February, the data was there and it was complete, so there would have been no need to change that data.[74]

[72] Ex. P-11 at P0131 (Tr: 77-78); *see also* Ex. P-11 at P0137 (Tr.103: 9-23).
[73] Ex. P-8 at P0067.
[74] Ex. P-11 at P0142 (Tr. 122-123).

Contrary to Salt Lake's assertion that, "Everything, the data was correct,"[75] reliable evidence in the record, provided by Salt Lake, demonstrates otherwise.

The NHSN Line Listing Report for Monthly Plans indicates that on August 3, 2015 at 14:19PM, Salt Lake created its Monthly Reporting Plan for June 2015 using the "WARD_LTCH" location.[76] The NSHN Line Listing Report for All Summary Data indicates that on August 3, 2015 at 14:36PM, Salt Lake entered summary data for CAUTI and CLABSI for the month of June 2015, using the "WARD_LTCH" location.[77] Even the Monthly Reporting Plan provided by Salt Lake as Exhibit P-3, p. P0029 (dated/printed August 9, 2016, after the submission deadline) indicates a "Locations" selection of "WARD_LTCH – UNIT," which coincides with the aforementioned location selections. *By contrast*, Salt Lake's Exhibit P-3, p. P0033, which was printed on August 3, ***2015,*** long before the February 15, 2016 submission deadline, shows that when entering data for June 2015 on the *Denominators Form,* Salt Lake selected "N/A – UNIT" in the mandatory field for the Location Code.[78] This does not match the location selection on the Monthly Reporting Plan.

The same applies for the July 2015 CAUTI and CLABSI data entries. On August 24, 2015 at 12:39PM, Salt Lake created its Monthly Reporting Plan for July 2015 selecting "WARD_LTCH."[79] On August 24, 2015 at 12:39PM, Salt Lake entered summary data for CAUTI and CLABSI for the month of July 2015, using "WARD_LTCH."[80] On August 24, 2015 at 13:07PM, Salt Lake entered a patient CLABSI event that occurred on July 18, 2015, using location "WARD_LTCH."[81] But Salt Lake's Exhibit P-3, p. P0037, which was saved on August 24, ***2015***, indicates that when entering data on the Denominators Form for July 2015, Salt Lake again used "N/A – UNIT" in the mandatory field for the Location Code.[82] This does not match the location selection on the Monthly Reporting Plan.

On October 6, 2015 at 10:03AM, using the same location and location type as used for June and July, Salt Lake entered summary data for CAUTI and CLABSI for the month of August 2015.[83] On October 6, 2015 at 15:08PM, Salt Lake created its Monthly Reporting Plan for August 2015 using the same parameters as used for the June and July reporting plans.[84] It is unknown what "Location Code" was selected on the August 2015 Denominators Form, as it is not in the record. The Board notes that Exhibit P-3 is a copy of the reconsideration request filed by Salt Lake. It is

[75] Ex. P-11 at P0131 (Tr. 78).
[76] *See* Ex. P-8 at P0067.
[77] *Id.* at P0068 (where User 127324 entered 810 "numpatdays" for both CAUTI and CLABSI event types and entered 314 and 602 "numddays" for CAUTI and CLABSI, respectively).
[78] *See* Ex. P-3 at P0033 (where Salt Lake submitted various reports with its Reconsideration Request. The Denominator Form for the month of June 2015 was saved on August 3, 2015, as indicated in the footer on the page.)
[79] *See* Ex. P-8 at P0067.
[80] *Id.* at P0068 (where User 127324 entered 723 "numpat days" for both event types and entered 240 and 520 "numddays" for CAUTI and CLABSI, respectively).
[81] *Id.* at P0069.
[82] *See* Ex. P-3 at P0037.
[83] *See* Ex. P-8 at P0068 (where User 127324 entered 701 "numpat days" for both event types and entered 202 and 526 "numddays" for CAUTI and CLABSI, respectively).
[84] *Id.* at P0067.

important to note that the fact that there was no Denominators Form for August 2015 included with the request makes it impossible to verify if the data was properly submitted for that month. As such, this submission does not fulfill the requirements stated in 42 C.F.R. § 412.560(b)(2)(vii) (Oct. 1, 2015), which states:

> (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.*** (Bold and italics emphasis added)

As previously referenced, the CMS LTCH QRP Manual states that the CAUTI and CLABSI reporting requirements:

> include reporting of ***denominator data*** (patient days, urinary catheter days, and central line days) ***by location***, as well as CAUTIs and CLABSIs (event data), to NHSN each month. Monthly denominator data must be reported on CAUTIs and CLABSIs, regardless of whether an infection occurred in the LTCH. ***Monthly reporting plans must be*** created or updated to include CAUTI and CLABSI surveillance ***in all locations*** that require reporting (i.e., surveillance must be "in-plan"). ***All required data fields in*** the numerator and the ***denominator***, including the "no events" field for any month during which no CAUTIs or CLABSIs were identified, ***must be submitted to NHSN***.[85]

Further, the manual states:

> All patient care units will need to be added ***as location(s)*** and mapped in NHSN in advance by a facility user. ***They must also be added to the monthly reporting plan under the device-associated module section*** for each month you plan on submitting the NHSN CAUTI Outcome Measure (NQF #0138), the NHSN CLABSI Outcome Measure (NQF #0139), and the NHSN VAE Outcome Measure data to CMS. After adding the location, please remember to check the "CAUTI," "CLABSI," and "VAE" boxes to ensure that the data will be appropriately sent to CMS.[86]

Based on the directives in the LTCH QRP Manual, proper location designation within the Device-Associated Module for CAUTI and CLABSI and on the Denominators Form is required

[85] LTCH QRP Manual at 5-7.
[86] *Id.* at 5-11.

for purposes of LTCH QRP compliance. Thus, when the location selections on Salt Lake's monthly reporting plans and denominators forms did not match, it is fathomable that the selections rendered the entries of any CAUTI and CLABSI data for June and July 2015, including the reporting of no events, null and void for purposes of attribution to Salt Lake's monitored patient care area designated as "WARD_LTCH – UNIT." And because Salt Lake's June and July 2015 Monthly Reporting Plans indicated the "WARD_LTCH – UNIT" as the Location being monitored for CAUTI and CLABSI, the data entered onto the Denominators Forms were not related back to the June and July 2015 Monthly Reporting Plans for purposes of reporting on the location being monitored because the selections did not match. Consequently, the CDC had no June or July 2015 CAUTI or CLABSI data to transfer to CMS on Salt Lake's behalf for LTCH QRP reporting purposes, rendering Salt Lake noncompliant for Q2 and Q3.

As for the failure to report CAUTI data for August 2015, it is unclear if the same issue contributed to the failed transmission. Nonetheless, based on the foregoing, the Board finds that failing to verify the accuracy of the locations on the Monthly Reporting Plans and the Denominators Forms for June and July 2015, renders Salt Lake noncompliant with the LTCH QRP reporting requirements for Q2 and Q3 2015.

As for any potential argument that selecting the wrong Location Code is merely a typographical error that does not warrant the imposition of the APU reduction, providers committing these types of errors and omissions and failing to timely verify their manual data entries and selections must understand 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 surveillance reporting for the purpose of minimizing healthcare-associated infections ("HAI"), such as CAUTI and CLABSI.[87] The technical structure or format and specificity of the input are crucial for proper HAI surveillance and prevention efforts.[88] 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 identification, tracking/ monitoring, responding to, and preventing HAIs.[89]

Moreover, the failure to use the correct CDC Location Code as well as the failure to properly map a location (i.e., assign a facility or a patient care area within the facility to one or more standard CDC location type descriptions within NHSN) invalidates NHSN database data.[90]

Further, in its reliance on *PAM Squared*,[91] where the selection of the wrong Location Code was at issue, Salt Lake overlooks the Court's following holding:

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[87] 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 Dec. 9, 2025).

[88] *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.

[89] *Id*.

[90] *See, e.g.*, *NHSN FAQs: Location, Location Mapping for CMS Reporting, Q24*, (Available at: https://www.cdc.gov/nhsn/faqs/faq-locations.html) (last accessed Dec. 9, 2025).

[91] *PAM Squared At Texarkana, LLC v. Azar,* 436 F.Supp.3d 52 (D.D.C. Jan. 22, 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]*.[92]

Additionally, in *Landmark*, Salt Lake overlooks the Court's statement that "Landmark might fare better under the correct standards***. It might not.***"[93] Accordingly, it is clear that the District Court did not hold in either of the foregoing cases that typographical errors or the like 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.

Unfortunately for Salt Lake, the devil is in the details. Providers, including Salt Lake, have long been placed on notice of the importance of data entry verification and of the significance of proper location and location code mapping as well as ensuring that the Denominator Forms are accurate, especially for CAUTI and CLABSI outcome measure reporting.

Therefore, based on the Court's remand, the Board has reconsidered whether Salt Lake met the requirements of 42 C.F.R. § 412.560(b), specifically, did Salt Lake submit complete CAUTI and CLABSI data measures for Q2 and Q3 of CY 2015 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."

As for Salt Lake's reliance on *Coyne*[94] and *In Defense of Animals*[95] to support its argument that "CMS possessed all required data from Salt Lake…before the reporting deadlines[,]"[96] such reliance is misplaced.[97] *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.[98] However, the documents had been produced by the FDA in response to his own FOIA Request (which rendered them publicly disclosed) before he

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[92] *Id.* at 61.
[93] *Landmark* at 335.
[94] *United States ex rel. Coyne v. Amgen, Inc.*, 229 F. Supp. 3d 159, 171 (E.D.N.Y. 2017).
[95] *In Def. of Animals v. Nat'l Institutes of Health*, 543 F. Supp. 2d. 70, 77 (D.D.C. 2008).
[96] Salt Lake's PPP at 40.
[97] *Id.* at 39-40.
[98] *See generally, Coyne* at 169 – 171.

initiated his *qui tam* complaint.[99] The court held that Coyne could not claim that he was the original source of information that had been deemed publicly disclosed.[100] To support its argument, Salt Lake 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."[101] 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.[102] 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.[103] 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."[104] To support its argument, Salt Lake 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."[105] 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, Salt Lake 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."[106] However, as previously stated, the Court went on to state, "Perhaps the typo does justify the full two-percent penalty."[107] Accordingly, the Court ***did not*** hold that submission of

[99] *Id.* at 171.
[100] *Id.* at 171, 174.
[101] *Id.* at 171.
[102] *Id*. at 171.
[103] *In Def. Animals* at 76 – 78.
[104] *Id.* at 77.
[105] *Id.*; see also Salt Lake's PPP at 40.
[106] Salt Lake's PPP at 50.
[107] *Pam Squared* at 61.

data to one component of HHS equates to the submission of the same to another distinct agency within the Department.

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] Salt Lake 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. Here, a Board appeal is not the appropriate forum to request equitable relief from penalty based on policy arguments about technical requirements. Salt Lake 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."

Based on the foregoing, the Board need not go further in determining whether Salt Lake submitted complete CAUTI and CLABSI outcome data measures for CY 2015 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.

2. 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,[111] and Salt Lake's contention with CMS' Second Reconsideration Determination issued via email on March 11, 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 Salt Lake City failed to submit to* HHS the following data by the applicable reporting deadlines: the Catheter Associated Urinary Tract Infection Outcome ("CAUTI") data for

[108] Salt Lake's PPP at 21.
[109] *Id.* at 38.
[110] *Id*. at 40.
[111] *See Landmark* at 332-333.

> June, July, and August of 2015; and Central Line-Associated Bloodstream Infections ("CLABSI") data for June 2015 and July 2015.
>
> CMS has also determined that your reconsideration request did not provide a valid or justifiable excuse for non-compliance.[112]

To support its argument that CMS failed to follow the reconsideration process and again failed to employ the correct standard of review, Salt Lake relies on the preamble to the FY 2015 Final 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. Salt Lake asserts that it met both of the reconsideration request requirements, which entitles them to exemption from the two-percentage point APU reduction penalty.

As previously addressed above in the *Relevant Applicable Law* Section, the ***codified*** regulation[113] at 42 C.F.R. § 412.560(d) fully addressed the reconsideration process in effect on August 18, 2016, when Salt Lake 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 Salt Lake met the procedural requirements of 42 C.F.R. § 412.560(d)(2)(vi) and (vii) (it provided its reasons and documentation it believes demonstrated compliance), that does not equate to a conclusion of law that Salt Lake 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 2 percentage point APU reduction.

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[112] Ex. P-10 at 100.

[113] *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.").

But before we delve further into whether CMS' Reconsideration Determinations should be reversed, we will address Salt Lake'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)***.[114]

In the March 11, 2021 Second 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.[115]

Here, Salt Lake's argument has ***some merit.*** Instead of focusing solely on the all-encompassing language set forth in the reconsideration provision 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 - a provider can articulate any reason it chooses for its noncompliance and it will be given due weight) or even what has been deemed the "extenuating circumstances standard" (the second prong of the 2015 Final Rule commentary),[116] CMS attempted to cover all its bases. However, is doing so fatal to CMS' Second Reconsideration Determination? In this instance, it is not. CMS reviewed the facts to determine whether Salt Lake's allegation that NHSN system errors were:

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.[117] It is not unfathomable that the same set of facts could result in a finding that such facts do not meet any of the three (3) "standards" under any review (applicable or not). Nonetheless, CMS' kitchen sink approach included a review of the "extenuating circumstances standard" invoked by Salt Lake.

Salt Lake 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

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[114] Salt Lake's PPP at 57, 91.
[115] Ex. P-10 at 100.
[116] *See* 79 Fed. Reg. at 50317.
[117] 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).

for less than full compliance."[118] Salt Lake 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."[119] Quoting the Black's Law Dictionary (11th ed. 2019), the District Court in *Landmark,* on which Salt Lake relies in its Preliminary Position Paper,[120] stated that "extenuating" is a "'fact or situation that does not justify or excuse a wrongful act or offence but that reduces the degree of culpability.'"[121]

As discussed *supra*, the record demonstrates that accurate completion of the Denominator Form, particularly, selecting the correctly mapped Location Code, is mandatory for submitting the CAUTI and CLABSI data. Salt Lake failed to do so. Accordingly, Salt Lake'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, the extenuating circumstances, i.e., a variety of technical issues with the NHSN system throughout 2016 and 2017, that Salt Lake 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, Salt Lake'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, Salt Lake 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.[122] Salt Lake, 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]"[123] Additionally, Salt Lake 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 connection with any agency proceeding,' the agency must provide "***a brief statement of the grounds for denial***," unless the denial is "self-explanatory."
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> ***

[118] Salt Lake's PPP at 53-54.
[119] *Id.* at 54.
[120] *Id*. at 56.
[121] *Landmark* at 334.
[122] *See* Salt Lake's PPP at 74-75.
[123] *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.

> 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][124]

Thus, nothing in the APA nor in common law requires that CMS respond to Salt Lake'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:

> 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 Salt Lake City failed to submit to HHS the following data by the applicable reporting deadlines: the Catheter-Associated Urinary Tract Infection Outcome ("CAUTI") data for June, July, and August of 2015; and the Central Line-Associated Bloodstream Infections ("CLABSI") data for June 2015 and July 2015.
>
> 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.[125]

Upon review, the question of why CMS denied Salt Lake's reconsideration request can be answered: Because the NHSN technical errors claimed by Salt Lake did not demonstrate the existence of an extenuating circumstance as asserted. CMS' "brief statement" explains why it chose to do what it did.

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

Finally, Salt Lake argues that applying the payment penalty is contrary to the intent of the LTCH QRP.[126] As stated by Salt Lake in its Preliminary Position Paper:

> 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.

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[124] *Tourus Recs., Inc. v. Drug Enf't Admin.*, 259 F.3d 731, 737 (D.C. Cir. 2001) (emphasis added).
[125] Ex. P-10 at P0100.
[126] Salt Lake's PPP at 89-90.

> 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. 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.[127]

The Board notes that, where Salt Lake failed to submit the CAUTI and CLABSI outcome measure 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, Salt Lake, 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 Salt Lake.

Salt Lake also contends that the doctrine of substantial compliance precludes application of any payment penalties.[128] The doctrine of substantial compliance is inapplicable in this case and the cases cited by Salt Lake 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.[129] As previously discussed *supra*, Salt Lake acknowledges that the Social Security Act itself mandates that LTCHs submit data in the form, manner, and time specified by CMS. Accordingly, Salt Lake's argument that it substantially complied fails.

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Based on the foregoing, the Board finds:

1. Salt Lake failed to submit complete data for the CAUTI and CLABSI outcome measures for Q2 and Q3 2015 as specified by CMS in violation of 42 C.F.R. § 412.560(b)(1);

2. CMS' Reconsideration Decisions should not be reversed because Salt Lake did not meet the requirements of 42 C.F.R. § 412.560(b)(1). Specifically, Salt Lake 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 the selection of the wrong location code on the Denominator Form resulted from Salt Lake's failure to identify the error and does not reduce its culpability in its noncompliance;

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[127] *Id.*
[128] *Id.* at 90.
[129] In *Fox Ins. Co. v. Centers for Medicare & Medicaid Servs.*, 715 F.3d 1211, 1221-1222 (9th Cir. 2013) ("The term should have the same meaning under both Parts.").

3. CMS' March 11, 2021 Second 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.

DECISION:

After considering 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 in this decision, the Board finds the Provider failed to prove that it ***properly*** submitted the Catheter-Associated Urinary Tract Infection ("CAUTI") and Central Line-Associated Bloodstream Infection ("CLABSI") data measures for calendar year ("CY") 2015 in the form, manner, and at a 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 in this decision, 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 Salt Lake's failure to submit the CAUTI and CLABSI data measures in the form, manner, and at a time, specified by CMS .

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FOR THE BOARD:

12/16/2025

X Kevin D. Smith, CPA

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