PROVIDER REIMBURSEMENT REVIEW BOARD DECISION

2011-D13

PROVIDER –
Western Medical Center – Santa Ana
Santa Ana, California

Provider No.: 05-0746

vs.

INTERMEDIARY –
BlueCross BlueShield Association/
First Coast Service Options-CA
(succeeding Wisconsin Physicians Service)

DATE OF HEARING -
June 25-26, 2008

Cost Reporting Period Ended -
September 30, 2008

CASE NO.: 08-1695

INDEX

ISSUE

Whether it was proper for the Centers for Medicare and Medicaid Service ("CMS") to reduce by two percent (2%) the Medicare annual payment update for Western Medical Center – Santa Ana for federal fiscal year ("FY") 2008.

MEDICARE STATUTORY AND REGULATORY BACKGROUND

A. Applicable Statutes

The Medicare program reimburses acute care hospitals for the operating costs of inpatient services furnished to Medicare beneficiaries based on a prospectively-determined amount per patient discharge. 42 U.S.C. § 1395ww(d). This system of payment is known as the Inpatient Prospective Payment System ("IPPS"), and the hospitals reimbursed under IPPS are often referred to as "subsection (d) hospitals." The IPPS payment for operating costs includes a "standardized amount" comprised of two components: 1) the portion of hospital costs that are attributable to wage and wage-related costs; and 2) other hospital costs. 42 U.S.C. § 1395ww(d)(3)(D); 68 Fed. Reg. 45,348 (Aug. 1, 2003). The standardized amount is increased each year by the "market basket update" to account for the increase in the costs of providing care. *See* Social Security Act ("SSA") § 1886(b)(3) (42 U.S.C. § 1395ww(b)(3)).

In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (the "MMA"). Pub. L. No. 108-173, 117 Stat. 2066. Section 501(b) of the MMA amended SSA § 1886(b)(3)(B) (42 U.S.C. § 1395ww(b)(3)(B)) to add a new subclause (vii) to revise the market basket update. Specifically, under this revision, a subsection (d) hospital was subject to a 0.4 percent reduction in its market basket updates in fiscal years 2005 through 2007 if it failed to report data on certain quality indicators. *See* MMA § 501(b); *see also* 42 U.S.C. § 1395ww(b)(3)(B)(vii).

In 2006, Congress again passed legislation revising the market basket update for subsection (d) hospitals for fiscal year 2007 and subsequent years if they failed to report on an expanded set of quality indicators. *See* Deficit Reduction Act of 2005 (the "DRA"), Pub. L. No. 109-171, § 5001(a)(3), 120 Stat. 4 (2006).[1] The DRA also increased to two percent the reduction in hospitals' market basket update for failure to report and mandated that CMS expand the list of quality indicators.

> For purposes of clause (i) for fiscal year 2007 and each subsequent fiscal year, in the case of a subsection (d) hospital that does not submit, to the Secretary in accordance with this clause, data required to be submitted on measures selected under this clause with respect to such a fiscal year, the applicable percentage increase under clause (i) for such fiscal year shall be reduced by 2.0 percentage points.

[1] The DRA also revised the applicability of the MMA provision to only fiscal years 2005 and 2006. *See id.* at § 5001(a)(1)-(2).

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

B. CMS' Implementation of IPPS Quality Reporting

The quality reporting program mandated under the MMA is known as the Reporting Hospital Quality Data for Annual Payment Update, or RHQDAPU, program. Several entities and guidelines play a role in the RHQDAPU program. CMS established a website called the QualityNet Exchange (formerly, QNet Exchange) for the purposes of providing healthcare quality improvement news, resources, and data reporting tools and applications used by healthcare providers and others. *See* http://www.qualitynet.org. After implementation of the RHQDAPU program, the QualityNet Exchange had the added responsibility of providing hospitals with the necessary instructions, forms, tools and applications for properly reporting information related to the RHQDAPU quality indicators. 72 Fed. Reg. 47,346; *see also* http://www.qualitynet.org.

Among the guidance on the QualityNet Exchange website is the Specifications Manual for National Inpatient Hospital Quality Measures. CMS stated "[t]he technical specifications for each RHQDAPU program measure are listed in the CMS/[JCAHO] Specifications Manual for National Inpatient Hospital Quality Measures (Specifications Manual)." The Specifications Manual contains the detailed instructions and calculation algorithms that hospitals are to use in collecting, abstracting, and submitting the data for each quality measure. Exhibit P-3. The Specifications Manual also includes a "Data Dictionary" that describes the data elements required to report various quality measurements. Exhibit P-4.

The Specifications Manual and Data Dictionary are updated at least semiannually (frequently on a quarterly basis). *See* 73 Fed. Reg. 23,528, 23,655 (Apr. 30, 2008). Hospitals must match the effective date of the guidance in the Data Dictionary to the discharge date of the patient whose data the hospital is reporting. *Id.*; *see also* Exhibit P-5.

Quality Improvement Organizations ("QIOs") were created under statutory authority:

> The Secretary shall … for the purposes of promoting the effective, efficient, and economical delivery of health care services, and of promoting the quality of services of the type for which payment may be made under this title, enter into contracts with utilization and quality control peer review organizations pursuant to part B of title XI of this Act.

SSA § 1862(g) (42 U.S.C. § 1395y(g)). QIOs coordinate and facilitate the collection of the quality measures under the RHQDAPU program. *See* 69 Fed. Reg. 48,916, 49,078-80 (2004). The QIO Clinical Warehouse is the virtual repository for receiving and storing the quality indicator information submitted by hospitals under the RHQDAPU program. *Id.*

The Clinical Data Abstraction Center (the "CDAC") is the entity that requests paper medical records from hospitals to carry out RHQDAPU chart validation. *See* 69 Fed. Reg. 48,916, 49,079 (Aug. 24, 2004). The CDAC re-abstracts the chart information for the sampled medical records and calculates the percent agreement between the original data as abstracted by a hospital and the re-abstracted data. *See id.*; *see also* 70 Fed. Reg. 47,278, 47,425 (Aug. 12, 2005). The CDAC staff members are described as "professional abstractors specifically trained to abstract these data as described in the measures and validation criteria." 70 Fed. Reg. 47,427. CDAC abstractors have a minimum of two years of experience in hospital medical record review activities and undergo a multi-phase training program consisting of "knowledge transfer, simulation, evaluation and feedback" prior to taking on actual abstraction duties. *Id.* These abstractors are also subject to ongoing performance monitoring. *Id.*

Following Congress's passage of the MMA, CMS began implementing the RHQDAPU program. *See* 69 Fed. Reg. at 49,078. The quality measures on which a hospital must report for each quarter of a calendar year are established through formal rulemaking. Initially, the RHQDAPU program measured reporting for a set of ten quality indicators (the "starter set"), which Congress mandated be established by the Secretary of the Department of Health and Human Services (the "Secretary") as of November 1, 2003. *See* MMA § 501(b); *see also* 69 Fed. Reg. 49,078. Specifically, these ten indicators are:

Heart Attack (Acute Myocardial Infarction)

- Was aspirin given to the patient upon arrival to the hospital?
- Was aspirin prescribed when the patient was discharged?
- Was a beta-blocker given to the patient upon arrival to the hospital?
- Was a beta-blocker prescribed when the patient was discharged?
- Was an ACE inhibitor given for the patient with heart failure?

Heart Failure

- Did the patient get an assessment of his or her heart function?
- Was an ACE inhibitor given to the patient?

Pneumonia

- Was an antibiotic given to the patient in a timely way?
- Had a patient received a pneumococcal vaccination?
- Was the patient's oxygen level assessed?

See 69 Fed. Reg. 49,078.

As noted above, the DRA required expansion of the original ten-measure starter set. *See* DRA § 5001(a)(3); *see also* SSA § 1886(b)(3)(B)(viii)(III). Under this authority, for

quality reporting related to discharges in the third quarter of calendar year ("CY") 2006, CMS added 11 more quality measure indicators, for a total of 21 indicators, as follows:

Heart Attack (Acute Myocardial Infarction)

- Aspirin at arrival
- Aspirin prescribed at discharge
- ACE inhibitor (ACE-I) or Angiotensin Receptor Blocker (ARBs) for left ventricular systolic dysfunction
- Beta blocker at arrival
- Beta blocker prescribed at discharge
- Thrombolytic agent received within 30 minutes of hospital arrival
- Percutaneous Coronary Intervention (PCI) received within 120 minutes of hospital arrival
- Adult smoking cessation advice/counseling

Heart Failure (HF)

- Left ventricular function assessment
- ACE inhibitor (ACE-I) or Angiotensin Receptor Blocker (ARBs) for left ventricular systolic dysfunction
- Discharge instructions
- Adult smoking cessation advice/counseling

Pneumonia (PNE)

- Initial antibiotic received within 4 hours of hospital arrival
- Oxygen assessment
- Pneumococcal vaccination status
- Blood culture performed before first antibiotic received in hospital
- Adult smoking cessation advice/counseling
- Appropriate initial antibiotic selection
- Influenza vaccination status

Surgical Care Improvement Project (SCIP)—Named SIP for Discharges Prior to July 2006 (3Q06)

- Prophylactic antibiotic received within 1 hour prior to surgical incision
- Prophylactic antibiotics discontinued within 24 hours after surgery end time

71 Fed. Reg. 47,870, 48,032, 48,034 (Aug. 18, 2006).

In order to participate in the RHQDAPU program and receive a full market basket update for FY 2008, a hospital was required to take the following steps:

- Identify a QualityNet Exchange Administrator to follow the registration process and submit the information through the QIO Clinical Warehouse.

- Submit a RHQDAPU registration form to the hospital's QIO no later than August 15, 2007.

- Register with the QualityNet Exchange.

- Collect and report data for each of the required measures to the QIO Clinical Warehouse using the CMS Abstraction & Reporting Tool ("CART"), the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") ORYX® Core Measures Performance Measurement System, or another third party vendor tool that met the measurement specification requirements for data transmission to QualityNet Exchange. (The QIO Clinical Warehouse submits the data to CMS on behalf of the hospitals.)

- Submit complete data regarding each applicable quality measure in accordance with the joint CMS/JCAHO sampling requirements located on the QualityNet Exchange website. These requirements specify that hospitals must submit a random sample or a complete population of cases for each of the topics covered by the quality measures.

- Submit to CMS on a quarterly basis aggregate population and sample size counts for Medicare and non-Medicare discharges for the quality measures.

See 72 Fed. Reg. 47,360.

Each hospital was required to pass a chart-audit validation process in order to receive the full market basket update for FY 2008. 72 Fed. Reg. 47,363. As stated above, this chart-audit validation process entails a request from CDAC for patient charts and re-abstraction of the data for comparison with the hospital's abstracted data. 71 Fed. Reg. 48,040-44. Under the chart-audit validation process, those hospitals achieving an 80 percent or better agreement between their abstractions and the CDAC's re-abstractions receive the full market basket updates, with no reduction. *Id.*

To receive the full market basket update for FY 2008, the chart-audit validation process entailed a review of five charts from each of the first three quarters of CY 2006. *See* 70 Fed. Reg. at 47,422; *see also* 72 Fed. Reg. at 47,361 (requiring hospitals to continue to meet the chart validation requirements implemented in the FY 2006 IPPS final rule). The

five charts from each quarter were pooled into a single sample to determine whether the 80 percent reliability level was achieved. *Id.* CMS first calculates the percent agreement between the abstracted and re-abstracted data for *all* variables present in the five selected charts. If the percent agreement still falls below 80 percent, CMS calculates the percent agreement between the abstracted and re-abstracted data for only the relevant quality measures. CMS describes this process as follows:

> We will use a two-step process to determine if a hospital is submitting valid data. In the first step, we calculate the percent agreement for all of the variables submitted in all of the charts. If a hospital falls below the 80-percent cutoff, we proceed to the second step and restrict the comparison to those variables associated with payment. For the first and second quarter CY 2006 discharges (1Q06, 2Q06), that means we limit the calculations to the 10-measure starter set. For third quarter CY 2006 discharges (3Q06), we include 21 measures. We recalculate the percent agreement and the estimated 95-percent confidence interval, and again compare the sum to the 80-percent cutoff point.

72 Fed. Reg. 47,361.[2]

If the percent agreement between the hospital's abstractions and the CDAC's abstraction falls below 80 percent, CMS uses confidence intervals to test the reliability of the scores. CMS describes this process as follows:

> We use confidence intervals to determine if a hospital has achieved an 80-percent reliability aggregated over the three quarters. The use of confidence intervals allows us to establish an appropriate range below the 80-percent reliability threshold that demonstrates a sufficient level of reliability to allow the data to still be considered validated. We estimate the percent reliability based upon a review of five charts, and then calculate the upper 95-percent confidence limit for that estimate. If this upper limit is above the required 80-percent reliability, the hospital data are considered validated.

Id.

The quality data reported by hospitals is used not only for the RHQDAPU program, but is also reported on CMS' *Hospital Compare* website, available at http://www.hospitalcompare.hhs.gov. *See* 69 Fed. Reg. at 49,082 (showing CMS' intent to publish the submitted data); SSA § 1886(b)(3)(B)(viii)(VII) (42 U.S.C. § 1395ww(b)(3)(B)(viii)(VII)) (requiring CMS's publication of the submitted data as codified in DRA § 5001(a)(3)). CMS makes the results of the data submission process available, as well as a summary of the underlying data itself. *See* 72 Fed. Reg. 47,350.

[2] The quality measures were not identified for the fourth quarter of CY 2006; presumably because the chart-audit validation process for FY 2008 only involved data from the first three quarters of CY 2006. *Id.* at 47,361.

A print-out from the *Hospital Compare* website that shows measures related to pneumonia from the RHQDAPU program for the Provider and its sister hospital, Western Medical Center – Anaheim is in Exhibit P-6.

C. Scoring of Parent/Child Questions

Certain of the quality measures which a hospital is required to report under the RHQDAPU program are part of an algorithm of questions. For example, if certain questions are answered "yes," a series of other, related questions have to be answered by the chart abstractor. If the initial questions are answered "no," the related questions should not be answered.[3] CMS refers to these algorithm questions as "parent/child" questions. *See* 70 Fed. Reg. 47,425; Exhibit P-8.

Certain chart abstraction software, including the Quantro software used by the Provider, blacks out any child questions that should not be answered in response to a particular parent question. This software, therefore, doesn't allow child questions to be answered when they are not triggered by the parent question. Previous versions of CMS's own abstraction software (called CART), also blacked out child questions in these circumstances. Testimony of Mary Cox, June 26, 2008 ("Cox Testimony"), transcript at 271-272.

As one example, hospitals are measured on whether they perform an oxygenation assessment in a timely manner for a patient with a working diagnosis of pneumonia on admission. Exhibit P-7 is a discussion of this measurement from the Specifications Manual for the period January 1, 2006 to March 30, 2006, along with the algorithm that leads to this question. If a hospital responds "no" to the question of whether the patient had a working diagnosis of pneumonia, no further questions are asked. If the hospital answers yes, the hospital is then asked whether there was an order for the patient to receive "comfort measures" only. If the response to this question is "yes", no further questions are asked. If the hospital responds "no," the hospital is asked whether the patient was a transfer from another emergency department. If the answer to that question is "yes," no further questions are asked. If the hospital answers "no" to the transfer question, however, the hospital is asked a series of questions, including whether, and when, a pulse oximetry or arterial blood gas measurement ("ABG") was performed on the patient. *See* Exhibit P-7.

Under the RHQDAPU scoring methodology, if a hospital answers "no" to the initial question (*i.e.*, was there a working diagnosis of pneumonia on admission), but CDAC later determines that that response was incorrect, the hospital receives a negative score for that question. In addition, the hospital receives a negative score for all of the related questions under the algorithm.

In a 2005 Federal Register preamble discussion, CMS stated that it received a comment stating that it was unfair for hospitals to fail chart validation based on a parent element that causes a child element not to validate. CMS responded as follows:

[3] Child questions are also sometimes triggered by a "no" response to the parent question.

> Parent/child relationships are defined in the analytic flows. The responses to the parent element, and possibly the child element, determine the measure category assignment. The response to this parent element also determines whether the child questions are then answered or not. Validation follows this same relationship. In validation, if the parent response causes a stop abstraction, then no further elements are answered. *Only the elements answered (parent only) are included in the validation score.* If the parent response causes the child element(s) to be answered, then both the parent and child elements are validated and count in the validation score. For example, the parent is Working Diagnosis of Pneumonia and the response is no, the measure category assignment is "B" (not in the measure population), this record would not need to be processed through the individual measure algorithms. In another example, the parent is Working Diagnosis of Pneumonia and the response is yes. Per the algorithm, if the child element is Comfort Measures Only and if the response is no, continue to the child element transfer from another ED and if that response is no, continue to the next child element Admission Source and continue through the algorithm based on the response to each child question.

70 Fed. Reg. 47,425 (emphasis added); Exhibit P-8.

In 2006, commenters again pointed out to CMS that an incorrect response to a “parent” question, and particularly a question asking whether the patient had a working diagnosis for pneumonia, would lead to several “child” elements being answered incorrectly. The comments and the CMS response follow:

> *Comment:* Eight commenters stated payment for 2007 will be reduced by 2.0 percentage points for performance indicators that have a track record of poor reliability, such as the working diagnosis of pneumonia. The commenters noted that some hospitals resort to answering working diagnosis for pneumonia as a yes for all pneumonia charts regardless of actual documentation, since the penalty is disproportionately more severe if the no answer is found to be incorrect. The commenters noted that a couple of mismatches on the no response to working diagnosis can drive the hospitals to the brink of losing 2.0 percentage points of their annual payment update.
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> *Response:* The working diagnosis element is only one of over 15 elements in a single episode of care that is used to calculate the pneumonia measures. Many of the hospitals that failed quarterly validation due to submitting inaccurate pneumonia elements did not submit additional elements used in the calculation of pneumonia measures and validation score. All hospitals are able to submit all

> elements potentially used to calculate validation scores, and we encourage hospitals to submit all of these elements to improve their likelihood to pass quarterly validation.

71 Fed. Reg. 48,035. Exhibit P-9.

This case involves a challenge to the procedures used to implement the above policies.

STATEMENT OF THE CASE AND PROCEDURAL HISTORY

Western Medical Center - Santa Ana (Provider) is an urban acute care hospital located in Santa Ana, California. The Provider was reimbursed under the inpatient prospective payment system during Federal fiscal year 2008. Wisconsin Physicians Service ("Intermediary") has assumed the responsibility as intermediary for providers previously serviced by Mutual of Omaha. By letter dated September 27, 2007, the Office of Clinical Standards and Quality ("OCSQ") informed the Provider that it did not meet the RHQDAPU program requirements and that its FY 2008 market basket update would be reduced by two percentage points.[4] The Provider requested reconsideration prior to November 1, 2007. By letter dated January 29, 2008, OCSQ informed the Provider that it had decided to uphold the decision to reduce the Provider's market basket update for FY 2008.[5] The Provider filed an appeal of this decision with the Provider Reimbursement Review Board ("Board") by letter dated March 26, 2008 and satisfied the jurisdictional requirements of 42 U.S.C. § 1395oo(a)(2)-(3).

The Provider was represented by Barbara Straub Williams, Esq. and Kate Romanow, Esq. of Powers, Pyles, Sutter & Verville, P.C. The Intermediary was represented by Terry Gouger of Wisconsin Physicians Service.

CONTENTIONS OF THE PARTIES

1. Exhaustion of Administrative Remedies

   a. Intermediary's Contentions:

The Intermediary contends that Congress granted the Secretary broad authority and wide discretion to implement the RHQDAPU program. Section 5001(a) of the Deficit Reduction Act of 2005, Pub. L. 109-171 (DRA), amended section 1886(b)(3)(B)(viii)(I) as follows:[6]

[4] Exhibit P-1.
[5] Exhibit P-2. The reimbursement period affected by the two percent reduction for Federal Fiscal Year 2008 is October 1, 2007 through September 30, 2008. In a final rule published on November 24, 2006, CMS delayed implementing the OPPS RHQDAPU program until Fiscal Year 2009. Therefore, the reimbursement effect only applies to inpatient reimbursement.
[6] Exhibit I-1.

> For purposes of clause (i) for fiscal year 2007 and each subsequent fiscal year, in the case of a subsection (d) hospital that does not submit, to the Secretary in accordance with this clause, data required to be submitted on measures selected under this clause with respect to such a fiscal year, the applicable percentage increase under clause (i) for such fiscal year shall be reduced by 2.0 percentage points.

Section 1886(b)(3)(B)(viii)(II) further emphasizes this wide discretion stating:

> Each subsection (d) hospital shall submit data on measures selected under this clause to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this clause.

The CMS amended its regulations at 42 CFR § 412.64(d)(2) to reflect the 2.0 percentage point reduction in the payment update for FFY 2008 as follows:

> (2)(i) In the case of a "subsection (d) hospital," as defined under section 1886(d)(1)(B) of the Act, that does not submit quality data on a quarterly basis to CMS**,** in the form and manner specified by CMS, the applicable percentage change specified in paragraph (d)(1) of this section is reduced –
>
> (A) For fiscal years 2005 and 2006, by 0.4 percentage points; and
>
> (B) For fiscal year 2007 and subsequent fiscal years, by 2.0 percentage points.

The Intermediary argues that the CMS regulation is fully consistent with statute and the intent of the Congress.

The Intermediary contends that the Provider failed to exhaust its administrative remedies to cure the results of its evaluation. Once the CDAC quarterly validation results are released, hospitals have 10 business days from the date the results are released to appeal the CDAC findings to the QIO.[7] The QIO has the ability to correct any coding and data abstraction errors prior to calculation of the upper bound reliability percentage. The Provider did not pursue the administrative remedy available to them by timely appealing the CDAC validation results to the QIO. Further, the CDAC current recordkeeping policy is to destroy validation medical records 180 days following receipt. Since the Provider did not appeal the chart validation results to its local QIO,[8] the records were not retained.

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[7] See 70 Fed. Reg. 47422. ("If the hospital fails validation, the hospital is provided 10 business days to notify the QIO that it wishes to appeal the validation decision. This timeframe helps expedite the final determination and minimizes data lag for public reporting and payment determination.").

[8] See Exhibit I-6.

b. Provider's Contentions:

In its initial brief and at hearing, the Intermediary argued that the Provider had not exhausted its administrative remedies and therefore was not entitled to appeal to the Board. The Provider argues that at hearing the Intermediary's witness conceded that there is no impediment to this appeal.[9] The Provider contends that the witness conceded that, if CMS had a requirement that providers appeal to the QIO prior to bringing a Board appeal, notice of that requirement to providers was never provided by CMS. The Provider argues further that, even if there were an exhaustion requirement, it would not apply to the Provider's third quarter 2006 because the Provider passed the validation test for that quarter. Hospitals are not permitted to appeal a quarter to the QIO if they receive a passing score for that quarter.[10] Accordingly, the Provider contends that the Intermediary has conceded this issue.

2. Adequacy of Notice

a. Provider's Contentions

The Provider contends that CMS did not follow the requirements of the Administrative Procedure Act ("APA") because it did not give proper notice of its scoring methodology for parent/child questions. The Provider notes that CMS addressed "parent/child" questions in 2005 stating:

> [O]nly the elements answered (parent only) are included in the validation score. If the parent response causes the child element(s) to be answered, then both parent and child elements are validated and count in the validation score.[11]

The Provider then argues that where it did not answer a "child" element that would have been answered had the hospital answered the "parent" question differently, it received a mismatch for all those "child" elements. CMS's instruction is inconsistent with its practice and clearly did not provide hospitals with notice relative to the scoring methodology for parent/child questions or the disproportionate penalties that result from answering a parent question incorrectly. The failure of such notice is a violation of the requirements of the APA.[12]

The Provider also contends that CMS failed to give notice that the design of certain reporting software gave providers a greater opportunity to pass the RHQDAPU validation process. The Provider used software developed by Quantros, Inc. as its tool for

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[9] Transcript at 297, 303, 315, June 25, 2008.
[10] *See* 70 Fed. Reg. 47,278, 47,427 (Aug. 12, 2005).
[11] 70 Fed. Reg. 47,425 (August 12, 2005); Exhibit P-8.
[12] *See* Kennecott Utah Copper Corp. v. Dept. of Interior, 88 F.3d 1191, 1220 (D.C. Cir. 1996) (Court invalidated a regulation that was inconsistent with the agency's explanation in the Federal Register preamble); PPG Industries, Inc. v. EPA, 659 F.2d 1239, 1249 (D.C. Cir. 1981) (a required procedure that is part of a rule must be published or incorporated by reference in the Federal Register); State of California ex rel. Lockyer v. FERC, 329 F.3d 700, 707 (9th Cir. 2003) (Federal Register must disclose 'true intent').

submission of the quality data to the QIO Clinical Warehouse.[13] The program does not allow a hospital to submit additional "child' elements to improve its score and blocks such elements where the hospital's response to the initial question did not require completion of the additional questions. Quantros was an approved vendor under the Hospital Quality Net website and, therefore, satisfied CMS specifications for reporting under the RHQDAPU program. Nevertheless, application of the program disadvantaged the Provider and is evidence that the RHQDAPU reporting methodology was not implemented in the manner CMS stated.[14]

b. Intermediary's Contentions

The Intermediary asserts that adequate notice of the CDAC review criteria and the evaluation process was furnished to the provider community. CMS established a website, the QualityNet website (www.QualityNet.org), to provide detailed information and instructions to acute-care inpatient prospective payment hospitals for submission of their quality data in the form, manner and timeframe specified by the Secretary. The website includes complete instructions for complying with the quality reporting requirements in the *Specifications Manual for National Inpatient Hospital Quality Measures* and the RHQDAPU FY 2008 Reference Checklist. The RHQDAPU FY 2008 Reference Checklist is a valuable resource developed by CMS to be used by hospitals in the submission of their quality data.[15] *The Specifications Manual for National Hospital Quality Measures* is also found on the QualityNet website and is specific to the service dates of the data being reported. In addition to the QualityNet website, the Secretary established QIOs to receive and warehouse the patient's private quality information as reported by hospitals. The CDAC is an entity independent of CMS that uses abstraction instructions and software that are available free of charge to all hospitals. CMS updates the *Specifications Manual for National Hospital Quality Measures* semi-annually to be used by hospitals to abstract their data.[16] This manual is posted on this website at least four months in advance of the period of reporting. The Intermediary argues that Providers are sufficiently informed of the CDAC review criteria consistent with the requirements of the APA.

3. Sampling Methodology and Validation Process

a. Provider's Contentions

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[13] The Quantros software is a JCAHO ORYX® Core Measures Performance Measurement System. ORYX® is the JCAHO's performance reporting and measurement initiative. http://www.jointcommission.org/AccreditationPrograms/Hospitals/ORYX/facts_oryx.htm. Hospitals were required to submit data using either the CMS CART software, the JCAHO ORYX® Core Measures Performance Measurement System, or another third party vendor tool that met the measurement specification requirements for data transmission to QualityNet Exchange. 72 Fed. Reg. at 47,360.

[14] *See* Kennecott Utah Copper Corp. v. Dept. of Interior, 88 F.3d at 1220; PPG Industries, Inc. v. EPA, 659 F.2d at 1249; State of California ex rel. Lockyer v. FERC, 329 F.3d at 707.

[15] Exhibit I-4; *See also* 70 Fed. Reg. 47,421 (Requirements for Hospital Reporting of Quality Data).

[16] *See also* 70 Fed. Reg. 47,424.

The Provider contends that several aspects of the RHQDAPU sampling methodology and validation process, including the scoring methodology for parent/child questions, are inconsistent with the purpose of 42 U.S.C. § 1395ww(b)(3)(B)(viii)(IV), and also with proper sampling and survey methodology.

The Provider argues that CMS chose the ten quality measures under the RHQDAPU program to:

1. Provide useful and valid information about hospital quality to the public;
2. Provide hospitals with a sense of predictability about public reporting expectations;
3. Begin to standardize data and data collection mechanisms; and
4. Foster hospital quality improvement.[17]

The Provider argues that the algorithm employed by the program for parent/child questions may stop after one question or proceed through an entire series of questions.[18] As a result of a hospital's answer to an initial question, one additional mismatch or many additional mismatches may occur.[19] The Provider argues that the variant results produced by the algorithm are arbitrary[20] and asserts that they do not "provide hospitals with a sense of predictability about public reporting responsibilities" or help to "standardize data and data collection mechanisms."

The Provider also contends that CMS' sampling and survey methodology is invalid. The Provider asserts that CMS' sample of five charts per quarter, or 15 total charts, was too small to be statistically valid. Further, the Provider contends that using four quarters of data (instead of three) would provide a more reliable estimate. The Provider argues that there was wide variability in the reliability rates across quarterly groupings that would be reduced by the use of topic sampling. The Provider further asserts that CMS' upper confidence bound calculation was inaccurate because it did not take into account CDAC coding errors. The Provider argues that the margin of error that CMS calculated through the confidence interval should be adjusted to recognize that CDAC sometimes incorrectly gives a hospital a "mismatch." The Provider contends that, if any of these factors are properly adjusted, the Provider passes its validation.

b. Intermediary's Contentions

The Intermediary argues that CMS' validation system and methodology is proper. The following exchange occurred at 70 Fed. Reg. 47,424 (August 12, 2005):

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[17] 70 Fed. Reg. 47,420; Exhibit I-11.
[18] Exhibit P-7.
[19] Exhibit P-12, P-17.
[20] Menorah Medical Center v. Heckler, 768 F.2d 292, 297 (8th Cir. 1985) (finding that a Medicare reimbursement rule related to malpractice premiums was invalid where it led to the "peculiar" result that some providers were over-reimbursed and some were under-reimbursed).

> *Comment*: A few commenters suggested that the only requirement to receive the full market basket update should be the submission of data to the warehouse. These commenters stated the intent of the law was to limit the requirement to data submission, and not require validation. In addition, there were comments that the validation process is flawed and any link to payment should be delayed until data infrastructure and processes are improved.
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> *Response*: We disagree with the comments indicating the section 501(b) of Pub. L. 108-173 only requires the submission of data. The commenters stated that additional requirements were not contemplated by Congress. However, the validation process does not contradict Pub. L. 108-173. Section 501(b) also states the submission of data to be in the "form and manner specified by the Secretary". We believe the validation requirements fall under this broad authority. This requirement does not appear to be stringent based on validation results showing 98 percent of providers that submitted data for the third quarter 2004 are eligible for the full market basket update. While hospitals did encounter abstraction and processing issues, these problems were immediately resolved. CMS's policy on validation requirements are (sic) very lenient, and offer hospitals several opportunities to validate their data in order to receive the full update.

The Intermediary contends that during calendar year 2006, for the FFY 2008 payment update (which used three quarters of data), 99.5 percent of hospitals qualified for the payment update.[21]

The Intermediary also contends that CMS's statistical practices are in accordance with CMS's broad authority and wide discretion in implementing the quality reporting program. CMS selected five charts per quarter for validation based upon the rationale at 70 Fed. Reg. 47,423 (August 12, 2005):

> *Comment*: Three commenters stated that five charts per hospital for validation is not a sufficient number to judge the quality of care delivered in the hospital.
>
> *Response*: CMS factored cost, burden, and precision of the validation results when deciding to implement the current validation sampling methodology. The goal of the chart audit validation process is to ensure that the hospital is abstracting and submitting accurate data. In order to calculate quality measures, which are used to determine the standard of care, we need to have complete and accurate data. Errors of omission and transcription errors contribute to the overall errors in calculating quality measures. We agree it is important to differentiate between these errors in order to provide feedback to hospitals. The

[21] Transcript at 282, June 25, 2008.

> process we have in place to provide this feedback gives each hospital the detailed abstraction results from the CDAC reabstraction so that hospital staff may determine the type of errors and take appropriate action.
>
> The five sampled charts usually yield 100 data elements that are used to determine the validation rate. This sample of data elements is sufficient to produce reliable validation rate estimates. Analysis of previous quarters' submitted data indicates that the clustering effect caused by the five chart sample boosts sampling variability by a relatively small proportion. Despite this increase in sampling variability, the sample still produces reliable validation rate estimates. The relative sampling variability is largely determined by the number of data elements abstracted, while incorporating the increased variability caused by the number of records. Analysis of previous quarters' submitted data indicates that the sampling variability is increased by a relatively small proportion.

The Intermediary argued that the five charts per quarter were randomly selected which resulted in unbiased selection and that each chart had an equal chance of being selected.[22] Further the intermediary contends that the number of data elements tested is approximately 200.[23] The Intermediary also argues that stratifying the sample by topic would require two charts per quarter per topic, or at a *minimum* eight charts per quarter, which would drive up costs by about 60 percent per year.[24] The Intermediary contends that its sampling practices are consistent with accepted standards in the statistical industry[25] and argues that there is no established statistical floor which audits must exceed in order to guarantee a provider due process.[26]

The Provider submitted 244 charts[27] and 15 were reviewed by CMS; therefore, six percent (6%) of the charts were validated. As noted by the court in Chavez County Home Health Service v. Sullivan, 931 F.2d 914 (D.C. Cir. 1991), to challenge the accuracy of a sample projection, "a provider could separately present evidence of a different random sample from the universe of claims that yields a lower result of denials or prove that the projection estimated 100 percent denials in the non-sample universe, a provider could demonstrate that one or more of those un-reviewed claims was proper."[28]

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[22] Transcript at 265-266, June 25, 2008.
[23] Transcript at 267, June 25, 2008.
[24] Transcript at 355-357, June 25, 2008.
[25] Transcript at 279, June 25, 2008.
[26] Michigan Dept. of Education v. U.S. Department of Education, 875 F. 2d 196 (6th Cir. 1989), ("There is no case law that states how large a percentage of the entire universe must be sampled." *Id.* at 1206.); Ratanansen v. State of California, 11 F. 3d 1467, 1472 (9th Cir. 1993) ("Indeed, the sample of 3.4 percent in the instant case exceeds that of the sample in Michigan where a random, stratified sample of .4 percent was used as a starting point for determining improper expenditures."); Webb v. Shalala, 49 F.Supp.2d 1114 (W.D. AK. 1999) ("We do not believe there is a 'statistical floor.").
[27] Transcript at 85.
[28] Intermediary's Post Hearing Brief at 38.

The Intermediary contends that the Provider did not conduct another *simple random sample* to determine whether the upper bound reliability percentage would change, nor did the Provider review the non-sample universe.

The Intermediary contends that use of the fourth quarter of 2005 was not prescribed in the final rule by CMS for the 2008 payment update[29] and CMS did not use fourth quarter of 2005 data since the validation results would not be available by the time of the 2008 final rule (when CMS performed its analysis) in August of 2007.[30] There were no exceptions to allow use of the fourth quarter and some providers may not have qualified for a payment update if the fourth quarter of 2005 were used.[31] Further all hospitals were treated in the same manner[32] and CMS had used less than four quarters of data for other Federal fiscal years. CMS validated/scored child questions when abstraction required the information for proper quality data. CMS indicated in the Federal Register it is the responsibility of each hospital and its vendor to adhere to the skip logic (parent/child questions). As stated in 70 Fed. Reg. 47,426 (August 12, 2005):

> All of the elements used for determining data validation are used to calculate the quality measures. It is the responsibility of each vendor (and ultimately, of the hospital) to adhere to skip logic as defined in the CMS measures …

All elements are used by CMS for each measure; therefore, CMS requires accurate submission of the required elements.[33] The Intermediary contends further that the hospital to vendor relationship is external to CMS. CMS does not have a contractual relationship with vendors and holds no sanctioning or licensing authority for software that is used to meet the requirements for transmission.[34] CMS holds hospitals responsible for submitting accurate data. The parent/child scoring method (blanks scored negatively) is a non-issue if a provider submits accurate data.

4. CDAC Abstraction Accuracy

a. Provider's Contentions:

The Provider contends that the CDAC abstractor's determinations with regard to certain data elements on several of the Provider's sampled charts were incorrect and should not have been scored as a mismatch. At the hearing the Provider contested the CDAC abstractor's determinations on five charts. [35]

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[29] Transcript at 365-366, June 25, 2008; *See also* 72 Fed. Reg. 47,361 (August 22, 2007).
[30] Transcript at 271-272, June 25, 2008.
[31] Transcript at 388; June 25, 2008.
[32] Transcript at 272-273; June 25, 2008.
[33] Transcript at 382-383; June 25, 2008.
[34] Transcript at 341; June 25, 2008.
[35] In its initial Position Paper, the Provider contested the CDAC's determinations on one chart and the Intermediary subsequently agreed that the Provider was correct. *See* Provider Exhibit P-60 (Stipulations).

b. Intermediary's Contentions:

At the hearing, CMS's witness[36] testified that CDAC made correct reabstraction determinations that were in accordance with the Specifications Manual and Data Dictionary. The witness testified further that although much training and education guidance was available to Providers, it is beneficial to be an RN when abstracting charts since physicians determine how things are stated in the Specifications Manual and the terminology may be more understandable with advanced RN training. The abstracter has an advantage at the outset to be an RN.[37] In addition, the witness testified the entire Specifications Manual[38] should be used to abstract charts; not just a cut-out of an Inclusion/Exclusion Table. The Specifications Manual indicates sections are inter-related and most useful when considered together. The Intermediary contends the Data Dictionary and Inclusion/Exclusion tables cannot be used in isolation, arguing that to do so may very well result in abstraction errors.[39] The Provider's chart witness testified they used the Data Dictionary's inclusion/exclusion table as a quick reference to abstract charts.[40]

c. Illustrative Abstraction Examples:

The following examples are illustrative of the parties' positions:

> Patient 0853 – The Provider determined that the medical record for this patient did not support a finding that the patient had left ventricular systolic dysfunction ("LVSD"), but the CDAC disagreed. The CDAC abstractor relied on a note in an echocardiogram ("echo") report. However, the CDAC abstractor ignored instructions in the Data Dictionary to use assessments performed closer to discharge to determine if LVSD is present. A cardiac catheterization performed on this patient after the echo, and closer to the time of discharge, shows that the patient did not have LVSD. The Intermediary witness also contended that the catheterization report and the echo conflict because the echo indicates that LVSD was present. The Provider contends that this is incorrect because guidance in the Data Dictionary regarding conflicting documentation indicates that language in the echo report should be disregarded. The Provider contends that the Data Dictionary provides an example of how to abstract for certain conflicting documentation and that example confirms that the Provider's abstraction was correct.
>
> Patient 1132 – The Provider determined that the medical record for this patient showed a contraindication for beta blocker on discharge, but the CDAC disagreed. The Intermediary's witness testified that the CDAC abstractor scored

[36] CMS called Mary Cox as its witness. Ms. Cox has been a Registered Nurse ("RN") since 1974 and was previously a Director of Nursing at a long-term care facility. She is the Director for the Hospital Reporting Program Quality Improvement Organization Support Center ("HRP-QIOSC").
[37] Transcript at 153-155; June 26, 2008.
[38] Exhibit I-1.5
[39] Transcript at 158-160; June 26, 2008.
[40] Transcript at 27; June 26, 2008.

> this question correctly because the patient's History and Physical Report included a directive to hold the patient's antihypertensives. The Intermediary's witness claimed the directive to hold antihypertensives was an exception in the Data Dictionary for a contraindication to beta blockers because it was a "general medication class." However, the Provider contends that the patient's medical record included two definitive indications of a contraindication to beta blocker on discharge; specifically third degree heart block and AV pacing. Accordingly, the Provider argues that its abstraction was correct.

FINDINGS OF FACTS, CONCLUSIONS OF LAW AND DISCUSSION

After consideration of Medicare law and guidelines, the parties' contentions and the evidence presented at the hearing, the Board finds and concludes as follows:

1. Exhaustion of Administrative Remedies/CDAC Abstraction Accuracy

The process for the appeal of the CDAC re-abstraction is presented at 70 Fed. Reg. 47,422 (August12, 2005) which states:

> Under the standard appeal process, all hospitals are given the detailed results of the Clinical Data Abstraction Center (CDAC) reabstraction along with their estimated percent reliability and the upper bound of the 95 percent confidence level. If a hospital does not meet the required 80 percent threshold, the hospital has 10 days to appeal these results to their QIO. The QIO will review the appeal with the hospital and make a final determination on the appeal. If the QIO does not agree with the hospital's appeal, then the original results stand.

The standard appeal process requires filing the appeal form within 10 business days so that the QIO contractor may review the original abstractions. The Federal Register also advised hospitals that detailed information about the process was available at the CMS website.[41] The Federal Register states further that:

> The QIO receives from the hospital the element or elements that are to be evaluated during the appeal process, along with the hospital rationale for the difference between the hospital's abstraction and the CDAC's abstraction. The QIO has available to it the hospital's answer and the CDAC decision when it reviews the hospital rationale and a copy of the medical record sent to it by the CDAC. The QIO then makes a final decision on the response to the element or elements . . . QIOs are obligated to make appeal decisions based on the data that was submitted to the clinical warehouse from the hospitals.[42]

[41] *See* http://www.qnetexchange.org
[42] 70 Fed. Reg. 47,425 (August 12, 2005).

The Board can find nothing in the Federal Register that makes the filing with the QIO an elective step. Rather, it appears the filing is an integral and necessary part of the appeals process. Under 42 U.S.C. § 1395oo(a) of the Medicare Act and the regulations at 42 C.F.R § 405.1835, a provider receiving payments in amounts computed under PPS has the right to a hearing before the Board with respect to such payments provided other jurisdictional criteria are met. However, the Secretary has established specific administrative processes for the correction of clinical records. The Secretary explained in the August 12, 2005 Federal Register, the process and their deadlines are necessary to expedite the final determinations and minimize data lag for public reporting and payment determination.[43] The prospective nature of the rate is central to the Medicare payment scheme. The Court in W.A. Foote Memorial Hospital v. Shalala, 2001 U.S. Dist. Lexis 24981 (E.D. Mich. 2001) found that where a provider fails to seek a correction within the time frame established by the Secretary, it has failed to exhaust its administrative remedies.[44] It is undisputed that the Provider did not file its appeal of the original abstraction with QIO as required by the process. Accordingly the Board finds that the Provider failed to exhaust its administrative remedies when it did not ask the QIO for its evaluation and hence the Provider's challenge at the Board that the abstractor's determination contains errors is foreclosed. The exhaustion doctrine applies to complaints in chart abstraction itself, but does not foreclose challenges to the overall method as being arbitrary.

2. Adequacy of Notice

The scoring methodology for parent/child questions is articulated at 70 Fed. Reg. 47,425:

> [O]nly the elements answered (parent only) are included in the validation score. If the parent response causes the child element(s) to be answered, then both parent and child elements are validated and count in the validation score.[45]

CMS' policy clearly states that only elements answered would be included in the validation score. However, the Board's examination revealed that where the Provider did not answer "child" elements as a result of its incorrect answer to the "parent" question, the Provider received a mismatch for all those "child" elements. CMS' scoring practice departed from the method that it committed to following and evidence indicates that this methodology was critical to the Provider's passing or failing the process.[46] The Board finds that CMS' published policy is inconsistent with its practice and clearly did not provide hospitals with notice relative to the scoring methodology for parent/child questions or the penalties that result from answering a parent question incorrectly. The

[43] 70 Fed. Reg. 47,422, (August 12, 2005).
[44] The Foote case involved the 2000 wage index which was based on data from the provider's 1996 cost report.
[45] *See* Exhibit P-8.
[46] *See* Exhibit P-9 at 30.

Board concludes that failure of such notice undermines the entire purpose of the validation process and violates the requirements of the APA.[47]

3. Sampling Methodology and Validation Process

The Board's examination of CMS' sampling methodology indicated that CMS had considered sampling size and stratification alternatives. However, CMS supplied the rationale that supports its sampling policy at 71 Fed. Reg. 48,043 (August 18, 2006) which states:

> Although we will consider using additional quarters of data, we believe that the current 3 quarters stratified sample provides sufficiently reliable results. The abstraction accuracy estimate is an element level estimate, and the chart is considered a cluster of elements. Each quarterly validation sample generally contains 50 to 100 elements cluster in 5 charts. Analysis of previous quarters of submitted data indicates that clustering effect increases sampling variability by a relatively small proportion. However the increase in sampling variability is so small that the sample still produces reliable validation rate estimates. The median hospital standard error using the three quarter stratified sample was about 3 percent.

The Board believes that the three percent error rate is significantly reliable. Further, the use of the CMS process allows over 90 percent of participating Providers to successfully pass the process.[48] The Board does not dispute the Provider's arguments that additional data, alternative stratification or alternative sampling methodologies may produce enhanced accuracy. However, the Board finds that CMS' current sampling methodology is founded upon a rational basis that produces significantly reliable results as evidenced by the high passing rate among all hospitals scored. Accordingly the Board concludes that the methodology is neither arbitrary nor inconsistent with the letter and intent of the program.

DECISION AND ORDER

1. Exhaustion of Administrative Remedies/CDAC Abstraction Accuracy

The Provider's challenge that the abstractor's determination contains errors is foreclosed at the Board.

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[47] *See* Kennecott Utah Copper Corp. v. Dept. of Interior, 88 F.3d 1191, 1220 (D.C. Cir. 1996) (Court invalidated a regulation that was inconsistent with the agency's explanation in the Federal Register preamble); PPG Industries, Inc. v. EPA, 659 F.2d 1239, 1249 (D.C. Cir. 1981) (a required procedure that is part of a rule must be published or incorporated by reference in the Federal Register); State of California ex rel. Lockyer v. FERC, 329 F.3d 700, 707 (9th Cir. 2003) (Federal Register must disclose 'true intent').

[48] Exhibit I-8.

2. Adequacy of Notice

CMS' policy for scoring parent/child questions is inconsistent with its practice and clearly did not provide hospitals with notice relative to the penalties that result from answering a parent question incorrectly. The parent/child questions should be scored consistent with the policy articulated at 70 Fed. Reg. 47425. The case is remanded to the Intermediary to correct the Provider's validation score consistent with this finding.

3. Sampling Methodology and Validation Process

CMS' sampling methodology is neither arbitrary nor inconsistent with the letter and intent of the program.

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