

**PROVIDER REIMBURSEMENT REVIEW BOARD
DECISION**

2026-D34

PROVIDER –
Houston Methodist Hospital

PROVIDER NUMBER – 45-0358

vs.

MEDICARE CONTRACTOR –
Novitas Solutions, Inc. c/o GuideWell Source

HEARING DATE –
April 17, 2025

**COST REPORTING PERIOD
ENDED –**
December 31, 2016

CASE NUMBER – 19-2411

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ISSUE STATEMENT:

Whether the Medicare Contractor's adjustments denying the Provider, Houston Methodist Hospital's, fiscal year ("FY") 2016 organ acquisition costs were proper.¹

DECISION:

After considering Medicare law, regulations, and program guidance, the arguments presented, and the evidence admitted, the Provider Reimbursement Review Board ("Board") finds the Medicare Contractor properly calculated the Provider's FY 2016 organ acquisition reimbursement cost.

INTRODUCTION:

Houston Methodist Hospital ("Houston Methodist" or "Provider") is a Medicare participating acute care hospital located in Houston, Texas.² The Provider operates as a Medicare Certified Transplant Center ("CTC") transplant center.³ During the cost reporting period at issue, the Medicare contractor⁴ assigned to Houston Methodist was Novitas Solutions, Inc. ("Medicare Contractor").⁵

The costs for organs acquired by a CTC are reimbursed by Medicare on a reasonable cost basis and not under the Inpatient Prospective Payment System ("IPPS").⁶ Upon audit of Houston Methodist's FY 2016 cost report, the Medicare Contractor determined that, although the transplants claimed as Medicare organs by the Provider were billed to Medicare, the claims were not paid by the Medicare program for the transplant DRG; and therefore they were denied for purposes of organ acquisition reimbursement.⁷ Specifically, the Medicare Contractor removed these organs from the counts reported on Worksheet D-4, line 63 as "Medicare Usable" organs on Houston Methodist's Fiscal Year Ending ("FYE") December 31, 2016 cost report.⁸

¹ Transcript ("Tr.") at 5:8-16 (Apr. 17, 2025).

² Stipulations ("Stip.") at ¶ 1 (April 11, 2025).

³ CMS provides a listing of Medicare-Approved Transplant Programs at <http://www.cms.gov/files/document/october-19-2018-approved-listpdf> (last visited Sept. 26, 2026). This list identifies Houston Methodist as having approved programs in Kidney and Pancreas (coverage date Sept. 1, 1977), Heart (coverage date Oct. 17, 1986), Liver (coverage date Mar. 13, 2001), and Lung (coverage date Oct. 10, 2008).

⁴ CMS' payment and audit functions under the Medicare program were historically contracted to organizations known as fiscal intermediaries ("FIs") and these functions are now contracted with organizations known as Medicare administrative contractors ("MACs"). The 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 Stip. at ¶ 2.

⁶ 42 C.F.R. § 412.2(e)(4).

⁷ Medicare Contractor's Final Position Paper ("Medicare Contractor's FPP") at 16 (Feb. 12, 2024).

⁸ *Id.*

From its Notice of Program Reimbursement (“NPR”) dated March 29, 2019, Houston Methodist timely filed an individual appeal request on August 14, 2019.⁹ Following transfers, withdrawals and dismissals, the sole issue remaining in this appeal relates to Medicare organ acquisition cost reimbursement. The Provider has stated the amount in controversy for this issue is \$1,229,436.¹⁰

The Board held a virtual hearing on April 17, 2025. The Provider was represented by Alan Sedley, Esq. with Alan J. Sedley Law Corp. Novitas Solutions was represented by Joseph Bauers, Esq. with Federal Specialized Services (“FSS”). The Parties’ representatives were permitted to make oral arguments before the Board with no fact witnesses presented. Following the hearing, the Board instructed the parties to submit post-hearing briefs on the specific issue of the differentiation, if any, between a non-covered service versus a denied or disallowed service and whether the denial of a service equates to that service being non-covered.¹¹

STATEMENT OF FACTS:

As stipulated by the Parties, for the FYE December 31, 2016, Houston Methodist claimed organ acquisition costs for a total of twelve (12) transplanted organs (*i.e.*, ten (10) livers and two (2) kidneys).¹² Specifically, for two (2) of the kidneys and four (4) of the livers, the Medicare Contractor denied payment noting that the Explanations of Benefits (“EOB”) included code A1, which led to the decision that “it was determined claim/service denied. At least one remark code must be provided.” For the remaining six (6) livers, the Medicare Contractor denied payment noting that the EOBs contained code 50, which led to the decision that “it was determined these were non-covered services because this not deemed a 'medical necessity' by the payer.”¹³

STATUTORY AND REGULATORY BACKGROUND:

Medicare reimburses Medicare Certified Transplant Centers, such as Houston Methodist, on a reasonable cost basis for costs associated with organ acquisition.¹⁴ 42 U.S.C. § 1395x(v)(1)(A) addresses Medicare reasonable costs and states, in pertinent part:

The reasonable cost of any services shall be the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services, and shall be determined in accordance with regulations establishing the method or methods to be used, and the items to be included, in determining such costs for various types or classes of institutions, agencies, and services; except that in any case to which paragraph

⁹ See Provider’s Final Position Paper (“Provider’s FPP”) at 1 (January 11, 2024). This appeal was filed with 12 issues; the Provider transferred nine to Common Issue Related Party (CIRP) group appeals, and the Board dismissed two for non-compliance with the Board’s Rules.

¹⁰ *Id.* at 13.

¹¹ Tr. at 67:7-20.

¹² Stip. at ¶ 4.

¹³ Ex. C-4.

¹⁴ See 42 U.S.C. § 1395x(v)(1)(A); 42 C.F.R. §§ 412.113(d), 412.2(e)(4); *see also* Provider’s FPP at 11.

(2) or (3) applies, the amount of the payment determined under such paragraph with respect to the services involved shall be considered the reasonable cost of such services. In prescribing the regulations referred to in the preceding sentence, the Secretary shall consider, among other things, the principles generally applied by national organizations or established prepayment organizations (which have developed such principles) in computing the amount of payment, to be made by persons other than the recipients of services, to providers of services on account of services furnished to such recipients by such providers. Such regulations may provide for determination of the costs of services on a per diem, per unit, per capita, or other basis, may provide for using different methods in different circumstances, may provide for the use of estimates of costs of particular items or services, may provide for the establishment of limits on the direct or indirect overall incurred costs or incurred costs of specific items or services or groups of items or services to be recognized as reasonable based on estimates of the *costs necessary in the efficient delivery of needed health services to individuals covered by the insurance programs established under this subchapter*, and may provide for the use of charges or a percentage of charges where this method reasonably reflects the costs. Such regulations shall (i) take into account both direct and indirect costs of providers of services (excluding therefrom any such costs, including standby costs, which are determined in accordance with regulations to be unnecessary in the efficient delivery of services covered by the insurance programs established under this subchapter) in order that, under the methods of determining costs, the necessary costs of efficiently delivering covered services to individuals covered by the insurance programs established by this subchapter will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by such insurance programs, and (ii) provide for the making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or excessive.

The implementing regulation for determining reasonable costs is found at 42 C.F.R. § 413.9, which states, in pertinent part:

(a) *Principle.* All payments to providers of services must be based on the reasonable cost of services covered under Medicare and related to the care of beneficiaries. Reasonable cost includes all necessary and proper costs incurred in furnishing the services, subject to principles relating to specific items of revenue and cost.

However, for cost reporting periods beginning after December 31, 1973, payments to providers of services are based on the lesser of the reasonable cost of services covered under Medicare and furnished to program beneficiaries or the customary charges to the general public for such services, as provided for in § 413.13.

(b) *Definitions.*—

(1) *Reasonable cost.* Reasonable cost of any services must be determined in accordance with regulations establishing the method or methods to be used, and the items to be included. The regulations in this part take into account both direct and indirect costs of providers of services. The objective is that under the methods of determining costs, the costs with respect to individuals covered by the program will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by the program. These regulations also provide for the making of suitable retroactive adjustments after the provider has submitted fiscal and statistical reports. The retroactive adjustment will represent the difference between the amount received by the provider during the year for covered services from both Medicare and the beneficiaries and the amount determined in accordance with an accepted method of cost apportionment to be the actual cost of services furnished to beneficiaries during the year.

(2) *Necessary and proper costs.* Necessary and proper costs are costs that are appropriate and helpful in developing and maintaining the operation of patient care facilities and activities. They are usually costs that are common and accepted occurrences in the field of the provider's activity.

The Medicare program has established policies which support organ transplantation by providing payment for the variety of organ acquisition services required to support quality transplant programs.¹⁵ In particular, the Provider Reimbursement Manual, Part 1 (“PRM-1”) § 3100 states, in relevant part:

The Medicare program has established policies which support organ transplantation by providing an equitable means of payment for the variety of organ acquisition services required to support quality transplant programs. The following instructions explain ***how Medicare reimburses for organ acquisition costs of covered transplants provided to Medicare beneficiaries.***

¹⁵ See 42 C.F.R. § 412.2(e)(4); see also 42 C.F.R. § 412.100(a)(2) and 42 C.F.R. § 412.113(d).

To participate in the Medicare program, a certified transplant center (CTC) or organ procurement organization (OPO) must be a member of the Organ Procurement and Transplantation Network (OPTN). An OPO can be a hospital-based OPO (HOPO) or an independent OPO (IOPO). (We refer to organ procurement organizations generally as “OPOs” throughout this chapter, unless differentiation of HOPO or IOPO is required for context.) Hospitals are required to notify the OPO designated for its service area of deaths or imminent deaths in its hospital. Organs may be procured by OPOs from CTCs, local community hospitals or other OPOs.

There are two payment components for organ transplantation. CTCs are paid a prospective payment system rate based on a Diagnostic Related Groups (DRG) for the actual organ transplant and they are *also* reimbursed for the reasonable and necessary costs associated with acquiring the organ (i.e., organ acquisition costs). Organ acquisition costs incurred by the CTC/HOPO are included on the appropriate organ acquisition cost center on its Medicare cost report (MCR), Form CMS-2552. Organ acquisition costs incurred by the IOPO are included on the appropriate organ acquisition cost center on its MCR, Form CMS-216.¹⁶

The implementing regulation specifying that organ acquisition costs are excluded from IPPS and reimbursed on a reasonable cost basis is found at 42 C.F.R. § 412.2(e)(4), which states:

(e) Excluded costs. The following inpatient hospital costs are excluded from the prospective payment amounts and are paid for on a reasonable cost basis:

* * *

(4) The acquisition costs of hearts, kidneys, livers, lungs, pancreas, and intestines (or multivisceral organs) incurred by approved transplantation centers.

The reimbursement for organ acquisition costs depends, in part, on the provider’s number of Medicare usable organs and total usable organs.¹⁷ To calculate a provider’s net organ acquisition costs, the ratio of the provider’s Medicare usable organs to total usable organs is multiplied by the provider’s total organ acquisition costs, and the calculated Medicare cost is then reduced by

¹⁶ (Emphasis added). *Available at* Exhibit II (April 2025).

¹⁷ See PRM, Part 1 § 2775.3 (2012). The Board notes that this section was deleted by Transmittal 471, dated Apr. 1, 2016, but chooses to include it as informational for the explanation of calculation of organ costs based upon organ counts.

the payments received from organ procurement organizations, military hospitals, and other transplant centers for Medicare organs.¹⁸

In April 2016, CMS issued Transmittal 471 “to update, reorganize, and clarify Medicare’s [Part A] payment policy regarding organ acquisition costs formerly found in [PRM-1] Chapter 27 – ESRD Services and Supplies, sections 2770 through 2775.4 . . .”¹⁹ creating a new chapter in PRM-1 entitled, “Chapter 31- Organ Donation and Transplant Reimbursement.”²⁰ This new chapter details the Medicare program policies supporting organ transplantation and Medicare’s reimbursement for its share of organ acquisition costs.

As a result, PRM-1 § 3102 states, in relevant part:

A. Outpatient Costs.--Included in the CTC’s organ acquisition costs are hospital services classified as outpatient and applicable to a potential organ transplant. These outpatient services include donor and recipient work-ups furnished prior to admission and costs of services rendered by interns and residents not in an approved teaching program. These costs would otherwise be paid under Part B of the Program. ***Because such costs are applicable to organ acquisitions which are predominantly cadaveric donor related and incurred without an identifiable beneficiary, the services are not billed to a beneficiary when the services are rendered but are included in the CTC’s organ acquisition cost center.***

B. Multiple Organ Retrieval.--CTCs/HOPOs that participate in multiple organ retrieval must establish a formula for cost finding for these organs. They must separately identify the costs associated with the retrieval of all organs and appropriately apportion the acquisition costs by organ type. When the CTC/HOPO procures multiple organs, it must allocate and record the direct costs associated with each organ type. Also, ancillary charges must be allocated among the types of organs procured. See §3111, Intent to Transplant. For example, if an operating room charge for procuring multiple organs is \$1,000 and one kidney and one heart are procured, then the charge attributable to each organ is \$500. However, if the CTC/HOPO has a more accurate basis for allocation that is verifiable by the Medicare

¹⁸See *id.*; see also 42 C.F.R. § 413.203(b)–(c) (instructing hospitals to “separate costs for procuring . . . organs transplanted in patients other than Medicare beneficiaries from Medicare allowable costs” and that “Medicare costs are based on the ratio of the number of usable organs transplanted into Medicare beneficiaries to the total number of usable organs”).

¹⁹ CMS Transmittal 471 at 1 (Apr. 1, 2016).

²⁰ *Id.* at 2.

Administrative Contractor, (hereinafter “contractor”), e.g., number of operating room minutes, this may be used.

The indirect costs associated with preservation technicians, transplant coordinators, and administrators, etc. must be allocated among the types of organs procured. The provider must establish a unit cost per organ by dividing the indirect cost by the total number of organs procured. The indirect costs are allocated using the unit cost per organ multiplied by each organ procured. For example, if the indirect cost equals \$5,000 and five organs are procured (one heart, one liver, one pancreas, and two kidneys) then the cost for each organ is \$1,000 (\$2,000 must be allocated to kidney because two kidneys were procured). Organs procured and transplanted en bloc (two organs transplanted as one unit) must be counted as one organ for cost allocation purposes, see §3115, Counting of Organs.

C. Laboratory Services.--Pre-transplant evaluation services for recipients and donors, including laboratory services, are paid through the organ acquisition costs of the CTC. When laboratory tests are performed by the CTC, it uses the related costs in establishing the standard charge. The CTC also includes the reasonable charges paid for physician tissue typing services provided to living donors and recipients.

When the laboratory services are performed by a histocompatibility laboratory, interim rates established by the contractor are used by the laboratory in billing a CTC. Information on the interim rates are disseminated by the contractor to all CTCs, OPOs, and other contractors or can be found on the contractor’s website. The CTC pays the laboratory the approved interim rate. When the laboratory bills an OPO for services, the OPO is responsible for paying the interim rate. The contractor determines the final payment to the histocompatibility laboratory by reconciling interim payments and reasonable costs during final settlement of the Medicare cost report.

D. Cost Adjustment.--Medicare cost reimburses a CTC for organ acquisition costs. The organ acquisition costs are accumulated on the MCR (Form CMS-2552) by specific organ type. CTCs/HOPOs that claim organ acquisition costs on the cost report must separate, from Medicare allowable costs, any costs associated with organs sent to foreign countries or transplanted in patients other than Medicare beneficiaries. The contractors will compute the ratio of the number of organs used for Medicare beneficiaries to the total number of organs used and adjust the costs for organs

sent to foreign countries or transplanted in non-Medicare patients at cost report settlement. Services provided to patients other than Medicare beneficiaries are paid by those patients or their third party payers.

Kidneys sent to United States military renal transplant centers (MRTCs) by a HOPO are counted as Medicare organs for payment purposes on the CTC's cost report if the requirements are met within §3114, Military Renal Transplant Centers.

The Medicare program generally continues to pay for its proportionate share of costs incurred in procuring organs that are not transplanted. See §3116, Calculation of Medicare Costs.²¹

Additionally, Section 3115 of this new chapter details the policy for counting organs:

OPOs and CTCs are responsible for accurately counting both Medicare and non-Medicare organs to ensure that costs are properly allocated on the [Medicare Cost Report]. The OPO and CTC should count organs procured and transplanted en bloc (two organs transplanted as one unit) as one organ. This can include but is not limited to en bloc kidneys and en bloc lungs.

A. Counting Medicare Usable Organs at CTCs/HOPOs.--Medicare usable organs include organs transplanted into Medicare beneficiaries (excluding Medicare Advantage beneficiaries), organs that had partial payments by a primary insurance payer in addition to Medicare, organs sent to other CTCs, organs sent to OPOs and kidneys sent to MRTCs (that have a reciprocal sharing agreement with the OPO in effect prior to March 3, 1988 and approved by the contractor). Medicare usable organs do not include organs used for research, organs sent to veterans' hospitals, organs sent outside the United States, organs transplanted into non-Medicare beneficiaries, organs that were totally paid by primary insurance other than Medicare, organs that were paid by a Medicare Advantage plan, organs procured from a non-certified OPO and kidneys sent to MRTCs (without a reciprocal sharing agreement with the OPO in effect prior to March 3, 1988 and approved by the contractor).

In determining whether an organ will be counted as a Medicare usable organ, PRM-1, § 3104 states:

²¹ (Bold and italics emphasis added).

If a Medicare beneficiary has a primary health insurance coverage other than Medicare, determining whether an organ will be counted as a Medicare usable organ depends on the amount paid by the primary insurance. A provider must submit a bill to Medicare when payment from the primary payer is insufficient to cover the entire cost of a transplant including the DRG and the organ acquisition costs. ***However, when the primary insurance requires the acceptance of their payment in full, a bill is not required, because under the contractual agreement, Medicare has no liability because the primary payer has made the payment in full. Accordingly, the organ under the paid in full contractual agreement will not be counted as a Medicare usable organ.***

When the provider submits a bill and the primary payer does not require the provider to accept the contractual payment in full, it is necessary to compare the total cost of the transplant, including the DRG and the organ acquisition costs, to the payment received from the primary payer. The provider's remittance advice may or may not show that Medicare has a liability because the bill is only submitted for the transplant portion of the payment. Thus, the provider will need to compare the total Medicare cost (DRG from the transplant and the organ acquisition costs) to the payment from the primary payer to determine whether Medicare has a liability for the organ acquisition costs. ***If the payment from the primary payer is greater than the cost of the DRG and the organ acquisition costs, there is no Medicare liability and the organ cannot be counted as a Medicare usable organ.*** If the payment from the primary payer is less than the DRG and the organ acquisition costs, there is a Medicare liability and the organ can be counted as a Medicare usable organ. The payment from the primary payer is pro-rated between the DRG payment and the organ acquisition payment. If the organ is counted as Medicare usable, the organ acquisition portion of the primary payment should be included on the appropriate line as a revenue offset on the MCR, Form CMS-2552. This is consistent with the Medicare Claims Processing Manual (CMS Pub. 100-04) and cost reporting instructions set forth in CMS Pub. 15, Part 2.²²

In determining whether organ acquisition costs can be billed separately, PRM-I, § 3101 states, in relevant part –

The costs of procuring an organ cannot be billed directly to the Program because the procurement of an organ is not a covered

²² (Bold and italics emphasis added).

service when performed independent of a Medicare covered transplant. However, the reasonable costs of procuring an organ are reimbursable when incurred in procuring the organ for a Medicare covered transplant. The costs are paid on an interim basis and reconciled through the MCR at the end of the CTC's cost reporting period.²³

In September 2014, CMS issued Transmittal 6, which revised PRM, Part 2, the “Provider Cost Reporting Forms and Instructions, Chapter 40, Form CMS-2552-10.” This Transmittal “[c]larified the instructions and eliminated the “other” organ category and check off box from the worksheet [D-4].”²⁴ Accordingly, the instructions for completing the usable organs counts on the Medicare Cost Report included in the Provider Reimbursement Manual, Part 2 (“PRM-2”), Section 4028.3, were updated to state, in pertinent part:

Line 62--Enter the number of total usable organs excised and purchased minus all unusable or discarded organs that could not be transplanted (usable organs equals Worksheet D-4, Part IV, line 74, sum of columns 1 and 2, minus Worksheet D-4, Part IV, line 83, sum of columns 1 and 2). For islets since the number of islets cells injected into a recipient will vary depending on the patient, enter the number of patients who received islets injections. Each patient is allowed a maximum of two islet injections per inpatient stay.

Line 63--Enter the total Medicare usable organs that are included on line 62. ***Medicare usable organs include organs transplanted into Medicare beneficiaries (this excludes Medicare Advantage beneficiaries),*** organs sent to military hospitals (that have a reciprocal sharing agreement with the Organ Procurement Organization (OPO) in effect prior to March 3, 1988 and approved by the contractor), ***organs that had partial payments by a primary insurance payer in addition to Medicare,*** organs sent to other providers and organs sent to OPOs. ***Do not include organs*** used for research, organs sent to military hospitals (without a reciprocal sharing agreement with the OPO) in effect prior to March 3, 1988 and approved by the contractor), organs sent to veterans’ hospitals, organs sent outside the United States, organs transplanted into non-Medicare beneficiaries, ***organs that were totally paid by primary insurance other than Medicare, organs that were paid by a Medicare Advantage plan, and organs procured from a non-certified OPO.***²⁵

²³ (Bold, italics and underline emphasis added).

²⁴ Transmittal 6, R6P240 at 2 (Sept. 2014).

²⁵ (Bold and italics emphasis added).

In 2021, after the period in question in the instant appeal, CMS finalized several proposed changes to organ acquisition payment policy and reorganized organ acquisition payment regulations under subpart L of title 42 of the CFR. 42 C.F.R. § 413.404 (effective Jan. 1, 2023) details the procedures for Providers to develop a Standard Acquisition Charge (“SAC”), and states “*the reasonable costs to procure an organ are reimbursable when billed in connection with a Medicare covered transplant.*”²⁶

Finally, in order to be reimbursed for any Medicare services, providers must substantiate items claimed on their cost reports with proper documentary evidence. Particularly, 42 C.F.R. § 413.24(c) provides:

(c) Adequacy of cost information. Adequate cost information must be obtained from the provider's records to support payments made for services furnished to beneficiaries. The requirement of adequacy of data implies that the data be accurate and in sufficient detail to accomplish the purposes for which it is intended. Adequate data capable of being audited is consistent with good business concepts and effective and efficient management of any organization, whether it is operated for profit or on a nonprofit basis. It is a reasonable expectation on the part of any agency paying for services on a cost-reimbursement basis. In order to provide the required cost data and not impair comparability, financial and statistical records should be maintained in a manner consistent from one period to another. However, a proper regard for consistency need not preclude a desirable change in accounting procedures if there is reason to effect such change.

DISCUSSION, FINDINGS OF FACT, AND CONCLUSIONS OF LAW:

The Provider’s Position

The Provider contends that CMS PRM-I § 3116 “does not require that Medicare make a DRG claim payment, in order for organ transplant to be counted in the Medicare Usable Organs for the calculation of the organ acquisition cost payment.”²⁷

Additionally, the Provider details its interpretation of the applicable regulations –

It makes sense that the “Medicare usable organ” ratio includes unpaid organ transplants into Medicare beneficiaries. The ratio is merely an allocation statistic that, as the PRM explains, is used to adjust total organ acquisition costs to exclude cost associated with organs transplanted into non-beneficiaries (Id. § 3115). Because

²⁶ 42 C.F.R. § 413.404(a)(1) (emphasis added). See also Exhibit C-6.

²⁷ Provider’s FPP at 11.

many of these acquisition costs are not specifically attributable to specific patients or beneficiaries, the Medicare program does not attempt to directly tie specific organ acquisition costs to specific organs in order to determine the Medicare program's share of these costs. Rather, it uses the allocation ratio to divide up a larger pool of diffuse costs as the most accurate methodology for allocating some of these costs to the Medicare program. If the Medicare program were to include only "paid" Medicare organs in the allocation ratio, then some portion of those pre-transplant costs that would otherwise be attributed to those organs would not be covered by the Medicare program. Rather, they would be borne by other non-Medicare payers. This result would violate the prohibition against cross-subsidization of the Medicare program by commercial insurers. See Social Security Act, § 1861(v) (setting forth anti-cross subsidization rule).

The PRM excludes from the "Medicare usable organ" definition organs that were transplanted into a Medicare Advantage (MA) beneficiary and organs where Medicare is the secondary payer. But it does include organs where Medicare makes partial payments in addition to a commercial insurer (PRM Part 1, Chapter 31, § 3115.A). This further supports the fact that the ratio is designed to allocate or adjust organ acquisition costs so that only those costs attributable to organs provided to Medicare fee-for-service beneficiaries are paid by Medicare. The capitated rates CMS pays to Medicare Advantage plans would include costs attributable to organ acquisition costs, so it would over-allocate costs to the Medicare program if MA organs were included in the numerator. Similarly, when Medicare is not financially liable for payment—as is the case when another insurer is primary—Medicare would not be responsible for the portion of organ acquisition costs attributable to that organ. But in those cases in which Medicare would be the primary payer, then the Medicare program would be responsible for the organ acquisition costs attributable to that organ. And that would be the case regardless of whether Medicare ultimately made payment for that inpatient transplant DRG. There could be a number of reasons as to why Medicare might not ultimately make payment for a transplant case, which have nothing to do with whether the organ transplant was reasonable and necessary and, therefore, could have been covered by the Medicare program. For example, the claim might be denied for a technical document requirement or a timely filing deadline might have been missed. Medicare might not pay for those inpatient DRGs for these technical reasons, but there is no question that there is also an allocation of organ acquisition costs that are attributable to the

organ “transplanted into the Medicare” beneficiary that should be covered by the Medicare program.

The provider understands that the DRG payments “conveniently” support the fact that the specific organ is transplanted into Medicare patient and therefore counts as Medicare portion. However, the DRG payments are not the only way to support the fact that these organs were transplanted into Medicare beneficiaries. During the audit, we have provided supporting documents, including Medicare HIC number, MedPar data, etc., to prove that these organs were transplanted into Medicare beneficiaries. However, MAC insists denying the count of Medicare organs.²⁸

Further, the Provider contends that “[t]he Administrative Law Judge (“ALJ”) has ruled favorable to [the Provider] in a decision made March 20, 2020. [The Provider] will receive Part A payments on these denied claims.”²⁹

The Provider insists that Medicare coverage and Medicare payment must be viewed as distinct concepts:

In its definition of a *Medicare Usable Organ*, the PRM does not expressly nor even implicitly couple a requirement that CMS must issue a payment for a DRG claim before allowing reimbursement for associated organ acquisition costs. PRM, *supra* § 3115 A. In fact, such a requirement is not addressed nor referenced anywhere within that section of the PRM applicable to “Organ Donation and Transplant Reimbursement[.]” *supra*. Instead, the PRM expressly states that, “[CTCs] are paid a prospective payment system rate based on a ... DRG... for the actual organ transplant and they are also reimbursed for the reasonable and necessary costs associated with acquiring the organ (i.e., organ acquisition costs).” See PRM at section 3100.³⁰

At hearing, the Provider argued that the Medicare program intended DRG payment for the organ transplant itself, and reimbursement for the reasonable and necessary costs for acquisition of the organ—as a separate component.³¹ To illustrate its point, the Provider stated:

An analogy would be a doctor performs a particular service at a hospital. Let’s assume that it is a cosmetic surgery procedure

²⁸ *Id.* at 12-13.

²⁹ *Id.* at 13. Contrary to this contention, the Medicare Contractor confirms that the Provider did not submit a copy of the ALJ decision for the record. See Medicare Contractor’s FPP at 17.

³⁰ Provider’s Post-Hearing Brief (unnumbered) at 5-6 (Jun. 9, 2025) (emphasis in original).

³¹ Tr. at 19:7-13.

which typically is not paid or covered by Medicare. Now, there are two payments: it's the professional service for the doctor for doing the procedure and a fee for hospital facilities and staff and all the other accoutrements used by the hospital staff for the procedure. One has nothing to do with the other in terms of payment. The physician may well submit his payment under Part B and receive a DRG type payment. The hospital, on the other hand, will receive its Part A payment for the use of that facility. If somehow the doctor is excluded, let's say he's not enrolled in Medicare, or alternatively in this example, he's doing a procedure that is not covered, nevertheless working on a Medicare patient, he cannot be paid by Medicare. But certainly the hospital can and will get paid its hospital facility expenses. It's the same here.³²

The Provider refers to this analogy as “two silos,” one that reimburses the transplants apart from the second that reimburses the procurement of the organ.³³

Further, the Provider contends that “there is no definition in this section regarding what the word ‘covered’ means. However, nowhere in the PRMs that have been provided as exhibits is there any language at all to prohibit the payment of an organ transplantation, that silo, in the absence of a DRG payment for whatever reason.”³⁴

Finally, in its post-hearing brief responding to the Board's request that the parties address the distinction between a “non-covered” service and a “denied or disallowed” claim, the Provider argues that a denied payment does not equate to a non-covered service.³⁵ The Provider contends that “the meaning of the polysemous term, “coverage”, must be analyzed in terms of context, something the MAC chose to ignore.”³⁶ The Provider further argues that a “kidney or liver transplant into a Medicare beneficiary is by definition vital and thus ‘reasonable and necessary’ for the obvious [reason that] no patient would submit to such a complex and inherently high risk, life-threatening procedure unless that procedure was deemed medically necessary . . .”³⁷ The Provider reiterates that “[a] vital organ transplanted into a Medicare beneficiary is in virtually every instance a *covered* service . . .” and that an administrative/technical error in submitting documentation “does not in any manner vitiate the fact that each of the subject liver/kidney transplants was a Medicare *covered* transplant surgically implanted.”³⁸ The Provider concludes that “Medicare *coverage* refers to the types of services and items that are *covered* under the Medicare program. Medicare *payment* refers to the portion of the costs of those *covered* services that Medicare pays. Vital organ transplantation is a Medicare-covered service.”³⁹

³² *Id.* at 19:14-20:14; *see also id.* at 59:22-63:24.

³³ *Id.* at 39:19-22.

³⁴ *Id.* at 60:15-23.

³⁵ Provider's PHB at “I. Introduction”.

³⁶ *Id.* (Emphasis included).

³⁷ *Id.* at II. Statement of Facts.

³⁸ *Id.* at III. Discussion.

³⁹ *Id.* at IV. Conclusion.

The Medicare Contractor's Position

The Medicare Contractor disagrees with the Provider's assertion that the Medicare DRG payment is not a factor in determining Medicare's share of organ acquisition costs and first points out that the Provider did not submit remark code or medical necessity information to support its claim in a timely manner.⁴⁰

The Medicare Contractor details its efforts during the audit:

The [Medicare Contractor] contacted CMS for direction regarding the handling of these denied claims in the calculation of the Medicare organ acquisition payment. In its reply[,] CMS instructed that in cases where Medicare denied payment for the transplant, Medicare would not make payment for the associated organ acquisition costs.

At this direction, the MAC removed the two kidneys and ten livers from the "Medicare Usable" category in the calculation of the Medicare organ acquisition payment . . .⁴¹

The Medicare Contractor argues that:

[T]he Provider cannot overcome the plain language of the regulation and the PRM, which both condition reimbursement of organ acquisition costs to 'covered transplants'. The Provider's argument that transplants which are denied or disallowed are somehow simultaneously covered, defies reason and is contrary to the plain language of both the regulation and the PRM.

...

If the transplant is not covered, which these twelve were not, the remainder of Chapter 31 of the PRM is not relevant, much less applicable. The coverage of the underlying transplant is a condition precedent for the application of the remainder of the PRM.⁴²

⁴⁰ Medicare Contractor's FPP at 16-17. Note: it appears the Medicare Contractor, as evidenced in Exhibit C-4, did review the EOB, Medicare Remittance Advice ("RA") and OPO documentation for the patients receiving transplants. However, the Medicare Contractor argues that these Medicare inpatient claims were denied as either (a) missing a remark code or (b) not being found as medically necessary, and the Provider had 180 days to appeal these denials. *See also* Tr. at 31-32, 36-39, and 40-43, for discussion on the denials due to missing remark codes.

⁴¹ *Id.* at 17.

⁴² Medicare Contractor's Post-Hearing Brief ("Medicare Contractor's PHB") at 3 (June 9, 2025).

Finally, the Medicare Contractor notes the Provider has produced no evidence that the twelve transplants were in fact covered by Medicare and thus, has not met its burden of proof.⁴³

Board Analysis

The core dispute between the parties pertains to whether a transplant episode not paid by the Medicare program should still be counted in the share of Medicare usable organs in computing a Provider's Medicare organ acquisition reimbursement cost. As set forth above, Houston Methodist contends that Medicare's payment of the underlying DRG claim is not a prerequisite to including an organ in the Medicare usable organ count on the cost report,⁴⁴ while the Medicare Contractor maintains that a covered transplant, which it contends that a denied or disallowed claim cannot be, is a condition precedent to any organ acquisition cost reimbursement.⁴⁵ The Board finds that both parties' arguments are flawed.

At length, the Provider has argued that the plain language of PRM-I § 3100 stating, "and they are also"⁴⁶ provides that CTCs are reimbursed for organ acquisition costs, in addition to the DRG payment for the transplant, and that the phrase establishes two payment streams which are "separate" from one another. Thus, the Provider believes a denial of the DRG claim has no bearing on the availability of organ acquisition cost reimbursement.⁴⁷

The Provider's argument posits that Medicare would pay the costs for acquiring an organ for which it denied reimbursement for the associated services involved in transplanting that organ. Although PRM-I § 3100 clearly states that "[t]here are two payment components for organ transplantation[.]" it does not indicate that those two components are separate or independent of one another with regard to the conditions for payment of each component. Instead, it simply identifies the two payment mechanisms through which payments for organ transplant are made—1) PPS rates based on DRGs for the transplant surgery itself, and 2) reasonable cost basis for the costs deemed reasonable and necessary to procure the organ for the transplant surgery.⁴⁸ Moreover, the language in the PRM follows the regulation at 42 C.F.R. 412.2(e)(4) that, since 1985, has set forth the "basis for payment" under the prospective payment system and those costs that "are excluded from the prospective payment amounts and are paid for on a reasonable cost basis[.]"⁴⁹ Accordingly, the Provider's "two silos" argument misses the point that the two silos are PPS and reasonable cost basis, both paid out of the same Part A/Part B trust funds, and that to be reimbursed for each component of organ transplantation under the respective payment mechanisms, a provider must meet the fundamental requirements of Medicare reimbursement, i.e., medical necessity (based upon adequate documentation) as well as other documentation required for reimbursement of a service that is deemed medically necessary. Neither the

⁴³ *Id.* at 4.

⁴⁴ Provider's PHB at III. Discussion.

⁴⁵ Medicare Contractor's PHB at 3-4.

⁴⁶ Tr. at 19:1-13.

⁴⁷ *See id.* at 17-19.

⁴⁸ PRM-1, § 3100.

⁴⁹ *See also* 50 Fed. Reg. 12740, 12742 (Mar. 29, 1985).

regulation nor the PRM provisions imply that a provider may be reimbursed for acquisition costs of an organ where they have failed to meet medical necessity requirements or claims reimbursement documentation requirements for the organ transplant surgery in the first place.

With this, while the Medicare Contractor is correct that the actual organ transplant must be reimbursed in order to be paid for the costs of procuring the organ, the Medicare Contractor's position that denied or disallowed services are not "covered" services is also flawed—particularly in the context of payer nomenclature. The Board further discusses this point below. Nonetheless, as outlined further below, the Board finds the Medicare Contactor properly calculated Houston Methodist's organ acquisition costs.

A. Houston Methodist Failed to Carry its Burden of Production of Evidence

Upon review of the record in this case, the Board finds that the Provider has not presented any additional evidence or documentation that sufficiently counters the Medicare Contractor's basis for denial. At the outset, the Board looks to Exhibit C-4, a one-page audit work paper supplied by the Medicare Contactor and documenting the auditor's analysis to determine if Medicare usable organs have been properly reported on the Medicare cost report. The work paper outlines the twelve transplant episodes sorted by transplant date, lists the patient admission date, discharge date, and verifies whether the beneficiary was eligible for Medicare coverage. In viewing Exhibit C-4, for six liver transplants, the Medicare contractor notes:

Per EOB, code 50, it was determined these were non-covered services because this not deemed a 'medical necessity' by the payer.⁵⁰

For the remaining six transplants, two kidney transplants and four liver transplants, the Medicare Contractor states:

Per EOB, code A1, it was determined claim/service denied. At least one remark code must be provided.⁵¹

⁵⁰ Ex. C-4 at 000056. Based on the Medicare Contractor's audit work paper notes, these claims for these six liver transplants were denied by Medicare because they did not meet medical necessity criteria. Because medical necessity is a prerequisite for any Medicare reimbursement, any service or item that is not deemed medically necessary will not be reimbursed—even if listed as a "covered" service or item in the Medicare (or any payer's) plan of benefits. But here, the Medicare Contractor's auditor's notes indicate that these six transplants fell into the "non-covered services" category based on the primary requirement for medical necessity not being met. This is not to be confused with instances where a reimbursement for a covered service is denied because it too did not meet medical necessity criteria or where it did meet medical necessity criteria but other billing or coverage criteria are not met.

⁵¹ *Id.* By contrast to the aforementioned liver transplants, here the auditor's note regarding its review of the EOB indicate that these six organ claims were denied because they failed to meet a claims submission requirement for reimbursement—the provision of a remark code. So here, even if the transplants were deemed medically necessary, the provider failed to properly submit its claims, that is, there was a billing/coding error when the claims were submitted.

The Provider included only one exhibit in the record in relation to this issue, which was a copy of PRM-I, Chapter 31. The Provider did not offer any contractual or patient accounting information in the record demonstrating the Provider's billing attempts, a redacted explanation of benefits, or redacted medical records to support that the transplants at issue in this appeal met all Medicare reimbursement requirements and thus, that the Medicare Contractor's audit work paper notes, regarding the claims denial reasons set forth in the EOBs, were inaccurate.

Additionally, the Board questioned the Provider's representative during the hearing regarding the possibility of other payers to which the Provider replied: "I don't believe there has been any factual information or dispute that Medicare was a payer. It may have been a co-payer, but, in fact, it was a payer or should have been a payer."⁵² To this point, the Board also requested that the Provider representative discuss its interpretation of PRM-I § 3115, specifically the line stating, "Medicare usable organs include.....***organs that had partial payments by a primary insurance payer in addition to Medicare***"⁵³ and whether any payments were made by another payer other than Medicare:

CHAIRMAN SMITH: Do we know that any of these were not totally paid by a primary insurance other than Medicare, based on the record before us that was provided?

MR. SEDLEY: Well, we have verified payer for transplants 1 through 12 in Exhibit C-4 and under the column Verify Payor, it does say Medicare Part A for each one of those.

CHAIRMAN SMITH: Most hospital systems have multiple payers for claims, up to four or five.

MR. SEDLEY: Mm-hmm. Yes, sir.

CHAIRMAN SMITH: So it may be a verified payer, it may not be the only verified payer, and it may not be the primary payer. Is that correct?

MR. SEDLEY: That would be correct. It does not indicate that here. But we can provide that information, as I said, post hearing to the Board.⁵⁴

Also during the hearing, the Board explored the Provider's interpretation of Chapter 31, Section 3101, and its relationship to the timing of reimbursement:

⁵² Tr. at 30:15-19.

⁵³ PRM-1, § 3115 A.

⁵⁴ Tr. at 47:11-48:5.

MS. KELLY: And I think that was the intent that when you procure an organ that it be reasonable and it also be necessary. And I think that that's -- I interpret that that's the reason why you don't get reimbursed for the organ acquisition until you perform the transplant procedure. Would you agree?

MR. SEDLEY: That is correct.

MS. KELLY: Because CMS Medicare program does not want to reimburse for the organ itself until it is transplanted into the intended Medicare beneficiary. And how they determine that is through the billing of the actual transplant. Would you agree?

MR. SEDLEY: That is true.⁵⁵

In addition to the Board's questioning of the Provider representative, the Board notes PRM-1 § 3104, which states:

A provider must submit a bill to Medicare when payment from the primary payer is insufficient to cover the entire cost of a transplant including the DRG and the organ acquisition costs. *However, when the primary insurance requires the acceptance of their payment in full, a bill is not required, because under the contractual agreement, Medicare has no liability because the primary payer has made the payment in full. Accordingly, the organ under the paid in full contractual agreement will not be counted as a Medicare usable organ.*⁵⁶

As the Provider has submitted no additional documentation or internal patient or accounting records to support the claims, the Board cannot determine whether or not there were other payers (either primary or secondary), or whether the Provider was dissatisfied with any alleged primary payer payments. Thus, the Board has no basis to determine whether Medicare was the primary payer or if other payers were involved in these twelve transplant episodes.

Additionally, the Board looks to PRM-1, § 2775.1 (which was in place until April 2016, when Transmittal 471 updated the PRM-1 to move the organ transplant instructions from § 2700 to § 3100). PRM-1, § 2775.1 discusses the process for determining what constitutes a Medicare transplant for reporting on the Medicare Cost Report:

If a Medicare beneficiary has some group health insurance coverage, determining Medicare transplant status depends on the amount paid by the primary insurance. *Specifically, if a*

⁵⁵ *Id.* at 28:10–29:1.

⁵⁶ (Emphasis added).

beneficiary has primary insurance coverage and payment by the primary payer satisfies the liability of the Medicare program, the transplant is considered a non-Medicare transplant for cost reporting purposes. This is consistent with Medicare billing and cost reporting instructions.⁵⁷

Again, the Provider has not demonstrated whether the transplants in question had any other payers or whether it received any payments from other payers, or whether it was dissatisfied with any such payments it received from any other payers. Further, the Provider has not supplied any evidence indicating it did not receive additional organ acquisition reimbursement outside of its claim-based payment from other payers.

Accordingly, the Board looks to 42 C.F.R § 405.1871(a)(3) which discusses the requirements of a Board hearing decision:

(3) The decision must include findings of fact and conclusions of law regarding the Board's jurisdiction over each specific matter at issue (see § 405.1840(c)(1)), and ***whether 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.***⁵⁸

In the Board's view, the Provider has not satisfied its burden of production of evidence and burden of proof that it is entitled to relief to receive payment for organ acquisition costs on these twelve transplant episodes. In fact, the Provider's only substantive exhibit relative to this issue in the appeal is a copy of PRM-I Chapter 31, and the Provider's only argument relies on its interpretation of the manual instructions in order to support the allowance of the organs in question. The Provider had nearly six years, from the time the appeal was received by the Board, to the date of the hearing, to supply additional documentation or evidence that it should be provided relief on the merits of the organ acquisition cost issue. The Provider has provided nothing in the record of this appeal which the Board can evaluate and, thus, has not met its burden of proof.

B. The Provider's transplant claims were denied as not meeting medical necessity or for lack of documentation.

As referenced above, six liver transplant episodes were determined to be non-covered services because they were not deemed a medical necessity by Medicare. Based on the Exhibit C-4, these transplant episodes were denied payment under claim adjustment reason code 50, which states:

These are non-covered services because this is not deemed a 'medical necessity' by the payer. Usage: Refer to the 835

⁵⁷ (Bold and italics emphasis added).

⁵⁸ (Bold and italics emphasis added).

Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.⁵⁹

42 U.S.C. 1395y(a)(1)(A) states:

(a) Items or services specifically excluded

Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B for any expenses incurred for items or services—

(1)(A) which, except for items and services described in a succeeding subparagraph, . . . *are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.*⁶⁰

The Medicare Program Integrity Manual (“PIM”), CMS Pub. 100-08, Chapter 3, further elaborates on payment determination matters, specifically the reasonable and necessary criteria:

CMS issues national coverage determinations (NCDs) that specify whether certain items, services, procedures or technologies are reasonable and necessary under §1862(a) (1) (A) of the Act. In the absence of an NCD, Medicare contractors are responsible for determining whether services are reasonable and necessary. If no local coverage determination (LCD) exists for a particular item or service, the MACs, CERT, Recovery Auditors, and ZPICs shall consider an item or service to be reasonable and necessary if the item or service meets the following criteria:

- It is safe and effective;
- It is not experimental or investigational; and
- It is appropriate, including the duration and frequency in terms of whether the service or item is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the beneficiary's condition or to improve the function of a malformed body member;

⁵⁹ X12 Claim Adjustment Reason Codes. <https://x12.org/codes/claim-adjustment-reason-codes> (Last accessed Sept. 27, 2026).

⁶⁰ (Emphasis added).

- Furnished in a setting appropriate to the beneficiary's medical needs and condition;
- Ordered and furnished by qualified personnel; and,
- One that meets, but does not exceed, the beneficiary's medical need.

There are several exceptions to the requirement that a service be reasonable and necessary for diagnosis or treatment of illness or injury in order to be considered for payment. The exceptions appear in the full text of §1862(a) (1) (A) of the Act. See also PIM chapters 13, §5.1 and 7.1.⁶¹

As shown in Exhibit C-4, the remaining six transplant encounters – two kidney transplants and four liver transplants – were denied under claim adjustment reason code A1, which states:

Claim/Service denied. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Usage: Use this code only when a more specific Claim Adjustment Reason Code is not available.⁶²

As discussed in further detail above, other than the Medicare audit work paper, the Board received no other documents in the record which provided further clarity into why these transplant episodes did not receive Medicare payment, or any contractual or patient accounting information to support the rebilling of these encounters to Medicare.

The Board notes the Provider had one year to bill and rebill Medicare, citing to 42 C.F.R. § 424.44(a):

(1) Except as provided in paragraphs (b) and (e) of this section, for services furnished on or after January 1, 2010, the claim must be filed no later than the close of the period ending 1 calendar year after the date of service.

Again, the Provider did not demonstrate that it met any exceptions to the time limit for billing and rebilling Medicare for these encounters, only noting in its final position paper that upon audit, it supplied “supporting documents, including Medicare HIC number, MedPar data, etc., to prove that these organs were transplanted into Medicare beneficiaries.”⁶³

⁶¹ Medicare Program Integrity Manual, CMS Pub. 100-08, Chapter 3 (Verifying Potential Errors and Taking Corrective Actions), § 3.6.2.2.

⁶² X12 Claim Adjustment Reason Codes. <https://x12.org/codes/claim-adjustment-reason-codes> (Last accessed Sept. 27, 2026).

⁶³ Provider’s FPP at 13.

The Board questioned the Provider's representative regarding the appropriateness of these transplant encounters:

BOARD MEMBER KELLY: Okay. And so if we assume that these transplants -- of course, I would hope that all transplants are necessary, no one wants to have that procedure if it's not necessary. Why would these claims not be paid? Can you tell me -- translate for me, do you understand some of the reasoning? Like on this document when it talks about the absence of -- let me see, what is it? Like a remark code, do you know what that means?

MR. SEDLEY: I'll be honest, I'm not an auditor or consultant. I do not know specifically what it is. The observer who is from the consulting firm is attending, but cannot speak, if he wishes to indicate to me what that is. ***It would appear to be an insufficient documentation was supplied on each of those claims that were submitted, the 11 claims for DRG.***⁶⁴

The Board also notes Houston Methodist's assertion that it had appealed these claims to the Office of Medicare Hearings and Appeals, and, as a result, the Administrative Law Judge ("ALJ") ruled in the Provider's favor in a decision dated March 20, 2020.⁶⁵ However, the Provider never supplied evidence that these claims received Medicare Part A payments. The record does not contain the ALJ decision or "re-processed" claims which would show payment on these claims. Further, the Board notes that while the Provider's Final Position Paper stated that they would "receive Part A payments on these denied claims,"⁶⁶ the Provider's representative stated during the hearing that "[o]ne out of the 12 actually was adjudicated . . . via the administrative law judge process. And that DRG was paid for one transplant, whereas the other 11 [have] not been paid."⁶⁷ It is unclear to the Board if all twelve claims were appealed, as suggested in the Provider's Final Position Paper, or just one, as indicated during the hearing. The record contains no evidence, in either case, of which cases were determined to be payable or were paid.

The Board further questioned the Provider representative on whether the specific reason for denial of these transplant episodes, as explained above, would have bearing on whether organ acquisition costs would thereby be reimbursed:

MR. SEDLEY: [] For this particular case, there's no dispute that each of the 11 patients was a Medicare beneficiary. No doubt about that. Secondly, 1 out of the 12 actually organ transplantations, as I mentioned earlier, was adjudicated, and, in fact, the DRG claim was paid. The DRG claim that would have

⁶⁴ Tr. at 30:20-31:14.

⁶⁵ See *supra* n. 29.

⁶⁶ Provider's FPP at 13.

⁶⁷ Tr. at 34:20-24; see also *id.* at 38:21-39:2.

been submitted appropriately, as I understand, would cover the hospital facility costs and those associated with hospital bed, private bed, and other supplies that were used and other staff that was utilized and employed. That, to me, is separate and apart from the acquisition of the organ that was successfully transplanted into each of these patients, Medicare patients, therefore, and then referring back to [PRM-1 §] 3101 and the language specific there, that is plain and clear to say that the DRG payment and the cost for acquisition are to be deemed separate and individualized. There are two silos: one for DRG, one for organ transplantation costs. We do not get paid for our DRG. We should be paid for our acquisition costs. They have been submitted appropriately to the MAC at a cost of over \$1 million. And we feel that it was appropriately submitted separate and apart from the denial of the DRGs, which is the loss to the hospital, quite frankly. They don't get that revenue or that money back, I should say, but they certainly should for the organ transplantation that were undeniably transplanted in the Medicare beneficiaries.⁶⁸

The Board again looks to PRM-1 § 3101, which provides guidance on the two payment components for organ transplantation, ***and instructs CTCs to develop standard acquisition charges and outlines the procedures for claiming organ procurement costs:***

CTCs must develop two standard acquisition charges (SACs) based on costs expected to be reasonably and necessarily incurred in the acquisition of an organ:

- The SAC for acquiring a living donor organ; and
- The SAC for acquiring a cadaveric donor organ.

The SAC does not represent the acquisition cost of an individual organ. Instead, it is a charge which reflects an average of the total actual costs associated with procuring either a cadaveric donor organs or a living donor organs, by type of organ (e.g., heart, kidney or lung). When a CTC/HOPO provides an organ to another CTC or OPO, it must bill its SAC or its standard departmental charges reduced to cost. When a CTC bills Medicare for the transplant, it must use its SAC for the procured organ and its DRG charge for the transplant.

The costs of procuring an organ cannot be billed directly to the Program because the procurement of an organ is not a covered service when performed independent of a Medicare covered

⁶⁸ *Id.* at 38:21-40:8.

transplant. However, the reasonable costs of procuring an organ are reimbursable when incurred in procuring the organ for a Medicare covered transplant. The costs are paid on an interim basis and reconciled through the MCR at the end of the CTC's cost reporting period.⁶⁹

As previously stated, the Board rejects Houston Methodist's argument that it should be reimbursed for acquisition costs because they are separate and individualized, noting in these instances that the inpatient transplant episode was not paid by Medicare, and further that the record does not support that other payers were not involved.

The Board questioned the Medicare Contractor's representative during the hearing on the precise meaning of a "covered service" under the regulations and about the Medicare Contractor's audit work paper notes regarding the EOB denial reasons:

MR. BAUERS: [] Auditor workpapers are just that. They're not deemed to be legal documents from that perspective. But in items 1 through 5 and 12, clearly the auditor deems that, according to the EOB, the services were non-covered. And then on 6 through 11, the code A1 determined that the claim service was denied. If the claim is denied, by definition, that's not covered. You can't have a claim denied and covered. So by use of the term "denied," that is analogous to not covered. Again, it would be our position that if a claim is denied, it's not covered. You can't have it both ways. It can't be denied and covered. So the non-covered applies to all 12 of these organs. Thank you.⁷⁰

During the hearing, the Board requested post-hearing briefs from the parties on the purported differentiation between a non-covered service and a denied or disallowed service.⁷¹ The Medicare Contractor states, in its post-hearing brief:

There is no dispute that payment for the underlying twelve transplants was "denied or disallowed". The Provider attempts to differentiate "non-covered" from "denied or disallowed" by highlighting that "neither Medicare regulations nor CMS rules or policy couple the Medicare reimbursement for organ acquisition costs with the payment of DRG claims for transplant cases." However, the Provider cannot overcome the plain language of the regulation and the PRM, which both condition reimbursement of organ acquisition costs to "covered transplants". The Provider's argument that transplants which are denied or disallowed are

⁶⁹ (Bold, italics and underline emphasis added).

⁷⁰ Tr. at 53:5-22.

⁷¹ See *id.* at 67:7-20.

somehow simultaneously covered, defies reason and is contrary to the plain language of both the regulation and the PRM.⁷²

The Board disagrees with the Medicare Contractor's contention that a denied service should equate to a non-covered service, as the definitions of a denial versus a non-covered service are not synonymous and have distinct meanings. The Board notes a non-covered service is generally an item or service which Medicare does not cover under statute, regulation or the Medicare benefit policy,⁷³ whereas a denied service is one which is otherwise a Medicare benefit, but for which Medicare determines a payment cannot be made for various reasons, including a failure to meet reasonable and necessary criteria, documentation deficiencies, or unmet coverage criteria for the Medicare beneficiary.

Notwithstanding this distinction, the Provider ultimately failed to demonstrate, by a preponderance of evidence and a sufficiently supported record, that these claims should in fact have been counted as Medicare usable organs on its FY 2016 cost report (including that it was covered by Medicare *and* Medicare paid for the transplant, whether in part or in full). The details of the non-payment of the transplant stays remain unexplained by any evidence that the Provider placed in the record. No evidence such as discharge summary notes signed by a physician, was submitted to indicate that the auditor's notes regarding EOB denial reasons were not reliable as it relates to the determination of whether the organs were Medicare usable organs.

Additionally, the Provider did not offer any evidence that the twelve disallowed organs were discarded, and therefore the organs should remain in the denominator, as total usable organs, when computing its Medicare share.

Finally, were the Board to find in favor of the Provider, where the underlying facts were not sufficiently developed in the record, it would in essence establish a precedent that *any* transplant into a Medicare beneficiary, regardless of whether they had other insurance coverage, would be counted in the numerator of the Medicare ratio, contrary to the intent of the statute. The Board rejects this outcome, noting that the Provider never demonstrated that Medicare was in fact the primary payer in all instances, nor whether other payments were or were not received, either of which could result in the Provider being reimbursed more than is reasonable under the Medicare statute.

DECISION:

After considering Medicare law, regulations, and program guidance, the arguments presented, and the evidence admitted, the Board finds the Medicare Contractor properly calculated the Provider's FY 2016 organ acquisition reimbursement cost.

⁷² Medicare Contractor's PHB at 2-3. *Also see supra* n. 42.

⁷³ The National Coverage Determinations Manual, CMS Pub. 100-03 ("NCD"), sets forth coverage determinations based on the 42 U.S.C. § 1395x(v), including transplants in Chapter 1 § 260.

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FOR THE BOARD:

9/30/2026

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Signed by: KEVIN D. SMITH -A