

## § 413.375

## 42 CFR Ch. IV (10–1–24 Edition)

supplies that ESRD facilities are certified to furnish and that would otherwise be furnished to a beneficiary with AKI in a hospital outpatient setting.

### § 413.375 Notification of changes in rate-setting methodologies and payment rates.

(a) Changes to the methodology for payment for renal dialysis services furnished to beneficiaries with AKI as well as any adjustments to the AKI payment rate other than wage index will be adopted through notice and comment rulemaking.

(b) Annual updates in the AKI dialysis payment rate as described in § 413.372 that do not include those changes described in paragraph (a) of this section are announced by notice published in the FEDERAL REGISTER without opportunity for public comment.

(c) Effective for cost reporting periods beginning on or after January 1, 2017, on an annual basis CMS updates the AKI dialysis payment rate.

### Subpart L—Payment of Organ Acquisition Costs for Transplant Hospitals. Organ Procurement Organizations, and Histocompatibility Laboratories

SOURCE: 86 FR 73515, Dec. 27, 2021, unless otherwise noted.

#### § 413.400 Definitions.

As used in this subpart:

*Histocompatibility laboratory* means a laboratory meeting the requirements set forth in § 493.1227 of this chapter and providing the services for the acquisition of kidneys or other organs for transplantation.

*Hospital-based organ procurement organization (HOPO)* means an organ procurement organization that is considered a department of the TH and reports organ acquisition costs it incurs on the TH's Medicare cost report.

*Independent organ procurement organization (IOPO)* means an organ procurement organization that files a Medicare cost report separate from a hospital and meets all of the following:

(1) Is not subject to the control of a hospital with respect to the hiring, firing, training, and paying of employees.

(2) Is not considered as a department of a hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance).

(3) Reports organ acquisition costs it incurs on the IOPO Medicare cost report.

*Organ*, for Medicare organ acquisition payment purposes, means:

(1) A human kidney, liver, heart, lung, pancreas, or intestine (or multi-visceral organs when transplanted at the same time as an intestine).

(2) Pancreata procured on or after October 1, 2004, for the purpose of acquiring pancreatic islet cells for transplantation into individuals who are participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial in accordance with section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

*Organ procurement organization (OPO)* means an organization defined in § 486.302 of this chapter. OPOs can be independent or hospital based.

*Standard acquisition charge (SAC)* means a charge as defined in § 413.404 of this chapter.

*Transplant hospital (TH)* means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

*Transplant hospital/HOPO (TH/HOPO)* refers to a TH, or a TH that operates a HOPO (as previously defined in this section) and performs organ procurement activities as one entity reported on the TH's Medicare cost report.

*Transplant program* means an organ-specific transplant program within a TH (as defined in this section).

[86 FR 73515, Dec. 27, 2021, as amended at 87 FR 72287, Nov. 23, 2022]

#### § 413.402 Organ acquisition costs.

(a) *Costs related to organ acquisition.* Costs recognized in paragraph (b) of this section are allowable costs incurred in the acquisition of organs intended for transplant, including those

organs that are subsequently determined unsuitable for transplant and furnished for research from a living donor or a deceased donor by the hospital, or from a deceased donor by an OPO. Additionally, there are administrative and general costs that may be allowable and included on the cost report for an OPO or a TH.

(b) *Types of costs.* Organ acquisition costs are as follows:

(1) Tissue typing, including tissue typing furnished by independent laboratories.

(2) Donor and beneficiary evaluation.

(3) Other costs associated with excising organs, such as general routine and special care services (for example, intensive care unit or critical care unit services), provided to the living or deceased donor.

(4) Operating room and other inpatient ancillary services applicable to the living or deceased donor.

(5) Organ preservation and perfusion costs.

(6) Organ Procurement and Transplantation Network registration fees, and the reasonable and necessary cost of other fees, such as the registration fees for a kidney paired exchange, to register candidates for organ transplants. These allowable registry fees must support or promote organ transplantation and must not be duplicative in nature.

(7) Surgeons' fees for excising deceased organs (currently limited to \$1,250 for kidneys).

(8) Transportation of the:

(i) Excised organ to the TH; and

(ii) Deceased donor to procure organs when it is necessary to preserve clinical outcomes or to avoid loss of potentially transplantable organs.

(9) Costs of organs acquired from other hospitals or organ procurement organizations.

(10) Hospital costs normally classified as outpatient costs applicable to organ excisions (services include donor and recipient tissue typing, work-up, and related services furnished prior to inpatient admission).

(11) Costs of services applicable to organ excisions which are rendered by residents and interns not in approved teaching programs.

(12) All pre-admission services applicable to organ excisions, such as laboratory, electroencephalography, and the costs of physicians' services.

(c) *Living donor complications.* (1) *Living kidney donor complications.* Living kidney donor complications directly related to the kidney donation, which occur after the date of the donor's discharge, must not be reported as kidney acquisition costs on the Medicare cost report.

(A) Medicare covers reasonable costs incurred for living kidney donor complications only if they are directly related to a kidney donation for a covered transplant into a Medicare beneficiary.

(B) Living kidney donor complications are paid through the claims processing system under Medicare Part A or Part B, as applicable for the services provided, with no donor liability for deductibles or coinsurance. Living kidney donor complications are billed under the Medicare Beneficiary Identifier of the transplant recipient.

(2) *Living non-renal donor complications.* Hospital costs incurred for living non-renal donor complications directly related to the non-renal organ donation, which occur after the date of the donor's discharge are not paid through the claims processing system but are reported as organ acquisition costs on the hospital's Medicare cost report.

(A) Medicare covers reasonable hospital costs incurred for living non-renal organ donor complications only if they are directly related to a non-renal organ donation for a covered transplant into a Medicare beneficiary.

(B) Hospital costs incurred for living non-renal organ donor complications are reported as organ acquisition costs on the Medicare cost report, and paid through the cost report on a reasonable cost basis.

(d) *Costs not related to organ acquisition.* (1) Items or services that are not related or reasonable to acquire an organ for transplantation, non-allowable administrative and general costs, or costs that are not related to patient care, are not considered organ acquisition costs.

(2) Examples of items or services that are not organ acquisition costs include, but are not limited to the following:

- (i) Donor burial and funeral expenses.
- (ii) Transportation costs of the deceased donor after organ procurement for funeral services or for burial.
- (iii) Transportation costs for a living donor.
- (iv) Fees or in-center payments for donor referrals.
- (v) Costs associated with and incurred for OPO-sponsored seminars where continuing education credits are given and where the attendee is not on the OPO's staff (as described at § 486.326(b)).
- (vi) Unreasonable costs incurred for administrator's duties associated with professional organizations.

[86 FR 73515, Dec. 27, 2021, as amended at 87 FR 72288, Nov. 23, 2022]

**§ 413.404 Standard acquisition charge.**

- (a) *General.* (1) Procuring an organ is not a covered service when performed independent of a Medicare covered transplant, however, the reasonable costs to procure an organ are reimbursable when billed in connection with a Medicare covered transplant.
- (2) The SAC represents the average of the total organ acquisition costs associated with procuring either deceased donor organs or living donor organs, by organ type.
- (3) When a TH/HOPO or IOPO furnishes an organ to another TH/HOPO or IOPO, it bills its SAC to the TH/HOPO or IOPO receiving the organ.
- (b) *THs/HOPOs SACs.* (1) A TH/HOPO must develop a SAC for each organ type (for example heart, liver, or lung).
- (2) When a TH/HOPO furnishes an organ to another TH or IOPO, it must bill the receiving TH or IOPO its SAC by organ type, or the hospital's standard departmental charges that are reduced to cost.
- (3) A TH must establish SACs for living donor organs. A TH/HOPO must establish SACs for deceased donor organs.
- (i) *Living donor SAC for THs—(A) Definition.* The living donor SAC is an average organ acquisition cost that a TH incurs to procure an organ from a living donor.
- (B) *Establishment of living donor SAC.* A TH must establish a living donor SAC before the TH bills its first living donor transplant to Medicare.

(C) *Calculating the living donor SAC.—*  
*(1) Initial living donor SAC.* A TH calculates its initial living donor SAC for each living donor organ type as follows:

- (i) By estimating the reasonable and necessary organ acquisition costs it expects to incur for services furnished to living donors, and pre-admission services furnished to recipients of living donor organs during the hospital's cost reporting period.
- (ii) By dividing the estimated amount described in paragraph (b)(3)(i)(C)(1)(i) of this section by the projected number of usable living donor organs to be procured by the TH during the TH's cost reporting period.

*(2) Subsequent living donor SAC.* A TH calculates its subsequent years' living donor SAC for each living donor organ type as follows:

- (i) By using the TH's actual organ acquisition costs for the living donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year.
- (ii) Dividing the costs in paragraph (b)(3)(i)(C)(2)(i) of this section by the actual number of usable living donor organs procured by the TH during that prior cost reporting period.

(D) *Costs used to develop the living donor SAC.* Costs that may be used to develop the living donor SAC include, but are not limited to the following:

- (1) Costs of tissue typing services, including those furnished by independent laboratories.
- (2) Costs of physician pre-admission transplant evaluation services.
- (3) Registry fees as specified at § 413.402(b)(6) of this subpart.
- (4) Costs for donor and recipient evaluations and workups furnished prior to admission for transplantation.
- (5) Other costs associated with procurement, for example, general routine and special care services (for example, intensive care unit or critical care unit services), related to the donor.
- (6) Costs of operating room and other inpatient ancillary services related to the donor.
- (7) Organ preservation and perfusion costs.
- (8) Transportation costs of the excised organ as specified in § 413.402(b)(8)(i) of this subpart.

(ii) *Deceased donor SAC for TH/HOPOs*—(A) *Definition*. The deceased donor SAC is an average cost that a TH/HOPO incurs to procure a deceased donor organ.

(B) *Calculating the deceased donor SAC*—(1) *Initial deceased donor SAC*. A TH/HOPO calculates its initial deceased donor SAC for each deceased donor organ type as follows:

(i) By estimating the reasonable and necessary costs it expects to incur to procure deceased donor organs, combined with the expected costs of acquiring deceased donor organs from OPOs or other THs.

(ii) By dividing the estimated amount described in paragraph (b)(3)(ii)(B)(1)(i) of this section by the projected number of usable deceased donor organs to be procured by the TH/HOPO within the TH's cost reporting period.

(2) *Subsequent deceased donor SAC*. A TH/HOPO calculates its subsequent years' deceased donor SAC for each deceased donor organ type as follows:

(i) By using the TH's actual organ acquisition costs for the deceased donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year.

(ii) By dividing the costs in paragraph (b)(3)(ii)(B)(2)(i) of this section by the actual number of usable deceased donor organs procured by the TH/HOPO during that prior cost reporting period.

(C) *Costs to develop the deceased donor SAC*. Costs that may be used to develop the deceased donor SAC include, but are not limited to the following:

(1) Costs of organs acquired from other THs or OPOs.

(2) Costs of transportation as specified in §413.402(b)(8).

(3) Surgeons' fees for excising deceased donor organs (currently limited to \$1,250 for kidneys).

(4) Costs of tissue typing services, including those furnished by independent laboratories.

(5) Organ preservation and perfusion costs.

(6) General routine and special care service costs (for example, intensive care unit or critical care unit services related to the donor).

(7) Operating room and other inpatient ancillary service costs.

(c) *Independent OPO SACs*—(1) *Non-renal SAC*. An IOPO establishes non-renal SACs based on its costs of procuring non-renal organs for each organ type, by—

(i) Estimating the reasonable and necessary costs it expects to incur for services furnished to procure deceased donor non-renal organs during the IOPO's cost reporting period; and

(ii) Dividing the amount estimated in paragraph (c)(1)(i) of this section by the projected number of deceased donor non-renal organs the IOPO expects to procure within its cost reporting period.

(iii) An IOPO may adjust its non-renal SACs during the year if necessary to account for cost changes.

(2) *Kidney SAC*. (i) *General*. An IOPO's contractor establishes the kidney SAC based on an estimate of, initial year projected or subsequent years' actual, reasonable and necessary costs the IOPO expects to incur to procure deceased donor kidneys during the IOPO's cost reporting period, divided by the, initial year projected or subsequent years' actual, number of usable deceased donor kidneys the IOPO expects to procure.

(ii) *Initial year*. The contractor develops the IOPO's initial kidney SAC based on the IOPO's budget information.

(iii) *Subsequent years*. The contractor computes the kidney SAC for subsequent years using the IOPO's costs related to kidney acquisition that were incurred in the prior cost reporting period and dividing those costs by the number of usable deceased donor kidneys procured during that cost reporting period. The kidney SAC amount is the interim payment made by the TH or other OPO to the IOPO, as set forth in §413.420(d)(1).

(iv) *SAC adjustments*. The IOPO's contractor may adjust the kidney SAC during the year, if necessary, for cost changes.

(v) The IOPO cannot use or change its kidney SAC without the contractor's approval.

(3) *Billing SACs for organs generally*. When an IOPO obtains an organ from another IOPO, the receiving IOPO is responsible for paying the procuring IOPO's SAC. The receiving IOPO uses

#### § 413.406

#### 42 CFR Ch. IV (10–1–24 Edition)

its SAC for each organ type and not the procuring IOPO's SAC when billing the TH receiving the organ.

[86 FR 73515, Dec. 27, 2021, as amended at 87 FR 72288, Nov. 23, 2022]

#### § 413.406 Acquisition of pancreata for islet cell transplant.

(a) Medicare only covers and pays for reasonable costs of acquisition on or after October 1, 2004, of pancreata for islet cell transplants into Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial of islet cell transplantation in accordance with section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

(b) Pancreata procured under paragraph (a), for covered islet cell transplants must be assigned a full standard acquisition charge and be treated as solid organs for procurement purposes.

#### § 413.408 [Reserved]

#### § 413.410 [Reserved]

#### § 413.412 Intent to transplant, intent for research, counting en bloc, and unusable organs.

(a) *Principles for organs intended for transplant for organ acquisition payment purposes.* (1) An organ is intended for transplant when the OPO or TH designates it for transplant prior to the time the donor enters the hospital's operating room for surgical excision/recovery of the organ(s).

(2) OPOs and THs must identify the costs associated with the recovered and unrecovered organs and apportion those costs to the appropriate cost centers by organ type. These costs include the costs associated with an organ intended for transplant, but subsequently determined unsuitable for transplant and furnished for research.

(3) An organ intended for transplant but subsequently determined unsuitable for transplant and instead furnished for research is not counted as a Medicare usable organ or as a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs.

(4) Subject to paragraph (a)(4)(iii) of this section, OPOs and THs must re-

duce total organ acquisition costs, when the organ is intended for transplant but determined unsuitable for transplant and instead furnished for research, as follows:

(i) By deducting the costs to furnish organs for research from total organ acquisition costs; or

(ii) By offsetting the total organ acquisition costs by the revenue received for these organs.

(iii) In no event may the reduction in total organ acquisition costs as a result of application of paragraph (a)(4) of this section exceed the costs incurred to furnish organs for research.

(5) When the costs to furnish organs for research are not included in total organ acquisition costs but are included in a non-reimbursable cost center, no offset is necessary.

(b) *Principles for organs intended for research for organ acquisition payment purposes.* (1) An organ is intended for research when the OPO or TH designates it for research

prior to the time the donor enters the hospital's operating room for surgical removal of the organ.

(2) Medicare does not share in the acquisition costs of an organ intended for research and costs to procure these organs must not be included in organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)).

(3) An organ intended for research is not counted as a Medicare usable organ or as a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)).

(c) *Counting en bloc organs.* En bloc organs can be en bloc lungs or en bloc kidneys. For Medicare cost allocation purposes, OPOs and THs count -

(1) En bloc lungs or en bloc kidneys procured and transplanted en bloc (two organs transplanted as one unit) as one total usable organ. En bloc organs transplanted into a Medicare beneficiary count as one Medicare usable organ or one Medicare usable kidney.

(2) En bloc lungs and en bloc kidneys procured en bloc but separated and transplanted into two different recipients as two total usable organs. For

each organ transplanted into a Medicare beneficiary, count each as one Medicare usable organ or one Medicare usable kidney.

(d) *Unusable organs.* (1) An organ is not counted as a Medicare usable organ or a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs if a physician determines, upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and is therefore unusable.

(2) OPOs and THs include the cost to procure unusable organs, as described in paragraph (d)(1) of this section, in total organ acquisition costs reported on their Medicare cost report.

[87 FR 72289, Nov. 23, 2022]

**§413.414 Medicare secondary payer and organ acquisition costs.**

(a) *General principle.* If a Medicare beneficiary has a primary health insurer other than Medicare and that primary health insurer has primary liability for the transplant and organ acquisition costs, the Medicare Program may share a liability for organ acquisition costs as a secondary payer to the TH that performs the transplant in certain instances. To determine whether Medicare has liability to the TH that performs the transplant as a secondary payer for organ acquisition costs, it is necessary for the TH that performs the transplant to review the TH's agreement with the primary insurer.

(b) *Medicare has no secondary payer liability for organ acquisition costs.* If the primary insurer's agreement requires the TH to accept the primary insurer's payment as payment in full for the transplant and the associated organ acquisition costs, Medicare has zero liability as a secondary payer with no payment obligation for the transplantation costs or the organ acquisition costs, and the organ at issue is not a Medicare usable organ.

(c) *Medicare may have secondary payer liability for organ acquisition costs.* When the primary insurer's agreement does not require the TH that performs the transplant to accept the payment from the primary insurer as payment in full, and the payment the TH receives from the primary insurer for the transplant

and organ acquisition costs is insufficient to cover the entire cost, Medicare may have a secondary payer liability to the TH that performs the transplant for the organ acquisition costs.

(1) To determine whether Medicare has a secondary payer liability for the organ acquisition costs, it is necessary for the TH that performs the transplant to submit a bill to its contractor and to compare the total cost of the transplant, including the transplant DRG amount and the organ acquisition costs, to the payment received from the primary payer.

(2) If the payment from the primary payer is greater than the cost of the transplant DRG and the organ acquisition costs, there is no Medicare liability and the TH must not count the organ as a Medicare usable organ.

(3) If the payment from the primary payer is less than the transplant DRG and the organ acquisition costs, there is a Medicare secondary payer liability and all of the following must occur:

(i) The TH must pro-rate the payment from the primary payer between the transplant DRG payment and the organ acquisition payment.

(ii) Only the TH that performs the transplant counts the organ as a Medicare usable organ.

(iii) The portion of the payment applicable to organ acquisition is used on the cost report to reduce the Medicare organ acquisition costs.

[86 FR 73515, Dec. 27, 2021, as amended at 87 FR 72289, Nov. 23, 2022]

**§413.416 Organ acquisition charges for kidney-paired exchanges.**

(a) *Initial living donor evaluations.* When a recipient and donor elect to participate in a kidney paired exchange, the costs of the initial living donor evaluations are incurred by the originally intended recipient's TH, regardless of whether the living donor actually donates to their originally intended recipient, a kidney paired exchange recipient, or does not donate at all.

(b) *Additional tests after a match.* In a kidney paired exchange, regardless of whether an actual donation occurs, once the donor and recipient are

matched, any additional tests requested by the recipient's TH and performed by the donor's TH, are billed to the recipient's TH as charges reduced to cost (using the donor's TH's cost to charge ratio) and included as acquisition costs on the recipient TH's Medicare cost report.

(c) *Procurement and transport of a kidney.* When a donor's TH procures and furnishes a kidney to a recipient's TH all of the following are applicable:

(1) All costs must be reasonable and necessary.

(2)(i) The donor's TH bills the recipient's TH.

(ii) The donor's TH bills its charges reduced to cost, or bills its applicable kidney SAC for the reasonable costs associated with procuring, packaging, and transporting the kidney.

(3) The donor's TH records the costs described in paragraph (c)(2)(ii) of this section on its Medicare cost report as kidney acquisition costs and offsets any payments received from the recipient's TH against its kidney acquisition costs.

(4) The recipient's TH records as part of its kidney acquisition costs -

(i) The amounts billed by the donor's TH for the reasonable costs associated with procuring, packaging, and transporting the organ; and

(ii) Any additional testing performed and billed by the donor's TH.

(d) Donor's procurement occurs at recipient TH. In a kidney-paired exchange—

(1) When a donor's TH does not procure a kidney, but the donor travels to the recipient's TH for the organ procurement, the reasonable costs associated with the organ procurement are included on the Medicare cost report of the recipient's TH; and

(2) The travel expenses of the living donor are not allowable Medicare costs.

[86 FR 73515, Dec. 27, 2021, as amended at 87 FR 72290, Nov. 23, 2022]

**§ 413.418 Amounts billed to organ procurement organizations for hospital services provided to deceased donors and included as organ acquisition costs.**

(a) *General.* A donor community hospital (a Medicare-certified non-TH) and a TH incur costs for hospital services

attributable to a deceased donor or a donor whose death is imminent. These services must not be part of medical treatment that primarily offers a medical benefit to the patient as determined by a healthcare team, must be authorized by the OPO, and are included as organ acquisition costs when:

(1) There is consent to donate; and

(2) Declaration of death has been made, or if a declaration of death has not been made, death is imminent and it is necessary that the services be provided prior to declaration of death in order to avoid compromising the viability of the organs for transplant.

(b) *Amounts billed for organ acquisition costs.* When a donor community hospital or TH incurs costs for services furnished to a deceased donor, or a donor whose death is imminent as described in paragraph (a) of this section, as authorized by the OPO, the donor community hospital or TH must bill the OPO the lesser of its customary charges that are reduced to cost by applying its most recently available hospital specific inpatient operating cost-to-charge ratio for the period in which the service was rendered, or a negotiated rate.

[87 FR 72290, Nov. 23, 2022]

**§ 413.420 Payment to independent organ procurement organizations and histocompatibility laboratories for kidney acquisition costs.**

(a) *Principle.* (1) Covered services furnished by IOPOs and histocompatibility laboratories in connection with kidney acquisition and transplantation are reimbursed under the principles for determining reasonable cost contained in this part.

(2) Services furnished by IOPOs and histocompatibility laboratories, that have an agreement with the Secretary in accordance with paragraph (c) of this section, are paid directly by the TH using a kidney SAC (for an IOPO) or contractor-established rates (for a histocompatibility laboratory). (The reasonable costs of services furnished by IOPOs or laboratories are reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.)

(b) *Definitions.* Definitions relevant to this section can be found in § 413.400.

(c) *Agreements with IOPOs and laboratories.* (1) Any IOPO or histocompatibility laboratory that

wishes to have the cost of its pre-transplant services reimbursed under the Medicare program must file an agreement with CMS under which the IOPO or laboratory agrees to do all of the following:

(i) To file a cost report in accordance with §413.24(f) within 5 months following the close of the period covered by the report.

(ii) To permit CMS to designate a contractor to determine the interim reimbursement rate, payable by the THs for services provided by the IOPO or laboratory, and to determine Medicare's reasonable cost based upon the cost report filed by the IOPO or laboratory.

(iii) To provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate.

(iv) To pay to CMS amounts that have been paid by CMS to THs and that are determined to be in excess of the reasonable cost of the services provided by the IOPO or laboratory.

(v) Not to charge any individual for items or services for which that individual is entitled to have payment made under section 1881 of the Act.

(2) The initial cost report due from an IOPO or laboratory is for its first fiscal year during any portion of which it had an agreement with the Secretary under paragraphs (c)(1) and (2) of this section. The initial cost report covers only the period covered by the agreement.

(d) *Interim reimbursement.* (1) THs with approved kidney transplant programs pay the IOPO or histocompatibility laboratory for their pre-transplantation services on the basis of an interim rate established by the contractor for that IOPO or laboratory.

(2) The interim rate is a kidney SAC or contractor established rates, based on costs associated with procuring a kidney for transplantation, incurred by an IOPO or laboratory respectively, during its previous fiscal year. If there is not adequate cost data to determine the initial interim rate, the contractor determines it according to the IOPO's

or laboratory's estimate of its projected costs for the fiscal year.

(3) Payments made by THs on the basis of interim rates are reconciled directly with the IOPO or laboratory after the close of its fiscal year, in accordance with paragraph (e) of this section.

(4) Information on the interim rate for all IOPOs and histocompatibility laboratories must be disseminated to all THs and contractors.

(e) *Retroactive adjustment*—(1) *Cost reports.* Information provided in cost reports by IOPOs and histocompatibility laboratories must meet the requirements for cost data and cost finding specified in §413.24. These cost reports must provide the following:

(i) A complete accounting of the cost incurred by the IOPO or laboratory in providing covered services, the total number of Medicare beneficiaries who received those services.

(ii) Any other data necessary to enable the contractor to determine the reasonable cost of covered services provided to Medicare beneficiaries.

(2) *Audit and adjustment.* A cost report submitted by an IOPO or histocompatibility laboratory is reviewed by the contractor and a new interim reimbursement rate for kidney acquisition costs for the subsequent fiscal year is established based upon this review.

(i) *Retroactive adjustment.* A retroactive adjustment in the amount paid under the interim rate is made in accordance with §413.64(f).

(ii) *Lump sum adjustment.* If the determination of reasonable cost reveals an overpayment or underpayment resulting from the interim reimbursement rate paid to THs, a lump sum adjustment is made directly between that contractor and the IOPO or laboratory.

(f) *Payment requirements.* For services furnished on or after April 1, 1988, no payment may be made for services furnished by an IOPO that does not meet the requirements of part 486, subpart G, of this chapter.

(g) *Appeals.* If the amount in controversy is \$1,000 or more, any IOPO or histocompatibility laboratory that disagrees with a contractor's cost determination under this section is entitled to a contractor hearing, in accordance

**§ 413.420**

**42 CFR Ch. IV (10–1–24 Edition)**

with the procedures set forth in §§ 405.1811 through 405.1833 of this chapter.

[86 FR 73515, Dec. 27, 2021, as amended at 87 FR 72290, Nov. 23, 2022]