

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.