

#### § 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