

records and by which SNFs must submit the requested medical records is as follows:

(i) On an annual basis, a CMS contractor will select up to 1,500 SNFs for validation. A SNF is eligible for selection for a year if it submitted at least one MDS record to CMS in the fiscal year that is 2 years prior to the applicable program year, and if the SNF has been randomly selected for a periodic audit for the same year under §413.338.

(ii) For each SNF selected under this paragraph (g)(1), the CMS contractor will request up to 10 medical records. Each SNF selected will only be required to submit records once in a fiscal year, for a maximum of 10 records for each SNF selected. Each requested medical record must be the same medical record that has been requested for submission by the SNF for the same year under §413.338. CMS will submit its request in writing to the selected SNF.

(iii) A SNF that receives a request for medical records under this paragraph (g)(1) must submit a digital or paper copy of each of the requested medical records within 45 days of the date of the request.

(2) Beginning with the FY 2027 payment year: the information reported through claims for all claims-based measures are validated for accuracy by Medicare Administrative Contractors (MACs).

[82 FR 36634, Aug. 4, 2017, as amended at 83 FR 39290, Aug. 8, 2018; 84 FR 38832, Aug. 7, 2019; 87 FR 47618, Aug. 3, 2022; 88 FR 53346, Aug. 7, 2023; 89 FR 64162, Aug. 6, 2024]

Subpart K—Payment for Acute Kidney Injury (AKI) Dialysis

SOURCE: 81 FR 77965, Nov. 4, 2016, unless otherwise noted.

§413.370 Scope.

This subpart implements section 1834(r) of the Act by setting forth the principles and authorities under which CMS is authorized to establish a payment amount for renal dialysis services furnished to beneficiaries with an acute kidney injury in or under the supervision of an ESRD facility that meets the conditions of coverage in

part 494 of this chapter and as defined in §413.171.

§413.371 Definition.

For purposes of the subpart, the following definition applies:

Individual with acute kidney injury. The term individual with acute kidney injury means an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14) of the Act.

§413.372 AKI dialysis payment rate.

The amount of payment for AKI dialysis services shall be the base rate for renal dialysis services determined for such year under section 1881(b)(14), that is, the ESRD base rate as set forth in §413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in §413.196(d)(1), adjusted for wages as set forth in §413.231, and adjusted by any other amounts deemed appropriate by the Secretary under §413.373.

§413.373 Other adjustments to the AKI dialysis payment rate.

The payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r)) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act.

§413.374 Renal dialysis services included in the AKI dialysis payment rate.

(a) The AKI dialysis payment rate applies to renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or provider of services paid under section 1881(b)(14) of the Act.

(b) Other items and services furnished to beneficiaries with AKI that are not considered to be renal dialysis services as defined in §413.171, but that are related to their dialysis treatment as a result of their AKI, would be separately payable, that is, drugs, biologicals, laboratory services, and

§ 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