

§ 413.370

United States Postal Service, or via email from the CMS Medicare Administrative Contractor (MAC).

(e) *Appeals.* A SNF that is dissatisfied with CMS' decision on a request for reconsideration may file an appeal with the Provider Reimbursement Review Board (PRRB) under 42 CFR part 405, subpart R.

(f) *Data completion threshold.* (1) SNFs must meet or exceed the following data completeness thresholds with respect to a calendar year:

(i) The threshold set at 100 percent completion of measures data and standardized patient assessment data collected using the Minimum Data Set (MDS) on at least 80 percent of the assessments SNFs submit through the CMS designated data submission system for FY 2018 through FY 2025 program years.

(ii) The threshold set at 100 percent completion of measures data and standardized patient assessment data collected using the MDS on at least 90 percent of the assessments SNFs submit through the CMS designated data submission system for FY 2026 and for all subsequent payment updates.

(iii) The threshold set at 100 percent for measures data collected and submitted through the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) for FY 2023 and for all subsequent payment updates.

(2) These thresholds apply to all measures and standardized patient assessment data requirements adopted into the SNF QRP.

(3) A SNF must meet or exceed both thresholds to avoid receiving a 2-percent point reduction to their annual payment update for a given fiscal year.

[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]

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

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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 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 procure-

ment 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