

years. After this period the ESRD facility would follow the general attestation process for the low-volume adjustment specified in paragraph (e) of this section and this paragraph (g).

(iv) The ESRD facility that attests under this paragraph (g)(6) to have closed due to a disaster or other emergency would need to notify CMS and the MAC, in the form and manner specified by CMS, within 30 days reopening and providing renal dialysis services. Within 30 days of CMS's receipt of the facility's notification, CMS will confirm receipt to the facility and the MAC of the facility's notification and the ESRD facility will be able to receive the low-volume adjustment as of the date of reopening, so long as all other requirements for the low-volume adjustment are met.

(v) The ESRD facility must maintain documentation regarding its closure, and must provide such supporting documentation to CMS and/or the MAC upon request.

(h) When an ESRD facility provides an attestation in accordance with paragraph (e) of this section, for the third eligibility year, the MAC verifies the as-filed cost report and takes one of the following actions:

(1) If the MAC determines an ESRD facility meets the definition of a low-volume facility as described in paragraph (b) of this section, CMS adjusts the low-volume facility's base rate for the entire payment year; or

(2) If the MAC determines an ESRD facility does not meet the definition of a low-volume facility as described in paragraph (b) of this section, the MAC reprocesses claims and recoups low-volume adjustments paid during the payment year.

[75 FR 49200, Aug. 12, 2010, as amended at 76 FR 70314, Nov. 10, 2011; 79 FR 66262, Nov. 6, 2014; 80 FR 69076, Nov. 6, 2015; 83 FR 57069, Nov. 23, 2018; 85 FR 71485, Nov. 9, 2020; 88 FR 76505, Nov. 6, 2023]

§413.233 Rural facility adjustment.

CMS adjusts the base rate for facilities in rural areas, as defined in §413.231(b)(2).

[80 FR 69077, Nov. 6, 2015]

§413.234 Drug designation process.

(a) *Definitions.* For purposes of this section, the following definitions apply:

ESRD PPS functional category. A distinct grouping of drugs or biological products, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD.

New renal dialysis drug or biological product. An injectable, intravenous, oral or other form or route of administration drug or biological product that is used to treat or manage a condition(s) associated with ESRD. It must be approved by the Food and Drug Administration (FDA) on or after January 1, 2020, under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, have an HCPCS application submitted in accordance with the official Level II HCPCS coding procedures, and designated by CMS as a renal dialysis service under §413.171. Oral-only drugs are excluded until January 1, 2025.

Oral-only drug. A drug or biological product with no injectable equivalent or other form of administration other than an oral form.

(b) *Drug designation process.* New renal dialysis drugs or biological products are included in the ESRD PPS bundled payment using the following drug designation process:

(1) If the new renal dialysis drug or biological product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new renal dialysis drug or biological product is considered included in the ESRD PPS bundled payment and the following steps occur:

(i) The new renal dialysis drug or biological product is added to an existing ESRD PPS functional category.

(ii) Except as provided in paragraph (e) of this section, the new renal dialysis drug or biological product is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(1) of this section.

(iii) The new renal dialysis drug or biological product is paid for using the add-on payment adjustment described