

authorizes the Secretary to develop a method for controlling unnecessary increases in the volume of covered hospital outpatient department services.

(b) *Scope.* This subpart specifies the process and requirements for prior authorization for certain hospital outpatient department services as a condition of Medicare payment.

§ 419.81 Definitions.

As used in this subpart, unless otherwise specified, the following definitions apply:

List of hospital outpatient department services requiring prior authorization means the list of hospital outpatient department services described in § 419.83(a) that CMS adopts in accordance with § 419.83(b) that require prior authorization as a condition of Medicare payment.

Prior authorization means the process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the service is provided to the beneficiary and before the claim is submitted for processing.

Provisional affirmation means a preliminary finding that a future claim meets the Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act.

§ 419.82 Prior authorization for certain covered hospital outpatient department services.

(a) *Prior authorization as condition of payment.* As a condition of Medicare payment for the services in the categories of services on the list of hospital outpatient department services requiring prior authorization as specified in § 419.83(a), a provider must submit to CMS or its contractors a prior authorization request in accordance with the requirements of paragraph (c) of this section.

(b) *Denial of claim.* (1) CMS or its contractors will deny a claim for a service that requires prior authorization if the provider has not received a provisional affirmation of coverage on the claim from CMS or its contractor unless the provider is exempt under § 419.83(c).

(2) CMS or its contractor may deny a claim that has received a provisional

affirmation based on either of the following:

(i) Technical requirements that can only be evaluated after the claim has been submitted for formal processing; or

(ii) Information not available at the time of a prior authorization request.

(3) CMS or its contractor may deny claims for services related to services on the list of hospital outpatient department services for which the provider has received a denial.

(c) *Submission of prior authorization request.* A provider must submit to CMS or its contractor a prior authorization request for any service on the list of outpatient department services requiring prior authorization.

(1) *Prior authorization request requirements.* A prior authorization request must—

(i) Include all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act.

(ii) Be submitted before the service is provided to the beneficiary and before the claim is submitted.

(2) *Request for expedited review.* A provider may submit a request for expedited review of a prior authorization request. The request for expedited review must comply with the requirements in paragraphs (c)(1)(i) and (ii) of this section and include documentation showing that the processing of the prior authorization request must be expedited due to the beneficiary's life, health, or ability to regain maximum function being in serious jeopardy.

(d) *Reviews—*(1) *Review of prior authorization request.* Upon receipt of a prior authorization request, CMS or its contractor will review the request for compliance with applicable Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act.

(i) CMS or its contractor will issue a provisional affirmation to the provider if it is determined that applicable Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act are met.

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(ii) CMS or its contractor will issue a non-affirmation to the provider if it is determined that applicable Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act are not met.

(iii) The provisional affirmation or non-affirmation will be issued within 10 business days of receipt of the prior authorization request.

(2) *Review of expedited review request.* Upon receipt of a request for expedited review, CMS or its contractor will complete an expedited review of the prior authorization request if it is determined that a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function, and issue a provisional affirmation or non-affirmation decision in accordance with paragraph (d)(1) of this section within 2 business days of the expedited review request.

(e) *Resubmission.* (1) A provider may resubmit a prior authorization request, upon receipt of a non-affirmation, consistent with the requirements in paragraph (c)(1) of this section.

(2) A provider may resubmit a request for expedited review consistent with the requirements in paragraph (c)(1) of this section.

§ 419.83 List of hospital outpatient department services requiring prior authorization.

(a) *Service categories for the list of hospital outpatient department services requiring prior authorization.* (1) The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2020:

- (i) Blepharoplasty.
- (ii) Botulinum toxin injections.
- (iii) Panniculectomy.
- (iv) Rhinoplasty.
- (v) Vein ablation.

(2) The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2021:

- (i) Cervical Fusion with Disc Removal.
- (ii) Implanted Spinal Neurostimulators.

(3) The Facet Joint Interventions service category requires prior authorization beginning for service dates on or after July 1, 2023.

(b) *Adoption of the list of services and technical updates.* (1) CMS will adopt the list of hospital outpatient department service categories requiring prior authorization and any updates or geographic restrictions through formal notice-and-comment rulemaking.

(2) Technical updates to the list of services, such as changes to the name of the service or Current Procedural Terminology (CPT) code, will be published on the CMS website.

(c) *Exemptions.* CMS may elect to exempt a provider from the prior authorization process in § 419.82 upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act through such prior authorization process.

(1) An exemption will remain in effect until CMS elects to withdraw the exemption.

(2) Notice of an exemption or withdrawal of an exemption will be provided at least 60 days prior to the effective date.

(d) *Suspension of prior authorization process or services.* CMS may suspend the outpatient department services prior authorization process requirements generally or for a particular service(s) at any time by issuing notification on the CMS website.

[84 FR 61491, Nov. 12, 2019, as amended at 85 FR 86303, Dec. 29, 2020; 87 FR 72292, Nov. 23, 2022]

§§ 419.84–419.89 [Reserved]

Subpart J—Payments to Rural Emergency Hospitals (REHs)

SOURCE: 87 FR 72292, Nov. 23, 2022, unless otherwise noted.

§ 419.90 Basis and scope of subpart.

(a) *Basis.* This subpart implements sections 1861(kkk) and 1834(x) of the Act, which establish the rural emergency hospital Medicare provider type and the payment requirements applying to such entities.

(b) *Scope.* This subpart describes the methodologies used to determine payment for REH services and the monthly facility payment amount paid to REHs.

§ 419.91 Definitions.

As used in this subpart—

Rural emergency hospital or REH means an entity as defined in § 485.502 of this chapter.

Rural emergency hospital (REH) services means all covered outpatient department (OPD) services, as defined in section 1833(t)(1)(B) of the Act, excluding services described in section 1833(t)(1)(B)(ii), furnished by an REH that would be paid under the outpatient prospective payment system (OPPS) when provided in a hospital paid under the OPPS for outpatient services, provided that such services are furnished consistent with the conditions of participation at §§ 485.510 through 485.544 of this chapter.

§ 419.92 Payment to rural emergency hospitals.

(a) *Payment for REH services—(1) Medicare payment.* A rural emergency hospital that furnishes a REH service on or after January 1, 2023, is paid an amount equal to the amount of payment that would otherwise apply under section 1833(t) of the Act for the equivalent covered OPD service, increased by 5 percent.

(2) *Beneficiary copayment.* The beneficiary copayment for a REH service is the amount determined under section 1833(t)(8) of the Act for the equivalent covered OPD service, excluding the 5 percent payment increase described in paragraph (a)(1) of this section.

(b) *Monthly facility payment.* Effective January 1, 2023, REHs are paid a monthly facility payment equal to $\frac{1}{12}$ of the annual additional facility payment amount described in paragraphs (b)(1) and (2) of this section.

(1) *Calculation of monthly facility payment for 2023.* For calendar year 2023, the annual additional facility payment amount is:

(i) The total amount that the Secretary determines was paid by the Medicare program and from beneficiary copayments to all critical access hospitals in calendar year 2019; minus

(ii) The estimated total amount that the Secretary determines would have been paid by the Medicare program and from beneficiary copayments to critical access hospitals in calendar year 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems for such services during calendar year 2019; divided by

(iii) The total number of critical access hospitals enrolled in Medicare in calendar year 2019.

(2) *Calculation of monthly facility payment for 2024 and subsequent years.* For calendar year 2024 and each subsequent calendar year, the amount of the additional annual facility payment is the amount of the preceding year's additional annual facility payment, increased by the hospital market basket percentage increase as described under section 1886(b)(3)(B)(iii) of the Act.

(3) *Recording and Reporting the use of the monthly facility payment.* A rural emergency hospital receiving the monthly facility payment must maintain detailed information as specified by the Secretary as to how the facility has used the monthly facility payments and must make this information available to the Secretary upon request.

(c) *Payment for services furnished by an REH that do not meet the definition of REH services.* A service furnished by an REH that does not meet the definition of an REH service under § 419.91, including a hospital service that is excluded from payment under the OPPS as described in § 419.22, is paid for under the payment system applicable to the service, provided the requirements for payment under that system are met.

(1) *Payment for ambulance services.* Ambulance services furnished by an entity owned and operated by a rural emergency hospital are paid under the ambulance fee schedule as described at section 1834(l) of the Act.

(2) *Payment for post-hospital extended care services.* Post-hospital extended care services furnished by a rural emergency hospital that has a unit that is a distinct part licensed as a skilled nursing facility are paid under the skilled nursing facility prospective payment

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system described at section 1888(e) of the Act.

(d) *REH payment for the costs of graduate medical education.* (1) For portions of cost reporting periods beginning on or after October 1, 2023, an REH that incurs costs of training full-time equivalent (FTE) residents that rotate to the REH may receive direct graduate medical education payments for those costs.

(2) Payment is equal to the Medicare reasonable costs that the REH incurs to train the FTE residents that rotate to the REH, as determined in accordance with section 1861(v)(1)(A) of the Act and the applicable principles of cost reimbursement in part 413 of this chapter, except that the following payment principles are excluded:

(i) Lesser of cost or charges.

(ii) Ceilings on hospital operating costs.

(3) An REH that does not incur costs of training FTE residents that rotate to the REH is considered a nonprovider setting for purposes of graduate medical education payments, consistent with §§ 412.105(f)(1)(ii)(E) and 413.78(g) of this chapter.

(4) Direct graduate medical education payments to REHs made under this section are made from the Federal Hospital Insurance Trust Fund.

(e) *Payment for Indian Health Service (IHS) or tribal REHs.* An IHS or tribal REH, as defined in paragraph (f) of this section will be paid under the outpatient hospital All-Inclusive Rate that is established and published annually by the IHS rather than the rates for REH services described in paragraph (a)(1) of this section.

(f) *IHS or tribal REHs.* An IHS or tribal REH is an REH, as defined in § 485.502 of this chapter, that is operated by the IHS or by a tribe or tribal organization with funding authorized by Title I or V of the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638).

[87 FR 72292, Nov. 23, 2022, as amended at 88 FR 59335, Aug. 28, 2023; 88 FR 82181, Nov. 22, 2023]

§ 419.93 Payment for an off-campus provider-based department of a rural emergency hospital.

(a) Items and services furnished by an off-campus provider-based department of an REH, as defined in paragraph (b) of this section, are not applicable items and services under sections 1833(t)(1)(B)(v) and (t)(21) of the Act and are paid as follows:

(1) REH services furnished by an off-campus provider-based department of an REH are paid as described in § 419.92(a)(1).

(2) Services that do not meet the definition of REH services under § 419.91 that are furnished by an off-campus provider-based department of an REH are paid as described under § 419.92(c) or, if applicable, § 419.92(e).

(b) For the purpose of this section, “off-campus provider-based department of an REH” means a “department of a provider” (as defined at § 413.65(a)(2) of this chapter) that is not located on the campus (as defined in § 413.65(a)(2) of this chapter) or within the distance described in such definition from a “remote location of a hospital” (as defined in § 413.65(a)(2) of this chapter) that meets the requirements for provider-based status under § 413.65 of this chapter.

[87 FR 72292, Nov. 23, 2022, as amended at 88 FR 82181, Nov. 22, 2023]

§ 419.94 Preclusion of administrative and judicial review.

There is no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

(a) The determination of whether a rural emergency hospital meets the requirements of this subpart.

(b) The determination of payment amounts under this subpart.

(c) The requirements established by this subpart.

§ 419.95 Requirements under the Rural Emergency Hospital Quality Reporting (REHQR) Program.

(a) *Statutory authority.* Section 1861(kkk)(7) of the Social Security Act authorizes the Secretary to implement a quality reporting program requiring Rural Emergency Hospitals (REHs) to submit data on measures in accordance

with the Secretary's requirements in this part.

(b) *Participation in the REHQR Program.* To participate in the REHQR Program, an REH as defined in section 1861(kkk)(2) of the Act must—

(1) Register on a CMS website before beginning to report data;

(2) Identify and register a security official as part of the registration process under paragraph (b)(1) of this section; and

(3) Submit data on all quality measures to CMS as specified under paragraph (c) of this section.

(c) *Submission of REHQR Program data—(1) General rule.* REHs that participate in the REHQR Program must submit to CMS data on measures selected under section 1861(kkk)(7)(C) of the Act in a form and manner and at a time specified by CMS. REHs sharing the same CMS Certification Number (CCN) must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes.

(2) *Submission deadlines.* Submission deadlines by measure and by data type are posted on a CMS website. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a non-work day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a non-work day for Federal employees by statute or Executive order.

(3) *Review and corrections period.* For all quality data submitted, REHs will have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, REHs can enter, review, and correct data submitted. However, after the submission deadline, these data cannot be changed.

(d) *Technical specifications and measure maintenance under the REHQR Program.* (1) CMS will update the specifications manual for measures in the REHQR Program at least every 12 months.

(2) CMS follows different procedures to update the measure specifications of a measure previously adopted under

the REHQR Program based on whether the change is substantive or non-substantive. CMS will determine what constitutes a substantive versus a non-substantive change to a measure's specifications.

(i) *Substantive changes.* CMS will use rulemaking to adopt substantive updates to measures in the REHQR Program.

(ii) *Non-substantive changes.* If CMS determines that a change to a measure previously adopted in the REHQR Program is non-substantive, CMS will use a sub-regulatory process to revise the specifications manual for the REHQR Program so that it clearly identifies the change to that measure and provide links to where additional information on the change can be found. When a measure undergoes sub-regulatory maintenance, CMS will provide notification of the measure specification update on a designated website and in the specifications manual and will provide sufficient lead time for REHs to implement the revisions where changes to the data collection systems would be necessary.

(e) *Retention and removal of quality measures under the REHQR Program—(1) General rule for the retention of quality measures.* Quality measures adopted for the REHQR Program measure set are retained for use, except when they are removed, suspended, or replaced as set forth in paragraphs (e)(2) and (3) of this section.

(2) *Immediate measure suspension from reporting.* In cases where CMS believes that the collection and reporting activities related to a quality measure as specified raises patient safety concerns, CMS will immediately suspend the measure from the REHQR Program and will promptly notify REHs and the public of the suspension of the measure. CMS will address the suspension and propose any permanent action regarding the measure in the next appropriate rulemaking cycle.

(3) *Measure removal, suspension, or replacement through the rulemaking process.* Unless a measure raises specific safety concerns as set forth in paragraph (e)(2) of this section, CMS will use rulemaking to remove, suspend, or replace quality measures in the REHQR Program.