

(13) Gross drug cost.

§ 425.708 Beneficiaries may decline claims data sharing.

(a) Beneficiaries must receive notification about the Shared Savings Program and the opportunity to decline claims data sharing and instructions on how to inform CMS directly of their preference.

(1) FFS beneficiaries are notified about the opportunity to decline claims data sharing through CMS materials such as the Medicare & You Handbook and through the notifications required under § 425.312.

(2) The notifications provided under § 425.312 must state that the ACO may have requested beneficiary identifiable claims data about the beneficiary for purposes of its care coordination and quality improvement work, and inform the beneficiary how to decline having his or her claims information shared with the ACO in the form and manner specified by CMS.

(3) Beneficiary requests to decline claims data sharing will remain in effect unless and until a beneficiary subsequently contacts CMS to amend that request to permit claims data sharing with ACOs.

(b) The opportunity to decline having claims data shared with an ACO under paragraph (a) of this section does not apply to the information that CMS provides to ACOs under § 425.702(c).

(c) In accordance with 42 U.S.C. 290dd-2 and the implementing regulations at 42 CFR part 2, CMS does not share beneficiary identifiable claims data relating to the diagnosis and treatment of alcohol and substance abuse without the explicit written consent of the beneficiary.

(d) The provisions of this section relate only to the sharing of Medicare claims data between the Medicare program and the ACO under the Shared Savings Program and are in no way intended to impede existing or future data sharing under other authorities.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32840, June 9, 2015]

§ 425.710 Data use agreement.

(a)(1) Before receiving any beneficiary identifiable data, ACOs must enter into a DUA with CMS. Under the

DUA, the ACO must comply with the limitations on use and disclosure that are imposed by HIPAA, the applicable DUA, and the statutory and regulatory requirements of the Shared Savings Program.

(2) If the ACO misuses or discloses data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the DUA, it will no longer be eligible to receive data under subpart H of this part, may be terminated from the Shared Savings Program under § 425.218, and may be subject to additional sanctions and penalties available under the law.

(b) [Reserved]

Subpart I—Reconsideration Review Process

§ 425.800 Preclusion of administrative and judicial review.

(a) There is no reconsideration, appeal, or other administrative or judicial review of the following determinations under this part:

(1) The specification of quality and performance standards under §§ 425.500, 425.502, 425.510, and 425.512.

(2) The assessment of the quality of care furnished by an ACO under the performance standards established in § 425.502 or § 425.512, as applicable.

(3) The assignment of Medicare fee-for-service beneficiaries under Subpart E of this part.

(4) The initial determination or revised initial determination of whether an ACO is eligible for shared savings, and the amount of such shared savings, including the initial determination or revised initial determination of the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries assigned to the ACO and the average benchmark for the ACO in accordance with section 1899(d) of the Act, as implemented under §§ 425.601, 425.602, 425.603, 425.604, 425.605, 425.606, 425.610, and 425.652.

(5) The percent of shared savings specified by the Secretary and the limit on the total amount of shared savings established under §§ 425.604, 425.605, 425.606, and 425.610.

§ 425.802

(6) The termination of an ACO for failure to meet the quality performance standards established under § 425.502 or § 425.512, as applicable.

(7) The termination of a beneficiary incentive program established under § 425.304(c).

(b) [Reserved]

[76 FR 67973, Nov. 2, 2011, as amended at 81 FR 38017, June 10, 2016; 83 FR 68082, Dec. 31, 2018; 85 FR 85044, Dec. 28, 2020; 87 FR 70249, Nov. 18, 2022]

§ 425.802 Request for review.

(a) An ACO may appeal an initial determination that is not prohibited from administrative or judicial review under § 425.800 by requesting a reconsideration review by a CMS reconsideration official.

(1) An ACO that wants to request reconsideration review by a CMS reconsideration official must submit a written request by an authorized official for receipt by CMS within 15 days of the notice of the initial determination.

(i) If the 15th day is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(ii) Failure to submit a request for reconsideration within 15 days will result in denial of the request for reconsideration.

(2) The reconsideration review must be held on the record (review of submitted documentation).

(b) An ACO that requests a reconsideration review for termination will remain operational throughout the review process.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32845, June 9, 2015]

§ 425.804 Reconsideration review process.

(a) *Acknowledgement of reconsideration review request.* The reconsideration official sends an acknowledgement of the reconsideration review request to the ACO and CMS that includes the following:

(1) Review procedures.

(2) Procedures for submission of evidence including format and timelines.

(3) A briefing schedule that permits each party to submit only one written brief, including any evidence, for consideration by the reconsideration official

42 CFR Ch. IV (10–1–23 Edition)

in support of the party's position. The submission of any additional briefs or supplemental evidence will be at the sole discretion of the reconsideration official.

(b) *Burden of proof, standard of proof, and standards of review.* The burden of proof is on the ACO to demonstrate to the reconsideration official with convincing evidence that the initial determination is not consistent with the requirements of this part or applicable statutory authority.

(c) *Reconsideration official.* The reconsideration official is an independent CMS official who did not participate in the initial determination that is being reviewed.

(d) *Evidence.* (1) The reconsideration official's review will be based only on evidence submitted by the reconsideration official's requested deadline, unless otherwise requested by the reconsideration official.

(2) Documentation submitted for the record as evidence cannot be documentation that was not previously submitted to CMS by the applicable deadline and in the requested format.

(3) All evidence submitted by the ACO and CMS, in preparation for the reconsideration review will be shared with the other party to the hearing.

(e) The reconsideration official will notify CMS and the ACO of his or her recommendation.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32845, June 9, 2015]

§ 425.806 On-the-record review of reconsideration official's recommendation by independent CMS official.

(a)(1) If CMS or the ACO disagrees with the recommendation of the reconsideration official, it may request an on the record review of the initial determination and recommendation by an independent CMS official who was not involved in the initial determination or the reconsideration review process.

(2) In order to request an on-the-record review, CMS or the ACO must submit an explanation of why it disagrees with the recommendation by the timeframe and in the format indicated in the reconsideration official's recommendation letter.

(b) The on-the-record review process is based only on evidence presented during the reconsideration review.

(c) The independent CMS official considers the recommendation of the reconsideration official and makes a final agency determination.

§ 425.808 Effect of independent CMS official's decision.

(a) The decision of the independent CMS official is final and binding.

(b) The reconsideration review process under this subpart must not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by other government agencies.

§ 425.810 Effective date of decision.

(a) If the initial determination denying an ACO's application to participate in the Shared Savings Program is upheld, the application will remain denied based on the effective date of the original notice of denial.

(b) If the initial determination to terminate an agreement with an ACO is upheld, the decision to terminate the agreement is effective as of the date indicated in the initial notice of termination.

(c) If the initial determination to terminate an ACO is reversed, the ACO is reinstated into the Shared Savings Program, retroactively back to the original date of termination.

PART 426—REVIEW OF NATIONAL COVERAGE DETERMINATIONS AND LOCAL COVERAGE DETERMINATIONS

Subpart A—General Provisions

Sec.

- 426.100 Basis and scope.
- 426.110 Definitions.
- 426.120 Calculation of deadlines.
- 426.130 Party submissions.

Subpart B [Reserved]

Subpart C—General Provisions for the Review of LCDs and NCDs

- 426.300 Review of LCDs, NCDs, and deemed NCDs.
- 426.310 LCD and NCD reviews and individual claim appeals.

- 426.320 Who may challenge an LCD or NCD.
- 426.325 What may be challenged.
- 426.330 Burden of proof.
- 426.340 Procedures for review of new evidence.

Subpart D—Review of an LCD

- 426.400 Procedure for filing an acceptable complaint concerning a provision (or provisions) of an LCD.
- 426.403 Submitting new evidence once an acceptable complaint is filed.
- 426.405 Authority of the ALJ.
- 426.406 *Ex parte* contacts.
- 426.410 Docketing and evaluating the acceptability of LCD complaints.
- 426.415 CMS' role in the LCD review.
- 426.416 Role of Medicare Managed Care Organizations (MCOs) and State agencies in the LCD review.
- 426.417 Contractor's statement regarding new evidence.
- 426.418 LCD record furnished to the aggrieved party.
- 426.419 LCD record furnished to the ALJ.
- 426.420 Retiring or revising an LCD under review.
- 426.423 Withdrawing a complaint regarding an LCD under review.
- 426.425 LCD review.
- 426.431 ALJ's review of the LCD to apply the reasonableness standard.
- 426.432 Discovery.
- 426.435 Subpoenas.
- 426.440 Evidence.
- 426.444 Dismissals for cause.
- 426.445 Witness fees.
- 426.446 Record of hearing.
- 426.447 Issuance and notification of an ALJ's decision.
- 426.450 Mandatory provisions of an ALJ's decision.
- 426.455 Prohibited provisions of an ALJ's decision.
- 426.457 Optional provisions of an ALJ's decision.
- 426.458 ALJ's LCD review record.
- 426.460 Effect of an ALJ's decision.
- 426.462 Notice of an ALJ's decision.
- 426.463 Future new or revised LCDs.
- 426.465 Appealing part or all of an ALJ's decision.
- 426.468 Decision to not appeal an ALJ's decision.
- 426.470 Board's role in docketing and evaluating the acceptability of appeals of ALJ decisions.
- 426.476 Board review of an ALJ's decision.
- 426.478 Retiring or revising an LCD during the Board's review of an ALJ's decision.
- 426.480 Withdrawing an appeal of an ALJ's decision.
- 426.482 Issuance and notification of a Board decision.
- 426.484 Mandatory provisions of a Board decision.