

(3) The beneficiary did not exercise the opportunity to decline having his/her claims data shared with the ACO as provided in § 425.708.

(e) At the ACO's request, CMS continues to provide ACOs with updates to the requested beneficiary identifiable claims data, subject to beneficiary's opportunity to decline data sharing under § 425.708.

(f) If an ACO requests beneficiary identifiable information, compliance with the terms of the data use agreement described in § 425.710 is a condition of an ACO's participation in the Shared Savings Program.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32844, June 9, 2015; 83 FR 68082, Dec. 31, 2018; 87 FR 70249, Nov. 18, 2022]

§ 425.706 Minimum necessary data.

(a) ACOs must limit their identifiable data requests to the minimum necessary to accomplish a permitted use of the data. The minimum necessary Parts A and B data elements may include but are not limited to the following data elements:

- (1) Beneficiary ID.
- (2) Procedure code.
- (3) Gender.
- (4) Diagnosis code.
- (5) Claim ID.
- (6) The from and through dates of service.
- (7) The provider or supplier ID.
- (8) The claim payment type.
- (9) Date of birth and death, if applicable.
- (10) TIN.
- (11) NPI.

(b) The minimum necessary Part D data elements may include but are not limited to the following data elements:

- (1) Beneficiary ID.
- (2) Prescriber ID.
- (3) Drug service date.
- (4) Drug product service ID.
- (5) Quantity dispensed.
- (6) Days supplied.
- (7) Brand name.
- (8) Generic name.
- (9) Drug strength.
- (10) TIN.
- (11) NPI.
- (12) Indication if on formulary.
- (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

§ 425.800

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.

(6) The termination of an ACO for failure to meet the quality perform-

42 CFR Ch. IV (10–1–24 Edition)

ance 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 in support of the party's position. The submission of any additional briefs