§ 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.
   (12) Indication if on formulary.
   (13) Gross drug cost.

(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.

§ 425.708 Beneficiaries may decline data sharing.

(a) Before requesting claims data about a particular beneficiary, the ACO must inform the beneficiary that it may request personal health information about the beneficiary for purposes of its care coordination and quality improvement work, and give the beneficiary meaningful opportunity to decline having his/her claims information shared with the ACO.

(b) ACOs may contact preliminarily prospective assigned beneficiaries in writing to request data sharing.

(1) If these beneficiaries do not decline within 30 days after the letter is sent, the ACO may request identifiable claims data from CMS.

(2) These beneficiaries must also be provided a form explaining the beneficiary’s opportunity to decline data sharing as part of their first primary care service visit with an ACO participant upon whom assignment is based (under Subpart E of this part) during the agreement period.

(c) For beneficiaries that have a primary care service office visit with an ACO participant who provides primary care services, the ACO must supply the beneficiaries with a written notification explaining their opportunity to decline data sharing. The form must be provided to each beneficiary as part of their first primary care service visit with an ACO participant upon whom assignment is based (under Subpart E of this part) during the agreement period.

(d) The requirements specified in paragraphs (a) through (c) of this section do not apply to the initial identifiable data points that CMS provides to ACOs under § 425.702(d).

(e) CMS does not share beneficiary identifiable claims data relating to treatment for alcohol and substance abuse in accordance with 42 CFR 290dd–2 and the implementing regulations at 42 CFR part 2.

(f) 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.

§ 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.