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## 42 C.F.R. § 423.514

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### Validation of Part D reporting requirements.

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(a) *Required information.* Each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, information indicating the following—

- (1) The cost of its operations.
- (2) The procedures related to and utilization of its services and items.
- (3) The availability, accessibility, and acceptability of its services.
- (4) Information demonstrating that the Part D plan sponsor has a fiscally sound operation.
- (5) Pharmacy performance measures.
- (6) Other matters that CMS may require.

(b) *Significant business transactions.* Each Part D plan sponsor must report to CMS annually, within 120 days of the end of its fiscal year (unless, for good cause shown, CMS authorizes an extension of time), the following:

- (1) A description of significant business transactions, as defined in § 423.501, between the Part D plan sponsor and a party in interest, including the following:
  - (i) Indication that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or
  - (ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

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