

§ 423.506

42 CFR Ch. IV (10–1–10 Edition)

§ 423.322(b) of this part must not be construed to limit the Secretary's authority to use the information collected under paragraph (f)(3).

(m)(1) CMS may release the minimum data necessary for a given purpose from the data collected under paragraph (f)(3) of this section to Federal executive branch agencies, States, and external entities in accordance with the following:

(i) Applicable Federal laws.

(ii) CMS data sharing procedures.

(iii) Subject, in certain cases, to encryption of certain identifiers and aggregation of cost data to protect beneficiary confidentiality and commercially sensitive data of Part D sponsors, in accordance with all of the following principles:

(A) Subject to the restrictions in this paragraph, all elements on the claim are available to HHS.

(B) Cost data elements on the claim generally are aggregated for releases to other executive branch agencies, States, and external entities.

(C) Plan identifier elements on the claim are encrypted or unavailable for release to external entities with the exception of HHS grantees that CMS determines meet all of the following criteria:

(1) The plan identifier is essential to the study.

(2) The study is key to the mission of the sponsoring agency.

(3) The study provides significant benefit to the Medicare program.

(4) The requestor attests that any public findings or publications will not identify plans.

(D) Beneficiary, pharmacy, and prescriber identifier elements on the claim generally are encrypted for releases to external entities, except in limited circumstances, such as to link to another data set.

(iv) For purposes of paragraph (m)(1)(iii) of this section, States and executive-branch Federal agencies are not considered to be external entities.

(2) Any restriction set forth by § 423.322(b) of this part must not be construed to limit the Secretary's authority to release the information collected under paragraph (f)(3) of this section.

(3) CMS shall make available to Congressional support agencies (the Con-

gressional Budget Office, the Government Accountability Office, the Medicare Payment Advisory Commission, and the Congressional Research Service when it is acting on behalf of a Congressional committee in accordance with 2 U.S.C. 166(d)(1)) all information collected under paragraph (f)(3) of this section for the purposes of conducting congressional oversight, monitoring, making recommendations, and analysis of the Medicare program.

(n)(1) CMS may determine that a Part D plan sponsor is out of compliance with a Part D requirement when the sponsor fails to meet performance standards articulated in the Part D statutes, regulations, or guidance.

(2) If CMS has not already articulated a measure for determining non-compliance, CMS may determine that a Part D sponsor is out of compliance when its performance in fulfilling Part D requirements represents an outlier relative to the performance of other Part D sponsors.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 73 FR 30683, May 28, 2008; 73 FR 54251, Sept. 18, 2008; 73 FR 70599, Nov. 21, 2008; 74 FR 1545, Jan. 12, 2009; 75 FR 19821, Apr. 15, 2010]

§ 423.506 Effective date and term of contract.

(a) *Effective date.* The contract is effective on the date specified in the contract between the Part D plan sponsor and CMS.

(b) *Term of contract.* Each contract is for a period of 12 months.

(c) *Qualification to renew a contract.* In accordance with 423.507, an entity is determined qualified to renew its contract annually only if the Part D plan sponsor has not provided CMS with a notice of intention not to renew and CMS has not provided the Part D organization with a notice of intention not to renew.

(d) *Renewal of contract contingent on reaching agreement on the bid.* Although a Part D plan sponsor may be determined qualified to renew its contract under this section, if the sponsor and CMS cannot reach agreement on the bid under subpart F, no renewal takes place, and the failure to reach agreement is not subject to the appeals provisions in subpart N of this part.

(e) The provisions of this section do not apply to fallback entities.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68732, Dec. 5, 2007]

§ 423.507 Nonrenewal of contract.

(a) *Nonrenewal by a Part D plan sponsor.* (1) Except for fallback entities, a Part D plan sponsor may elect not to renew its contract with CMS, effective at the end of the term of the contract for any reason provided it meets the timeframes for doing so set forth in paragraphs (a)(2) and (a)(3) of this section.

(2) If a Part D plan sponsor does not intend to renew its contract, it must notify—

(i) CMS in writing by the first Monday of June in the year in which the contract ends;

(ii) Each Medicare enrollee by mail at least 90 calendar days before the date on which the nonrenewal is effective. The sponsor must also provide information about alternative enrollment options by doing one or more of the following:

(A) Provide a CMS approved written description of alternative MA plan and PDP options available for obtaining qualified prescription drug coverage within the beneficiaries' region.

(B) Place outbound calls to all affected enrollees to ensure beneficiaries know who to contact to learn about their enrollment options.

(3) If a Part D plan sponsor does not renew a contract under this paragraph (a), CMS cannot enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

(4) If a Part D plan sponsor does not renew a contract under this paragraph (a), it must ensure the timely transfer of any data or files.

(b) *CMS decision that a Part D plan sponsor is not qualified to renew.* (1) Except for fallback entities, CMS may determine that a Part D plan sponsor is not qualified to renew its contract for any of the following reasons:

(i) The reasons listed in § 423.509(a) that also permit CMS to terminate the contract.

(ii) The Part D plan sponsor has committed any of the acts in § 423.752 that

support the imposition of intermediate sanctions or civil money penalties under § 423.750.

(iii) The contract must be non-renewed as to an individual PDP if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

(2) *Notice of non-renewal.* CMS provides notice of its decision not to authorize renewal of a contract as follows:

(i) To the Part D plan sponsor by August 1 of the contract year.

(ii) To each of the Part D plan sponsor's Medicare enrollees by mail at least 90 calendar days before the date on which the nonrenewal is effective, or at the conclusion of the appeals process if applicable.

(iii) The notice provisions in paragraph (b)(2)(ii) of this section also apply in cases where a non-renewal results because CMS and the Part D plan sponsor are unable to reach agreement on the bid under subpart F.

(3) *Opportunity to develop and implement a corrective action plan.* (i) Before providing a notice of intent of non-renewal of the contract, CMS will provide the Part D plan sponsor with notice specifying the Part D sponsor's deficiencies and reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

(ii) The Part D plan sponsor is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

(4) *Notice of appeal rights.* CMS gives the Part D plan sponsor written notice of its right to appeal the decision that the sponsor is not qualified to renew its contract in accordance with § 423.642(b).

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68733, Dec. 5, 2007; 74 FR 1546, Jan. 12, 2009; 75 FR 19821, Apr. 15, 2010]

§ 423.508 Modification or termination of contract by mutual consent.

(a) *General rule.* A contract may be modified or terminated at any time by written mutual consent.