

(c) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(2) of this section must display in separate columns the financial information for the Part D plan sponsor and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must be examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from a Part D plan sponsor showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) of this section for a particular entity.

(d) *Reporting and disclosure under Employee Retirement Income Security Act of 1974 (ERISA).* (1) For any employees' health benefits plan that includes a Part D plan sponsor in its offerings, the PDP sponsor must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (for the particular PDP sponsor) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The PDP sponsor must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term "administrator" is defined in ERISA.

(e) *Loan information.* Each Part D plan sponsor must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(f) *Enrollee access to information.* Each Part D plan sponsor must make the information reported to CMS under this section available to its enrollees upon reasonable request.

(g) *Data validation.* Each Part D sponsor must subject information collected under paragraph (a) of this section to a yearly independent audit to determine its reliability, validity, completeness, and comparability in accordance with specifications developed by CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19822, Apr. 15, 2010]

§ 423.516 Prohibition of midyear implementation of significant new regulatory requirements.

CMS may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

§ 423.520 Prompt payment by Part D sponsors.

(a) *Contract between CMS and the Part D sponsor.* (1) Effective contract year 2010, the contract between the Part D sponsor and CMS must provide that the Part D sponsor will issue, mail, or otherwise transmit payment with respect to all clean claims, as defined in paragraph (b) of this section, submitted by network pharmacies (other than mail-order and long-term care pharmacies) within—

(i) 14 days after the date on which the claim is received, as defined in paragraph (a)(2)(i) of this section, for an electronic claim; or

(ii) 30 days after the date on which the claim is received, as defined in paragraph (a)(2)(ii) of this section, for any other claim.

(2) *Date of receipt of claim.* A claim is considered to have been received—

(i) On the date on which the claim is transferred, for an electronic claim; or

(ii) On the 5th day after the postmark day of the claim or the date specified in the time stamp of the transmission, for any other claim, whichever is sooner.

(b) *Clean claim.* A clean claim means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment of the claim from being made under this section.

(c) *Procedures involving claims—*(1) *Claims determined to be clean.* A claim is deemed to be a clean claim if the Part D sponsor receiving the claim does not provide notice to the submitting network pharmacy of any deficiency in the claim within—

(i) 10 days after the date on which the claim is received, as defined in paragraph (a)(2)(i) of this section, for an electronic claim; or

(ii) 15 days after the date on which the claim is received, as defined in paragraph (a)(2)(ii) of this section, for any other claim.

(2) *Claims determined not to be clean—*

(i) *General.* If a Part D sponsor determines that a submitted claim is not a clean claim, as defined in paragraph (b) of this section, the Part D sponsor must notify the submitting network pharmacy of such determination within the period described in paragraph (c)(1) of this section. Such notification must specify all defects or improprieties in the claim and must list all additional information necessary for the proper processing and payment of the claim.

(ii) *Determination after submission of additional information.* A claim is deemed to be a clean claim under paragraph (b) of this section if the Part D sponsor that receives the claim does not provide notice to the submitting network pharmacy of any defect or impropriety in the claim within 10 days of the date on which additional information is received under paragraph (c)(2)(i) of this section.

(3) *Obligation to pay.* A claim submitted to a Part D sponsor that is not paid or contested by the Part D sponsor within the timeframes specified in paragraphs (a)(1)(i) and (ii) of this section must be deemed to be a clean claim and must be paid by the Part D sponsor in accordance with paragraph (a) of this section.

(d) *Date of payment of claim.* Payment of a clean claim under paragraph (c)(3) of this section is considered to have been made on the date on which—

(1) The payment is transferred, for an electronic claim; or

(2) The payment is submitted to the United States Postal Service or common carrier for delivery, for any other claim.

(e) *Interest payment—(1) General.* Subject to paragraph (e)(2) of this section, if payment is not issued, mailed or otherwise transmitted for a clean claim as required under paragraph (a) of this section, the Part D sponsor must pay interest to the network pharmacy that submitted the claim at a rate equal to the weighted average of interest on 3-month marketable Treasury securities determined for such period, increased

by 0.1 percentage point for the period beginning on the day after the required payment date and ending on the date on which the payment is made, as determined under paragraph (d). Interest amounts paid under this paragraph will not count against the Part D sponsor's administrative costs, as defined in § 423.308, and will not be treated as allowable risk corridor costs, as defined in § 423.308.

(2) *Authority not to charge interest.* As CMS determines appropriate, including in exigent circumstances such as natural disasters and other unique and unexpected events that prevent the timely processing of claims, a Part D sponsor will not be charged interest under paragraph (e)(1) of this section.

(f) *Electronic transfer of funds.* A Part D sponsor must pay all clean claims submitted electronically by electronic transfer of funds provided the submitting network pharmacy so requests or has so requested previously that contract year. When such payment is made electronically, remittance may also be made electronically by the Part D sponsor.

(g) *Protecting the rights of the claimants—(1) General.* Nothing in this section may be construed to prohibit or limit a claim or action that any individual or organization has against a pharmacy, provider, or Part D sponsor that is not covered by the subject matter of this section.

(2) *Anti-retaliation.* Consistent with applicable Federal or State law, a Part D sponsor may not retaliate against an individual, pharmacy, or provider for exercising a right of action under paragraph (g)(1) of this section.

(h) *Construction.* A determination under this section that a claim submitted by a network pharmacy is a clean claim shall not be construed as a positive determination regarding eligibility for payment under title XVIII of the Act, nor is it an indication of government approval of, or acquiescence regarding, the claim submitted. The determination does not relieve any party of civil or criminal liability with respect to the claim, nor does it offer a defense to any administrative, civil, or criminal action with respect to the claim.

[73 FR 54252, Sept. 18, 2008]