

(c) *CMS rebuttal*. CMS may file a rebuttal to the MA organization's hearing official review request.

(1) The rebuttal must be submitted within 30 calendar days of the MA organization's submission of its hearing official review request.

(2) CMS sends its rebuttal to the MA organization at the same time it is submitted to the hearing official.

(d) *Conducting a review*. A CMS-designated hearing official conducts the hearing on the record.

(1) The hearing is not to be conducted live or via telephone unless the hearing official, in his or her sole discretion, requests a live or telephonic hearing.

(2) In all cases, the hearing official's review is limited to information that meets one or more of the following:

(i) The Part C RAC used in making its determinations.

(ii) The independent reviewer used in making its determinations.

(iii) The MA organization submits with its hearing request.

(iv) CMS submits in accordance with paragraph (c) of this section.

(3) Neither the MA organization nor CMS may submit new evidence.

(e) *Hearing official decision*. The CMS hearing official decides the case within 60 days and sends a written decision to the MA organization and CMS, explaining the basis for the decision.

(f) *Effect of hearing official decision*. The hearing official's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with § 422.2615.

§ 422.2615 Review by the Administrator.

(a) *Request for review by Administrator*. If an MA organization is dissatisfied with the hearing official's decision, it may request that the CMS Administrator review the decision.

(1) The request must be filed with the CMS Administrator within 30 calendar days of the date of the hearing official's decision.

(2) The request must provide evidence or reasons to substantiate the request.

(b) *Content of request*. The MA organization must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(1) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(2) Neither the MA organization, nor CMS may submit new evidence.

(c) *Discretionary review*. After receiving a request for review, the CMS Administrator has the discretion to review the hearing official's decision in accordance with paragraph (e) of this section or to decline to review said decision.

(d) *Notification of decision whether to review*. The Administrator notifies the MA organization within 45 days of receiving the MA organization's hearing request of whether he or she intends to review the hearing official's decision.

(1) If the Administrator agrees to review the hearing official's decision, CMS may file a rebuttal statement within 30 days of the Administrator's notice to the plan that the request for review has been accepted. CMS sends its rebuttal statement to the plan at the same time it is submitted to the Administrator.

(2) If the CMS Administrator declines to review the hearing official's decision, the hearing official's decision is final and binding.

(e) *CMS Administrator's review*. If the CMS Administrator agrees to review the hearing official's decision, he or she determines, based upon this decision, the hearing record, and any arguments submitted by the MA organization or CMS in accordance with this section, whether the determination should be upheld, reversed, or modified. The Administrator furnishes a written decision, which is final and binding, to the MA organization and to CMS.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

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AUTHORITY: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

SOURCE: 70 FR 4525, Jan. 28, 2005, unless otherwise noted.

Subpart A—General Provisions

§ 423.1 Basis and scope.

(a) *Basis.* (1) This part is based on the indicated provisions of the following sections of the Social Security Act:

42 CFR Ch. IV (10–1–23 Edition)

1106. Disclosure of Information in Possession of Agency.

1128J(d). Reporting and Returning of Overpayments.

1860D–1. Eligibility, enrollment, and information.

1860D–2. Prescription drug benefits.

1860D–3. Access to a choice of qualified prescription drug coverage.

1860D–4. Beneficiary protections for qualified prescription drug coverage.

1860D–11. PDP regions; submission of bids; plan approval.

1860D–12. Requirements for and contracts with prescription drug plan (PDP) sponsors.

1860D–13. Premiums; late enrollment penalty.

1860D–14. Premium and cost-sharing subsidies for low-income individuals.

1860D–14A. Medicare coverage gap discount program.

1860D–15. Subsidies for Part D eligible individuals for qualified prescription drug coverage.

1860D–16. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

1860D–21. Application to Medicare Advantage program and related managed care programs.

1860D–22. Special rules for Employer-Sponsored Programs

1860D–23. State pharmaceutical assistance programs.

1860D–24. Coordination requirements for plans providing prescription drug coverage.

1860D–31. Medicare prescription drug discount card and transitional assistance program.

1860D–41. Definitions; treatment of references to provisions in Part C.

1860D–42. Miscellaneous provisions.

1860D–43. Condition for coverage of drugs under this part.

(2) The following specific sections of the Medicare Modernization Act also address the prescription drug benefit program:

Sec. 102 Medicare Advantage conforming amendments.

Sec. 103 Medicaid amendments.

Sec. 104 Medigap.

Sec. 109 Expanding the work of Medicare Quality Improvement Organizations to include Parts C and D.