In conducting the reconsideration, CMS reviews the payment determination, the evidence and findings upon which it was based, and any other written evidence submitted by the Part D sponsor or by CMS before notice of the reconsidered determination is made.

CMS informs the sponsor of the decision orally or through electronic mail. CMS sends a written decision to the Part D sponsor on the sponsor’s request.

A reconsideration decision, whether delivered orally or in writing, is final and binding unless a request for hearing is filed in accordance with paragraph (c) of this section, or it is revised in accordance with §423.346.

A Part D sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing as provided in this section.

A request for a hearing must be made in writing and filed with CMS within 15 days of the date the Part D sponsor receives the CMS reconsideration decision.

The request for informal hearing must include a copy of the CMS reconsideration decision (if any) and must specify the findings or issues in the decision with which the Part D sponsor disagrees and the reasons for the disagreements.

CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

The hearing are conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its contractors explaining CMS’ determination, or CMS or its contractors may, on their own, submit the written statement to the hearing officer. Failure of CMS to submit a written statement does not result in any adverse findings against CMS and may not in any way be taken into account by the hearing officer in reaching a decision.

The CMS hearing officer decides the case and sends a written decision to the Part D sponsor, explaining the basis for the decision.

The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (d) of this section.

The Administrator may review the hearing officer’s decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer’s decision and determine whether to uphold, reverse or modify the hearing officer’s decision.

The Administrator’s determination is final and binding.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20506, Apr. 15, 2008]

Subpart H [Reserved]

Subpart I—Organization Compliance with State Law and Preemption by Federal Law

§423.401 General requirements for PDP sponsors.

(a) General requirements. Each PDP sponsor of a prescription drug plan must meet the following requirements:

(1) Licensure. Except in cases where there is a waiver as specified at §423.410 or §423.415, the sponsor is organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in
§ 423.410 Waiver of certain requirements to expand choice.

(a) Authorizing waiver. In the case of an entity that seeks to offer a prescription drug plan in a State, CMS waives the licensure requirement at § 423.401(a)(1), which requires that the entity be licensed in that State if CMS determines, based on the application and other evidence presented, that any of the grounds for approval of the application described in paragraphs (b), (c), or (d) of this section are met.

(b) Grounds for approval of waivers. Subject to the waiver requirements specified in § 423.410(e), waivers may be granted under any of the following conditions:

1. Failure to act on licensure application on a timely basis. The State failed to complete action on the licensing application within 90 days of the date that the State received a substantially complete application.

2. Denial of application based on discriminatory treatment. The State denied the license application on either of the following bases:
   i. The State imposed material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or
   ii. The State required, as a condition of licensure, that the organization offer any product or plan other than a prescription drug plan.

(c) Waiver when licensing process not in effect. The grounds for approval specified in paragraph (b)(1) of this section are deemed met if CMS determines that the State does not have a licensing process in effect for PDP sponsors.

(d) Special waiver for plan years beginning before January 1, 2008. For plan years beginning before January 1, 2008, if the State has a prescription drug plan or PDP sponsor licensing process in effect, CMS grants a waiver upon a demonstration that an applicant to become a PDP sponsor has submitted a substantially completed application for licensure to the State.

(e) Waiver requirements. The following rules apply to waiver applications or waivers granted under this section.

1. Treatment of waiver. The waiver applies only to that State, is effective for 36 months, and cannot be renewed.

2. Prompt action on application. CMS grants or denies a waiver application under this section within 60 days after CMS determines that a substantially complete waiver application is received by CMS.

3. A State that does not have a PDP sponsor. In the case of a State that does

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(b) Grounds for approval of waivers. Subject to the waiver requirements specified in § 423.410(e), waivers may be granted under any of the following conditions:

1. Failure to act on licensure application on a timely basis. The State failed to complete action on the licensing application within 90 days of the date that the State received a substantially complete application.

2. Denial of application based on discriminatory treatment. The State denied the license application on either of the following bases:
   i. The State imposed material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or
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