§ 423.162 Quality improvement organization activities.

(a) General rule. Quality improvement organizations (QIOs) are required to offer providers, practitioners, and Part
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§ 423.168 Accreditation organizations.

(a) Conditions for approval. CMS may approve an accreditation organization for a given standard under this part if the organization meets the following conditions:

(1) In accrediting Part D sponsors and Part D plans, it applies and enforces standards that are at least as stringent as Medicare requirements for the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in §423.171.

(3) It ensures that—

(i) Any individual associated with it, who is also associated with an entity

(2) The date the Part D sponsor is accredited by the accreditation organization.

(d) Obligations of deemed Part D sponsors. A Part D sponsor deemed to meet Medicare requirements must—

(1) Submit to surveys by CMS to validate its accreditation organization’s accreditation process; and

(2) Authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(e) Removal of deemed status. CMS removes part or all of a Part D sponsor’s deemed status for any of the following reasons—

(1) CMS determines, on the basis of its own investigation, that the Part D sponsor does not meet the Medicare requirements for which deemed status was granted.

(2) CMS withdraws its approval of the accreditation organization that accredited the Part D sponsor.

(3) The Part D sponsor fails to meet the requirements of paragraph (d) of this section.

(f) Authority. Nothing in this section limits CMS’ authority under subparts K and O of this part, including, but not limited to the ability to impose intermediate sanctions, civil money penalties, and terminate a contract with a Part D plan sponsor.

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