§ 423.162 Quality improvement organization activities.

(a) General rule. Quality improvement organizations (QIOs) are required to offer providers, practitioners, and Part D sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy, in accordance with contracts established with the Secretary.

(b) Collection of information. Information collected, acquired, or generated by a QIO in the performance of its responsibilities under this section is subject to the confidentiality provisions of part 480 of this chapter. Part D sponsors are required to provide specified information to CMS for distribution to the QIOs as well as directly to QIOs.

(c) Applicability of QIO confidentiality provisions. The provisions of part 480 of this chapter apply to Part D sponsors in the same manner as such provisions apply to institutions under part 480 of this chapter.

§ 423.165 Compliance deemed on the basis of accreditation.

(a) General rule. A Part D sponsor is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(b) Deemable requirements. The requirements relating to the following areas are deemable:

(1) Access to covered drugs, as provided under §§423.120 and 423.124.

(2) Drug utilization management programs, quality assurance measures and systems, and MTMPs as provided under §423.153.

(3) Privacy, confidentiality, and accuracy of enrollee records, as provided under §423.136.

(c) Effective date of deemed status. The date the Part D sponsor is deemed to meet the applicable requirements is the later of the following:

1. The date the accreditation organization is approved by CMS.

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.