

NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, for the NCPDP Data Record in the Detail Data Record, from the National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260–7518; Telephone (480) 477–1000; and FAX (480) 767–1042 or <http://www.ncdp.org>.

Authority: Section 1860D–4(e) of the Social Security Act (42 U.S.C. 1395w–104(e))

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§ 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—

(1) The Part D sponsor is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization uses the standards approved by CMS

for the purposes of assessing the Part D sponsor's compliance with Medicare requirements.

(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.

(4) A program to protect against fraud, waste and abuse, as described in § 423.504(b)(4)(vi)(H).

(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.

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

(f) *Enforcement authority.* CMS retains the authority to initiate enforcement action against any Part D sponsor that it determines, on the basis of its own