

(c) *Incorporation by reference.* The Director of the Federal Register approves, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, the incorporation by reference of certain publications into this section. You may inspect copies of these publications at the headquarters of the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday from 8:30 a.m. to 4 p.m. or at the National Archives and Records Administration (NARA). For more information on the availability of this material at NARA, call (202) 741-6030, or go to <http://www.archives.gov/federal-register/code-of-federal-regulations/ibr-locations.html>. The publications approved for incorporation by reference and their original sources are as follows:

(1) National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260-7518; Telephone (480) 477-1000; and Facsimile (480) 767-1042 or <http://www.ncdp.org>.

(i) National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005.

(ii) The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0, October 2005.

(iii) National Council for Prescription Drug Programs Telecommunication Standard Specification, Version D, Release 0 (Version D.0), August 2007 and equivalent National Council for Prescription Drug Programs (NCPDP) Batch Standard Batch Implementation Guide, Version 1, Release 2 (Version 1.2), August 2007 supporting Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0) for the NCPDP Data Record in the Detail Data Record.

(iv) National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide, Version 5, Release 0, May 12, 2004, excluding the Prescription Fill Status Notification Transaction (and its three business cases; Prescription Fill Status Notification Transaction—Filled, Prescription Fill Status Notification Transaction—Not

Filled, and Prescription Fill Status Notification Transaction—Partial Fill).

(v) National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 10.6, approved November 12, 2008.

(vi) The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), published April 2012.

(vii) National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 2017071, approved July 28, 2017.

(2) Accredited Standards Committee, 7600 Leesburg Pike, Suite 430, Falls Church, VA 22043; Telephone (301) 970-4488; and Facsimile: (703) 970-4488 or <http://www.x12.org>.

(i) Accredited Standards Committee (ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008, ASC X12N/005010X279.

(ii) [Reserved]

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

[70 FR 67593, Nov. 7, 2005, as amended at 71 FR 36023, June 23, 2006; 72 FR 66405, Nov. 27, 2007; 73 FR 18941, Apr. 7, 2008; 73 FR 69938, Nov. 19, 2008; 75 FR 38030, July 1, 2010; 77 FR 29030, May 16, 2012; 77 FR 69371, Nov. 16, 2012; 78 FR 74822, Dec. 10, 2013; 83 FR 16743, Apr. 16, 2018; 83 FR 27915, June 15, 2018; 84 FR 23883, May 23, 2019; 85 FR 85037, Dec. 28, 2020; 85 FR 86835, Dec. 31, 2020; 86 FR 65682, Nov. 19, 2021; 87 FR 70231, Nov. 18, 2022]

§ 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.

(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) *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.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19818, Apr. 15, 2010]

§ 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 it accredits, does not influence the accreditation decision concerning that entity;

(ii) The majority of the membership of its governing body is not comprised of managed care organizations, Part D sponsors or their representatives; and

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

(b) *Notice and comment—(1) Proposed notice.* CMS publishes a notice in the FEDERAL REGISTER whenever it is considering granting an accreditation organization's application for approval. The notice—