

is unable to conduct electronic prescribing of controlled substances (EPCS) due to circumstances beyond the prescriber's control.

(b) *Standards*—(1) *Prescriptions, electronic prior authorization, and medication history*. The communication of a prescription or prescription-related information must comply with a standard in 45 CFR 170.205(b) (incorporated by reference, *see* paragraph (c) of this section) for the following transactions, as applicable to the version of the standard in use:

- (i)(A) GetMessage.
- (B) Status.
- (C) Error.
- (D) RxChangeRequest and RxChangeResponse.
- (E) RxRenewalRequest and RxRenewalResponse.
- (F) Resupply.
- (G) Verify.
- (H) CancelRx and CancelRxResponse.
- (I) RxFill.
- (J) DrugAdministration.
- (K) NewRxRequest.
- (L) NewRx.
- (M) NewRxResponseDenied.
- (N) RxTransferInitiationRequest.
- (O) RxTransfer.
- (P) RxTransferConfirm.
- (Q) RxFillIndicatorChange.
- (R) Recertification.
- (S) REMSInitiationRequest and REMSInitiationResponse.
- (T) REMSRequest and REMSResponse.
- (U) RxHistoryRequest and RxHistoryResponse.
- (V) PAInitiationRequest and PAInitiationResponse.
- (W) PArequest and PAreponse.
- (X) PAAppealRequest and PAAppealResponse.
- (Y) PACancelRequest and PACancelResponse.
- (Z) PANotification.
- (ii) [Reserved]

(2) *Eligibility*. Eligibility inquiries and responses between the Part D sponsor and prescribers and between the Part D sponsor and dispensers must comply with 45 CFR 162.1202.

(3) *Formulary and benefits*. The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), (in-

corporated by reference, *see* paragraph (c)) of this section) or comply with a standard in 45 CFR 170.205(u) (incorporated by reference, *see* paragraph (c) of this section) for transmitting formulary and benefits information between prescribers and Part D sponsors. Beginning January 1, 2027, transmission of formulary and benefit information between prescribers and Part D sponsors must comply with a standard in 45 CFR 170.205(u) (incorporated by reference, *see* paragraph (c) of this section).

(4) *Provider identifier*. The National Provider Identifier (NPI), as defined at 45 CFR 162.406, to identify an individual health care provider to Medicare Part D sponsors, prescribers and dispensers, in electronically transmitted prescriptions or prescription-related materials for Medicare Part D covered drugs for Medicare Part D eligible individuals.

(5) *Real-time benefit tools*. Part D sponsors must implement one or more electronic real-time benefit tools (RTBT) that are capable of integrating with at least one prescriber's e-Prescribing (eRx) system or electronic health record (EHR) to provide complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit information to the prescriber in real time for assessing coverage under the Part D plan. Such information must include enrollee cost-sharing information, clinically appropriate formulary alternatives, when available, and the formulary status of each drug presented including any utilization management requirements applicable to each alternative drug. Beginning January 1, 2027, Part D sponsors' RTBT must comply with a standard in 45 CFR 170.205(c) (incorporated by reference, *see* paragraph (c) of this section).

(c) *Incorporation by reference*. The material listed in this paragraph (c) is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the Centers for Medicare & Medicaid Services (CMS) and at the National Archives and Records Administration (NARA). Contact CMS at: CMS 7500 Security Boulevard, Baltimore, Maryland

## § 423.162

21244; phone: (410) 786-4132 or (877) 267-2323; email: [PartDPolicy@cms.hhs.gov](mailto:PartDPolicy@cms.hhs.gov). For information on the availability of this material at NARA, visit [www.archives.gov/federal-register/cfr/ibr-locations](http://www.archives.gov/federal-register/cfr/ibr-locations) or email [fr.inspection@nara.gov](mailto:fr.inspection@nara.gov). The material may be obtained from National Council for Prescription Drug Programs (NCPDP), Incorporated, 9240 E Raintree Drive, Scottsdale, AZ 85260-7518; phone: (480) 477-1000; email: [info@ncdpd.org](mailto:info@ncdpd.org); website: [www.ncdpd.org](http://www.ncdpd.org).

(1) NCPDP Formulary and Benefit Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), ANSI-approved January 28, 2011.

(2) NCPDP SCRIPT Standard, Implementation Guide Version 2017071, ANSI-approved July 28, 2017.

(3) NCPDP SCRIPT Standard, Implementation Guide Version 2023011, ANSI-approved January 17, 2023.

(4) NCPDP Real-Time Prescription Benefit Standard, Implementation Guide Version 13, ANSI-approved May 19, 2022.

(5) NCPDP Formulary and Benefit Standard, Implementation Guide Version 60, ANSI-approved April 12, 2023.

[89 FR 51263, June 17, 2024]

## § 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.

## 42 CFR Ch. IV (10-1-24 Edition)

## § 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 MTM programs 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