

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