

(i) To optimize therapeutic outcomes through improved medication use, as such phrase is used in paragraph (d)(1)(i) of this section.

(ii) To improve care coordination so as to prevent adverse health outcomes, such as preventable emergency department visits and hospital readmissions.

(iii) For activities falling under paragraph (1) of the definition of “health care operations” under 45 CFR 164.501.

(iv) For activities falling under paragraph (2) of the definition of “health care operations” under 45 CFR 164.501.

(v) For “fraud and abuse detection or compliance activities” under 45 CFR 164.506(c)(4)(ii).

(vi) For disclosures that qualify as “required by law” disclosures at 45 CFR 164.103.

(4) *Limitations.* A PDP sponsor must comply with the following requirements regarding the data provided by CMS under this paragraph (g):

(i) The PDP sponsor will not use the data to inform coverage determinations under Part D.

(ii) The PDP sponsor will not use the data to conduct retroactive reviews of medically accepted indications determinations.

(iii) The PDP sponsor will not use the data to facilitate enrollment changes to a different prescription drug plan or an MA–PD plan offered by the same parent organization.

(iv) The PDP sponsor will not use the data to inform marketing of benefits.

(v) The PDP sponsor will contractually bind its contractors that have access to the Medicare claims data, and require their contractors to contractually bind any other potential downstream data recipients, to the terms and conditions imposed on the PDP sponsor under this paragraph (g).

(5) *Ensuring the privacy and security of data.* As a condition of receiving the requested data, the PDP sponsor must attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data listed in paragraphs (g)(3) and (4) of this section.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19818, Apr. 15, 2010; 75 FR 32860, June 10, 2010; 76 FR 21573, Apr. 15, 2011; 77 FR 22169, Apr. 12, 2012; 80 FR 7963, Feb. 12, 2015; 83 FR 16739, Apr. 16, 2018; 84 FR 15841, Apr. 16, 2019; 86 FR 6116, Jan. 19, 2021; 89 FR 30834, Apr. 23, 2024; 89 FR 79452, Sept. 30, 2024]

**§ 423.154 Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA–PD plans.**

(a) *In general.* Except as provided in paragraph (b) of this section, when dispensing covered Part D drugs to enrollees who reside in long-term care facilities, a Part D sponsor must—

(1) Require all pharmacies servicing long-term care facilities, as defined in § 423.100 to—

(i) Dispense solid oral doses of brand-name drugs, as defined in § 423.4, to enrollees in such facilities in no greater than 14-day increments at a time;

(ii) Permit the use of uniform dispensing techniques for Part D drugs dispensed to enrollees in long-term care facilities under paragraph (a)(1)(i) of this section as defined by each of the long-term care facilities in which such enrollees reside; and

(2) Not penalize long-term care facilities’ choice of more efficient uniform dispensing techniques described in paragraph (a)(1)(ii) of this section by prorating dispensing fees based on days’ supply or quantity dispensed.

(3) Ensure that any difference in payment methodology among long-term care pharmacies incentivizes more efficient dispensing techniques.

(4) Collect and report information, in a form and manner specified by CMS, on the dispensing methodology used for each dispensing event described by paragraph (a)(1) of this section.

(b) *Exclusions.* CMS excludes from the requirements under paragraph (a) of this section—

(1) Solid oral doses of antibiotics; or

(2) Solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance (for example, oral contraceptives).

(c) *Waivers.* CMS waives the requirements under paragraph (a) of this section, except paragraphs (a)(2) and (3) of this section, for pharmacies when they service intermediate care facilities for individuals with intellectual disabilities (ICFs/IID) and institutes for mental disease (IMDs) as defined in § 435.1010 and for I/T/U pharmacies (as defined in § 423.100).

(d) *Applicability date.* The applicability date for this section is January 1, 2013. Nothing precludes a Part D sponsor and pharmacy from mutually agreeing to an earlier implementation date.

(e) *Unused drugs returned to the pharmacy.* The terms and conditions that must be offered by a Part D sponsor under § 423.120(a)(5) must include provisions that address the disposal of drugs that have been dispensed to an enrollee in a long-term care facility but not used and which have been returned to the pharmacy, in accordance with Federal and State regulations, as well as whether return for credit and reuse is authorized where permitted under State law.

[76 FR 21573, Apr. 15, 2011, as amended at 80 FR 7963, Feb. 12, 2015; 88 FR 22337, Apr. 12, 2023]

#### § 423.156 Consumer satisfaction surveys.

Part D contracts with 600 or more enrollees as of July of the prior year must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Part D plan enrollees in accordance with CMS specifications and submit the survey data to CMS. Part D sponsors are not required to submit CAHPS data that would otherwise be required for the calculation of the 2021 Star Ratings.

[75 FR 19818, Apr. 15, 2010, as amended at 85 FR 19290, Apr. 6, 2020]

#### § 423.159 Electronic prescription drug program.

(a) *Definitions.* For purposes of this section, the following definitions apply:

*Dispenser* means a person or other legal entity licensed, registered, or otherwise permitted by the jurisdiction in which the person practices or the entity is located to provide drug products for human use by prescription in the course of professional practice.

*Electronic media* has the same meaning given this term in 45 CFR 160.103.

*E-prescribing* means the transmission using electronic media, of prescription or prescription-related information between a prescriber, dispenser, phar-

macy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser.

*Electronic prescription drug program* means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals.

*Prescriber* means a physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use.

*Prescription-related information* means information regarding eligibility for drug benefits, medication history, or related health or drug information for Part D eligible individuals.

(b) [Reserved]

(c) *Requirement.* Part D sponsors must support and comply with electronic prescription standards relating to covered Part D drugs for Part D enrollees developed by CMS once final standards are effective.

(d) *Promotion of electronic prescribing by MA-PD plans.* An MA organization offering an MA-PD plan may provide for a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with electronic prescription standards, including initial standards and final standards established by CMS once final standards are effective. Any payments must be in compliance with applicable Federal and State laws related to fraud and abuse, including the physician self-referral prohibition (section 1877 of the Act) and the Federal anti kickback statute (section 1128B(b) of the Act).

[70 FR 4525, Jan. 28, 2005, as amended at 70 FR 67593, Nov. 7, 2005]

#### § 423.160 Standards for electronic prescribing.

(a) *General rules.* (1) Part D sponsors must establish and maintain an electronic prescription drug program that complies with the applicable standards in paragraph (b) of this section when transmitting, directly or through an

intermediary, prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals.

(2) Except as provided in paragraph (a)(3) of this section, prescribers and dispensers that transmit, directly or through an intermediary, prescriptions and prescription-related information using electronic media (including entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider, such as a nursing facility, that in turn forwards the prescription to a dispenser), must comply with the applicable standards in paragraph (b) of this section when e-prescribing for covered Part D drugs for Part D eligible individuals.

(3)(i) Entities transmitting prescriptions or prescription-related information must utilize the NCPDP SCRIPT standard, consistent with paragraph (b)(1) of this section, in all instances other than temporary/transient network transmission failures.

(ii) Electronic transmission of prescriptions or prescription-related information by means of computer-generated facsimile is only permitted in instances of temporary/transient transmission failure and communication problems that would preclude the use of the NCPDP SCRIPT standard adopted by this section.

(iii) Entities may use either HL7 messages or the NCPDP SCRIPT standard to transmit prescriptions or prescription-related information internally when the sender and the recipient are part of the same legal entity. If an entity sends prescriptions outside the entity (for example, from an HMO to a non-HMO pharmacy), it must use the adopted NCPDP SCRIPT standard or other applicable adopted standards. Any pharmacy within an entity must be able to receive electronic prescription transmittals for Medicare beneficiaries from outside the entity using the adopted NCPDP SCRIPT standard. This exemption does not supersede any HIPAA requirement that may require the use of a HIPAA transaction standard within an organization.

(4) In accordance with section 1860D-4(e)(5) of the Act, the standards under

this paragraph (b) of this section supersede any State law or regulation that—

(i) Is contrary to the standards or restricts the ability to carry out Part D of Title XVIII of the Act; and

(ii) Pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs under Part D of Title XVIII of the Act.

(5) Beginning on January 1, 2021, prescribers must, except in the circumstances described in paragraphs (a)(5)(i) through (iii) of this section, conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically using the applicable standards in paragraph (b) of this section, subject to the exemption in paragraph (a)(3)(iii) of this section. Prescriptions written for a beneficiary in a long-term care facility will not be included in determining compliance until January 1, 2025. Compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a long-term care facility will commence on or after January 1, 2025. Compliance actions against prescribers who do not meet the compliance threshold based on other prescriptions will commence on or after January 1, 2023. Prescribers will be exempt from this requirement in the following situations:

(i) Prescriber issues 100 or fewer controlled substance prescriptions for Part D drugs per calendar year as determined using CMS claims data with dates of service as of December 31st of the current year.

(ii) Prescriber has an address in PECOS in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. If a prescriber does not have an address in PECOS, prescriber has an address in NPPES in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. Starting in the 2024 measurement year, CMS will identify which emergencies or disasters qualify for this exception.

(iii) Prescriber has received a CMS-approved waiver because the prescriber

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 PResponse.
- (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