Centers for Medicare & Medicaid Services, HHS § 423.160

(f) 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]

§ 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.

[75 FR 19818, Apr. 15, 2010]

§ 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, pharmacy 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]


(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 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) Exemptions. (i) Until January 1, 2012, entities transmitting prescriptions or prescription-related information by means of computer-generated facsimile are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information. After January 1, 2012, entities transmitting prescriptions or prescription-related information must utilize the NCPSP SCRIPT standard in all instances other than temporary/transient network transmission failures. 

(ii) After January 1, 2009, 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 by means of computer-generated facsimile if the entity was part of the same legal entity when the senders and beneficiaries were 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.

(iv) Until November 1, 2014, 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 are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information. As of November 1, 2014, such entities will be required to use the adopted NCPCP SCRIPT standard(s).

(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.

(b) Standards. (1) Entities described in paragraph (a) of this section must comply with the following adopted standards for transactions under this section:

(i) Before April 1, 2009 the standards specified in paragraphs (b)(2)(i), (b)(3), (b)(4), (b)(5), and (b)(6) of this section.

(ii) From April 1, 2009 until January 14, 2013, the standards specified in paragraphs (b)(2)(ii), (b)(3)–(b)(4), (b)(5) and (b)(6) of this section.

(iii) From January 15, 2013 until October 31, 2013 the standards specified in paragraphs (b)(2)(ii), (b)(3)–(b)(4), (b)(5) and (b)(6) of this section.

(2) Prescription. (i) The National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide, Version 5, Release 0, (Version 5.0) May 12, 2004 (incorporated by reference in paragraph (c)(1)(iv) of this section), or the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, (Version 8.1) October 2005 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

(A) Get message transaction.

(B) Status response transaction.

(C) Error response transaction.

(D) New prescription transaction.

(E) Prescription change request transaction.
(F) Prescription change response transaction.  
(G) Refill prescription request transaction.  
(H) Refill prescription response transaction.  
(I) Verification transaction.  
(J) Password change transaction.  
(K) Cancel prescription request transaction.  
(L) Cancel prescription response transaction.  
(ii) The National Council for Prescription Drug Programs SCRIPT standard, Implementation Guide Version 10.6, approved November 12, 2008 (incorporated by reference in paragraph (c)(1)(v) of this section), or the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1 (Version 8.1), October 2005 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or prescription-related information between prescribers and dispensaries, for the following:  
(A) Get message transaction.  
(B) Status response transaction.  
(C) Error response transaction.  
(D) New prescription transaction.  
(E) Prescription change request transaction.  
(F) Prescription change response transaction.  
(G) Refill prescription request transaction.  
(H) Refill prescription response transaction.  
(I) Verification transaction.  
(J) Password change transaction.  
(K) Cancel prescription request transaction.  
(L) Cancel prescription response transaction.  
(M) Fill status notification.  
(3) Eligibility.  
(i) The Accredited Standards Committee X12N 270/271–Health Care Eligibility Benefit Inquiry and Response, Version 5010, April 2008, ASC X12N/005010x279 (incorporated by reference in paragraph (c)(2)(i) of this section), for transmitting eligibility inquiries and responses between prescribers and Part D sponsors.  
(4) Medication history.  
The National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide Version 10.6 approved November 12, 2008 (incorporated by reference in paragraph (c)(1)(v) of this section), to provide for the communication of a prescription or related prescription related information between prescribers and dispensers for the following:
§423.162  Quality improvement organization activities.

(a) General rule. Quality improvement organizations (QIOs) are required to offer providers, practitioners, and Part