

of claims data under Medicare parts A and B for items and services furnished under such parts to beneficiaries who are enrolled in a plan offered by the PDP sponsor at the time of the disclosure.

(3) *Purposes.* A PDP sponsor must comply with all laws that may be applicable to data received under this provision, including State and Federal privacy and security laws, and, furthermore subject to the limitations in paragraph (g)(4) of this section may only use or disclose the data provided by CMS under paragraph (g)(1) of this section for the following purposes:

(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]

§ 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, 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