systems, and medication therapy management programs (MTMP) for Part D sponsors.

(b) Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA–PD plans.

(c) Consumer satisfaction surveys of Part D plans.

(d) Electronic prescription drug programs for prescribers, dispensers, and Part D sponsors.

(e) Quality improvement organization (QIO) activities.

(f) Compliance deemed on the basis of accreditation.

(g) Accreditation organizations.

(h) Procedures for the approval of accreditation organizations as a basis for deeming compliance.

[70 FR 4525, Jan. 28, 2005, as amended at 70 FR 67593, Nov. 7, 2005; 76 FR 21573, Apr. 15, 2011]

§ 423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).

(a) *General rule.* Each Part D sponsor must have established, for covered Part D drugs furnished through a Part D plan, a drug utilization management program, quality assurance measures and systems, and an MTMP as described in paragraphs (b), (c), and (d) of this section.

(b) *Drug utilization management.* A Part D sponsor must have established a reasonable and appropriate drug utilization management program that address all of the following:

(1) Includes incentives to reduce costs when medically appropriate.

(2) Maintains policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications.

(3) Provides CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS.

(4)(i) Establishes a daily cost-sharing rate and applies it to a prescription presented to a network pharmacy for a covered Part D drug that is dispensed for a supply less than 30 days, and in the case of a monthly copayment, multiplies the daily cost-sharing rate by the days supply actually dispensed—

(A) If the drug is in the form of a solid oral dose, subject to paragraph (b)(4)(i)(B) of this section and may be dispensed for a supply less than 30 days under applicable law;

(B) The requirements of this paragraph (b)(4)(i) do not apply to either of the following:

(*1*) Solid oral doses of antibiotics.

(*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.

(ii) [Reserved]

(c) *Quality assurance.* A Part D sponsor must have established quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use that include all of the following—

(1) Representation that network providers are required to comply with minimum standards for pharmacy practice as established by the States.

(2) Concurrent drug utilization review systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's Part D plan, typically at the point-of-sale or point of distribution. The review must include, but not be limited to,

(i) Screening for potential drug therapy problems due to therapeutic duplication.

(ii) Age/gender-related contraindications.

(iii) Over-utilization and under-utilization.

(iv) Drug-drug interactions.

(v) Incorrect drug dosage or duration of drug therapy. (vi) Drug-allergy contraindications.

(vii) Clinical abuse/misuse.

(3) Retrospective drug utilization review systems, policies, and procedures designed to ensure ongoing periodic examination of claims data and other records, through computerized drug claims processing and information retrieval systems, in order to identify patterns of inappropriate or medically unnecessary care among enrollees in a

sponsor's Part D plan, or associated with specific drugs or groups of drugs.

(4) Internal medication error identification and reduction systems.

(5) Provision of information to CMS regarding its quality assurance measures and systems, according to guidelines specified by CMS.

(d) *Medication therapy management program (MTMP)*—(1) *General rule.* A Part D sponsor must have established a MTMP that—

(i) Is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries described in paragraph (d)(2) of this section are appropriately used to optimize therapeutic outcomes through improved medication use;

(ii) Is designed to reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries described in paragraph (d)(2) of this section;

(iii) May be furnished by a pharmacist or other qualified provider; and

(iv) May distinguish between services in ambulatory and institutional settings.

(v) Must enroll targeted beneficiaries using an opt-out method of enrollment only.

(vi) Must target beneficiaries for enrollment in the MTMP at least quarterly during each plan year.

(vii) Must offer a minimum level of medication therapy management services for each beneficiary enrolled in the MTMP that includes all of the following:

(A) Interventions for both beneficiaries and prescribers.

(B) *Annual comprehensive medication review with written summaries.* (*1*) The beneficiary's comprehensive medication review—

(*i*) Must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider; and

(*ii*) May result in a recommended medication action plan.

(*2*) If a beneficiary is offered the annual comprehensive medication review and is unable to accept the offer to participate, the pharmacist or other qualified provider may perform the comprehensive medication review with the beneficiary's prescriber, caregiver, or other authorized individual.

(C) Quarterly targeted medication reviews with follow-up interventions when necessary.

(D) Standardized action plans and summaries that comply with requirements as specified by CMS for the standardized format.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the MTMP described in paragraph (d)(1) of this section are enrollees in the sponsor's Part D plan who meet all of the following:

(i) Have multiple chronic diseases, with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment.

(ii) Are taking multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment.

(iii) Are likely to incur the following annual Part D drug costs:

(A) For 2011, costs for covered Part D drugs greater than or equal to $3,000.

(B) For 2012 and subsequent years, costs for covered Part D drugs in an amount greater than or equal to $3000 increased by the annual percentage specified in § 423.104(d)(5)(iv) of this part.

(3) *Use of experts.* The MTMP must be developed in cooperation with licensed and practicing pharmacists and physicians.

(4) *Coordination with care management plans.* The MTMP must be coordinated with any care management plan established for a targeted individual under a chronic care improvement program (CCIP) under section 1807 of the Act. A Part D sponsor must provide drug claims data to CCIPs for those beneficiaries that are enrolled in CCIPs in a manner specified by CMS.

(5) *Considerations in pharmacy fees.* An applicant to become a Part D sponsor must—

(i) Describe in its application how it takes into account the resources used and time required to implement the MTMP it chooses to adopt in establishing fees for pharmacists or others providing MTMP services for covered Part D drugs under a Part D plan.

(ii) Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for

MTMP services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

(6) *MTMP reporting.* A Part D sponsor must provide CMS with information regarding the procedures and performance of its MTMP, according to guidelines specified by CMS.

(e) *Exception for private fee-for-service MA plans offering qualified prescription drug coverage.* In the case of an MA plan described in §422.4(a)(3) of this chapter providing qualified prescription drug coverage, the requirements under paragraphs (b) and (d) of this section do not apply.

[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]

§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) 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, and on the nature and quantity of unused brand and generic drugs, as defined in §423.4, dispensed by the pharmacy to enrollees residing in a LTC facility. Reporting on unused drugs is waived for Part D sponsors for drugs dispensed by pharmacies that dispense both brand and generic drugs, as defined in §423.4, in no greater than 7-day increments.

(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 for pharmacies when they service intermediate care facilities for the mentally retarded (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) *Copayments.* Regardless of the number of incremental dispensing events, the total cost sharing for a Part D drug to which the dispensing requirements under this paragraph (a) apply must be no greater than the total cost sharing that would be imposed for such Part D drug if the requirements under paragraph (a) of this section did not apply.

(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