

42 CFR §423.153

(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]

ATTACHMENT B: CMS HPMS Memo from April 7, 2015

<https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/mtm.html>

ATTACHMENT C: PCMA Comments on 2015 Proposed Rule MTM Construct