

15 days before the beginning of the Annual Coordinated Election Period as defined in section 1860D-1(b)(1)(B) of the Act.

(3) Provide notice of all other changes in accordance with notice requirements as specified in this part.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 54222, Sept. 18, 2008; 74 FR 1544, Jan. 12, 2009; 75 FR 19818, Apr. 15, 2010; 76 FR 21573, Apr. 15, 2011; 80 FR 7963, Feb. 12, 2015; 83 FR 16739, Apr. 16, 2018; 84 FR 23883, May 23, 2019; 86 FR 6115, Jan. 19, 2021; 89 FR 30834, Apr. 23, 2024]

#### **§ 423.129 Resolution of complaints in complaints tracking module.**

(a) *Definitions.* For the purposes of this regulation, the following terms have the following meanings:

*Assignment date* is the date CMS assigns a complaint to a particular Part D sponsor in the Complaints Tracking Module.

*Complaints Tracking Module* is an electronic system maintained by CMS to record and track complaints submitted to CMS about Medicare health and drug plans from beneficiaries and others.

*Immediate need complaint* is a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 2 or fewer days.

*Urgent complaint* is a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they do not have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 3 to 14 days.

(b) *Timelines for complaint resolution—*

(1) *Immediate need complaints.* The Part D sponsor must resolve immediate need complaints within 2 calendar days of the assignment date.

(2) *Urgent complaints.* The Part D sponsor must resolve urgent complaints within 7 calendar days of the assignment date.

(3) *All other complaints.* The Part D sponsor must resolve all other complaints within 30 calendar days of the assignment date.

(4) *Extensions.* Except for immediate need complaints, urgent complaints, and any complaint that requires expedited treatment under § 423.564(f), if a complaint is also a grievance within the scope of § 423.564 and the requirements for an extension of the time to provide a response in § 423.564(e)(2) are met, the Part D sponsor may extend the timeline to provide a response.

(5) *Coordination with timeframes for grievances, PACE service determination requests, and PACE appeals.* When a complaint under this section is also a grievance within the scope of §§ 423.564 or 460.120, a PACE service determination request within the scope of § 460.121, or a PACE appeal within the definition of § 460.122, the Part D sponsor must comply with the shortest applicable timeframe for resolution of the complaint.

(c) *Timeline for contacting individual filing a complaint.* Regardless of the type of complaint received, the Part D sponsor must attempt to contact the individual who filed a complaint within 7 calendar days of the assignment date.

[89 FR 30834, Apr. 23, 2024]

#### **§ 423.132 Public disclosure of pharmaceutical prices for equivalent drugs.**

(a) *General requirements.* Except as provided under paragraph (c) of this section, a Part D sponsor must require a pharmacy that dispenses a covered Part D drug to inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that covered Part D drug that is therapeutically equivalent and bioequivalent and available at that pharmacy, unless the particular covered Part D drug being purchased is the lowest-priced therapeutically equivalent and bioequivalent version of that drug available at that pharmacy.

(b) *Timing of notice.* Subject to paragraph (d) of this section, the information under paragraph (a) of this section must be provided after the drug is dispensed at the point of sale or, in the case of dispensing by mail order, at the time of delivery of the drug.

(c) *Waiver of public disclosure requirement.* CMS waives the requirement under paragraph (a) of this section in any of the following cases:

#### § 423.136

(1) An MA private fee-for-service plan described in §422.4 of this chapter that—

(i) Offers qualified prescription drug coverage and provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies; and

(ii) Does not charge additional cost-sharing for access to covered Part D drugs dispensed at out-of-network pharmacies.

(2) An out-of-network pharmacy.

(3) An I/T/U network pharmacy.

(4) A network pharmacy that is located in any of the U.S. territories.

(5) A long-term care network pharmacy.

(6) Other circumstances where CMS deems compliance with the requirements of paragraph (a) of this section to be impossible or impracticable.

(d) *Modification of timing requirement.* CMS modifies the requirement under paragraph (b) of this section under circumstances where CMS deems compliance with this requirement to be impossible or impracticable.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19818, Apr. 15, 2010]

#### § 423.136 Privacy, confidentiality, and accuracy of enrollee records.

For any medical records or other health and enrollment information it maintains with respect to enrollees, a PDP sponsor must establish procedures to do the following—

(a) Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The PDP sponsor must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify—

(1) For what purposes the information is used within the organization; and

(2) To whom and for what purposes it discloses the information outside the organization.

(b) Ensure that medical information is released only in accordance with applicable Federal or State law, or under court orders or subpoenas.

(c) Maintain the records and information in an accurate and timely manner.

#### 42 CFR Ch. IV (10–1–24 Edition)

(d) Ensure timely access by enrollees to the records and information that pertain to them.

### Subpart D—Cost Control and Quality Improvement Requirements

#### § 423.150 Scope.

This subpart sets forth the requirements relating to the following:

(a) Drug utilization management programs, quality assurance measures and systems, and MTM programs 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; 89 FR 30834, Apr. 23, 2024]

#### § 423.153 Drug utilization management, quality assurance, medication therapy management (MTM) programs, drug management programs, and access to Medicare Parts A and B claims data extracts.

(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 MTM program as described in paragraphs (b), (c), and (d) of this section. No later than January 1, 2022, a Part D plan sponsor must have established a drug management program for at-risk beneficiaries enrolled in their prescription drug benefit plans to address overutilization of frequently abused drugs, as described in paragraph (f) 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) *Daily cost sharing rate.* Subject to paragraph (b)(4)(ii) of this section, establishes a daily cost-sharing rate (as defined in § 423.100) 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 the approved month's supply, if the drug is in the form of a solid oral dose and may be dispensed for less than the approved month's supply under applicable law.

(ii) *Exceptions.* The requirements of paragraph (b)(4)(i) of this section do not apply to either of the following:

(A) Solid oral doses of antibiotics.

(B) 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.

(iii) *Cost-sharing*—(A) *Copayments.* In the case of a drug that would incur a copayment, the Part D sponsor must apply cost-sharing as calculated by multiplying the applicable daily cost-sharing rate by the days' supply actually dispensed when the beneficiary receives less than the approved month's supply.

(B) *Coinsurance.* In the case of a drug that would incur a coinsurance percentage, the Part D sponsor must apply the coinsurance percentage for the drug to the days' supply actually dispensed.

(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 (MTM) program*—(1) *General rule.* A Part D sponsor must have established a MTM program 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 MTM program at least quarterly during each plan year.

(vii) Must offer a minimum level of medication therapy management services for each beneficiary enrolled in the MTM program 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 consultation, performed by a pharmacist or other qualified provider, that is either in person or performed via synchronous telehealth; 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 due to cognitive impairment, 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.

(E) Beginning January 1, 2022, for enrollees targeted in paragraph (d)(2) of this section, provide at least annually as part of the comprehensive medication review, a targeted medication review, or other MTM correspondence or service, information about safe disposal of prescription drugs that are controlled substances, drug take back programs, in-home disposal and cost-effective means to safely dispose of such drugs.

(F) The information to be provided under paragraph (d)(1)(vii)(E) of this section must comply with all requirements of § 422.111(j) of this chapter.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the MTM program described in paragraph (d)(1) of this section are enrollees in the sponsor's Part D plan who meet the characteristics of at least one of the following two groups:

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

(B) 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; and

(C) Are likely to incur annual covered Part D drug costs greater than or equal to the MTM cost threshold determined by CMS, as specified in this paragraph (d)(2)(i)(C) of this section.

(1) For 2011, the MTM cost threshold is set at \$3,000.

(2) For 2012 through 2024, the MTM cost threshold is set at \$3,000 increased by the annual percentage specified in § 423.104(d)(5)(iv).

(3) For 2025, the MTM cost threshold is set at the average annual cost of eight generic drugs, as defined at § 423.4, as determined using the PDE data specified at § 423.104(d)(2)(iv)(C).

(ii) Beginning January 1, 2022, are at-risk beneficiaries as defined in § 423.100.

(iii) Beginning January 1, 2025, in identifying beneficiaries who have multiple chronic diseases under paragraph (d)(2)(i)(A) of this section, Part D plan sponsors must include all of the following diseases, and may include additional chronic diseases:

(A) Alzheimer's disease.

(B) Bone disease-arthritis (including osteoporosis, osteoarthritis, and rheumatoid arthritis).

(C) Chronic congestive heart failure (CHF).

(D) Diabetes.

(E) Dyslipidemia.

(F) End-stage renal disease (ESRD).

(G) Human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS).

(H) Hypertension.

(I) Mental health (including depression, schizophrenia, bipolar disorder, and other chronic/disabling mental health conditions).

(J) Respiratory disease (including asthma, chronic obstructive pulmonary disease (COPD), and other chronic lung disorders).

(iv) Beginning January 1, 2025, in identifying the number of Part D drugs under paragraph (d)(2)(i)(B) of this section, Part D plan sponsors must include all Part D maintenance drugs, relying on information in a widely accepted, commercially or publicly available drug database to make such determinations, and may include all Part D drugs.

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

(4) *Coordination with care management plans.* The MTM program 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 MTM program it chooses to adopt in establishing fees for pharmacists or others providing MTM 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 MTM 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) *MTM program reporting.* A Part D sponsor must provide CMS with information regarding the procedures and performance of its MTM program, 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.

(f) *Drug management programs.* A drug management program must meet all the following requirements:

(1) *Written policies and procedures.* A sponsor must document its drug management program in written policies and procedures that are approved by the applicable P&T committee and reviewed and updated as appropriate. In the case of a Part D sponsor, including a PACE organization, without its own or a contracted P&T committee because it does not use a formulary, the written policies and procedures described in this section must be approved by the Part D sponsor's medical director as described at § 423.562(a)(5) (or, for a PACE organization, at § 460.60(b)) and applicable clinical and other staff or contractors as determined appropriate by the medical director. These policies and procedures must address all aspects of the sponsor's drug management program, including but not limited to the following:

(i) The appropriate credentials of the clinical staff conducting case management required under paragraph (f)(2) of this section, including that the staff must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

(ii) The necessary and appropriate contents of files for case management required under paragraph (f)(2) of this section, which must include documentation of the substance of prescriber and beneficiary contacts.

(iii) Monitoring reports and notifications about incoming enrollees who meet the definition of an at-risk beneficiary or a potential at-risk beneficiary in § 423.100 and responding to requests from other sponsors for information about at-risk beneficiaries and potential at-risk beneficiaries who recently disenrolled from the sponsor's prescription drug benefit plan.

(2) *Case management/clinical contact/prescriber verification—(i) General rule.* The sponsor's clinical staff must conduct case management for each potential at-risk beneficiary for the purpose of engaging in clinical contact with the prescribers of frequently abused drugs

and verifying whether a potential at-risk beneficiary is an at-risk beneficiary. Except as provided in paragraph (f)(2)(ii) of this section, the sponsor must do all of the following:

(A) Send written information to the beneficiary's prescribers that the beneficiary met the clinical guidelines and is a potential at risk beneficiary.

(B) Elicit information from the prescribers about any factors in the beneficiary's treatment that are relevant to a determination that the beneficiary is an at-risk beneficiary, including whether prescribed medications are appropriate for the beneficiary's medical conditions or the beneficiary is an exempted beneficiary.

(C) In cases where prescribers have not responded to the inquiry described in paragraph (f)(2)(i)(B) of this section, make reasonable attempts to communicate with the prescribers telephonically and/or by another effective communication method designed to elicit a response from the prescribers within a reasonable period after sending the written information.

(ii) *Exception for identification by prior plan.* If a beneficiary was identified as a potential at-risk or an at-risk beneficiary by his or her most recent prior plan and such identification has not been terminated in accordance with paragraph (f)(14) of this section, the sponsor meets the requirements in paragraph (f)(2)(i) of this section, so long as the sponsor obtains case management information from the previous sponsor and such information is still clinically adequate and up to date.

(3) *Limitation on access to coverage for frequently abused drugs.* Subject to the requirements of paragraph (f)(4) of this section, a Part D plan sponsor may do any or all of the following:

(i) Implement a point-of-sale claim edit for frequently abused drugs that is specific to an at-risk beneficiary.

(ii) In accordance with paragraphs (f)(9) and (13) of this section, limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are—

(A) Prescribed for the beneficiary by one or more prescribers;

(B) Dispensed to the beneficiary by one or more network pharmacies; or

(C) Both.

(iii)(A) If the sponsor implements an edit as specified in paragraph (f)(3)(i) of this section, the sponsor must not cover frequently abused drugs for the beneficiary in excess of the edit, unless the edit is terminated or revised based on a subsequent determination, including a successful appeal.

(B) If the sponsor limits the at-risk beneficiary's access to coverage as specified in paragraph (f)(3)(ii) of this section, the sponsor must cover frequently abused drugs for the beneficiary only when they are obtained from the selected pharmacy(ies) or prescriber(s) or both, as applicable—

(1) In accordance with all other coverage requirements of the beneficiary's prescription drug benefit plan, unless the limit is terminated or revised based on a subsequent determination, including a successful appeal; and

(2) Except as necessary to provide reasonable access in accordance with paragraph (f)(12) of this section.

(4) *Requirements for limiting access to coverage for frequently abused drugs.* (i) A sponsor may not limit the access of an at-risk beneficiary to coverage for frequently abused drugs under paragraph (f)(3) of this section, unless the sponsor has done all of the following:

(A) Conducted case management as required by paragraph (f)(2) of this section and updated it, if necessary.

(B) Except in the case of a pharmacy limitation imposed pursuant to paragraph (f)(3)(ii)(B) of this section, obtained the agreement of at least one prescriber of frequently abused drugs for the beneficiary that the specific limitation is appropriate.

(C) Provided the notices to the beneficiary in compliance with paragraphs (f)(5) and (6) of this section.

(ii)(A) Except as provided in paragraph (f)(3)(ii)(A) of this section regarding a prescriber limitation, if the sponsor has complied with the requirement of paragraph (f)(2)(i)(B) of this section about attempts to reach prescribers, and the prescribers were not responsive after 3 attempts by the sponsor to contact them within 10 business days, then the sponsor has met the requirement of paragraph (f)(4)(i)(B) of this section for eliciting information from the prescribers.

(B) The sponsor may not implement a prescriber limitation pursuant to paragraph (f)(3)(ii)(A) of this section if no prescriber was responsive.

(5) *Initial notice to a beneficiary.* (i) After conducting the case management required by paragraph (f)(2) of this section, a Part D sponsor that intends to limit the access of a potential at-risk beneficiary, or subject to the exception in paragraph (f)(8)(ii) of this section, of an at-risk beneficiary (as defined in subparagraph (2) of the definition in § 423.100), to coverage for frequently abused drugs under paragraph (f)(3) of this section must provide an initial written notice to the beneficiary.

(ii) The notice must do all of the following:

(A) Use language approved by the Secretary.

(B) Be in a readable and understandable form.

(C) Provide all of the following information:

(1) An explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as a potential at-risk beneficiary.

(2) A description, of all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health and other counseling services and information on how to access such services, including any such services covered by the plan under its Medicare benefits, supplemental benefits, or Medicaid benefits (if the plan integrates coverage of Medicare and Medicaid benefits).

(3) An explanation of the beneficiary's right to a redetermination if the sponsor issues a determination that the beneficiary is an at-risk beneficiary and the standard and expedited redetermination processes described at §§ 423.582 and 423.584, including notice that if on redetermination the plan sponsor affirms its denial, in whole or in part, the case must be automatically forwarded to the independent review entity contracted with CMS for review and resolution.

(4) A request that the beneficiary submit to the sponsor within 30 days of the date of this initial notice any infor-

mation that the beneficiary believes is relevant to the sponsor's determination, including which prescribers and pharmacies the beneficiary would prefer the sponsor to select if the sponsor implements a limitation under paragraph (f)(3)(ii) of this section.

(5) An explanation of the meaning and consequences of being identified as an at-risk beneficiary, including the following:

(i) An explanation of the sponsor's drug management program, the specific limitation the sponsor intends to place on the beneficiary's access to coverage for frequently abused drugs under the program.

(ii) The timeframe for the sponsor's decision.

(iii) If applicable, any limitation on the availability of the special enrollment period described in § 423.38.

(6) Clear instructions that explain how the beneficiary can contact the sponsor, including how the beneficiary may submit information to the sponsor in response to the request described in paragraph (f)(5)(ii)(C)(4) of this section.

(7) Contact information for other organizations that can provide the beneficiary with assistance regarding the sponsor's drug management program.

(8) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

(iii) The Part D plan sponsor must make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required under paragraph (f)(5)(i) of this section.

(iv) If the Part D plan sponsor subsequently intends to make a change to the terms of an ongoing limitation(s) established under paragraph (f)(3) of this section, including the intention to impose an additional limitation on the at-risk beneficiary, the sponsor must comply with the requirements of paragraph (f)(3) of this section, as well as all applicable requirements for beneficiary notices described in paragraphs (f)(5) through (8) of this section.

(6) *Second notice.* (i) Upon making a determination that a beneficiary is an at-risk beneficiary and to limit the beneficiary's access to coverage for frequently abused drugs under paragraph

(f)(3) of this section, a Part D sponsor must provide a second written notice to the beneficiary.

(ii) The second notice must do all of the following:

(A) Use language approved by the Secretary.

(B) Be in a readable and understandable form.

(C) Provide all of the following information:

(1) An explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as an at-risk beneficiary.

(2) An explanation that the beneficiary is subject to the requirements of the sponsor's drug management program, including—

(i) The limitation the sponsor is placing on the beneficiary's access to coverage for frequently abused drugs and the effective and end date of the limitation; and

(ii) If applicable, any limitation on the availability of the special enrollment period described in § 423.38.

(3) The prescriber(s) or pharmacy(ies) or both, if and as applicable, from which the beneficiary must obtain frequently abused drugs in order for them to be covered by the sponsor.

(4) An explanation of the beneficiary's right to a redetermination under § 423.580, including all of the following:

(i) A description of both the standard and expedited redetermination processes.

(ii) The beneficiary's right to, and conditions for, obtaining an expedited redetermination.

(iii) Notice that if on redetermination the plan sponsor affirms its denial, in whole or in part, the case must be automatically forwarded to the independent review entity contracted with CMS for review and resolution.

(5) An explanation that the beneficiary may submit to the sponsor, if the beneficiary has not already done so, the prescriber(s) and pharmacy(ies), as applicable, from which the beneficiary would prefer to obtain frequently abused drugs.

(6) Clear instructions that explain how the beneficiary may contact the sponsor, including how the beneficiary may submit information to the sponsor

in response to the request described in paragraph (f)(6)(ii)(C)(5) of this section.

(7) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

(iii) The Part D plan sponsor must make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required by paragraph (f)(6)(i) of this section.

(7) *Alternate second notice.* (i) If, after providing an initial notice to a potential at-risk beneficiary under paragraph (f)(4) of this section, a Part D sponsor determines that the potential at-risk beneficiary is not an at-risk beneficiary, the sponsor must provide an alternate second written notice to the beneficiary.

(ii) The alternate second notice must do all of the following:

(A) Use language approved by the Secretary.

(B) Be in a readable and understandable form.

(C) Provide all of the following information:

(1) The sponsor has determined that the beneficiary is not an at-risk beneficiary.

(2) The sponsor will not limit the beneficiary's access to coverage for frequently abused drugs.

(3) If applicable, the SEP limitation no longer applies.

(4) Clear instructions that explain how the beneficiary may contact the sponsor.

(5) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

(iii) The Part D sponsor must make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required in accordance with paragraph (f)(7)(i) of this section.

(8) *Notices: Timing and exceptions.* (i) Subject to paragraphs (f)(8)(ii) and (iii) of this section, a Part D sponsor must provide the second notice described in paragraph (f)(6) of this section or the alternate second notice described in paragraph (f)(7) of this section, as applicable, on a date that is not less than



30 days after the date of the initial notice described in paragraph (f)(5) of this section and not more than the earlier of the following two dates:

(A) Within 3 days of the date the sponsor makes the relevant determination.

(B) Sixty days after the date of the initial notice described in paragraph (f)(5) of this section.

(ii) In the case of a beneficiary who is determined by a Part D sponsor to be exempt, the sponsor must provide the alternate second notice within 3 days of the date the sponsor makes the relevant determination, even if such determination is made less than 30 days from the date of the initial notice described in paragraph (f)(5) of this section.

(iii) A gaining plan sponsor may forgo providing the initial notice and may immediately provide a second notice described in paragraph (f)(6) of this section to an at-risk beneficiary as defined in subparagraph (2) of the definition in § 423.100), if the sponsor is implementing either of the following:

(A) A beneficiary-specific point-of-sale claim edit as described in paragraph (f)(3)(i) of this section, if the edit is the same as the one that was implemented in the immediately prior plan.

(B) A limitation on access to coverage as described in paragraph (f)(3)(ii) of this section, if such limitation would require the beneficiary to obtain frequently abused drugs from the same location of pharmacy and/or the same prescriber, as applicable, that was selected under the immediately prior plan under paragraph (f)(9) of this section.

(9) *Beneficiary preferences.* Except as described in paragraph (f)(10) of this section, if a beneficiary submits preferences for prescribers or pharmacies or both from which the beneficiary prefers to obtain frequently abused drugs, the sponsor must do the following:

(i) Review such preferences.

(ii) If the beneficiary is—

(A) Enrolled in a stand-alone prescription drug benefit plan and specifies a prescriber(s) or network pharmacy(ies) or both, select or change the selection of prescriber(s) or network pharmacy(ies) or both for the bene-

ficiary based on beneficiary's preference(s).

(B) Enrolled in a Medicare Advantage prescription drug benefit plan and specifies a network prescriber(s) or network pharmacy(ies) or both, select or change the selection of prescriber(s) or pharmacy(ies) or both for the beneficiary based on the beneficiary's preference(s).

(iii) The sponsor must inform the beneficiary of the selection or change in—

(A) The second notice; or

(B) If the second notice is not feasible due to the timing of the beneficiary's submission, in a subsequent written notice, issued no later than 14 days after receipt of the submission.

(10) *Exception to beneficiary preferences.* (i) If the Part D sponsor determines that the selection or change of a prescriber or pharmacy under paragraph (f)(9) of this section would contribute to prescription drug abuse or drug diversion by the at-risk beneficiary, the sponsor may change the selection without regard to the beneficiary's preferences if there is strong evidence of inappropriate action by the prescriber, pharmacy, or beneficiary.

(ii) If the sponsor changes the selection, the sponsor must provide the beneficiary with—

(A) At least 30 days advance written notice of the change; and

(B) A rationale for the change.

(11) *Reasonable access.* In making the selections under paragraph (f)(12) of this section, a Part D plan sponsor must ensure that the beneficiary continues to have reasonable access to frequently abused drugs, taking into account all relevant factors, including but not limited to—

(i) Geographic location;

(ii) Beneficiary preference;

(iii) The beneficiary's predominant usage of a prescriber or pharmacy or both;

(iv) The impact on cost-sharing;

(v) Reasonable travel time;

(vi) Whether the beneficiary has multiple residences;

(vii) Natural disasters and similar situations; and

(viii) The provision of emergency services.

(12) *Selection of prescribers and pharmacies.* (i) A Part D plan sponsor must select, as applicable—

(A) One, or, if the sponsor reasonably determines it necessary to provide the beneficiary with reasonable access, more than one, network prescriber who is authorized to prescribe frequently abused drugs for the beneficiary, unless the plan is a stand-alone PDP, or the selection of an out-of-network provider is necessary; and

(B) One, or, if the sponsor reasonably determines it necessary to provide the beneficiary with reasonable access, more than one, network pharmacy that may dispense such drugs to such beneficiary, unless the selection of an out-of-network pharmacy is necessary.

(ii)(A) For purposes of this paragraph (f)(12) of this section, in the case of a pharmacy that has multiple locations that share real-time electronic data, all such locations of the pharmacy must collectively be treated as one pharmacy.

(B) For purposes of this paragraph (f)(12) of this section, in the case of a group practice, all prescribers of the group practice must be treated as one prescriber.

(13) *Confirmation of selections(s).* (i) Before selecting a prescriber or pharmacy under this paragraph, a Part D plan sponsor must notify the prescriber or pharmacy, as applicable, that the beneficiary has been identified for inclusion in the drug management program for at-risk beneficiaries and that the prescriber or pharmacy or both is(are) being selected as the beneficiary's designated prescriber or pharmacy or both for frequently abused drugs. For prescribers, this notification occurs during case management as described in paragraph (f)(2) or when the prescriber provides agreement pursuant to paragraph (f)(4)(i)(B) of this section.

(ii) The sponsor must receive confirmation from the prescriber(s) or pharmacy(ies) or both, as applicable, that the selection is accepted before conveying this information to the at-risk beneficiary, unless the pharmacy has agreed in advance in a network agreement with the sponsor to accept all such selections and the agreement

specifies how the pharmacy will be notified by the sponsor of its selection.

(14) *Termination of identification as an at-risk beneficiary.* The identification of an at-risk beneficiary as such must terminate as of the earlier of the following:

(i) The date the beneficiary demonstrates through a subsequent determination, including but not limited to, a successful appeal, that the beneficiary is no longer likely, in the absence of the limitation under this paragraph, to be an at-risk beneficiary; or

(ii)(A) The end of a one year period calculated from the effective date of the limitation, as specified in the notice provided under paragraph (f)(6) of this section, unless the limitation was extended pursuant to paragraph (f)(14)(ii)(B) of this section.

(B) The end of a two year period calculated from the effective date of the limitation, as specified in a notice provided under paragraph (f)(6) of this section, subject to the following requirements:

(1) The plan sponsor determines at the end of the one year period that there is a clinical basis to extend the limitation;

(2) Except in the case of a pharmacy limitation imposed pursuant to paragraph (f)(3)(ii)(B) of this section, the plan sponsor has obtained the agreement of a prescriber of frequently abused drugs for the beneficiary that the limitation should be extended.

(3) The plan sponsor has provided another notice to the beneficiary in compliance with paragraph (f)(6) of this section.

(4) If the prescribers were not responsive after 3 attempts by the sponsor to contact them within 10 business days, then the sponsor has met the requirement of paragraph (f)(14)(ii)(B)(2) of this section.

(5) The sponsor may not extend a prescriber limitation implemented pursuant to paragraph (f)(3)(ii)(A) of this section if no prescriber was responsive.

(15) *Data disclosure.* (i) CMS identifies potential at-risk beneficiaries to the sponsor of the prescription drug plan in which the beneficiary is enrolled.

(ii) A Part D sponsor that operates a drug management program must disclose any data and information to CMS

and other Part D sponsors that CMS deems necessary to oversee Part D drug management programs at a time, and in a form and manner specified by CMS. The data and information disclosures must do all of the following:

(A) Provide information to CMS within 30 days of receiving a report about a potential at-risk beneficiary from CMS.

(B) Provide information to CMS about any potential at-risk beneficiary that meets paragraph (1) of the definition in § 423.100 that a sponsor identifies within 30 days from the date of the most recent CMS report identifying potential at-risk beneficiaries;

(C) Provide information to CMS about any potential at-risk beneficiary or at-risk beneficiary that meets paragraph (2) of the definitions in § 423.100 that a sponsor identifies within 30 days from the date of the most recent CMS report identifying potential at-risk beneficiaries.

(D) Provide information to CMS as soon as possible but no later than 7 days from the date of the initial notice or second notice that the sponsor provided to a beneficiary, or as soon as possible but no later than 7 days of a termination date, as applicable, about a beneficiary-specific opioid claim edit or a limitation on access to coverage for frequently abused drugs.

(E) Transfer case management information upon request of a gaining sponsor as soon as possible but not later than 2 weeks from the gaining sponsor's request when—

(1) An at-risk beneficiary or potential at-risk beneficiary disenrolls from the sponsor's plan and enrolls in another prescription drug plan offered by the gaining sponsor; and

(2) The edit or limitation that the sponsor had implemented for the beneficiary had not terminated before disenrollment.

(16) *Clinical guidelines.* Potential at-risk beneficiaries and at-risk beneficiaries are identified by CMS or a Part D sponsor using clinical guidelines that—

(i) Are developed with stakeholder consultation;

(ii) Are based on:

(1) The acquisition of frequently abused drugs from multiple prescribers,

multiple pharmacies, the level of frequently abused drugs used, or any combination of these factors; or

(2) Beginning January 1, 2022, a history of opioid-related overdose as determined by at least one recent claim that contains a principal diagnosis indicating opioid overdose, and at least one recent claim for an opioid medication other than an opioid used for medication assisted therapy (MAT).

(iii) Are derived from expert opinion and an analysis of Medicare data; and

(iv) Include a program size estimate.

(g) *Prescription drug plan sponsors' access to Medicare Parts A and B claims data extracts.* (1)(i) Beginning in plan year 2020, a PDP sponsor may submit a request to CMS for the data described in paragraph (g)(2) of this section about enrollees in its prescription drug plans.

(ii) CMS makes the data requested in paragraph (g)(1)(i) of this section available to eligible PDP sponsors, in accordance with all applicable laws. The data is provided at least quarterly on a specified release date, and in an electronic format to be determined by CMS.

(iii) If CMS determines or has a reasonable belief that the PDP sponsor has violated the requirements of this paragraph (g) or that unauthorized uses, reuses, or disclosures of the Medicare claims data have taken place, at CMS' sole discretion, the PDP sponsor may be denied further access to the data described in paragraph (g)(2) of this section.

(2) *Data described.* The data that may be requested under paragraph (g)(1) of this section are standardized extracts 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: