

an easy to understand manner, the following complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit real-time information in their beneficiary-specific portal or computer application:

- (i) Enrollee cost sharing amounts.
- (ii) Formulary medication alternatives for a given condition.
- (iii) Formulary status, including utilization management requirements applicable to each alternative medication, as appropriate for each enrollee and medication presented.

(5) The Part D sponsor may provide rewards and incentives to enrollees who use the beneficiary real time benefit tool (RTBT) described in paragraph (d)(4) of this section, provided the rewards and incentives comply with the requirements in paragraphs (d)(5)(i) through (vi) of this section, and the rewards and incentives information is made available to CMS upon request. Use is defined as logging into the RTBT, via portal or computer application, or calling the customer service call center to obtain the information described in paragraph (d)(4) of this section. The rewards and incentives must meet the following:

- (i) Be of reasonable value, both individually and in the aggregate.
 - (ii) Be designed so that all enrollees are eligible to earn rewards and incentives, and that there is no discrimination based on race, color, national origin, including limited English proficiency, sex, age, disability, chronic disease, health status, or other prohibited basis.
 - (iii) Not be offered in the form of cash or other cash equivalents.
 - (iv) Not be used to target potential enrollees.
 - (v) Be earned solely for logging onto the beneficiary RTBT and not for any other purpose.
 - (vi) Otherwise comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil money penalty prohibiting inducements to beneficiaries.
- (e) *Claims information.* A Part D sponsor must furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits when prescription drug benefits

are provided under qualified prescription drug coverage. The explanation of benefits must—

- (1) List the item or service for which payment was made and the amount of the payment for each item or service.
- (2) Include a notice of the individual's right to request an itemized statement.
- (3) Include the cumulative, year-to-date total amount of benefits provided, in relation to—
 - (i) The deductible for the current year.
 - (ii) The initial coverage limit for the current year.
 - (iii) The annual out-of-pocket threshold for the current year.
- (4) Include the cumulative, year-to-date total of incurred costs to the extent practicable.

(5) For each prescription drug claim, must include the cumulative percentage increase (if any) in the negotiated price since the first claim of the current benefit year and therapeutic alternatives with lower cost-sharing, when available as determined by the plan, from the applicable approved plan formulary.

(6) Include any negative formulary changes applicable to an enrollee for which Part D plans are required to provide notice as described in § 423.120(f).

(7) Be provided no later than the end of the month following any month when prescription drug benefits are provided under this part, including the covered Part D spending between the initial coverage limit described in § 423.104(d)(3) and the out-of-pocket threshold described in § 423.104(d)(5)(iii).

(f) *Disclosure requirements.* CMS may require a Part D plan sponsor to disclose to its enrollees or potential enrollees, the Part D plan sponsor's performance and contract compliance deficiencies in a manner specified by CMS.

(g) *Changes in rules.* If a Part D sponsor intends to change its rules for a Part D plan, it must do all of the following:

- (1) Submit the changes for CMS review under the procedures of Subpart V of this part.
- (2) For changes that take effect on January 1, notify all enrollees at least

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: