

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