§ 423.566 Coverage determinations.

(a) Responsibilities of the Part D plan sponsor. Each Part D plan sponsor must have a procedure for making timely coverage determinations in accordance with the requirements of this subpart regarding the prescription drug benefits an enrollee is entitled to receive under the plan, including basic prescription drug coverage as specified in § 423.100 and supplemental benefits as specified in § 423.104(f)(1)(ii), and the amount, including cost sharing, if any, that the enrollee is required to pay for a drug. The Part D plan sponsor must have a standard procedure for making determinations, in accordance with § 423.568, and an expedited procedure for situations in which applying the standard procedure may seriously jeopardize the enrollee’s life, health, or ability to regain maximum function, in accordance with § 423.570.

(b) Actions that are coverage determinations. The following actions by a Part D plan sponsor are coverage determinations:

(1) A decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan’s formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the Part D plan sponsor determines that the drug is otherwise excludable under section 1862(a) of the Act if applied to Medicare Part D) that the enrollee believes may be covered by the plan;

(2) Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee;

(3) A decision concerning an exceptions request under § 423.578(a);

(4) A decision concerning an exceptions request under § 423.578(b); or

(5) A decision on the amount of cost sharing for a drug.

(c) Who can request a coverage determination. Individuals who can request a standard or expedited coverage determination are—
§ 423.568 Standard timeframe and notice requirements for coverage determinations.

(a) Method and place for filing a request. An enrollee must ask for a standard coverage determination by making a request with the Part D plan sponsor in accordance with the following:

(1) Except as specified in paragraph (a)(2) of this section, the request may be made orally or in writing.

(2) Requests for payment must be made in writing (unless the Part D plan sponsor has implemented a voluntary policy of accepting oral payment requests).

(3) The Part D plan sponsor must establish and maintain a method of documenting all oral requests and retain the documentation in the case file.

(b) Timeframe for requests for drug benefits. When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or, for an exceptions request, the physician's or other prescriber's supporting statement.

(c) Timeframe for requests for payment. When a party makes a request for payment, the Part D plan sponsor must notify the enrollee of its determination and make payment (when applicable) no later than 14 calendar days after receipt of the request.

(d) Written notice for favorable decisions by a Part D plan sponsor. If a Part D plan sponsor makes a completely favorable decision under paragraph (b) of this section, it must give the enrollee written notice of the determination. The initial notice may be provided orally, so long as a written follow-up notice is sent within 3 calendar days of the oral notification.

(e) Form and content of the approval notice. The notice of any approval under paragraph (d) of this section must explain the conditions of the approval in a readable and understandable form.

(f) Written notice for denials by a Part D plan sponsor. If a Part D plan sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination.

(g) Form and content of the denial notice. The notice of any denial under paragraph (f) of this section must meet the following requirements:

(i) Use approved notice language in a readable and understandable form.

(ii) State the specific reasons for the denial.

(iii) For drug coverage denials, describe both the standard and expedited redetermination processes, including the enrollee’s right to, and conditions for, obtaining an expedited redetermination and the rest of the appeals process.

(iv) For payment denials, describe the standard redetermination process and the rest of the appeals process.

(h) Written notice for denials by a Part D plan sponsor. If a Part D plan sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination.

(i) Form and content of the approval notice. The notice of any approval under paragraph (d) of this section must explain the conditions of the approval in a readable and understandable form.

(j) Written notice for denials by a Part D plan sponsor. If a Part D plan sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination.

(k) Form and content of the denial notice. The notice of any denial under paragraph (f) of this section must meet the following requirements:

(1) Use approved notice language in a readable and understandable form.

(2) State the specific reasons for the denial.

(3) Inform the enrollee of his or her right to a redetermination.

(4) Comply with any other notice requirements specified by CMS.

(l) Effect of failure to meet the adjudicatory timeframe. If the Part D plan sponsor fails to notify the enrollee of its determination in the appropriate timeframe under paragraphs (b) or (c) of this section, the failure constitutes an adverse coverage determination, and the plan sponsor must forward the enrollee’s request to the IRE within 24 hours of the expiration of the adjudication timeframe.

§ 423.570 Expediting certain coverage determinations.

(a) Request for expedited determination. An enrollee or an enrollee’s prescribing physician or other prescriber may request that a Part D plan sponsor expedite a coverage determination involving issues described in § 423.566(b) of this part. This does not include requests for payment of Part D drugs already furnished.