

on his or her own, or directly from the enrollee.

(3) “Can be provided only by CMS, the IRE, and/or the Part D plan sponsor” means the information is not publicly available, is not in the possession of the enrollee, and cannot be requested and obtained by the enrollee. Information that is publicly available is information that is available to the general public via the Internet or in a printed publication. It includes, but is not limited to, information available on a CMS, IRE or Part D Plan sponsor website or information in an official CMS or HHS publication.

(b) *ALJ remands a case to an IRE.*

(1) Consistent with § 423.2004(b), the ALJ will remand a case to the appropriate IRE if the ALJ determines that an IRE’s dismissal of a request for reconsideration was in error.

(2) The ALJ will remand a case to the appropriate Part D IRE if the ALJ determines that the enrollee wishes evidence on his or her change in condition after the coverage determination to be considered in the appeal.

**§ 423.2036 Description of an ALJ hearing process.**

(a) *The right to appear and present evidence.* (1) An enrollee has the right to appear at the hearing before the ALJ to present evidence and to state his or her position. An enrollee may appear by video-teleconferencing, telephone, or in person as determined under § 423.2020.

(2) An enrollee may also make his or her appearance by means of a representative, who may make his or her appearance by video-teleconferencing, telephone, or in person, as determined under § 423.2020.

(3) Witness testimony may be given and CMS, IRE, and Part D plan sponsor participation may also be accomplished by video-teleconferencing, telephone, or in person, as determined under § 423.2020.

(b) *Waiver of the right to appear.* (1) An enrollee may send the ALJ a written statement indicating that he or she does not wish to appear at the hearing.

(i) For expedited hearings, an enrollee may indicate in writing or orally that he or she does not wish to appear at the hearing.

(ii) The ALJ hearing office must document all oral waivers in writing and maintain the documentation in the case files.

(2) The enrollee may subsequently withdraw his or her waiver in writing at any time before the notice of the hearing decision is issued; however, by withdrawing the waiver the enrollee agrees to an extension of the adjudication period as specified in § 423.2016, that may be necessary to schedule and hold the hearing.

(3) Even if the enrollee waives his or her right to appear at a hearing, the ALJ may require him or her to attend an oral hearing if the ALJ believes that a personal appearance and testimony by the enrollee is necessary to decide the case.

(c) *Presenting written statements and oral arguments.* An enrollee or an enrollee’s appointed representative, as defined at § 423.560, may appear before the ALJ to state the enrollee’s case, to present a written summary of the case, or to enter written statements about the facts and law material to the case in the record.

(d) *Waiver of adjudication period.* At any time during the hearing process, the enrollee may waive the adjudication deadline specified in § 423.2016 for issuing a hearing decision. The waiver may be for a specific period of time agreed upon by the ALJ and the enrollee.

(e) *What evidence is admissible at a hearing.* The ALJ may receive evidence at the hearing even though the evidence is not admissible in court under the rules of evidence used by the court. However, the ALJ may not consider evidence on any change in condition of an enrollee after a coverage determination. If the enrollee wishes for the evidence to be considered, the ALJ must remand the case to the Part D IRE as set forth in § 423.2034(b)(2).

(f)(1) *Subpoenas.* When it is reasonably necessary for the full presentation of a case, an ALJ may, on his or her own initiative, issue subpoenas for the appearance and testimony of witnesses and for the enrollee and/or the Part D plan sponsor to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection

and copying. An ALJ may not issue a subpoena to CMS, or the IRE to compel an appearance, testimony, or the production of evidence, or to the Part D plan sponsor to compel an appearance or testimony.

(2) *Reviewability of an ALJ Subpoena.* A subpoena issued by an ALJ is not subject to immediate review by the MAC. The subpoena may be reviewed solely during the MAC's review specified in § 423.2102 and § 423.2110.

(3) *Exception.* To the extent a subpoena compels disclosure of a matter which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before an ALJ, the MAC may review immediately the ruling of the ALJ on the objections to the subpoena or that portion of the subpoena as applicable.

(i) Upon notice to the ALJ that the enrollee or a non-party, as applicable, intends to seek MAC review of the ALJ's ruling on the subpoena, the ALJ must stay all proceedings affected by the subpoena.

(ii) The proceedings are stayed for 15 calendar days or until the MAC issues a written decision that affirms, reverses, or modifies the ALJ's subpoena, whichever comes first.

(iii) If the MAC does not take action within the 15 calendar days, then the stay is lifted and the enrollee or non-party must comply with the ALJ's subpoena.

(4) *Enforcement.* (i) If the ALJ determines that an enrollee or person other than the enrollee subject to a subpoena issued under this section has refused to comply with the subpoena, the ALJ may request that the Secretary seek enforcement of the subpoena in accordance with section 205(e) of the Act, 42 U.S.C. 405(e).

(ii) After submitting the enforcement request, the time period for the ALJ to issue a decision, dismissal or remand a case in response to a request for hearing is stayed for 15 calendar days or until the Secretary makes a decision with respect to the enforcement request, whichever occurs first.

(iii) Any enforcement request by an ALJ must consist of a written notice to the Secretary describing in detail the ALJ's findings of noncompliance

and his or her specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the enrollee or person other than the enrollee subject to the subpoena.

(iv) The ALJ must promptly mail a copy of the notice and related documents to the individual or entity subject to the subpoena, to the enrollee, and to any other affected person.

(g) *Witnesses at a hearing.* Witnesses may appear at a hearing. They testify under oath or affirmation, unless the ALJ finds an important reason to excuse them from taking an oath or affirmation. The ALJ may ask the witnesses any questions relevant to the issues and allow the enrollee or his or her appointed representative, as defined at § 423.560.

#### **§ 423.2038 Deciding a case without a hearing before an ALJ.**

(a) *Decision wholly favorable.* If the evidence in the hearing record supports a finding in favor of the enrollee(s) on every issue, the ALJ may issue a hearing decision without giving the enrollee(s) prior notice and without holding a hearing. The notice of the decision informs the enrollee(s) that he or she has the right to a hearing and a right to examine the evidence on which the decision is based.

(b) *Enrollee does not wish to appear.* (1) The ALJ may decide a case on the record and not conduct a hearing if—

(i) The enrollee indicates in writing or, for expedited hearings orally or in writing, that he or she does not wish to appear before the ALJ at a hearing, including a hearing conducted by telephone or video teleconferencing, if available. The ALJ hearing office must document all oral requests not to appear at a hearing in writing and maintain the documentation in the case files; or

(ii) The enrollee lives outside the United States and does not inform the ALJ that he or she wants to appear.

(2) When a hearing is not held, the decision of the ALJ must refer to the evidence in the record on which the decision was based.