AUTHENTICATED
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INFORMATION
GPO

(iv) Telephone number, if any.

(v) Health Insurance Claim number, if applicable.

(vi) E-mail address, if applicable.

(2) *If the beneficiary has a representative,* the representative-identifying information must include the following:

(i) Name.

(ii) Mailing address.

(iii) Telephone number.

(iv) E-mail address, if any.

(v) Copy of the written authorization to represent the beneficiary.

(3) *Treating physician written statement.* A copy of a written statement from the treating physician that the beneficiary needs the service that is the subject of the LCD. This statement may be in the form of a written order for the service or other documentation from the beneficiary's medical record (such as progress notes or discharge summary) indicating that the beneficiary needs the service.

(4) *LCD-identifying information:*

(i) Name of the contractor using the LCD.

(ii) Title of LCD being challenged.

(iii) The specific provision (or provisions) of the LCD adversely affecting the aggrieved party.

(5) *Aggrieved party statement.* A statement from the aggrieved party explaining what service is needed and why the aggrieved party thinks that the provision(s) of the LCD is (are) not valid under the reasonableness standard.

(6) *Clinical or scientific evidence.* (i) Copies of clinical or scientific evidence that support the complaint and an explanation for why the aggrieved party thinks that this evidence shows that the LCD is not reasonable.

(ii) Any documents or portions of documents that include proprietary data must be marked ''proprietary data,'' and include a legal basis for that assertion.

(iii) Proprietary data submitted by a manufacturer concerning a drug or device for which the manufacturer has submitted information to the Food and Drug Administration, must be considered and given substantive weight only when supported by an affidavit certifying that the submission contains true and correct copies of all data submitted by the manufacturer to the Food and Drug Administration in relation to that drug or device.

(d) *Joint complaints*—(1) *Conditions for a joint complaint.* Two or more aggrieved parties may initiate the review of an LCD by filing a single written complaint with the ALJ if all of the following conditions are met:

(i) Each aggrieved party named in the joint complaint has a similar medical condition or there are other bases for combining the complaints.

(ii) Each aggrieved party named in the joint complaint is filing the complaint in regard to the same provision(s) of the same LCD.

(2) *Components of a valid joint complaint.* A joint complaint must contain the following information:

(i) The beneficiary-identifying information described in paragraph (c)(1) of this section for each aggrieved party named in the joint complaint.

(ii) The LCD-identifying information described in paragraph (c)(2) of this section.

(iii) The documentation described in paragraphs (c)(3) and (c)(4) of this section.

(3) *Timeliness of a joint complaint.* Aggrieved parties, who choose to seek review of an LCD—

(i) Before receiving the service, must file with the ALJ a joint complaint within 6 months of the written statement from each aggrieved party's treating physician.

(ii) After receiving the service, must file with the ALJ a complaint within 120 days of each aggrieved party's initial denial notice.

§ 426.403 Submitting new evidence once an acceptable complaint is filed.

Once an acceptable complaint is filed, the aggrieved party may submit additional new evidence without withdrawing the complaint until the ALJ closes the record.

§ 426.405 Authority of the ALJ.

(a) An ALJ conducts a fair and impartial hearing, avoids unnecessary delay, maintains order, and ensures that all proceedings are recorded.

(b) An ALJ defers only to reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(c) The ALJ has the authority to do any of the following:

(1) Review complaints by an aggrieved party (or aggrieved parties).

(2) Dismiss complaints that fail to comply with § 426.400.

(3) Set and change the date, time, and place of a hearing upon reasonable notice to the parties.

(4) Continue or recess a hearing for a reasonable period of time.

(5) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding.

(6) Consult with scientific and clinical experts on his or her own motion concerning clinical or scientific evidence.

(7) Set schedules for submission of exhibits and written reports of experts.

(8) Administer oaths and affirmations.

(9) Examine witnesses.

(10) Issue subpoenas requiring the attendance of witnesses at hearings as permitted by this part.

(11) Issue subpoenas requiring the production of existing documents before, and relating to, the hearing as permitted by this part.

(12) Rule on motions and other procedural matters.

(13) Stay the proceedings in accordance with § 426.340.

(14) Regulate the scope and timing of documentary discovery as permitted by this part.

(15) Regulate the course of a hearing and the conduct of representatives, parties, and witnesses.

(16) Receive, rule on, exclude, or limit evidence, as provided in § 426.340.

(17) Take official notice of facts, upon motion of a party.

(18) Decide cases, upon the motion of a party, by summary judgment when there is no disputed issue of material fact.

(19) Conduct any conference, argument, or hearing in person or, upon agreement of the parties, by telephone, picture-tel, or any other means.

(20) Issue decisions.

(21) Exclude a party from an LCD review for failure to comply with an ALJ order or procedural request without good cause shown.

(22) Stay the proceedings for a reasonable time when all parties voluntarily agree to mediation or negotiation, and provide mediation services upon request.

(d) The ALJ does not have authority to do any of the following under this part:

(1) Conduct an LCD review or conduct LCD hearings on his or her own motion or on the motion of a non-aggrieved party.

(2) Issue a decision based on any new evidence without following § 426.340, regarding procedures for review of new evidence.

(3) Review any decisions by contractors to develop a new or revised LCD.

(4) Conduct a review of any draft, retired, archived, template, or suggested LCDs.

(5) Conduct a review of any policy that is not an LCD, as defined in § 400.202 of this chapter.

(6) Conduct a review of any NCD according to section 1869(f)(1)(A)(i) of the Act.

(7) Conduct a review of the merits of an unacceptable LCD complaint as discussed in § 426.410.

(8) Allow participation by individuals or entities other than—

(i) The aggrieved party and/or his/her representative;

(ii) CMS and/or the contractor; and

(iii) Experts called by the parties or the ALJ.

(9) Compel the parties to participate in a mediation process or to engage in settlement negotiations.

(10) Deny a request for withdrawal of a complaint by an aggrieved party.

(11) Compel the contractor to conduct studies, surveys, or develop new information to support an LCD record.

(12) Deny a contractor the right to reconsider, revise or retire an LCD.

(13) Find invalid applicable Federal statutes, regulations, rulings, or NCDs.

(14) Enter a decision specifying terms to be included in an LCD.

§ 426.406 *Ex parte* contacts.

No party or person (except employees of the ALJ's office) communicates in