

§ 426.431

(3) If the ALJ determines that the LCD record is not complete and adequate to support the validity of the LCD, the ALJ permits discovery and the taking of evidence in accordance with §§ 426.432 and 426.440 and evaluates the LCD in accordance with § 426.431.

(d) The process described in paragraphs (a), (b), and (c) of this section applies when an LCD record has been supplemented, except that discovery and the taking of evidence are not repeated. The period for the aggrieved party to file a statement begins when the aggrieved party receives the supplement.

§ 426.431 ALJ's review of the LCD to apply the reasonableness standard.

(a) *Required steps.* To review the provision(s) listed in the aggrieved party's complaint based on the reasonableness standard, an ALJ must:

(1) Confine the LCD review to the provision(s) of the LCD raised in the aggrieved party's complaint.

(2) Conduct a hearing, unless the matter can be decided on the written record.

(3) Close the LCD review record to the taking of evidence.

(4) Treat as precedential any previous Board decision under § 426.482 that involves the same LCD provision(s), same specific issue and facts in question, and the same clinical conditions.

(5) Issue a decision as described in § 426.447.

(b) *Optional steps.* The ALJ may do the following to apply the reasonableness standard to the provision(s) listed in the aggrieved party's complaint:

(1) Consult with appropriate scientific or clinical experts concerning evidence.

(2) Consider any previous ALJ decision made under § 426.447 regarding the same provision(s) of the LCD under review and for the same clinical conditions.

(c) *Authority for ALJs in LCD reviews when applying the reasonableness standard.* In applying the reasonableness standard to a provision (or provisions) of an LCD, the ALJ must follow all applicable laws, regulations, rulings, and NCDs.

42 CFR Ch. IV (10–1–14 Edition)

§ 426.432 Discovery.

(a) *General rule.* If the ALJ orders discovery, the ALJ must establish a reasonable timeframe for discovery.

(b) *Protective order—(1) Request for a protective order.* Any party receiving a discovery request may file a motion for a protective order before the date of production of the discovery.

(2) *The ALJ granting of a protective order.* The ALJ may grant a motion for a protective order if (s)he finds that the discovery sought—

(i) Is irrelevant or unduly repetitive;

(ii) Is unduly costly or burdensome; or

(iii) Unduly delays the proceeding.

(c) *Types of discovery available.* A party may obtain discovery via a request for the production of documents, and/or via the submission of up to 10 written interrogatory questions, relating to a specific LCD.

(d) *Types of documents.* For the purpose of this section, the term “documents” includes relevant information, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing contained in this section is interpreted to require the creation of a document.

(e) *Types of discovery not available.* Requests for admissions, depositions, or any other forms of discovery, other than those permitted under paragraph (c) of this section, are not authorized.

(f) *Privileged information and proprietary data.* The ALJ must not, under any circumstance, order the disclosure of privileged information or proprietary data filed under seal without the consent of the party who possesses the right to protection of the information.

(g) *Notification.* The ALJ notifies all parties in writing when the discovery period closes.

§ 426.435 Subpoenas.

(a) *Purpose of a subpoena.* A subpoena requires the attendance of an individual at a hearing and may also require a party to produce evidence authorized under § 426.440 at or before the hearing.

(b) *Filing a motion for a subpoena.* A party seeking a subpoena must file a written motion with the ALJ not less than 30 days before the date fixed for