

in the case of an NCD review) is not complete, or not adequate to support the validity of the coverage determination, under the reasonableness standard. This statement will be filed after the aggrieved party has had adequate time to review the record (30 days after receipt of the record, with a possible extension for good cause shown). The statement will be submitted to the adjudicator, to the contractor (if an LCD review), and to us (if applicable). In § 426.425(b) and § 426.525(b), we explain that the contractor/CMS has 30 days to respond.

In § 426.425(c) and § 426.525(c), we explain that, after the time for filing has expired, the ALJ or the Board will evaluate whether the record is complete and adequate to support the validity of the policy by applying the reasonableness standard. If the adjudicator determines that the record is not complete, not adequate to support the validity of the coverage determination, or both, the adjudicator will notify all parties to the review of this decision and allow discovery (as proposed in § 426.432 and § 426.532 and discussed later in this section of the preamble). If the adjudicator determines that the record is complete and adequate to support the validity of the coverage determination, the adjudicator will issue a decision finding the LCD/NCD record complete and adequate to support the validity of the LCD/NCD and the review process ends. In § 426.425(d) and § 426.525(d), we state that the process described in (a), (b), and (c) applies whenever an LCD/NCD record is supplemented.

Under § 426.431 and § 426.531, we describe the process that adjudicators will use to review the provision(s) named in a complaint based on the reasonableness standard. The actions of this process include the following:

- Confining the LCD/NCD review to the provision(s) of the LCD/NCD raised in the aggrieved party's complaint;
- Conducting a hearing, unless the matter can be decided on the written record;
- Closing the LCD/NCD review record to the taking of evidence;
- Issuing a decision as described in § 426.447 and § 426.547. We further state that ALJs may consider previous ALJ decisions regarding the LCD provisions with the same issues and facts and the same clinical conditions. We also provide that ALJs must treat as precedential any previous Board decision that involves the same LCD provision(s), same specific issues and facts in question, and same clinical conditions. We also provide that the Board will follow applicable Board

precedent regarding the same NCD provisions and the same clinical conditions.

In addition, the adjudicator has the option, under § 426.431(b) and 426.531(b), to consult with appropriate scientific or clinical experts, and to consider previous ALJ decisions (discussed in the section of the preamble on § 426.440 and § 426.540).

In § 426.431(c) and § 426.531(c), we explain that ALJs and the Board must follow all applicable laws and regulations, and NCDs, with the exception that the Board is not bound by the NCD that is before it.

Under § 426.432 and § 426.532, paragraph (a), if the ALJ or the Board orders discovery, the ALJ or the Board will establish a reasonable timeframe for discovery and ensure that a party to the LCD or NCD review who receives a discovery request has certain rights. In paragraph (b), we state that any party receiving a discovery request may file a motion for a protective order before the date of production of the discovery.

Under § 426.432 and § 426.532, we also set forth the rules for discovery during an LCD or NCD review, respectively.

We have eliminated proposed § 426.432(a)(3) and § 426.532(a)(3) because we do not expect any non-parties to be required to submit evidence in these proceedings.

In § 426.432(c) and § 426.532(c), we list the types of discovery that are available. In § 426.432(d) and § 426.532(d), we explain what the term discovery includes and state that discovery does not require the creation of any document. In § 426.432(e) and § 426.532(e), we identify forms of discovery that are not available. We believe that this is consistent with normal practice and will avoid unnecessary delays in the coverage determination reviews.

For proprietary data or privileged information, § 426.432(f) and § 426.532(f), we have clarified that the ALJ/Board may not, under any circumstances, disclose this material to the public without consent from the party who possesses the right to protection of the information.

In § 426.432(g) and § 426.532(g), we state that the ALJ/Board will notify all parties in writing of the date when the discovery period will close.

While reviewing a provision of an LCD or NCD, the adjudicator may, if necessary, issue subpoenas. In § 426.435 and § 426.535, we describe the process for obtaining and responding to subpoenas during a coverage determination review. A request for a subpoena to require the attendance of an

individual at a hearing (or provide evidence at a hearing) must be filed with the adjudicator by a party to the coverage determination review at least 30 days before the date of a hearing. In addition to designating the witnesses (and their locations) and the evidence to be produced by those witnesses, the subpoena must state the facts that the party expects the witness to establish, and state whether these facts could be established by other evidence or without the use of a subpoena.

The subpoena sections also detail the role of adjudicators in granting subpoenas, the role of a party in serving a subpoena, and the role and rights of the individual receiving a subpoena (including the right to file a motion to quash a subpoena). In addition, in § 426.435(h) and § 426.535(h), we also set forth the remedy afforded under section 205(e) of the Act, if a subpoena is not obeyed.

We describe the rules relating to evidence in coverage determination reviews in § 426.440 and § 426.540. In § 426.440(a) and § 426.540(a), we state the ALJ or the Board is not bound by the Federal Rules of Evidence, but may apply the rules, if appropriate. In § 426.440(b) and § 426.540(b), we provide that the ALJ or the Board must exclude evidence that is clearly irrelevant, immaterial, or unduly repetitive. Sections 426.440(c) and § 426.540(c) provide admission of, and protection for the submission of proprietary/privileged information under seal. Sections 426.440(d) and § 426.540(d) address the authority of the ALJ/Board over the use of expert witnesses. Under § 426.440(e) and § 426.540(e), we require experts submitting reports to be available for cross-examination at an evidentiary hearing. Under § 426.440(f) and § 426.540(f), we require that, unless otherwise ordered by the adjudicator for good cause shown, all documents and other evidence be open to examination by all parties to the review, except as set forth in § 426.440(c) and § 426.540(c).

Under § 426.444 and § 426.544, we describe an adjudicator's dismissal for cause of a complaint regarding an LCD or an NCD, respectively. A dismissal is effectuated by the issuance of a decision dismissing a complaint. In general, an adjudicator may dismiss a complaint if an aggrieved party fails to attend or participate in a pre-hearing conference (the pre-hearing may be conducted by telephone) or hearing without good cause shown or fails to comply with a lawful order from an adjudicator (see § 426.444(a) and § 426.544(a)). Under § 426.444(b) and § 426.544(b), we require that the adjudicator dismiss