

would allow contractors to produce existing records rather than requiring them to develop and produce new documentation.

*Response:* We appreciate the commenter's support of our proposals and have taken its views into account in considering the comments of those commenters who recommended revisions.

*Comment:* One commenter objected to our proposal not to initiate discovery between parties until after an adjudicator has made a determination about the adequacy of the record. The commenter suggested that discovery should be available any time after the complaint is filed.

*Response:* We note that the statute establishes the timing of discovery. Section 1869(f)(1)(A)(iii)(I) and section 1869(f)(2)(A)(i)(I) of the Act provide for discovery and the taking of evidence only in instances where an ALJ or the Board has reviewed the record and made a determination that it is incomplete or lacks adequate information to support the validity of the LCD or NCD at issue. Therefore, we believe that an initial determination regarding the completeness and adequacy of a record must precede the initiation of discovery between parties.

*Comment:* Several commenters opposed our rule limiting discovery to requests for documents only. The commenters suggested that parties should be permitted to use interrogatories and other discovery means. A commenter also objected to the rules at § 426.435 and § 426.535 setting forth the subpoena procedures on the basis that they are inconsistent with the Federal Rules of Civil Procedure, particularly with respect to the 30-day notice requirement. Finally, one commenter suggested that discovery should not be restricted to material relating to a specific LCD or NCD but should include other policies that might be relevant to an evaluation of whether a coverage policy is reasonable.

*Response:* The BIPA gives a right to discovery, but does not specify permissible forms and does not require that these administrative proceedings follow the discovery or subpoena rules set forth in the Federal Rules of Civil Procedure or the rules of any other administrative proceedings. We proposed limiting discovery to requests for documents and believe this approach is consistent with other Departmental rules permitting discovery. (See, for example, 42 CFR 1005.7). After consideration of the comments, however, we are expanding discovery under § 426.432(c) and § 426.532(c) to include the opportunity

to submit 10 written interrogatory questions. This is intended to be a limited opportunity, available when needed to promote the overall efficiency of the review proceeding, that we expect ALJs and the Board to narrowly construe to minimize the burden on the agency. We are also revising § 426.432(e) and § 426.532(e) to exclude written interrogatories from the list of unavailable discovery. We are not allowing for depositions, requests for admissions, or other types of discovery because we view them as unnecessary for this kind of administrative proceeding and because this limitation will reduce the time and expense associated with these appeals. We believe that limiting discovery in this way will ensure the timely and efficient disposition of LCD and NCD challenges.

*Comment:* A commenter objected to an adjudicator's issuance of a protective order without the employment of a balancing test to determine whether the moving party has a sufficient basis for requesting the order. Another commenter objected to the absence of any provision authorizing a beneficiary or the Board to compel disclosure of documents by us.

*Response:* Sections 426.432(b)(2) and 426.532(b)(2) set forth criteria that adjudicators must utilize in determining whether to grant or deny protective orders. We believe that these criteria are sufficient to evaluate the merits of a request for a protective order without developing an additional balancing test. As a result, we will not be incorporating the commenter's suggestion into this final rule. Furthermore, we believe that a process for compelling disclosure of all documents by us is not necessary because these regulations already set forth and define the scope of what must be provided through discovery.

#### *Expert Witness*

*Comment:* One commenter objected to the restrictions on the introduction of expert evidence, having interpreted them as permitting oral testimony by an expert witness only if written evidence were submitted.

*Response:* Sections 426.440(e) and 426.540(e) do not require that a witness provide a written report, but rather require that any expert witness providing written testimony be available for oral cross examination. Under § 426.440(d) and § 426.540(d), the ALJ or the Board may require or permit expert witnesses to submit a written report. Moreover, it is common practice for expert witnesses to submit written reports in order to use hearing time efficiently and to focus questioning effectively.

#### *Withholding Evidence Deemed To Be Proprietary*

In the proposed rule, we sought to limit disclosure of "proprietary data" based on the parenthetical phrase included in section 1862(a) of the Act in the paragraph that follows. The provision in this paragraph establishes several procedural requirements that the Secretary must follow in making NCDs. The provision states:

In making a national coverage determination (as defined in paragraph (1)(B) of section 1869(f)) the Secretary shall ensure that the public is afforded notice and an opportunity to comment prior to implementation by the Secretary of the determination; meetings of advisory committees established under section 1114(f) with respect to the determination are made on the record; in making the determination, the Secretary has considered the applicable information (including clinical experience and medical, technical, and scientific evidence) with respect to the subject matter of the determination; and in the determination, provide a clear statement of the basis for the determination (including responses to comments received from the public), the assumptions underlying that basis, and make available to the public the data (other than proprietary data) considered in making the determination.

The reference to "proprietary data" reflects a limitation on disclosure to the public. We specifically invited public comments "on the scope of proprietary data and the extent to which this material should not be disclosed" (67 FR 54541). Comments we received on this issue follow.

*Comment:* We received several public comments concerning proprietary data and information disclosure. Several commenters agreed with the proposal to limit disclosure of proprietary data. One commenter suggested that the record contain only the materials referenced in the LCD. One commenter indicated that it should apply to the studies and analysis purchased or performed by a contractor. Another commenter observed that patient specific information should also be protected and disseminated only with patient permission.

Other commenters opposed the concept. One commenter asked that the regulation be revised to state that the record contains "all the information presented to the Agency and/or the Medicare contractor when the coverage determination was being established[.]" One commenter suggested that the record should be expanded to include relevant information that comes to CMS "after a policy is published." Another commenter wrote that, "a contractor or CMS can withhold from the reviewing body information it believes to be