

proprietary, creating a huge loophole that allows the withholding of evidence in support of the beneficiary's claim. Because the proposed regulation provides for very limited discovery, a beneficiary will have very little opportunity to determine whether supporting documentation has been withheld." Other commenters suggested that "these proposed regulations be revised to state that the record includes any document or materials that were presented to CMS or the contractor in the development of the LCD or NCD."

Another commenter suggested that when we compile the record of the LCD or NCD, we should also produce an index of all material that was excluded, and then seek a protective order from the adjudicator to exclude that material from the record. We would be required to state for each document the specific basis for a claim of privilege or the specific provisions of Federal statute authorizing the withholding or prohibiting disclosure. A beneficiary would be given an opportunity to respond and object.

*Response:* In section 1862(a) of the Act, the Congress provided that the Secretary was not required to disclose "proprietary data" to the public when making available the data considered in making the determination. We believe it is likely that this exception serves to encourage manufacturers and others to submit evidence that would be useful in making LCDs/NCDs. Prior to this statute, manufacturers may have been reluctant to submit valuable business and commercial data if they believed it would be publicly disclosed as part of a record in a judicial proceeding. This provision enables the Secretary to receive and consider proprietary data and to assure that proprietary data would not be disclosed without the expressed consent of the individual or entity that submitted the documents. This may enable the contractor/CMS to make LCDs/NCDs, including determinations that may expand Medicare coverage, more rapidly and accurately.

We are aware that there is tension in the statute between the specific right given to an aggrieved party to seek discovery during the appeal process (section 1869(f)(1)(A)(iii)(I) of the Act), and the opportunity that the Secretary is given to withhold from the public "proprietary data." The public comments include cogent views from both perspectives. The Secretary has the discretion and challenge to balance these competing interests, and must resolve this issue in order to implement the expanded appeal rights that the Congress has provided.

We are resolving this tension by issuing this regulation to inform the public that we will withhold proprietary data from the public during the ALJ or the Board process. We do not expect to have proprietary data in our possession in most cases. In the rare instance that we obtain and consider proprietary data, this information will be presented to the ALJ or the Board under seal but will not be disclosed to any party or disclosed as part of the public record of the LCD/NCD proceedings. We believe that the Congress's concern about disclosure of proprietary information to the public in section 1862(a) of the Act suggests that the Congress did not intend to mandate disclosure of that same data during the LCD/NCD appeal. The limited assurance of maintaining confidentiality during the process of preparing an LCD/NCD, but not during the administrative appeal, would discourage manufacturers from submitting crucial confidential information.

At § 426.110, we are specifically defining "proprietary data" and "privileged information" as information from a source external to CMS or a contractor, or protected health information, that meets the following criteria: (1) It is ordinarily protected from disclosure pursuant to 45 CFR Part 164, under the Trade Secrets Act (18 U.S.C. 1905) or under Exemptions 4 or 5 of the Freedom of Information Act (5 U.S.C. 552) as specifically interpreted in our Departmental regulations at 45 CFR 5.65; and (2) the party who possesses the right to protection of the information from public release or disclosure has not provided its consent to the public release or disclosure of the information. Any information submitted by the public that is not marked as proprietary will not be considered proprietary. We may review this assertion in determining whether the information is proprietary data. Any information received that is not designated as "proprietary data" will not be considered "proprietary data." In order for proprietary data to be considered and given weight in LCD or NCD reviews, any such proprietary data submitted by a manufacturer of a drug or device should contain true and complete records of all clinical and scientific data existent and, therefore, any submission must include an affidavit that the data consists of true and correct copies of all data submitted by the manufacturer to any other Federal or State agency or department in relation to that drug or device. This is to limit the possibility that review decisions are based on partial or biased presentations of available evidence.

Consistent with this requirement, CMS will request such certifications when receiving proprietary data for its initial NCD analysis, and would anticipate a similar procedure by carriers or intermediaries in their LCD analysis.

We believe this relatively narrow exception will still provide beneficiaries adequate access to all of the evidence that is typically considered in making LCDs/NCDs. There is a great deal of helpful and useful information available in publicly disclosable documents that are relevant to the subjects that we consider. In many cases the proprietary data may just reaffirm conclusions that are consistent with publicly available sources. While we recognize that this resolution may be somewhat awkward for a party challenging an LCD/NCD, we believe this result is in the best interests of the public. This approach will support more accurate and rapid coverage determinations through greater access to more data and may lead to faster and better LCDs/NCDs that may increase access to new advances in medicine and technology.

For the comment that we provide an index of all excluded material, we are adopting this comment in part. In the rare event that we rely on proprietary and privileged data in formulating a coverage decision, these data will be given to the ALJ/Board under seal. In this rare event, these data will not be furnished to the aggrieved party; rather, we, or our contractors, will include an index that lists all of the excluded material as part of the LCD/NCD record. To implement the statutory protections for proprietary data and privileged information in section 1862(a) of the Act, we are not furnishing proprietary and privileged data as part of the public record, but the seal will be maintained on that information for use by a court in relation to an NCD review. In the event that a court seeks to obtain or requires disclosure of proprietary data or privileged information, CMS or the Department will seek to have a protective order applied to that information, to prohibit any recipients of the information from further disclosing the information or from using it for any purpose other than the challenge. The statutory protection accorded this data ensures the availability of the best relevant information whether proprietary or not, and maximizes flexibility in developing coverage determinations.

#### *Consulting Scientific and Clinical Experts*

*Comment:* We received two comments requesting a clearer definition of who could be considered a scientific or