

clinical expert, and requesting that those with conflicts of interest not be considered as experts. A related comment stated that the ALJs/Board may solicit testimony from any expert on issues relevant to the LCD/NCD provision(s) in question.

Response: We agree with these comments. We are clarifying that scientific and clinical experts consulted by the ALJ/Board must be independent and impartial and have significant experience and published work pertaining to the subject of the review to be considered experts.

Comment: A commenter objected to the rule allowing the Board to call its own witnesses. The commenter suggested that the rule would compromise the role of the Board by placing it in an advocacy position.

Response: While we appreciate the commenter's concern regarding the appropriate role of the Board, we are obligated to comply with statutory requirements, and section 1869(f)(1)(A)(iii)(II) of the Act specifically provides that the Board "may, as appropriate, consult with appropriate scientific and clinical experts." Therefore, we believe it proper to interpret this statutory provision to permit adjudicators to call their own witnesses when reviewing LCDs or NCDs. Moreover, similar provisions exist in many administrative procedures, especially those involving public health or safety.

Witness and Legal Fees

Comment: One commenter referred to § 426.445 and questioned whether or not we would pay for witness fees for contractors' witnesses and legal fees incurred in connection with LCD review.

Response: The compensation of Medicare contractors and their witnesses is an internal policy matter, which need not be resolved in this final rule.

Role of CAC/MCAC

Comment: Two commenters suggested that members of the Contractor Advisory Committee (CAC) and members of the Medicare Coverage Advisory Committee (MCAC) should have substantial input into the LCD/NCD review process.

Response: The CAC/MCAC members already serve an important role in developing certain Medicare policies. We believe it would be inappropriate for these individuals to serve as expert witnesses in these proceedings. Therefore, we are not revising the final rule in response to this comment.

Burden of Proof

Comment: We received several comments regarding the proper burden of proof in the adjudicatory proceedings when an LCD or NCD is challenged. One commenter believed we should make it clearer that the burden of proof was on the challenger to show that an item or service is safe and effective for the proposed indication. Two commenters believed we should stop requiring proponents to show that Medicare coverage is appropriate. These commenters suggest that the Social Security Act places the burden of proof on us if it wishes to deny Medicare coverage and suggested that the contractor/CMS should have the burden of showing why evidence supports retention of an LCD or NCD.

Response: We disagree with the commenters who suggest that the burden of proof should rest on the government. The Social Security Act contains no "presumption that services are covered." Rather, the Act expressly provides that "[n]otwithstanding any other provision of this title, no payment may be made * * * for expenses incurred for items or services * * * not reasonable and necessary * * *." (Section 1862(a)(1)(A) of the Act (42 U.S.C. 1395y(a)(1)(A)). Courts have recognized that this language "which bars benefits for services 'not reasonable and necessary' for diagnosis or treatment, is not reasonably interpreted as an affirmative mandate to extend coverage to all necessary services." *Goodman v. Sullivan*, 891 F.2d 449, 450 (2d Cir. 1989). Moreover, section 205(a) of the Social Security Act, 42 U.S.C. 405(a), expressly incorporated in title XVIII by section 1872, 42 U.S.C. 1395ii, permits the Secretary to adopt "reasonable and proper rules and regulations to regulate and provide for the nature and extent of proofs and evidence" and the method of furnishing that evidence. In light of this authority, we are clarifying our final rule at § 426.330 to more clearly place the burden of production and persuasion on the individual challenging an LCD or NCD.

Reasonableness Standard

In the proposed rule, we adopted a reasonableness standard requiring the adjudicator to determine whether the findings of fact, interpretations of law, and applications of fact to law by CMS or the contractor were reasonable. Comments on this issue follow.

Comment: One commenter supported the approach we had taken to define reasonableness. One commenter suggested that we need a better

definition of reasonableness. Two commenters stated that the reasonableness standard is too "soft" or "lax" for a meaningful review, and instead, a substantial evidence or "de novo" standard should be used. One commenter suggested that a "totality of the circumstances test" should be used.

Response: We proposed a standard of review that was consistent with the specific language of the statute. Therefore, we believe it would not be appropriate to use any other standard. We use the "reasonableness standard" as the standard that an ALJ or the Board must apply when conducting an LCD or an NCD review. In determining whether LCDs or NCDs are valid, the adjudicator must uphold a challenged policy (or a provision or provisions of a challenged policy) if the findings of fact, interpretations of law, and applications of fact to law by the contractor or us are reasonable based on the LCD or NCD record and the record developed before the ALJ/Board. We are using the statutory language from sections 1869(f)(1)(A)(iii) and (f)(2)(A)(i) of the Act, which instructs adjudicators to defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

The logical corollary is that the ALJs and the Board must accord deference if the contractor's or CMS's findings of fact, interpretations of law, and application of fact to law are reasonable. The concept of deference is one that is generally applied by courts to administrative decisionmaking, in recognition of the expertise of a program agency. Thus, we view the statute as setting out a reasonableness standard that recognizes the expertise of the contractors and CMS in the Medicare program—specifically, in the area of coverage requiring the exercise of clinical or scientific judgment.

So long as the outcome is one that could be reached by a rational person, based on the evidence in the record as a whole (including logical inferences drawn from that evidence), the determination must be upheld. This is not simply based on the quantity of the evidence submitted, but also includes an evaluation of the persuasiveness of the material. If the contractor or CMS has a logical reason as to why some evidence is given more weight than other evidence, the ALJs and the Board may not overturn the determination simply because they would have accorded more weight to the evidence in support of coverage. In some situations, different judgments by different contractors may be supportable, especially if explained by differences