DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 405, and 426

[CMS–3063–F]

RIN 0938–AK60

Medicare Program: Review of National Coverage Determinations and Local Coverage Determinations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will create a new process to allow certain Medicare beneficiaries to challenge national coverage determinations (NCDs) and local coverage determinations (LCDs). It will implement portions of section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000. The right to challenge NCDs and LCDs will be distinct from the existing appeal rights that Medicare beneficiaries have for the adjudication of Medicare claims.

EFFECTIVE DATE: The provisions set forth in this final rule are effective December 8, 2003.

FOR FURTHER INFORMATION CONTACT: Vadim Lubarsky, 410–786–0840 for National Coverage Determinations. Misty Whitaker, 410–786–3087 for Local Coverage Determinations.

SUPPLEMENTARY INFORMATION:

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Note: The former name of the Centers for Medicare & Medicaid Services (CMS) was the Health Care Financing Administration (HCFA). The terms CMS and HCFA can be used interchangeably.

In addition, because of the many terms to which we refer by acronym in this final rule, we are listing these acronyms and their corresponding terms in alphabetical order below.

ALJ—Administrative Law Judge
CAC—Carrier Advisory Committee
CMP—Comprehensive Medical Plan
DMERC—Durable Medical Equipment Regional Carrier
FI—Fiscal Intermediary
HCPP—Health Care Prepayment Plan
HMO—Health Maintenance Organization
LCD—Local Coverage Determination
LMRP—Local Medical Review Policy
M+C—Medicare+Choice
MCAC—Medical Coverage Advisory Committee
NCD–National Coverage Determination
QIO—Quality Improvement Organization
RHHI—Regional Home Health Intermediary

I. Background

A. Background of Rulemaking

On August 22, 2002, we issued a proposed rule (67 FR 54534) implementing certain provisions of section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), proposing a process for the review of local coverage determinations (LCDs) and national coverage determinations (NCDs). The notice and comment period closed on October 21, 2002. We received 31 timely comments, which were quite useful in identifying issues and concerns. We have made significant changes to this final rule to address the public comments. We believe that these changes will contribute to a fairer and more efficient process. Significant changes to the proposed rule based on public comments, which are discussed in section III, below, include:

- More broadly defining beneficiaries ''in need.''
- Reducing the burden for physician certification requirements.
- Allowing for participation in the BIPA section 522 adjudicatory process as an amicus curiae (friend of the court) for NCD appeals.
- Creating a mechanism to allow new evidence to be received subject to time-limited remands.
- Expanding the effect of a final decision by the Administrative law judge (ALJ) or the HHS Departmental Appeals Board (Board).

B. Overview of Existing Statutes, Regulations, and Policies

Medicare is the nation's largest health insurance program covering approximately 41 million Americans. Beneficiaries consist primarily of individuals 65 years of age or older, some disabled people under 65 years of age, and people with end-stage renal disease (permanent kidney failure treated with dialysis or a transplant).

The original Medicare program consists of two parts. Part A, known as the hospital insurance program, covers certain care provided to inpatients in hospitals, critical access hospitals, skilled nursing facilities, as well as hospice care and some home health care. Part B, the supplementary medical insurance program, covers certain physicians' services, outpatient hospital care, and other medical services that are not covered under Part A. While the original Medicare program covers many health care items and services, it does not cover all health care expenses. The Medicare statute specifically excludes from coverage certain items and services under section 1862(a) of the Social Security Act (the Act).

In addition to the original Medicare program, beneficiaries may elect to receive health care coverage under the Medicare+Choice (M+C) program under Part C of the Medicare program. This program provides beneficiaries with various options, including the right to choose a Medicare managed care plan or a Medicare private fee-for-service plan. Under the M+C program, an individual is entitled to those items and services (other than hospice care) for which benefits are available under Part A and Part B. An M+C plan may provide additional health care items and services that are not covered under the original Medicare program.

The Act gives beneficiaries specific rights to challenge particular types of decisions. We are committed to providing beneficiaries an opportunity to fully exercise these statutory rights. Moreover, we are committed to resolution of these disputes in a fair and efficient manner.

C. Claims Appeal Process

Under the original Medicare program, a beneficiary may generally obtain health services from any institution, agency, or person qualified to participate in the Medicare program that undertakes to provide the service to the individual. Assuming that a qualified provider or supplier has furnished medical care, the health care provider or supplier, or, in some cases, a beneficiary would submit a claim for benefits under

the Medicare program. If the claim is for an item or service that falls within a Medicare benefit category, is reasonable and necessary for the individual, and is not otherwise statutorily excluded, a government contractor (either a fiscal intermediary for claims under Part A or Part B, or a carrier for claims under Part B) would pay the claim. However, if the Medicare contractor determines that the medical care is not covered under the Medicare program, the Medicare contractor would deny the claim.

This final rule does not seek to significantly alter the existing claims appeal process. Nor does this rule significantly alter our existing regulations for M+C beneficiaries as established at § 422.560 through § 422.622. However, it does create an expanded definition of aggrieved party to include a beneficiary who received a service, but whose claim for the service was denied, extending an opportunity to that beneficiary to file a complaint under § 426.400 or § 426.500. For further discussion of the claims appeal process please consult the proposed rule.

D. National Coverage Determinations (NCDs)

Section 1869(f)(1) of the Act defines national coverage determination as ''a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII, but does not include a determination of what code, if any, is assigned to a particular item or service covered under this title or a determination with respect to the amount of payment made for a particular item or service so covered.'' For the full discussion of NCDs please consult our proposed rule at 67 FR 54535 published on August 22, 2002.

E. Local Medical Review Policy (LMRP)

As explained in the preamble to the proposed rule, Local Medical Review Policies are contractor-specific policies that identify the circumstances under which particular items or services will be (or will not be) considered covered and correctly coded. An LMRP is not controlling authority for ALJs or the Board in the claims appeals process. These guidelines simply help to ensure that similar claims are processed in a consistent manner within those jurisdictions. LMRPs may not conflict with an NCD, but may be written in the absence of, or as an adjunct to, an NCD.

An LMRP may contain any or all of the following:

- Coding provisions.
- Benefit category provisions.
- Statutory exclusion provisions.
- Provisions related to the authority under section 1862(a)(1)(A) of the Act, which prohibits payment for any expenses incurred for services that are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member.

Some LMRPs contain only a single type of provision, while other LMRPs contain all four types. The provisions described in bullets two through four above constitute coverage provisions.

For further information on LMRPs please consult our proposed rule at 67 FR 54535.

F. Local Coverage Determinations

Section 522 of BIPA does not use the term ''LMRP,'' but uses the term ''Local Coverage Determination'' (LCD). Section 522 of BIPA amends section 1869(f)(2)(B) of the Act, to define LCD as ''a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary-or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A).''

An LMRP may contain four different types of provisions (coding, benefit category, statutory exclusion, and reasonable and necessary). Section 1869(f)(2)(B) of the Act limits an LCD as a determination only under section 1862(a)(1)(A) of the Act's ''reasonable and necessary provision.'' For the purposes of this regulation, we will use the term ''reasonable and necessary provision'' to describe section 1862(a)(1)(A) of the Act. We intend to work with contractors to divide LMRPs into separate LCD and non-LCD documents; however, it is likely that LMRPs will continue to exist for the next several years. During this time, the term LCD will refer to both of the following:

- Separate, stand-alone documents entitled ''LCDs'' that contain only reasonable and necessary language; and
- The reasonable and necessary provisions of an LMRP.

G. Differences Between NCDs and LMRPs/LCDs

Under our claims appeals process, ALJs may consider, but are not bound by, LMRPs or LCDs. Thus, an ALJ may rule that Medicare payment is due on a particular item or service received by a beneficiary, based on the particular circumstances represented by the case, even if the contractor's LMRP or LCD clearly prohibits payment for the particular service. (We note that a regulation which may impact ALJ consideration of LCDs in claims appeal cases has been proposed. *See* 67 FR 69328, 69351.) On the other hand, contractors and ALJs are bound by NCDs. ALJs may not review an NCD.

H. Individual Claim Determinations

In addition to policy determinations, contractors may make individual claim determinations, even in the absence of an NCD, LMRP, or LCD. In circumstances when there is no published policy on a particular topic, decisions are made based on the individual's particular factual situation. *See Heckler* v. *Ringer,* 466 U.S. 602, 617 (1984) (recognizing that the Secretary has discretion to either establish a generally applicable rule or to allow individual adjudication).

I. Impact of Section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)

1. Overview of the Legislation

Section 522 of the BIPA created a new review process that enables certain beneficiaries to challenge LCDs and NCDs. These appeal rights are distinct from the existing appeal rights for the adjudication of Medicare claims. This section also creates additional avenues for beneficiaries to seek judicial review. Before BIPA, the statute did not provide an administrative avenue to challenge the facial validity of LCDs or NCDs.

2. Differences Between the Claims Appeal Process and the LCD/NCD Review Processes

The existing claims appeal rights were not significantly changed by section 522 of the BIPA. Our claims appeal regulations will continue to provide detailed administrative appeal rights for beneficiaries whose claims are denied. These claims appeal procedures permit beneficiaries to challenge the initial claims denial and include *de novo* review by an independent ALJ. If still dissatisfied after exhausting all administrative remedies, a beneficiary has a right to seek judicial review in a Federal district court. This claim appeal system enables beneficiaries to submit any relevant information pertaining to an individual claim. Moreover, because LCDs are not controlling authorities for ALJs, when an ALJ does not find an LCD persuasive, an individual claim appeal could result in the claim being paid without the need to challenge the underlying LCD. We have proposed rules that would modify the claims appeals process at 67 FR 69312 (November 15, 2002).

Section 522 of the BIPA created a review process that is separate and

independent from the claims appeal process. This process will be different, because the nature of the challenge and the relevant evidence is different. The procedures used in this process will be different from the claims appeals process. Review of an LCD or NCD requires examination of an entire policy, or specific provisions contained therein, and not just one claim denial. Therefore, such reviews may lead to changes that impact other beneficiaries if the policies are found to be unreasonable. A beneficiary, thus, may elect to pursue a claims denial through the claims appeal process, seek review of an LCD or NCD using the process in this final rule, or both. In no way does filing a 522 challenge, or a decision on a 522 challenge, affect beneficiary appeal rights or other issues that may arise in the claims appeal process.

Complaints under section 522 of the BIPA are subject to standing rules. Namely, under section 1869(f)(5) of the Act ''[a]n action under this subsection seeking review of a national coverage determination or local coverage determination may be initiated only by individuals entitled to benefits under part A, or enrolled under part B, or both, who are in need of the items or services that are the subject of the coverage determination.'' In this final rule, we are interpreting the standing provision to include individuals who have received the item or service and whose initial claim was denied based on an LCD or NCD and, thus, are in need of Medicare coverage. We will also permit the estates of certain individuals to have standing. Only individuals who have standing may bring a challenge under section 522 of the BIPA, and in this final rule, we refer to these individuals as ''aggrieved parties.''

As discussed in the proposed rule, the aggrieved party may not assign the right to bring a challenge under section 522 of the BIPA to anyone else. However, the aggrieved party is permitted to obtain assistance from any individual in pursuing the challenge. (We discuss the difference between assigning rights and receiving assistance in section IV of this final rule.)

The definition of an ''aggrieved party'' will permit an individual to bring a challenge to an LCD or NCD in advance of receiving an item or service, or after the LCD or NCD is applied to a claim causing the claim to be denied. As we discuss in greater detail in section IV.E of this preamble, a successful challenge would permit the individual to have his or her specific claim reviewed without reference to the challenged policy. Claims that are otherwise payable can be paid. In addition, a successful challenge to an LCD or NCD may result in the following:

- The policy being retired/withdrawn in its entirety, or
- The policy being revised to effectuate the Board decision, or the ALJ decision if it is not appealed to the Board.

3. The Reconsideration Process

We previously established a procedure by which individuals could seek reconsideration of policies established in an LCD or NCD. The procedures for NCDs were set forth in the September 26, 2003 notice (68 FR 55634, 55641). The procedures for LCDs were set forth in the Program Integrity Manual, Chapter 13, Section 11.

4. The Role of Other Interested Individuals or Entities

The section 522 review process is intended to be initiated only by aggrieved parties. However, consistent with several public comments, we are expanding § 426.510(f) to allow for limited participation in an NCD challenge by other individuals as amicus curiae when the individuals or entities meet the standards set forth in these regulations. Please note that the reconsideration process described in section I.I.3 of this preamble remains the appropriate process by which all other interested entities may submit new evidence pertaining to the review of current LCDs and NCDs.

5. Differences Between an LCD/NCD Review and an LCD/NCD Reconsideration

The main difference between an LCD/NCD review under section 522 of the BIPA and an LCD/NCD reconsideration is the avenue an individual chooses to take to initiate a change to a coverage policy and who may initiate the review. All interested parties, including an aggrieved party, may request a reconsideration of an LCD or NCD, rather than filing a complaint to initiate the review of an LCD or NCD. Conversely, only an aggrieved party may file a complaint to initiate the review of an LCD or NCD. If the aggrieved party believes that we, or the contractor, misinterpreted evidence or excluded available evidence in making the coverage determination or has new evidence to submit, then the aggrieved party has the option to file a request for a reconsideration by the contractor or us, respectively, or to file a complaint to seek review by an adjudicator.

In the reconsideration process, all interested parties, not just aggrieved parties, have the opportunity to submit new scientific and medical evidence for review by individuals with medical and scientific expertise. The reconsideration process permits experts to make judgments about those policies, rather than using an adjudicatory proceeding.

II. Provisions of the Proposed Rule

For a discussion of the specific provisions of the proposed rule, please see 67 FR 54534–54563. The significant changes to the final rule, based on public comments, are reflected in section III, below.

III. Analysis of and Response to Public Comments

We received 31 comments from the public on the proposed rule. Summaries of the major comments received and our responses to those comments are set forth below.

Definition of an NCD

Comment: We received several comments on our interpretation of what qualifies as an NCD, and which policies are subject to review. Some public comments stated that we interpreted the statute too narrowly, and that additional policies should be subject to review; other public comments suggested that we interpreted the statute too broadly, and that benefit category determinations should not be defined as NCDs, and should not be subject to review before the Board.

Response: Our definition of an NCD is consistent with the statutory language, and we are not accepting the public comments that suggest the definition is either too broad or too narrow. We continue to believe that the statute is clear, and that the Congress has created a new definition of NCD to include benefit category determinations. The Congress's definition of an NCD is now broader than the prior statute at section 1869(b)(3) of the Act. Moreover, it is broader than the definition of LCD that is specifically limited to determinations made in accordance with section 1862(a)(1)(A) of the Act. We presume that the Congress acted intentionally and precisely in defining an NCD, and we are following that definition in this final rule.

Definition of LCD

Comment: One commenter suggested that an LCD should be synonymous with LMRP.

Response: Because the statutory definition of an LCD is limited to the reasonable and necessary provisions in section 1862(a)(1)(A) of the Act, we could not make the definition of an LCD synonymous with the definition of an LMRP. As discussed earlier in this preamble, an LMRP may contain coding,

benefit category, and statutory exclusion provisions that are not based on section 1862(a)(1)(A) of the Act.

Comment: Several commenters suggested that both procedure codes and diagnosis codes be included within the definition of LCD. These commenters stated that the final regulation should not preclude an aggrieved party from challenging the reasonable and necessary provisions of an LCD that contain diagnosis codes.

Response: An LCD or LMRP provision stating that a service is not reasonable and necessary for specified diagnoses (whether listed in text or listed by ICD–9 diagnosis code) is considered part of the LCD.

Definition of an Aggrieved Party

Comments: We received two comments in support of our proposed definition of an aggrieved party as a beneficiary in need of a service and who has not yet received the service that is the subject of the coverage determination. While these commenters felt that it is correct to allow aggrieved parties to initiate the review of an LCD or NCD, they wrote that opening up the LCD/NCD review process to beneficiaries who have already received the service would result in unnecessarily complicated adjudications. However, over half of all commenters on the rule suggested that the definition was too narrow and should be expanded. Some commenters stated that the proposed definition was far too restrictive and suggested that we remove the requirement that the service not be received at the time the complaint is filed. One commenter pointed out that the proposed definition would insulate certain LCDs and NCDs from ever being challenged because some LCDs/NCDs address services that are only used in emergency or urgent situations where the beneficiary would be incapable of filing a challenge prior to receiving the service. Some commenters suggested that beneficiaries would lose their section 522 rights if they chose not to forego urgent treatment. One commenter suggested that we revise the definition to require that the beneficiary be in need of coverage for a service. One commenter specifically requested the establishment of an emergency appeals process.

Response: In response to these comments, we have interpreted the statutory requirements more broadly and have expanded the definition of aggrieved party to require that the beneficiary be in need of coverage of a service. Therefore, the definition includes beneficiaries who have already received the service. We believe this change obviates the need for an emergency appeals process because a beneficiary can obtain an emergency service and then seek review without forgoing his or her rights. In order to define which beneficiaries have standing as aggrieved parties, we have added a requirement in § 426.400(b)(2) and § 426.500(b)(2) that aggrieved parties, who have received a service and have filed a claim, must file their section 522 challenge within 120 days of the date of the initial denial notice from the contractor.

Comment: One commenter stated that beneficiaries should be allowed to challenge coverage NCDs as well as non-coverage NCDs.

Response: We conclude in this final rule that a beneficiary is aggrieved by an NCD only if it denies coverage for a service which that beneficiary needs. Therefore, the ALJ/Board may accept a complaint regarding an NCD that limits coverage. Since the Congress provided for review upon the filing of a complaint by an aggrieved party, we believe that the Congress intended the process to be available only when the beneficiary is in need of coverage for an item or service that would be denied or has been denied, under an LCD or NCD.

Allowing a Beneficiary To Assign Appeal Rights

Comment: We received a number of public comments suggesting that the aggrieved party should be able to assign LCD or NCD review rights under section 522 of the BIPA to another person or entity. Several of the comments suggested that the procedures were complex and that, by enabling a beneficiary to assign the rights to another person, it would relieve the beneficiary of the burden of participating in the process and would be more equitable, or, perhaps, more efficient. One commenter suggested that permitting providers to be aggrieved parties would have been consistent with an earlier proposal in a Senate bill. Some commenters suggested that allowing physicians or other interested parties to assist the beneficiary in requesting review would be useful to beneficiaries. Other commenters recognized that the Medicare program permitted the assignment of rights in other contexts.

On the other hand, one commenter noted that the statute requires a beneficiary in need to initiate a review. Another commenter agreed with our proposal, and believed it would be inappropriate under the statute to permit the assignment of rights to request a review of an LCD or NCD to other interested parties. That commenter noted that the ''Medicare program is fundamentally a beneficiary, or patient, program designed to assure access to clinically sound services.''

Response: We are retaining our position that an aggrieved party may not assign legal rights to request a review of an LCD or NCD to a third party, but are clarifying our rules to ensure that a challenger is not precluded from obtaining assistance or representation from individuals or entities who may assist the beneficiary in pursuing the individual's appeal.

We agree with the commenter who suggested that the statute was clear in this regard. The standing provision in section 1869(f)(5) of the Act is precise. Moreover, as one commenter correctly observed, a broader standing provision, that would have enabled other interested parties to file complaints about LCDs and NCDs, existed in earlier drafts of the legislation. It appears that the Congress's narrowing of the language in the final bill was intentional and deliberate. We do not believe it would be consistent with this history to expand the scope of individuals who have a legal right to initiate and pursue a challenge to an LCD or NCD.

We do, however, agree that beneficiaries may seek assistance from knowledgeable physicians, suppliers, providers, manufacturers, and attorneys in developing the individual's request for review. The individual is free to consult with these individuals and to follow those suggestions, recommendations, or advice. Thus, while these individuals may assist the beneficiary in navigating the adjudicatory process in an efficient manner, the beneficiary may not assign his or her legal right to request a review of an LCD or an NCD to a third party.

Comment: A commenter suggests that dually eligible Medicare and Medicaid beneficiaries have already assigned rights to third party payment to Medicaid agencies by virtue of sections 1902(a)(45) and 1912 of the Act, and § 433.137 of the Medicaid regulations, and that States, therefore, should be allowed to participate in the process.

Response: We disagree with the commenter. The provisions of the Act and regulations cited concern the assignment of rights to seek medical support or payments and in providing information to assist the State in pursuing financially liable third parties. In contrast, a person initiating a challenge to an LCD or NCD is seeking to have a coverage policy held invalid and is not establishing a right to medical support or payment. Should a dually eligible beneficiary prevail in a policy challenge, a State may benefit in the

claims adjudication process if it is determined that the policy was invalid. Furthermore, although this adjudicatory process is not available to a State directly, a State may always request reconsideration of an LCD or NCD.

Dismissal of Complaint Upon Death of Beneficiary

Comments: We received comments about the proposed policy that would have dismissed complaints if the beneficiary died after initiating a section 522 challenge. Approximately one third of the commenters were opposed to this policy, and only one supported it. That commenter concluded that since the deceased would no longer be considered ''in need,'' it would be appropriate to dismiss the claim. The majority of those who commented objected to permitting an estate to appeal a claim without permitting the estate to continue a challenge to the policy that could determine the outcome of the appeal, thereby denying meaningful relief. One commenter indicated that the policy of automatic dismissal of a complaint upon death runs contrary to Federal common law that allows for the survival of remedial, as distinguished from penal or punitive, claims. In describing the burdens created by an automatic dismissal, the commenters referred to the potential for delay, the requirement to seek meaningful redress in Federal court rather than through the administrative appeals process, wasted resources expended prior to the death of the beneficiary in LCD/NCD challenges, and the potential for devastating financial burdens on the estates of deceased beneficiaries.

Response: We have revised the final rule to permit the estate of a beneficiary, as a successor in interest, to continue a challenge in those cases where the aggrieved party received the service and filed a timely complaint prior to death. In addition, we will allow an estate to initiate a challenge within 120 days of the issuance of a denial notice.

Acceptability of Complaints

Comments: Some commenters stated their belief that the complaint filing process in the proposed rule was overly complex. One commenter suggested that complaints should be deemed acceptable if sent to the ALJ, the local Social Security office, carrier or fiscal intermediary (FI), or the Board.

Response: We have revised the final rule to simplify and clarify the complaint filing procedures and to make them more beneficiary-friendly. We have eliminated a number of requirements that we believe are unnecessary. However, it is the duty of the beneficiary to file the complaint correctly under these regulations. Nevertheless, we will issue instructions advising our contractors of procedures for a misdirected LCD/NCD complaint. These instructions will inform the contractor that it should forward the complaint to the proper location and notify the beneficiary.

Physician Certification

Comment: Some commenters stated that physician documentation of medical need is a reasonable way of determining whether beneficiaries have a basis for challenging LCDs/NCDs. However, other commenters felt that the physician certification requirements imposed unnecessary new paperwork burdens on physicians. Some commenters argued that it was unrealistic to require physicians to be certain of the intricacies of Medicare policies. Others felt these requirements would prove to be a significant impediment to the process and suggested that the original physician order for the service suffice as certification that the beneficiary needed the service. Finally, a number of commenters suggested that non-physician practitioners should be allowed to document the beneficiary's need.

Response: We have revised the certification requirements at § 426.400(c) and § 426.500(c) in this final regulation by clarifying that the certification of need can be in the form of a written order for the service in question or other documentation in the medical record, thus significantly simplifying the certification requirements. We have also removed the requirement that the practitioner predict that payment would be denied. However, we continue to believe that the beneficiary's treating physician—not any treating practitioner—is best situated to determine ''in need'' status, both because he or she is the primary caregiver and also is responsible for the beneficiary's overall care.

Joint Complaints

Comments: We proposed permitting multiple parties to file a single complaint. We received one comment in support of the joint complaint option noting that it permits more effective resource utilization in addressing complaints. One commenter recommended that the criterion for joint complaints should not require ''a similar medical condition,'' rather that the adverse impact created by the LCD or NCD should create standing. Another commenter asserted that requiring a similar medical condition was unnecessary and inconsistent with the Federal Rules of Civil Procedure and that requiring a challenge to the same provisions of the same policy should be sufficient.

Response: In response to the comments concerning the requirement of a ''similar medical condition'' for the filing of a joint complaint, we believe that this requirement is reasonable, given the specific focus of these adjudications. Moreover, the Federal Rules of Civil Procedure are not controlling on our administrative proceedings. We believe that these procedures appropriately fit the specific requirements for LCD and NCD adjudications and are consistent with the Secretary's authority (42 U.S.C. 405(a)). Moreover, we do not eliminate the possibility of combining actions based upon different medical conditions if a party believes, and the ALJ/Board finds, that there are other bases for consolidating complaints.

Adjudicator Consolidation of Complaints

Comment: We received three comments on adjudicator authority to consolidate complaints. One commenter recommended merging the provisions for joint and consolidated complaints or, alternatively, having the provisions cross-reference one another. Another commenter objected to the consolidation of complaints without the aggrieved party having reviewed the other complaint(s) to determine whether or not the consolidation might negatively impact the individual's specific issue with the LCD or NCD. Another commenter questioned whether the consolidation might result in lengthening the process if an adjudicator combined a later complaint with an earlier one.

Response: We believe that preserving the procedures for aggrieved parties to file joint complaints and for adjudicators to consolidate complaints promotes efficiency in adjudicating challenges to LCDs and NCDs. While we recognize that the two procedures support a common goal, we note that they are separate and distinct and therefore should remain in their respective sections. With respect to the comments concerning the possibility that a party might find consolidation adverse or burdensome, we believe it is appropriate for the adjudicator to determine whether consolidation is appropriate under the specific circumstances. We will allow any aggrieved party who feels disadvantaged by consolidation to raise these issues to the ALJ/Board. We have added language to § 426.410(e) and § 426.510(e) to

clarify that the ALJ/Board may not consolidate complaints if doing so would unduly delay the ALJ/Board decision.

Amending a Complaint

Comment: Several commenters indicated that they were concerned that the proposed rule allowed a beneficiary to amend a complaint only once and then required the ALJ/Board to dismiss the challenge if the aggrieved party failed to submit an acceptable amended complaint.

Response: The statute requires that the section 522 challenge begin with the filing of a complaint. We believe that it would be inefficient if an aggrieved party had an unlimited number of attempts to file an acceptable complaint. A complaint is a significant document in identifying issues on appeal and leads to the production of the record. The final rule continues to allow the aggrieved party one opportunity to amend an unacceptable complaint before a time penalty is imposed.

Withdrawal of Complaint—Six-Month Limit on Refiling

Comment: We received two comments in support of our proposal to establish a six-month limitation if an aggrieved party withdraws a complaint. One commenter was opposed, stating that if the aggrieved party has new evidence, he or she should be allowed to file another complaint regardless of the timeframe. We received two additional comments suggesting that, if the aggrieved party has new evidence, he or she should be allowed to file another complaint without a time limitation.

Response: We continue to believe that the six-month time limit is necessary to ensure the efficient use of scarce resources. If the aggrieved party withdraws a complaint, that aggrieved party must still wait six months before filing a new complaint on the same LCD/NCD. However, we have clarified that, once an acceptable complaint has been filed, if the aggrieved party identifies new evidence that was not available at the filing of the original complaint, the aggrieved party may submit that new evidence at any time without withdrawing and resubmitting the complaint.

Aggrieved Party Submitting a Brief

Comment: We received one comment suggesting that an aggrieved party should have the opportunity to submit a brief after the aggrieved party has had the opportunity to review the record upon which the LCD or NCD was based.

Response: We agree that an aggrieved party should have an opportunity to make his or her case. In seeking to make this process accessible to Medicare beneficiaries, who may or may not have legal representation, we did not want to mandate that parties submit legal briefs in support of their claims. However, in view of the changes we have made to the review process in this final rule, particularly for the introduction and use of new evidence, we are clarifying that, while briefs are not required in all cases, the adjudicator may request or permit the parties to submit written briefs and that the aggrieved party has the option to retain representation and to submit these written briefs.

Educating Beneficiaries and Providers About the Process

Comment: Many commenters stressed the importance of having a well-constructed and advertised educational campaign for providers and beneficiaries. Some commenters suggested that a template for an acceptable complaint, a physician's certification, and an acceptable appeal of an ALJ's decision be available on the CMS Web site to assist beneficiaries in filing an acceptable complaint. Another commenter suggested that beneficiaries should be informed of their rights in the LCD or NCD review process and that one means of providing this might be to include it with advanced beneficiary notice (ABN) forms. Another commenter encouraged us to inform beneficiaries clearly as to their financial obligations while the complaint is pending. Several other commenters suggested that we provide model language for use by Medicare managed care organizations to use in their evidence of coverage documents.

Response: In the proposed rule (67 FR 54547), we explained our intent to produce a user-friendly guide that beneficiaries may use in accessing the section 522 process. We will work with the ALJs and Board to develop educational materials to inform the public of—

(1) The elements of an acceptable complaint;

(2) The standards for treating physician certifications; and

(3) The elements of an acceptable appeal of an ALJ decision. We intend to prepare this educational material (including templates) and make it publicly available, but we will not delay implementation of the final rule to wait for these materials to be developed. We will work with ALJs and the Board to make available to Medicare managed care organizations and Medicaid State agencies, relevant information on complaints and decisions. We do not intend to revise ABNs as part of this educational program.

Allowing Participation by Interested Entities

Comment: Several commenters believed that we should allow for more public participation of interested entities in the process, along with submission of evidence by those parties.

Response: The LCD and NCD reconsideration processes currently exist to give all interested entities the right to request and participate in reconsiderations of these policies. These processes will continue to exist to provide an avenue for all interested entities to submit evidence that they consider pertinent. In contrast, the adjudicatory process created by section 522 is initiated only by a beneficiary in need of coverage, and not by all interested individuals. We are concerned that allowing any member of the public to submit evidence would make these adjudicatory proceedings unwieldy. We are modifying this final rule at § 426.513, however, to permit participation as *amicus curiae,* in the NCD process. We recognize that NCD reviews may impact a large number of stakeholders apart from the aggrieved parties initiating the review. We believe that the nationwide effect of an NCD review decision requires public notice and opportunities for input in a way that LCD reviews do not. In addition, this impact may be significant, even where no change to existing policy results from the review, such as when the Board concludes that an NCD record is complete and contains adequate information to support the validity of the NCD.

Anyone who has information that can assist the Board in reviewing an NCD challenge is permitted to request participation as an *amicus curiae.* Given the nationwide effect of an NCD review decision, the process must strike a careful balance between providing reasonable opportunities for input by those who may ultimately be substantially affected by any decision, and creating a workable process to address the issues presented by the aggrieved party seeking review. Because of the regional nature and high number of LCDs, allowing the opportunity for *amicus curiae* participation in the review of LCDs would create an inefficient process. However, at any time, any party within the contractor's jurisdiction who wishes to bring forward new evidence relating to a policy may do so through the contractor's LCD reconsideration process. This process is frequently used

and is an efficient method to bring new evidence to the contractor's attention.

Making NCD Complaints and Documentation Available and Announcing the Proceedings

Comments: A number of commenters suggested that all interested parties should have notice of an LCD/NCD complaint and have the opportunity to participate in the proceedings. One commenter recommended the use of an on-line docketing system whereby the public could learn of LCD/NCD challenges and determinations made by the ALJs and Board in these cases.

Response: The statute does not require that we develop such a nationwide online docketing system. While the concept is interesting, an online docketing system is beyond the scope of this regulation. Currently, we are exploring options for the best way to docket and track challenges.

Changes in NCDs may determine the health care services, technologies, and treatments to which beneficiaries have access. The denial of coverage for a service that is allegedly reasonable and necessary may have an adverse impact on others across the nation. Hence, it is important that the review decisions are based on a comprehensive and well-developed record.

In addition, the general public may have a substantial interest in the outcome of some NCD reviews. NCD review decisions will constitute a legal precedent with respect to the outcome. Board decisions will clarify the extent of available Medicare coverage.

Therefore, under the final rule, the Board will make available to the public information about all NCD complaints by means of posting on the Internet. This method will provide the broadest possible public notice, without unreasonably delaying review of the complaint already filed. Any request to participate as an *amicus* must then generally be filed within the timeframes set by the Board.

Although LCDs are also important, LCDs are regional in nature. Because LCD reviews generally impact only a limited geographic area, we will not require the ALJs to make public all LCD complaints.

Notice to Managed Care Organizations (MCOs) and State Agencies

Comment: Several commenters suggested that Medicare managed care organizations (MCOs) and State agencies receive timely notification when a challenge is filed at each stage of review, when an ALJ/Board decision is made, and when a revised LCD/NCD is effective. One commenter suggested that the regulation be revised to require the ALJ or the Board to notify MCOs when an enrollee challenges an LCD/NCD.

Response: We will work with the ALJs and the Board to make available to MCOs and State agencies, relevant information about complaints and decisions.

Mediation

Comment: We received one comment for and one comment against using mediation in an evidence-based review process.

Response: We have added a provision authorizing the Board to stay the review proceedings for a reasonable time when all parties voluntarily engage in settlement negotiations, with or without the assistance of an impartial mediator. In general, we do not consider it appropriate to negotiate about clinical issues that affect the health or safety of Medicare beneficiaries. In some instances, however, it may be worthwhile to explore alternative and less costly means of resolving a dispute. Mediation may be useful to narrow the issues in dispute in order to make the review process more efficient. Using alternative means of resolving disputes is consistent with the Federal Administrative Dispute Resolution Act and HHS policy. Under this final rule, the ALJ or the Board could not compel mediation. Where the parties consent to mediation, the ALJ or the Board may provide an impartial mediator or assist the parties in finding an impartial mediator acceptable to them.

Automatic Dismissal When a Contractor Retires an LCD or CMS Withdraws an NCD

Comments: One commenter agreed that, if an NCD is withdrawn, the purpose for the review has been eliminated and the claims can be adjudicated without consideration of the repealed NCD, but objected to the statement that the repeal will have the same effect as a decision under § 426.560(b). The commenter, however, interpreted section § 426.560(b) as permitting a contractor to continue to rely on a withdrawn NCD.

Response: Retiring an LCD or withdrawing an NCD would result in the retired/withdrawn policy no longer applying in the claims adjudication process for services rendered on or after the date that the policy is retired/withdrawn. Moreover, the aggrieved party would be granted individual claim review. Since a claimant would receive the same relief that would have been available had the adjudicator found that the relevant LCD or NCD was not valid, there would be no reason to continue the appeal.

Comment: One commenter recommended against automatic dismissal if a policy were retired or withdrawn. As an alternative, the commenter suggested giving the adjudicator discretion to dismiss ''where the decision normally occurs'' and opined that since a retired or withdrawn policy may be reconsidered or reaffirmed, the automatic dismissal provision effectively nullifies the entire policy appeal process.

Response: When we retire/withdraw an LCD/NCD we will not apply those policies for services furnished after the retirement/withdrawal date and we will reprocess the aggrieved party's affected claims without applying the retired/withdrawn policy. If, in the future, the contractor or CMS issues a new LCD/NCD on that subject the change would be adopted after an opportunity for public comment. Any such change would be prospective in nature, and a new LCD/NCD would be subject to challenge under this final rule.

Comment: Two commenters indicated that automatic dismissal would not permit an ALJ's or the Board's findings to be used in the appeal of claims decisions based upon the invalidated policy.

Response: Because the ALJ or the Board would not be required to make a decision in a case where the contractor/CMS retired/withdrew the LCD/NCD, there would be no Board decision with precedential effect. However, we believe our approach conserves resources for all parties and adjudicators.

Timeline for Beneficiary Getting the LCD/NCD Record

Comment: We received one comment on the timing of the LCD/NCD record production requirement. That commenter suggested that we should create a 45-day response timeframe to ensure that the review process proceeds without inordinate delays.

Response: We agree that the establishment of timeframes will promote the efficiency of the BIPA 522 process. However, we believe that the time required will vary with the size and scope of the record requested. Therefore, we have revised the final rule at § 426.410(d) and § 426.510(d) to state that the contractor or CMS must generally produce the record within 30 days, subject to extension for good cause shown.

Timeline for an Aggrieved Party to Review the LCD or NCD Record

Comment: One commenter suggested that 30 days might not be enough time

for the aggrieved party to review the record, particularly for an individual pursuing a complaint with minimal outside assistance. The commenter recommended a 45-to-60-day timeframe for the aggrieved party to respond.

Response: We accept the commenter's suggestion to increase the time for review of the record. While we have maintained the 30-day timeframe, we have added an exception for good cause shown, for review and response to the relevant LCD or NCD record, if additional time is required.

No Evidence To Support an LCD/NCD

Comment: We received several comments stating that where no record exists to support an LCD/NCD, the beneficiary should not have to introduce new evidence.

Response: We expect it would be a rare event that no record exists. In that rare event, we agree with the commenter. We have made changes to clarify that, in the rare event that no evidence exists to support an LCD or NCD, we will either voluntarily retire/withdraw the policy, or request the ALJ/Board to strike down the applicable provision(s) of the policy, whichever is the more expeditious option.

New Evidence

Comment: Approximately half of the commenters made comments on the issue of new evidence. Most of the comments stated that allowing us to have an automatic stay, coupled with the absence of specific deadlines, would unduly delay the review process. Other commenters suggested that the stay should be a matter of ALJ/Board discretion. Numerous comments specifically requested that the ALJ or Board review all evidence, including new evidence, to allow for a more efficient process.

Response: We agree that a more efficient and time-sensitive adjudicatory process is important, and we have addressed several aspects of these comments in the final rule. We have taken considerable steps to create an efficient adjudicatory process that still preserves the important role of the clinical and scientific experts in making LCDs and NCDs.

We have eliminated the proposed automatic stay when new evidence is submitted. Instead, our final rule will require that, if new evidence has been received by the ALJ/Board that would otherwise be admissible, the ALJ/Board will review the new evidence after the period for discovery and the taking of evidence is complete, and decide if it has the potential to significantly affect the LCD/NCD provision in question. If not, the review will continue. If the ALJ/Board determines that the new evidence has the potential to significantly affect the validity of the LCD/NCD, the ALJ/Board will stay the proceedings and forward the material to the contractor or to us for a brief review. The contractor/CMS will have 10 days to provide a statement indicating whether or not: (1) A reconsideration will be initiated, or (2) the policy will be revised or retired/withdrawn. If the Agency undertakes a reconsideration, it must be completed within a period set by the ALJ/Board that is not more than 90 days. We believe this 90-day timeframe is reasonable due to the potentially large body of evidence that must be reviewed. Following a reconsideration, the contractor/CMS will prepare and submit the new LCD/NCD record, and the ALJ/Board proceedings will continue on the revised LCD/NCD. If the contractor/CMS chooses not to initiate a reconsideration, the ALJ/Board proceedings will continue on the original LCD/NCD as supplemented with the new evidence. The aggrieved party will have an opportunity to submit a statement about whether the record still fails to support the validity of the LCD/NCD. The contractor/CMS will have an opportunity to respond. No further evidence will be taken at this stage, and the ALJ/Board will proceed to make a determination on the merits.

We have also made changes to the definition of ''new evidence'' to clarify that new evidence means evidence that was not considered by the contractor or CMS.

When Does the Review Stop?

Comments: In the proposed rule, we specifically asked for comments on alternatives for structuring the review process. We proposed to divide the decision making process for cases at the ALJ/Board level into two stages and thereby establish the prerequisites for discovery under the statutory framework set forth at section 1869(f)(1)(A)(iii)(I) and section 1869(f)(2)(A)(i)(I) of the Act. Under the proposed regulation, in order to obtain discovery, a challenger was required to first file a motion with the Board or ALJ alleging that the record was incomplete or lacked adequate information to support the validity of the determination. Only if the record was incomplete or otherwise inadequate would an aggrieved party be able to pursue discovery. Even if the challenger did not file such a discovery motion, however, a beneficiary could seek a decision on whether the determination was based on reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law.

We outlined another possible approach in our proposed rule at 67 FR 54542. That approach would require a party to file a statement regarding whether that party considers the record complete and adequate, and an ''offer of proof'' supporting factual allegations about incompleteness. The adjudicator would then decide whether the record is complete and adequate to support the decision and would prepare a written decision. If the adjudicator found that the record was complete and adequate, this decision would be a final Agency action appealable to the court.

There were two public comments on this issue. One commenter suggested that, if the adjudicator found that the record was incomplete or inadequate, the Board would be legally required to determine that the ''NCD is not reasonable.'' This commenter believed that the Board would be precluded from allowing discovery or any other new evidence at this point, but must automatically rule against CMS. A commenter appeared to prefer the following approach: ''If, upon review of the record, the aggrieved party does not have objections to the completeness or adequacy of the LCD or NCD record, then what is the basis of the aggrieved parties complaint? Presumably the coverage policy would be challenged on the basis that it is inconsistent with current clinical or scientific evidence. In such case, a motion by the aggrieved party would appear to be a necessary part of the complaint process and an appropriate step given the limited time and resources of adjudicators, CMS and contractors.'' The commenter ''believed that the aggrieved party should challenge the completeness or adequacy of the record before an adjudicator should make a determination with respect thereto.''

Response: We have re-examined our proposed procedures in light of the public comments and the unique statutory language in section 1869(f)(1)(A)(iii)(I) and section 1869(f)(2)(A)(i)(I) of the Act. In this final rule, we clarify at § 426.400 and § 426.500, the procedural and substantive steps involved in the appeal. The revised procedures incorporate approaches from both alternatives discussed in the proposed rule. We believe that the revised procedures are fair, consistent with the statutory framework, and will enable the ALJs and Board to fairly resolve challenges to LCDs and NCDs in an expeditious manner.

The administrative review provisions in BIPA section 522 are unique. While

the reviews are, at the outset, based on the medical and scientific evidence that the contractor/CMS considered in issuing the LCD/NCD, and the statute requires that the adjudicator ''shall review the record,'' it does permit discovery in some limited circumstances and also permits that adjudicator to consult with ''appropriate scientific and clinical experts.'' Obviously, new evidence obtained through discovery or testimony could not have been considered by the agency when the policy predates the new evidence. Thus, the procedures are not entirely based on the record, but new evidence and testimony may influence the ALJ's/Board's decision in some cases.

It is possible that an aggrieved party would attempt to challenge an LCD/NCD for several reasons. For instance, a challenger may believe that a policy that was correct when it was issued has become outdated and is no longer valid in light of advances in medicine. Those challengers may be most interested in presenting new medical evidence in support of changing the policy rather than challenging the original factual basis for the policy. As noted previously, we are modifying our procedures to allow a party to submit new evidence to the ALJ/Board. We have modified the procedures at § 426.340 to allow the ALJ/Board to make a preliminary determination on whether the new evidence submitted would have a significant bearing on the validity of the LCD/NCD. If the evidence is found significant, it would be sent to the contractor/CMS to determine whether the contractor/CMS agrees that the evidence warrants a formal reconsideration. As mentioned earlier, the reconsideration process would be time limited but would allow the public to submit medical and scientific evidence and allow the agency to fully develop the record in light of advances in medical science. Following the time-limited reconsideration, a supplemental record would be filed and the adjudication could continue, if necessary.

This approach will provide the contractor/CMS the initial opportunity to permit medical and scientific experts to examine the new evidence and to make findings of fact concerning the new evidence. Among other things, the statute requires that the ALJ/Board ''shall defer only to the reasonable findings of fact'' and it was impossible for the agency to have made findings on evidence that did not yet exist or that had not been furnished to the agency for consideration. We believe this approach is necessary to ensure that the medical and scientific opinions of the agency experts illuminate the record, since these appeals could involve very technical medical and scientific material related to the new evidence.

While it is possible that the challenger may submit credible medical and scientific studies that warrant a formal reconsideration, it is also possible that the evidence submitted would not be either relevant or persuasive, or that a challenger may seek to challenge the policy on other grounds. Because the public comments have highlighted the different types of disputes that may be presented, we have modified our procedures in attempt to fairly, yet expeditiously, resolve any type of challenge that may be presented. Our revised approach would allow the ALJ or the Board to resolve some cases without need for a reconsideration and would also allow the review proceedings to be resolved in a more expeditious manner. To resolve any confusion, we will describe the significant procedural and substantive steps of the review.

Under the revised procedures at § 426.425 and § 426.525, all aggrieved parties, after reviewing the LCD or NCD record, will be able to file a statement that includes the challenger's arguments as to why the record is not complete, or not adequate to support the validity of the LCD/NCD under the reasonableness standard. This may be the most important step in the review process from the aggrieved party's perspective because this is the opportunity to present any arguments for the LCD/NCD being held invalid. (*See* § 426.425(a), § 426.525(a)). CMS or the contractor will have 30 days to submit a response to this statement. (*See* § 426.425(b), § 426.525(b)).

After evaluating the materials and the record, our revised procedures will permit the ALJ/Board to make a prompt decision in the nature of a summary judgment if the case warrants this approach. For instance, if applying the reasonableness standard, the adjudicator finds that record is complete and has adequate information to support the validity of the LCD or NCD, the ALJ or the Board may issue a decision that ''the record is complete and adequate'' to support the policy. (*See* § 426.425(c)(1), and § 426.525(c)(1)). For cases involving an NCD, the aggrieved party would have the right to challenge this final agency action in Federal court. (Section 1869(f)(1)(A)(v) of the Act). For cases involving an LCD, the aggrieved party would have the right to challenge the ALJ's decision at the Board, and potentially in Federal Court. (§ 426.465).

If, on the other hand, after evaluating the materials submitted by the parties and the record, the ALJ/Board determines that the record is not complete or not adequate to support the validity of the LCD/NCD, the adjudicator will permit discovery and the taking of evidence. Following discovery and the taking of evidence as set forth in these final rules, the ALJ/Board will issue a final decision. (*See* § 426.447, § 426.547). Those final decisions may also be appealed in appropriate circumstances.

Although we recognize that one commenter suggested that the ALJ or the Board would be legally required to hold invalid the LCD/NCD rather than allowing the agency to supplement the record, the case cited is not relevant given the unique language and history of BIPA section 522. The ALJs and the Board are not acting as a Federal court reviewing final agency action. The case relied on by the commenter concerned the scope of review under the judicial review provisions of the Administrative Procedure Act, 5 U.S.C. 706. Moreover, under prior provisions for court review of NCDs, even courts were required to permit us to supplement the record before declaring an NCD invalid. We believe our approach is consistent with the specific requirements of the statute.

Scope and Weight of Evidence

Comment: One commenter believed that the proposed rule would have the effect of excluding highly relevant information such as physicians' standards of practice and their professional opinions from the review process. Another commenter believed that we should define the hierarchy of evidence strength to assure proper weighting by the ALJ or Board when considering scientific and clinical information.

Response: We are not accepting the recommendation to include a hierarchy of evidence in order to allow flexibility in analyzing evidence. We recognize that many types of evidence have value, and will consider clinical experience, as well as other forms of medical, technical, and scientific evidence in making LCDs and NCDs. We note that the ALJ/Board may seek input from clinical and scientific experts at their discretion. There is no prohibition against the ALJ or the Board seeking the input of practicing physicians or considering standards of practice.

Discovery

Comment: We received several comments on the nature and scope of discovery. One commenter supported the limitation upon discovery that

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 § 425.540(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

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

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

such as the ready availability of qualified medical professionals in one contractor's area, but not in another. Moreover, an ALJ or the Board may not determine that an LCD is unreasonable solely on the basis that another Medicare contractor has issued an LCD that permits coverage of the service at issue, under the clinical circumstances presented by the complaint.

For legal interpretations, the reasonableness standard would not be met if an interpretation is in direct conflict with the plain language of the statute or regulation being interpreted. Moreover, an interpretation in an LCD would not meet the reasonableness standard if it directly conflicts with an NCD or with a CMS Ruling. So long as an interpretation is one of the readings permitted by the plain language of the law and can be reconciled with relevant policy, however, it must be upheld, even if the ALJ or the Board might have reached a different result if interpreting the statute or regulation in the first instance.

Authority of ALJs and the Board

Comment: Some comments supported the limited authority granted to the ALJs/Board in issuing decisions, and many comments requested that the ALJ/Board be granted greater authority in issuing decisions. A number of comments suggested that the proposed rule restricted ALJ/Board authority so that the main outcome of a decision of unreasonableness would be contractor/CMS reconsideration, and that a decision of unreasonableness should result in the policy being null and void. Furthermore, numerous comments suggested that authority is not granted to the ALJ or the Board in the way that the Congress intended, and that the contractor/CMS retains too much authority over the process.

Response: We have revised the final regulation to allow for greater authority for the adjudicators in several respects. In appropriate cases, the ALJ/Board may find a provision(s) of the LCD/NCD invalid and may limit that holding to a beneficiary's clinical indication (or similar condition). Furthermore, the contractor or CMS would effectuate the ALJ/Board decision within 30 days (if not sooner), by either retiring or withdrawing the policy or revising the policy that would be applied prospectively. This means that neither the contractor nor CMS will apply a policy that has been held invalid to a claim of the aggrieved party or to any other similar Medicare claim with date(s) of service beginning on or after 30 days of the adjudicatory decision. Even though we are giving broader effect to the ALJ/Board decision by extending the decision to others on a prospective basis, we continue to believe that the Congress intended that CMS or its contractors would have the authority to develop clinical policies. Thus, we will maintain in the final rule the prohibition against adjudicators developing new language for LCDs and NCDs.

After a policy has been held invalid, it will not be applied to the beneficiary who raised the challenge or to others who receive services after the effective date of the invalidation. CMS or the contractor may issue a new or revised LCD/NCD that does not include the invalid provision(s). The new or revised LCD/NCD would be applied prospectively. The new/revised LCD/NCD would also be subject to challenge under this review process.

Please note that whenever we discuss claim relief or dates of service in the context of an ALJ or DAB decision holding invalid an LCD or NCD, the references should be read to include pre-service requests denied by an M+C organization and the dates of pre-service requests. The application of this regulation in the M+C context is discussed further below.

Effective Dates

Comment: Several commenters stated that timeframes should be set in this process to reflect the timeframes set in the NCD process notice.

Response: We agree with the concept of timeframes, but do not reference the ''NCD process notice'' since that notice does not speak to this issue, and we have added language to § 426.460 and § 426.560 requiring that contractors/CMS either—

1. Retire/withdraw the LCD/NCD in its entirety within 30 days of the ALJ/Board decision; or

2. Issue a revised LCD/NCD removing the invalid provisions, effective for claims with dates of service after the 30th day of the ALJ/Board decision.

If the Board issues a decision finding an NCD provision invalid and the NCD is revised to reflect the Board's decision, all contractors must review and appropriately revise any related LCDs so as not to be in conflict with the revised NCD. If we choose to withdraw the entire NCD, the contractors must review and appropriately revise any LCDs so as not to rely on the withdrawn NCD as the basis for the LCD.

Precedential Value of ALJ/Board Decisions

Comment: One commenter stated that previous ALJ/Board decisions should be controlling precedent. Another commenter recommended that ALJs/Board be bound by previous ALJ decisions on local policies in other jurisdictions.

Response: We have revised the final rule at § 426.431(a) to require ALJs to treat as precedential Board LCD and NCD decisions, and to require the Board to follow its own applicable precedents. We believe this will improve the efficiency of the review process. Because of differences in the local practice of medicine, we do not believe it would be prudent for ALJs to treat as precedential other ALJ decisions on an LCD challenge.

Appeals of Decisions Involving Joint Complaints and Consolidated Reviews

Comment: One commenter requested that for joint appeals, aggrieved parties should be prohibited from appealing decisions to higher levels unless all parties to the initial appeal agree to appeal.

Response: We will not require in this final rule that all parties must agree to appeal an ALJ decision as a prerequisite for the appeal to continue. Even if some individuals decide not to pursue an appeal, other parties in the case may exercise their appeal rights. Section 426.470 of the regulation allows the Board to consolidate similar appeals.

Appeal of ALJ Decision/Board Review of ALJ Decisions

Comment: One commenter suggested that we should not be allowed to appeal ALJ decisions to the Board due to conflicts of interest. Another commenter objected to having the Board overturn ALJ decisions that were favorable to the aggrieved party due to potential burdens on the beneficiary. Another commenter felt that the regulation should not require the Board to affirm or reverse the ALJ decision in its entirety and suggested that the Board should have the discretion to reverse a decision in part. We received one comment suggesting the Board should not support a policy based on a rationale that is not stated in the supporting documents that were submitted. We also received three comments requesting that the Board not be limited to fundamental rules of procedures, and that it have broader discretion in reviewing ALJ decisions.

Response: Nothing in the statutory language of section 522 suggests that the Congress intended to bar the government from appealing an adverse decision of an ALJ. We believe that such an appeal is warranted as a mechanism to ensure that ALJs are applying the statute and regulations correctly, even if we rarely employ this strategy. Because the statute provides that ALJ decisions

may be reviewed by the Board, we have retained the language allowing either the contractor or CMS to seek Board review of ALJ decisions. Furthermore, our final rule provides flexibility in the Board's review of ALJ decisions.

We have modified the final rule at § 426.476(b) to provide that the Board will review an ALJ decision on appeal to determine whether it contains any material error, including any failure to properly apply the reasonableness standard. The Board will not reverse a decision for harmless error, but may remand if a prejudicial procedural error was made. Further, if the ALJ erred in determining that the LCD record was complete and adequate to support the validity of the LCD, the Board will reverse and remand the case to the ALJ to complete discovery and the taking of evidence. We believe that this standard of review provides appropriate discretion for Board review of ALJ decisions.

Impact on Medicare+Choice (M+C)

Comment: One commenter suggested that we should clarify an M+C organization's obligations when a complaint is under review by both the section 522 process and the M+C organization's existing appeals process.

Response: If an M+C enrollee files both an LCD/NCD review request and a request for reconsideration of an adverse organization determination for the same item or service, the M+C organization should adjudicate the reconsideration using the coverage policies in place on the date the service or item was requested (in the case of a pre-service determination) or provided (in the case of a payment determination). If the LCD/NCD under review is subsequently found to be unreasonable, then the aggrieved party who sought review of the LCD/NCD is entitled to have the previously adjudicated organization determinations or reconsidered determinations reopened and adjudicated without consideration of the invalid LCD/NCD provision(s). M+C organizations would be responsible for reopening and adjudicating organization determinations, and the independent review entity (IRE) would be responsible for reopening and adjudicating reconsidered determinations.

Comment: One commenter requested that we clarify the obligations of M+C organizations when an enrollee has an appeal pending at the time the revised LCD/NCD becomes effective.

Response: The type of organization determination being reconsidered (payment or pre-service) will determine an M+C organization's obligations when an enrollee has a reconsideration pending at the time a revised LCD/NCD becomes effective. Consistent with original Medicare, LCD/NCD changes may only be applied prospectively to requests for payment. Therefore, when an enrollee requests reconsideration of a payment determination and the reconsideration is pending at the time a revised LCD/NCD becomes effective, the M+C organization should apply the LCD/NCD in place at the time the item or service was provided. In responding to a request for reconsideration of a pre-service determination that would be affected by a revised LCD/NCD, an M+C organization should dismiss the appeal and reopen the adverse organization determination on the basis of new and material evidence. The M+C organization should then apply the revised LCD/NCD in effect and issue a revised organization determination.

We recognize the importance of ensuring timely transmission of ALJ/Board decisions and intend to work closely with the Medicare managed care industry to make certain that an effective method of communicating LCD/NCD changes is in place.

Comment: Another M+C-related comment stated that claims that were adjudicated using the invalidated LCD/NCD should be eligible for a new decision (so long as the appeals timeframes have not passed).

Response: As noted in the comment above, LCD/NCD changes can only be applied prospectively to requests for payment, as was the case under original Medicare. Therefore, regardless of subsequent policy changes, for purposes of reconsidering a payment determination, the relevant LCD/NCD is the policy in effect at the time the item or service was provided.

Comment: One commenter requested that we clarify whether a decision made under individual claim review is considered an ''organization determination,'' as defined under parts 417 and 422, giving rise to appeal rights.

Response: When an M+C organization reopens and adjudicates an organization determination under § 426.460(b)(1), the M+C organization must issue a revised organization determination, which gives rise to appeal rights under parts 417 and 422. An enrollee could benefit from a revised LCD/NCD by filing a new request for an organization determination.

Comment: One commenter requested clarification as to whether our statutory obligation, under section 1852(a)(5) of the Act, to make fee-for-service payments for a significant cost, midyear change in benefits would apply if a significant cost threshold for an NCD is met as a result of a decision by the Board to revise an NCD.

Response: Section 1852(a)(5) of the Act provides that if an NCD or legislative change in benefits effective in the middle of an M+C contract year generates a significant change in the costs to a M+C organization of providing benefits that are the subject of the NCD, and if this significant change in costs was not incorporated into the M+C payment rates at the time the NCD becomes effective, the NCD does not apply to the M+C contracts until the first contract year after new M+C rates are published. Moreover, section 1853(c)(7) of the Act provides that, if there is a change in benefits resulting in a significant increase in costs to the M+C organization, we will adjust appropriately the M+C payment rates to reflect this change. The M+C organization must provide coverage of the NCD or legislative change in benefits by furnishing or arranging for the NCD service or legislative change in benefits. However, the M+C organization is not required to pay or assume risk for the costs of that service or benefit until the contract year for which payments are adjusted to take into account the cost of the NCD service or legislative change in benefits. Section 422.109 has been revised to define ''significant cost'' thresholds, and notes that, if the costs for new coverage or a change in benefits is significant, CMS will pay on a fee-for-service basis on behalf of the M+C organization for the new benefit until the M+C rates are appropriately adjusted. (These provisions do not apply if the change in benefits does not meet either significant cost threshold described at § 422.109.)

Automatic Stay Upon Appeal

Comment: Three commenters disagreed with the automatic stay of an ALJ decision when the contractor/CMS appeals a decision to the Board.

Response: We disagree. We believe it would be disruptive to beneficiaries overall to have ALJ decisions implement policies only to have these policies reversed by the Board. This would create both an inefficient and confusing process. Furthermore, a contrary ruling would require the expenditure of significant resources to implement an ALJ decision only to have to change the decision if the Board reverses.

Dual Track Process

Comment: We received one comment for and one comment against allowing aggrieved parties the option to pursue both a reconsideration and a review under these rules.

Response: We believe that both options should be available to aggrieved parties, in order to allow for the parties to seek a decision in the most appropriate way possible, and to allow the most flexibility to these parties.

Expedited Judicial Review

Comment: Several commenters suggested that the final regulations should address section 1869(f)(3) of the Act, which relates to circumstances where a challenger may seek expedited judicial review when there are no material issues of fact in dispute.

Response: We are not adopting these comments. This section of the statute does not require regulatory action by CMS because it is related to the jurisdiction of the judicial branch of the government. The statute is self-implementing and does not require additional rulemaking by the Secretary.

IV. Provisions of the Final Rule

A. Overview

We are establishing that a Medicare beneficiary who qualifies as an aggrieved party may challenge an LCD or an NCD (or specific provisions therein) by filing a complaint concerning an LCD with the office designated by CMS on the Medicare Web site, *http://www.medicare.gov/coverage/static/appeals.asp* (information on the designated office will be available by calling 1–800-Medicare) or by filing a complaint concerning an NCD with the Board of HHS. After a complaint is filed, the adjudicator determines whether the complaint is acceptable.

In this final rule, we are adding in § 400.202 a definition of ''Local coverage determination (LCD)'' and revising the definition of ''National coverage determination (NCD).'' The definitions are specific to Medicare and reflect the definitions for these terms found in section 522 of BIPA. With one exception described below, this final rule makes clear that a determination of the code assigned to a service, if any, or a determination with respect to the amount of payment to be made for the service is not included in the definition of an LCD or an NCD. We have clarified that diagnosis codes used in an LMRP to describe when a service is considered medically necessary are also part of the LCD. We use the term ''Services'' as defined in § 400.202 to include both ''items and services.''

In § 405.732, ''Review of a national coverage decision (NCD),'' we revise paragraph (a) regarding appeals of Part A cases, to state that an NCD is a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII. An NCD does not include a determination of what code, if any, is assigned to a particular item or service covered under title XVIII or a determination with respect to the amount of payment made for a particular item or service. NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act. An NCD is binding on all Medicare carriers, fiscal intermediaries, QIOs, HMOs, CMPs, HCPPs, the Medicare Appeals Council, and ALJs.

This final rule revises § 405.732(b) to specify that an ALJ may not disregard, set aside, or otherwise review an NCD. An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD has been applied correctly to the claim.

We are revising § 405.732(c) to specify that for initial determinations and NCD challenges under section 1862(a)(1) of the Act, arising before October 1, 2002, a court's review of an NCD is limited to whether the record is incomplete or otherwise lacks adequate information to support the validity of the decision, unless the case has been remanded to the Secretary to supplement the record regarding the NCD. In such cases, the court may not invalidate an NCD except upon review of the supplemental record. For Part B appeals, we are making similar changes.

In § 405.860, ''Review of a national coverage decision (NCD),'' we revise paragraph (a) regarding appeals of Part B cases to specify that an NCD is a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII. An NCD does not include a determination of what code, if any, is assigned to a particular item or service covered under title XVIII or a determination with respect to the amount of payment made for a particular item or service. NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act. An NCD is binding on all Medicare carriers, fiscal intermediaries, QIOs, HMOs, CMPs, HCPPs, Medicare Appeals Council, and ALJs.

We are revising § 405.860(b) to specify that an ALJ may not disregard, set aside, or otherwise review an NCD. An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD has been applied correctly to the claim.

In § 405.860(c), we specify that for initial determinations and NCD challenges under section 1862(a)(1) of the Act, arising before October 1, 2002, a court's review of an NCD is limited to whether the record is incomplete or otherwise lacks adequate information to support the validity of the decision, unless the case has been remanded to the Secretary to supplement the record regarding the NCD. The court may not determine that an item or service is covered except upon review of the supplemental record.

We are also adding a new part 426, titled ''Reviews of Local and National Coverage Determinations,'' to title 42 of the CFR to include the following subparts:

- Subpart A contains general provisions applicable to the entire part.
- Subpart B is reserved.
- Subpart C contains the general provisions applicable to the review of LCDs and NCDs.
- Subpart D contains the provisions specific to the review of LCDs
- Subpart E contains the provisions specific to the review of NCDs.

B. Subpart A (General Provisions)

Subpart A of part 426 specifies the general provisions applicable to the entire part. Section 426.100, ''Basis and scope,'' sets forth the basis (under sections 1869(f)(1) and (f)(2) of the Act), and the scope specifies the requirements and procedures for the review of LCDs and NCDs. In § 426.110, we define the terms used in part 426 whose definitions may not otherwise be implicit.

Under section 522 of BIPA, only an ''aggrieved party'' may file a complaint to initiate the review of an LCD or an NCD. In this final rule, we define ''aggrieved party'' as a Medicare beneficiary who is entitled to benefits under Part A, enrolled under Part B, or both (including an individual enrolled in fee-for-service Medicare, in a Medicare+Choice plan, or in another Medicare managed care plan), and is in need of coverage for a service that is the subject of an applicable LCD (in the relevant jurisdiction) or an NCD as documented by the beneficiary's treating physician. We revised the final rule to include also as an aggrieved party a beneficiary who has already received the service and is in need of coverage, or the estate of a deceased beneficiary in need of coverage.

Based on comments on our proposed rule, in this final rule we allow an aggrieved party's estate to pursue an LCD/NCD challenge if the aggrieved party died after filing a proper complaint and the aggrieved party received the service for which coverage is sought. We also allow the aggrieved

party's estate to file a complaint within 120 days of receipt of the denial notice.

In § 426.110 we define the following:

• ''Board'' to mean the Departmental Appeals Board.

• Clinical and scientific experts that are consulted by the ALJ or the Board as independent and impartial individuals, with significant experience and/or published work pertaining to the subject of the review.

• ''Contractor'' as a carrier (including a DMERC) or a fiscal intermediary (FI) (including an RHHI) that has jurisdiction for the LCD at issue.

• ''Deemed NCD'' as a determination that the Secretary makes in response to a request for an NCD by an aggrieved party under section 1869(f)(4)(B) and (C) of the Act, that no national coverage or noncoverage determination is appropriate, or the Secretary's failure to meet the deadline under section 1869(f)(4)(A)(iv) of the Act. Section 1869(f)(4)(C) of the Act deems certain decisions of the Secretary to be NCDs for purposes of administrative review. Please see our proposed rule for further discussion of deemed NCDs (67 FR 5434).

• ''New evidence'' is clinical or scientific evidence that was not previously considered by the contractor or by us before the LCD or NCD was issued.

• ''Party'' as an aggrieved party, which is an individual or estate who has the right to participate in the LCD or NCD review process, and, as appropriate, a contractor or CMS. In the case of an LCD review, we may choose whether to be a party in the review along with or instead of the contractor. These reviews involve challenges to important CMS policies that may impact many beneficiaries. We note that we are always a party to an NCD review and contractors would not participate in an NCD review.

• ''Proprietary data'' and ''privileged information'' are 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 Exemption 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 that information. Members of the public that send us proprietary data must mark these documents as such, and include the legal basis for any such assertion. Any information received from the public that is not designated as ''proprietary data'' will not be considered ''proprietary.''

• ''Reasonableness standard'' is 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 CMS are reasonable based on the LCD or NCD record and the relevant record developed before the ALJ/Board.

• ''Supplemental LCD/NCD record'' is a record that the contractor/CMS provides to the ALJ/Board and any aggrieved party and consists of all materials received and considered during a reconsideration. Materials that are already in the record before the ALJ/Board (for example, new evidence presented in the taking of evidence or hearing) need not be provided but may be incorporated by reference in the supplement to the LCD/NCD record. The contractor/CMS may provide statements, evidence, or other submissions to the ALJ/Board during the proceedings, as provided elsewhere in these regulations, but such submissions are not considered as supplementing the LCD/NCD record.

• ''Treating physician'' is the physician who is the beneficiary's primary clinician with responsibility for overseeing the beneficiary's care and either approving or providing the service at issue in the challenge.

In § 426.120, we explain how deadlines are calculated. In § 426.130, we explain that any documents submitted to the ALJ/Board after the initial challenge, excluding privileged or proprietary data, must also be served on all other parties simultaneously. These sections have been added to provide additional guidance in implementing the requirements of this final rule.

C. Subpart B (Reserved)

We are reserving subpart B.

D. Subpart C (General Provisions for the Review of LCDs and NCDs)

The general provisions common to both the review of LCDs and NCDs are established in subpart C. In § 426.300(a), we state that the review of a challenged provision (or provisions) of an LCD is conducted by an ALJ only upon the receipt of an acceptable complaint as described in § 426.400. We also state in § 426.300(b) that the review of a challenged provision (or provisions) of an NCD is conducted by the Board only upon the receipt of an acceptable complaint as described in § 426.500. An acceptable complaint must be filed with the applicable adjudicator by an aggrieved party. Additionally, § 426.300(c) would allow for the review of deemed NCDs, a process that would parallel the review of NCDs.

In § 426.310(a), we explain that LCD and NCD reviews are largely independent of the claims appeal processes set forth in part 405, subparts F and G; part 417, subpart Q; and part 422, subpart M. In § 426.310(b), we require the aggrieved party to notify the ALJ/Board of any pending claim or appeal related to the LCD/NCD appeal.

In § 426.320(a), we explain that only an aggrieved party may initiate a review to challenge an LCD or NCD (including a deemed NCD), or an existing specific provision or provisions of an LCD or an NCD by filing an acceptable complaint. In § 426.320(b), we explain that neither an ALJ nor the Board will recognize as valid any attempt to assign rights under section 1869(f) of the Act.

In § 426.325, we describe the policies that are, and are not, subject to this review. Under this requirement, an aggrieved party would be allowed only to challenge an LCD or NCD. Conversely, an aggrieved party may not use this process to challenge anything that does not meet the definition of an LCD or an NCD (*see* § 426.325). For example, draft LCDs or NCDs, and coverage decision memos would be excluded from review as they are predecisional. LCD and NCD provisions that are no longer in effect are excluded from review. Other interpretive policies that are not LCDs or NCDs would also not be subject to review under this process. Provisions of contractor policies that are based on things other than the reasonable and necessary provision of section 1862(a)(1)(A) of the Act, such as benefit category determinations, statutory exclusion determinations, and HCPCS/Revenue Code coding determinations, would not be subject to review under this part. In addition, any M+C or other managed care plan policy, rule, or procedure is not subject to review under this process. Individual claim determinations by adjudicators are also not subject to review under this process.

In § 426.330, we state that the aggrieved party filing the complaint bears the burden of proof and the burden of persuasion for the issue or issues raised in the complaint. The burden of persuasion will be judged by a preponderance of the evidence.

Section 426.340 provides procedures to be followed after discovery and the taking of evidence are complete. If an aggrieved party has submitted new evidence pertaining to an LCD or NCD which the ALJ or the Board finds admissible, the ALJ/Board must review the new evidence and decide if the new evidence has the potential to significantly affect the evaluation of the LCD/NCD provision(s) in question under the reasonableness standard. If the ALJ or the Board determines that the new evidence does not have the potential to significantly affect the ALJ's or the Board's evaluation of LCD/NCD provisions, the review shall go forward to a decision on the merits. If the ALJ or the Board decides that the new evidence has the potential to significantly affect the evaluation of the policy, the ALJ or the Board must stay the proceedings and send the new evidence to the contractor or CMS. The contractor or CMS has 10 days upon receiving the evidence from the ALJ or the Board to provide a statement indicating whether a revision/reconsideration will be initiated. If the contractor or CMS informs the ALJ or the Board that a revision/reconsideration has been or will be initiated, then the stay shall continue and the ALJ or the Board shall set appropriate timeframes (not more than 90 days) by which the revision/reconsideration will be completed. If the contractor or CMS chooses not to initiate a revision/reconsideration and does not retire/withdraw the LCD/NCD, the ALJ or the Board proceedings will continue on the original LCD/NCD.

E. Subpart D (The Review of an LCD) and Subpart E (The Review of an NCD)

In subparts D and E, we set forth the procedures for the review of LCDs and NCDs, respectively. The process for LCD and NCD reviews is largely the same with the exception of the following:

- LCDs are based on section 1862(a)(1)(A) of the Act; NCDs may also be based on other statutory provisions.
- LCD reviews are conducted by an ALJ; NCD reviews are conducted by the Board.
- ALJs and contractors participate in an LCD review; there is no role for ALJs or contractors in an NCD review.
- We are not always a party to an LCD review, but are always a party to an NCD review.
- Amicus participation is not allowed when reviewing an LCD, but may be allowed when reviewing an NCD.
- Board decisions regarding NCDs will be made available on the Medicare Internet site, without beneficiary-identifying information.

For the purpose of this preamble, we consolidate the discussion of the requirements and policy decisions when possible. Sections 426.400 and 426.500 contain the requirements for filing an acceptable complaint regarding a provision or provisions of an LCD and an NCD, respectively. In both cases, a complaint must be in writing and must be from an aggrieved party. In § 426.400(a), we require that complaints regarding LCDs be submitted to the office designated by CMS on the Medicare Web site, *http://www.medicare.gov/coverage/static/appeals.asp* (information on the designated office will be available by calling 1–800–Medicare) or by filing a complaint concerning an NCD with the Board of HHS (*see* § 426.500(a)). Should the appropriate office change in the future, this regulation shall be read to conform to that change, and the information will be made publicly available. We have simplified and clarified the complaint-filing procedures.

In § 426.400(b) and § 426.500(b), we explain the circumstances under which a complaint will be considered timely received. A complaint will not be considered timely unless it is received by the office designated by CMS/Board of HHS within—(1) 6 months of the written statement from each aggrieved party's treating physician for aggrieved parties who choose to file an LCD/NCD challenge before receiving the service; or (2) 120 days of the initial denial notice for aggrieved parties who choose to file an LCD/NCD challenge after receiving the service.

In § 426.400(c)(1) and § 426.500(c)(1), we require a valid complaint to contain beneficiary-identifying information and a written statement from the treating physician indicating that the beneficiary needs the service that is the subject of the LCD/NCD. We also require the information in § 426.400(c)(2) and (c)(3) and § 426.500(c)(2) and (c)(3), which is necessary to identify the LCD or NCD (or the specific provision or provisions of the LCD or NCD) that is (are) adversely affecting the aggrieved party. In addition, we require a statement from the aggrieved party that explains the rationale for the complaint.

In § 426.400(c)(4) and § 426.500(c)(4), we also allow the aggrieved party to submit copies of material clinical or scientific evidence that supports the complaint. We require that any proprietary data submitted be marked as ''proprietary data'' and include the legal basis for so identifying it. In addition, in § 426.400(c)(4) and § 426.500(c)(4), we require that, in order to be considered and given weight in LCD or NCD reviews, any such proprietary data submitted by a manufacturer of a drug or device must include an affidavit that the data consists of true and correct copies of all data submitted by the manufacturer to the Food and Drug Administration in relation to that drug or device. In § 426.400(d), we state that two or more aggrieved parties may initiate the review of an LCD by filing a single written complaint with the ALJ if the conditions in § 426.400(d)(1)(i) and (ii) are met. Similarly, in § 426.500(d), we state that two or more aggrieved parties may initiate the review of an NCD by filing a single complaint with the Board if the conditions in § 426.500(d)(1)(i) and (ii) are met.

Based on public comments, we have added § 426.403 and § 426.503 to allow the aggrieved party to submit new evidence without withdrawing the complaint.

Section 426.405 specifies the authority of the ALJ during an LCD review, including authority during a hearing, if applicable. Similarly, in § 426.505, we set forth the specific authority of the Board during an NCD review, if applicable.

Sections 426.406 and 426.506 prohibit *ex parte* contacts so that no party or person (except employees or consultants of the ALJ/Board's office) may communicate in any way with the ALJ/Board on any substantive matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

In § 426.410, we establish the ALJ's role in docketing and evaluating the acceptability of LCD complaints. These procedures are very similar to the Board's role in docketing and evaluating the acceptability of NCD complaints in § 426.510. Under the procedures, the adjudicatory body receives and dockets the complaint, evaluates the acceptability of the complaint, and resolves any consolidation issues. The appeal will be docketed under the name of the LCD or NCD rather than the aggrieved party or parties to protect the privacy of the party/parties.

In § 426.410 and § 426.510, we establish the criteria that a complaint must meet to be considered as an acceptable complaint by an ALJ or the Board. An aggrieved party must file the complaint; the complaint must meet all of the requirements of a valid complaint regarding an LCD in § 426.400, or regarding an NCD in § 426.500, and may only challenge a policy that meets the definition of an LCD or an NCD.

If a complaint is deemed to be unacceptable after being evaluated under § 426.410(b) or § 426.510(b), the applicable adjudicator will provide the aggrieved party (or parties) one opportunity to amend the unacceptable complaint within a timeframe set forth by the adjudicator (*see* § 426.410(c) and § 426.510(c)). If the aggrieved party (or parties) does not submit an acceptable amended complaint within this timeframe, the adjudicator will issue a decision dismissing the unacceptable complaint. The aggrieved party will be precluded from filing another complaint on the same issue for 6 months.

If, after having been evaluated under § 426.410(b) or § 426.510(b), a complaint is accepted, the adjudicator will send a letter to the aggrieved party (or parties) acknowledging the complaint and informing them of the docket number (*see* § 426.410(d)). The adjudicator will also forward a copy of the complaint and the acknowledgement letter to the applicable contractor and to us, and request that we or the contractor send a copy of the LCD record to the ALJ and all parties to the LCD review. The corresponding section in § 426.510(d) will require the adjudicator to follow the same process for NCDs, with the exception that the Board will make available to the public information concerning the complaint on its Web site (*see* § 426.510(f)) and specify a time period for affected parties to request amicus participation.

In § 426.410(e) and § 426.510(e), we allow for adjudicators to consolidate complaints regarding LCDs and NCDs, respectively. Under this provision, several complaints may be consolidated into one review if the complaints are appropriately similar. The review processes are not changed by a decision to consolidate complaints into one review.

In § 426.510(f) and § 426.513, we describe the opportunity and extent to which interested parties may participate in the NCD review process as amicus curiae.

In § 426.415, we explain that we may provide information to the ALJ, and all parties to the LCD review, identifying the person who would represent the contractor or CMS in the LCD review process. We can determine whether the contractor or CMS will participate in the review. Under the corresponding section in § 426.515, we provide a copy of the NCD record (as described in § 426.518) to the Board and all parties to the NCD review within 30 days of receiving the Board's order.

In § 426.416 and § 426.516, we describe the role of Medicare managed care organizations and Medicaid State agencies in the LCD and NCD review process. In § 426.417 and § 426.517, we describe the role of contractors and CMS in reviewing any new evidence.

Sections 426.418 and 426.518 describe, respectively, the elements of a contractor's LCD record and our NCD record, furnished to the aggrieved party. Sections 426.419 and 426.519 describe, respectively, the elements of a contractor's LCD record and our NCD record furnished to the ALJ or Board. These sections have been added in response to comments, and to facilitate the review process when privileged or proprietary data is submitted. Generally, an LCD or NCD record is composed of documents and materials that the contractor or we considered during the development of the LCD or NCD. Any MCAC transcripts would also be considered part of an NCD record. In the cases where comments are submitted, a ''comment and response'' summary document is sufficient for inclusion in the LCD record. In § 426.418(b) and § 426.518(b), we do not include privileged information or proprietary data, or any new evidence, as part of the record furnished to the aggrieved party. In § 426.419 and § 426.519, we state that official records presented to the Board may contain proprietary data or privileged information, if the information was considered in reaching the LCD or NCD under review. In these instances, the proprietary data and privileged information is filed under seal and is protected from inappropriate disclosure according to all applicable statutes and regulations, or common law privileges.

In § 426.420(a) and (b), we allow a contractor to retire the LCD under review or revise the LCD to remove or amend the provision in question before the date the ALJ issues a decision regarding the LCD. Retiring an LCD (or provision of the LCD) means that the contractor may no longer use that LCD in the adjudication of claims on a prospective basis. We also provide the aggrieved party individual claim review under § 426.460(b). Thus, in most cases, there would no longer be a need for an LCD review because relief would be provided. In § 426.520(a), we may withdraw an NCD under review or revise an NCD to remove or amend the provision in question before the date the Board issues a decision regarding that NCD. Withdrawing an NCD (or provision of the NCD) means this policy is no longer a controlling authority for our contractors and certain adjudicators. Thus, there no longer would be a need for an NCD review. In § 426.420(b), § 426.420(c), § 426.420(d), § 426.420(e) and § 426.520(b), § 426.520(c), § 426.520(d), § 426.520(e), we describe the process for LCDs and NCDs that are revised or reconsidered while under review. In cases where an LCD/NCD provision(s) has been revised, but not completely removed, the review continues because relief may not have been provided. This responds to comments received, and will ensure that aggrieved parties receive coverage relief when they prevail.

Under § 426.423 and § 426.523, we are permitting aggrieved parties who filed the complaint to withdraw complaints regarding LCDs and NCDs, respectively. We allow an aggrieved party to withdraw a complaint before the applicable adjudicator issues a decision regarding the complaint by simply sending a written notice to the ALJ, to the applicable contractor, and to us (if applicable) for LCDs, or to the Board and to us for NCDs (*see* § 426.423(b) and § 426.523(b)). Under this process, the adjudicator issues a decision (discussed later in this section of the preamble) dismissing the complaint, and the aggrieved party may not file another complaint to the same coverage determination for 6 months.

In the case of a joint complaint, one or more aggrieved parties may withdraw from the review without affecting the status of any remaining aggrieved party or parties named in the complaint. The adjudicator would issue a decision dismissing the complaint for the aggrieved party or parties who wish to withdraw, and the review would continue until the adjudicator issued a decision on the merits, or until each aggrieved party withdrew its complaint. Similarly, if the adjudicator had decided to hold a consolidated review, an aggrieved party or parties who are part of the consolidated review may withdraw without affecting the status of the other aggrieved party or parties who are part of the consolidated review (*See* § 426.423(c) and § 426.523(c)).

Sections 426.425(a) and 426.525(a) contain the processes for LCD and NCD reviews, respectively, that take place once the record has been filed. Section 522 of the BIPA added sections 1869(f)(1)(A)(iii) and 1869(f)(2)(A)(i) of the Act, which specify that the adjudicators of NCD and LCD reviews, respectively, ''* * * shall review the record and shall permit discovery and the taking of evidence to evaluate the reasonableness of the determination, if the [adjudicator] determines that the record is incomplete or lacks adequate information to support the validity of the determination.'' Therefore, we allow the aggrieved party who submitted the complaint to file a statement alleging that the LCD record (or the NCD record

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

complaints that fail to meet the requirements for acceptable complaints, including complaints regarding inapplicable policies or determinations. We also require the adjudicator to dismiss a complaint if the aggrieved party withdraws the complaint, or if the complaint seeks review of a matter beyond the adjudicator's authority.

Under § 426.444(b)(6), we also require an ALJ to dismiss a complaint if the applicable contractor notifies the ALJ that the LCD is being retired or revised to remove the provision in question. Similarly, in § 426.544(b)(6), the complaint must be dismissed when we notify the Board that the NCD (or provision of the NCD) is no longer in effect.

In § 426.445 and § 426.545, we require that witness fees, for appearances during a hearing, be paid by the party seeking to present the witness.

Under § 426.446 and § 426.546, we require that an ALJ and the Board, respectively, ensure that any hearing conducted regarding a LCD or NCD review is open to the public and electronically, mechanically, or stenographically recorded. These sections require that, except for privileged information and proprietary data, all evidence upon which the adjudicator relies for a decision be contained in the public record, and that any pertinent document or record be incorporated into the record of the LCD/NCD hearing.

Under § 426.447 and § 426.547, we set forth the procedures for the issuance and notification of ALJ and Board decisions, respectively. Within 90 days from closing the review record to the taking of evidence, the applicable adjudicator is required either to issue a decision, including a description of appeal rights, or to provide notice that the decision is pending, and an approximate date a decision will be issued. In § 426.547(b), we explain that Board decisions regarding NCDs will be available on the Medicare Web site of the Department of Health and Human Services and that steps will be taken to ensure the privacy of the parties to the review.

Under § 426.450, we describe the required elements of an ALJ's decision regarding an LCD. In § 426.550, we describe the required elements of the Board's decision regarding an NCD. Since Board decisions will be published, identifying information about beneficiaries may be placed in an accompanying cover letter giving notice of the decision. This cover letter, however, will not be published, in order to preserve beneficiaries' privacy. As discussed earlier in this section of the preamble, a decision may include the dismissal of a complaint or a finding that the LCD/NCD record is complete and adequate to support the validity of the LCD/NCD under the reasonableness standard. If the ALJ/Board decision neither dismisses the complaint nor finds that record complete and adequate, the decision must contain a statement pertaining to each provision listed in the complaint and state whether the provision is valid or invalid under the reasonableness standard. We also require that the decision include the information in § 426.450(b) and § 426.550(b), which include LCD review or NCD review identifying information, claim information (if known), the basis for the decision (including findings of fact, interpretations of laws, and application of facts to the law), a summary of the evidence reviewed during the review, and a statement about appeal rights. We provide that the materiality of any proprietary data or privileged information in the validity determination should be discussed in the decision without disclosing the substance or contents of the sealed evidence. In addition, a separate statement prepared and maintained under seal will explain the rationale for the treatment of the proprietary data or privileged information, including any necessary discussion of the data themselves. This statement will accompany the proprietary data or privileged information under seal if the decision is appealed to the next level of review.

In § 426.455 and § 426.555, we require that an ALJ or the Board decision be prohibited from doing any of the following:

- Ordering us or our contractors to add any language to an LCD or NCD or to pay a specific claim.
- Establishing a time limit for the creation of a new or revised LCD or NCD.
- Reviewing or evaluating an LCD or NCD other than the LCD or NCD under review.
- Including a requirement for us or our contractors that specifies payment, coding, or systems changes for an LCD or NCD, or deadlines for implementing these changes.
- Ordering or addressing how we or our contractors should implement an LCD or NCD.

As a result of comments we received on our proposed rule, we revised the requirements concerning ALJ or the Board decisions to allow such a decision to direct us or our contractors to delete language from a provision of an LCD or NCD, when the adjudicator finds provision(s) unreasonable with respect to the aggrieved party's clinical indications, and for same or similar conditions. While we have revised the rule accordingly, we continue to believe that ALJs or the Board should be prohibited from ordering us or our contractors to add language to a LCD or NCD provision and have maintained the prohibition in this final rule. The ALJ/Board decision requiring a contractor or CMS to strike an LCD/NCD provision may be written narrowly. In one example, an aggrieved party with condition X challenges an LCD stating that a particular service is covered for conditions Y and Z and contains the following sentence: ''This procedure is considered not reasonable or necessary for all other conditions.'' The ALJ may find that this sentence is invalid for condition X. The contractor would have several options for effectuating this decision. First, the contractor could remove the sentence altogether leaving coverage of all conditions other than Y and Z to individual consideration. Second, the contractor could add condition X to the list of covered conditions. Third, the contractor could revise the LCD to state that the service is covered for conditions Y and Z, individual consideration will determine coverage for condition X, and that the service is not covered for all other conditions.

In § 426.457 and § 426.557, we explain that ALJ or the Board decisions may be written narrowly to hold specific provision(s) invalid as applied to specific clinical indications and for similar conditions.

In § 426.458, we describe the ALJ's review record furnished to the public, and to the Board, and specify that proprietary data or privileged information must be under seal.

In § 426.460 and § 426.560, we describe the effect of ALJ or the Board decisions issued under § 426.447 and § 426.547. Although an ALJ or the Board will now be allowed to order us or our contractors to strike down a LCD or NCD provision, we continue to believe that the exact wording of a new coverage determination should be made by the contractor or by us. These policies affect other beneficiaries and, thus, these determinations must be made by clinicians and scientific experts who have the necessary specialized training. Thus, we and the contractor will remain the entities responsible for ensuring that the clinical and scientific policies are sound, in order to ensure the best quality of care for beneficiaries.

The effect of an ALJ or Board decision will depend on the outcome of the coverage determination review. If the

adjudicator finds that the provision(s) named in the complaint was (were) valid under the reasonableness standard, the aggrieved party or parties (in the case of an LCD review) could appeal that decision to the Board or (in the case of NCD review) may challenge the final Departmental action in Federal court.

If the adjudicator found that the provision(s) listed in the complaint was (were) invalid under the reasonableness standard and the contractor or we do not appeal this decision to the Board in a timely manner, the contractor must or we will do several things. First, there would be individual claim review for the aggrieved party or parties named in the complaint(s).

- If the aggrieved party received a (fee-for-service or managed care) service that was the subject of the challenged coverage determination, then the contractor (if applicable) or Medicare managed care organization will not use the provision(s) of the coverage determination that was (were) found invalid in the adjudication of that claim.
- If the aggrieved party has not received the service, the individual may obtain the service and file a claim, which could be reviewed by the contractor, without using the provision that has been found invalid.

Neither the first level appeal reviewer nor the hearing officer is bound by the invalid provision. Specifically, we will instruct the contractor to make a claim determination without using the LCD or NCD provision(s) that has been found invalid in each of the following situations: (1) The claim has not been adjudicated or; (2) the claim was denied. It is important to note that individual claim review can only be provided to an aggrieved party if his or her individual claim or appeal has not been paid during the individual claims adjudication process. Furthermore, the contractor/CMS will not use the invalid provision as guidance to deny claims.

Second, there would be coverage policy relief. Within 30 days of the issuance of an ALJ or the Board decision, the contractor or CMS must either retire/withdraw the LCD/NCD or revise the LCD/NCD to remove the provisions found to be invalid by the ALJ or the Board. The effective date of the retirement/withdrawal or revision must be for dates of service no later than the 30th day following issuance of the ALJ or Board decision. As discussed earlier, the retirement of a coverage determination or removal of a provision of a coverage determination means that it can no longer be used in the adjudication of claims with dates of service after the effective date of the ALJ/Board decision.

Under § 426.462 and § 426.562, ''Notice of an ALJ's decision,'' and ''Notice of the Board's decision,'' we require that, after the ALJ or the Board, respectively, has made a decision regarding an LCD or NCD complaint, the ALJ or the Board send a written notice of the decision to each party. The notice must state the outcome of the review and inform each party to the determination of his or her rights to seek further review if he or she is dissatisfied with the determination, and the time limit under which an appeal must be requested.

Under § 426.463 and § 426.563, ''Future New/Revised LCDs/NCDs,'' we state that the contractor and CMS may not reinstitute an LCD/NCD provision found to be unreasonable by an ALJ/Board unless the contractor/CMS has a different basis (such as additional evidence). However, nothing in this regulation shall be construed to prevent contractors or CMS from developing new or revised/reconsidered LCD/NCD provisions, as long as these provisions are developed using a different basis and evidence.

In the remainder of the sections proposed in subpart D, we set forth the procedure for appealing an ALJ's decision regarding an LCD review. In § 426.465(a), we state that an aggrieved party may appeal part or all of an ALJ's decision that states that a provision of the LCD listed in the complaint is valid under the reasonableness standard or that dismisses a complaint (with certain exceptions). We also allow an aggrieved party who was part of a joint complaint or a consolidated LCD review to appeal an ALJ's decision either independently or as a group.

In § 426.465(b), we state that a contractor or CMS may appeal to the Board an ALJ decision that an LCD was unreasonable. Because we allow Board consolidation of similar appeals, we believe that it is not necessary to prohibit aggrieved parties from appealing to higher levels if one or more parties to a joint complaint withdraw from that complaint.

In § 426.465(c), we require that the implementation of the ALJ decision will be stayed pending review by the Board.

In § 426.465(d), we establish that we do not allow an aggrieved party to appeal a dismissal in certain circumstances, namely, if the aggrieved party who filed the complaint withdraws the complaint, or because the contractor retired the LCD or revised the LCD to remove the provision in question.

Under § 426.465(e), we require that an appeal would have to be submitted to the Board within 30 days of the date the ALJ's decision was issued. We believe this is a reasonable timeframe to allow a party to make a decision on whether to appeal and to prepare the necessary documents, but we permit the Board to consider a late appeal if good cause is shown by the party.

Section 426.465(f) lists the necessary components of an appeal to identify the relevant parties and issues.

In § 426.565, ''Board's role in making an LCD or NCD review record available,'' we require that upon a request from a Federal Court, the Board must provide to the Federal Court, a copy of the Board's LCD or NCD review record (as described in § 426.567).

In § 426.566, we state that a Board decision is subject to judicial review.

In § 426.468, we explain that an aggrieved party who initiates an LCD review, but does not appeal any part or parts of an ALJ's decision to the Board in a timely manner, waives his or her right to any further review of that part or those parts.

In § 426.470, we state that the Board's role in docketing and evaluating the acceptability of appeals of ALJ decisions is similar to the process that an ALJ would use in docketing and evaluating the acceptability of a complaint. The Board assigns a number to the appeal and determines if it meets all of the requirements of an acceptable appeal proposed in § 426.465. Unlike the evaluation of an initial complaint, however, we require, in § 426.470(c), that the Board issue a decision dismissing an unacceptable appeal, instead of allowing an opportunity to amend an unacceptable appeal.

Upon the request from the Board to provide copies of the LCD review record under § 426.470, we require that an ALJ send a copy of the LCD review record to the Board.

Once the Board has accepted an appeal to an ALJ's decision and received the ALJ's LCD review record, we describe in § 426.476 the steps that the Board will take in reviewing the ALJ's decision. In addition to reviewing the ALJ's LCD review record and the ALJ's decision, the Board must allow the contractor or, if applicable, allow us, to submit a statement to the Board and the aggrieved party responding to the appeal. The final required step in the Board review of an ALJ's decision is to issue a Board decision. We require that the Board must evaluate the ALJ's application of the reasonableness standard to determine if the ALJ's decision was erroneous.

We believe that the Board review of an appeal of an ALJ's decision should remain a paper review of existing materials. Accordingly, we establish, in § 426.476(b), that the Board will determine whether the ALJ decision contains any material error, and prohibit the Board from considering any evidence that is not a part of the ALJ's LCD review record. We establish that the Board will remand the case for discovery and the taking of evidence if the ALJ erroneously determined that the contractor's record was complete, or if the ALJ permitted a prejudicial procedural error. In § 426.476(c), we establish the Board's scope of review and that the Board is bound by applicable laws, regulations, and NCDs when reviewing appeals of ALJ decisions. These include the applicable provisions of the Act, our regulations and rulings, and NCDs.

In § 426.476(d), we require the Board to dismiss an appeal of an ALJ's decision if the contractor retired the LCD or revised the LCD to remove the provision(s) in question during the appeal.

In § 426.478, we allow the contractor to retire an LCD or revise the LCD to remove the provision(s) in question during the Board's review of the ALJ's decision. As stated in the previous paragraph, this would lead to the Board dismissing the appeal.

In § 426.480, we allow a party to withdraw an appeal of an ALJ's decision. The provisions proposed in this section, for a party acting alone or as part of a joint or consolidated appeal, would be the same as the provisions for withdrawing a complaint in § 426.423.

In § 426.482, we require the issuance and notification of a Board decision regarding an appealed ALJ decision. These provisions are the same as the provisions we described for the issuance and notification of an ALJ decision.

In § 426.484, we set forth the mandatory provisions of a Board decision regarding an appealed ALJ decision. We require the Board to either dismiss the appeal or, for each part of the ALJ's decision named in the appeal, to uphold, modify or reverse that part or all of the ALJ's decision. Because the Board is conducting a review of the ALJ's decision using the ALJ's LCD review record, and is not conducting a *de novo* review of the LCD itself, a Board decision upholding, modifying or reversing each part, or all of the ALJ's decision is the proper outcome. The Board's decision must include the information necessary to identify the appeal, and the rationale for the Board's decision.

In § 426.486, we prohibit the Board's decision from including those provisions that we exclude from the ALJ's decision, for the reasons discussed earlier in this preamble. In § 426.487, ''Board's Record on Appeal of an ALJ Decision,'' we state in paragraph (a) that except as provided in paragraph (b) of this section, the Board's LCD review record furnished to the public consists of any document or material that the Board compiled or considered during an LCD review.

Paragraph (b) states that the LCD review record furnished to the Court under appeal includes, under seal, material that is privileged or proprietary.

Paragraph (c) states that in any instance where proprietary data or privileged information is contained in the LCD record and the information goes to court, CMS or the Department will seek to have a protective order issued for that information, as appropriate.

In § 426.587, ''Record for Appeal of a Board/NCD decision,'' we set forth in paragraph (a) that, except as provided in paragraph (b) of this section, the Board's NCD review record furnished to the court consists of any document or material that the Board compiled or considered during an NCD review. CMS or the Department may seek to have a protective order issued with respect to proprietary data or privileged information.

We describe in paragraph (b) that the NCD review record furnished the court maintain the seal on material that is privileged or proprietary. CMS or the Department may seek to have a protective order issued with respect to those documents.

In § 426.488, we set forth the effect of a Board decision. Section 426.488(a) explains the relief that is provided to a successful challenger. Moreover, there may be coverage relief for the aggrieved party. We also describe the effect of the Board reversing an ALJ decision.

We permit the Board to remand cases to the ALJ in a limited number of circumstances. In § 426.489(a), we explain the process the Board must follow to remand a case to the ALJ. In § 426.489(b), we explain required action by an ALJ upon a Board remand. In § 426.490, a decision by the Board would constitute a final Agency action and would be subject to judicial review. Neither the contractor nor we may appeal a Board decision.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 required that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We have solicited public comment on each of these issues for the following sections of this document that contain information collection requirements:

Sections 426.400 and 426.500

Sections 426.400, Procedure for filing an acceptable complaint to a provision (or provisions) of an LCD, and 426.500, Procedure for filing an acceptable complaint to a provision or provisions of an NCD, state that an aggrieved party may initiate a review of an LCD or NCD, respectively, by filing a written complaint. These sections also identify the information required in the complaint to qualify as an aggrieved party as defined in § 426.110, as well as the process and information needed for an aggrieved party to withdraw a complaint. The required documentation includes a copy of the written authorization to represent the beneficiary, if the beneficiary has a representative, and a copy of a written statement from the treating physician that the beneficiary needs a service that is the subject of the LCD.

Based on the lack of public comments, we continue to estimate that there will be 1,000 LCD complaints per year and that it will take the aggrieved party 4 hours to draft the complaint and gather the information to send to us. The national burden would be 4,000 hours annually. We estimate that there will be 15 to 20 NCD complaints per year. It will take 4 hours, maximum, to gather the information and to write each complaint. Thus, we estimate a total of 80 hours per year to comply with the requirement.

The estimate of 4 hours is based on previous experience in both the local and national coverage development processes, and the estimated time to submit beneficiary and policy-specific information (for example, name,

address, and policy challenged) and collect and photocopy scientific and clinical evidence. It should actually take less than that amount of time in NCD challenges, since the aggrieved party has already sent us the information and merely has to send it again.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn.: Dawn Willinghan, Attn: CMS–3063–F, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), as amended by Executive Order 13258, and the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), as amended. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). Based on provider, beneficiary, and Agency costs, our analysis indicates that the costs involved with the implementation of this rule will not exceed $100 million annually. Therefore, this rule is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined that this rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. We do not believe that this rule would have an effect on the governments mentioned, nor would the private sector costs associated with the rule be greater than $110 million.

B. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule will not have a substantial effect on State or local governments.

C. Anticipated Effects

1. Effects on Medicare Beneficiaries

In developing this rule, we considered how to make it user-friendly for the individual beneficiaries who qualify as aggrieved parties to initiate the review of an LCD or an NCD. Possible access obstacles for some aggrieved parties include limited financial resources, limited mobility, various disabilities, absence of legal representation, and difficulty in compiling and presenting scientific and clinical materials. We have sought to include means to alleviate these obstacles as much as possible through this rule, but would also expect the ALJs and the Board to use the flexibility in this rule to respond to obstacles that may confront individual aggrieved parties in particular cases.

Some concerns may remain about how to facilitate participation, especially when evidence is taken in person, by aggrieved parties with limited mobility or resources. This final rule seeks to address this by providing for most evidence to be submitted in written form and by allowing use of a variety of electronic means for remote attendance at any oral proceeding, if one is needed. In addition, the rule provides flexibility for ALJs and the Board to tailor proceedings in each case to best reflect the needs of the parties, the appropriate scope of participation, and the nature of the issues presented.

While we require some documentation to support a complainant's assertions of being an aggrieved party (*see* § 426.400 and § 426.500), we will accept that documentation as sufficient to show standing to challenge an LCD or an NCD. By limiting this documentation, we seek to simplify the process for the beneficiary, to alleviate privacy concerns about confidential medical records and other patient-specific information, and to reduce any intrusive discovery burden on beneficiaries.

Our intent is to ensure that beneficiaries fully understand these rights. When this final rule is published, we expect to produce a user-friendly guide that beneficiaries may use to assist them in accessing this process.

We have also provided for appropriate measures to be taken to address confidentiality and privilege issues relating to privileged or confidential trade secrets, commercial information, or financial information.

2. Effects on Providers

We do not believe that the provisions of this rule will have a significant effect on providers, since the Congress developed the BIPA 522 process for beneficiaries. Providers may be requested, however, to supply documentation that an aggrieved party is in need of a specific service, and to assist in representing an aggrieved party. In addition, we have clarified in the final rule that this document may be in the form of an order or other existing language from the beneficiary's medical record and need not be newly created material. It is also possible for a provider to be subpoenaed under § 426.435 and § 426.535, but § 426.445 and § 426.545 will allow for compensation under this circumstance. While there may be time requirements placed on providers and expert witnesses in this respect, there will be no additional monetary expenses. As a

result, we believe that the rule will have an insignificant economic impact on health care providers or the health care industry as a whole.

3. Effects on the Medicare Program

The Medicare program would incur certain significant administrative costs associated with coverage determination reviews, the cost of being a party to coverage determination reviews, the cost of reevaluating policies, and the cost of changes to the claim review and appeals procedures.

D. Alternatives Considered

We considered various alternative approaches for implementing the ALJ or the Board decisions with respect to an LCD and NCD. One alternative we considered was to allow an ALJ or the Board to specify the type of relief that would be afforded to the aggrieved party in those instances in which an ALJ or the Board issued a finding of unreasonable under the reasonableness standard. We contemplated whether it would be feasible based on the record developed in this proceeding for an ALJ or the Board to order us to make payment for a particular claim for the individual. We determined, however, that because the record in a policy challenge adjudication focuses on the challenged policy, and not on the beneficiary's particular medical circumstances or entitlement to Medicare benefits, it is not possible to allow an ALJ or the Board to order payment in those circumstances. In some cases, other statutory restrictions may apply for a particular claim that would prevent Medicare from making payment even if the LCD or NCD were found unreasonable. For instance, if care were furnished by an excluded physician in other than an emergency situation, section 1862(e)(1) of the Act would bar Medicare payment. There are other examples where rules other than an NCD may lead to the denial of a claim (such as statutory exclusion). To avoid redundant claims/appeals processes, individual review is performed through our existing claims appeals procedures, but the LCD or NCD that was found unreasonable by the ALJ or the Board will not be applied.

Further, we do not believe that it is appropriate for an ALJ or the Board to add language to coverage determinations. LCDs and NCDs are based on clinical and scientific evidence to develop policies that are both sound and effective, and continue to ensure the highest quality of covered care for Medicare recipients. For the sake of continuing to ensure that aggrieved parties receive the same quality care as all other Medicare recipients, and for the sake of efficiently administering this process, we believe that clinicians and scientific experts are best suited to continue to develop these policies.

In accordance with the provisions of Executive Order 12866, as amended by Executive Order 13258, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 400

Grant programs-health, Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 426

Administrative practice and procedure, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 400—INTRODUCTION; DEFINITIONS

■ 1. The authority citation for part 400 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

■ 2. Amend § 400.202 by adding the definitions of ''Departmental Appeals Board,'' and ''Local coverage determination (LCD),'' and by revising the definition of ''National coverage determination (NCD)'' to read as follows:

§ 400.202 Definitions specific to Medicare.

* * * * *

Departmental Appeals Board means: (1) Except as provided in paragraphs (2) and (3) of this definition, a Board established in the office of the Secretary, whose members act in panels to provide impartial review of disputed decisions made by operating components of the Department or by ALJs.

(2) For purposes of review of ALJ decisions under part 405, subparts G and H; part 417, subpart Q; part 422, subpart M; and part 478, subpart B of this chapter, the Medicare Appeals Council designated by the Board Chair.

(3) For purposes of part 426 of this chapter, a Member of the Board and, at the discretion of the Board Chair, any other Board staff appointed by the Board Chair to perform a review under that part.

* * * * *

Local coverage determination (LCD) means a decision by a fiscal intermediary or a carrier under Medicare Part A or Part B, as applicable, whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with section 1862(a)(1)(A) of the Act. An LCD may provide that a service is not reasonable and necessary for certain diagnoses and/or for certain diagnosis codes. An LCD does not include a determination of which procedure code, if any, is assigned to a service or a determination with respect to the amount of payment to be made for the service.

* * * * *

National coverage determination (NCD) means a decision that CMS makes regarding whether to cover a particular service nationally under title XVIII of the Act. An NCD does not include a determination of what code, if any, is assigned to a service or a determination with respect to the amount of payment to be made for the service.

* * * * *

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 3. The authority citation for part 405 continues to read as follows:

Authority: Secs. 1102, 1861, 1862(a), 1871, 1874, 1881, and 1888(k) of the Social Security Act (42 U.S.C. 1302, 1395x, 1395y(a), 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 4. Revise § 405.732 to read follows:

§ 405.732 Review of a national coverage determination (NCD).

(a) *General rule.* (1) An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under title XVIII of the Act.

(2) An NCD does not include a determination of what code, if any, is assigned to a particular item or service covered under title XVIII or a determination for the amount of payment made for a particular item or service.

(3) NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act.

(4) An NCD is binding on all Medicare carriers, fiscal intermediaries, QIOs, HMOs, CMPs, HCPPs, the Medicare Appeals Council, and ALJs.

(b) *Review by ALJ.* (1) An ALJ may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD has been applied correctly to the claim.

(c) *Review by Court.* For initial determinations and NCD challenges under section 1862(a)(1) of the Act, arising before October 1, 2002, a court's review of an NCD is limited to whether the record is incomplete or otherwise lacks adequate information to support the validity of the decision, unless the case has been remanded to the Secretary to supplement the record regarding the NCD. In these cases, the court may not invalidate an NCD except upon review of the supplemental record.

■ 5. Revise § 405.860 to read as follows:

§ 405.860 Review of a national coverage determination (NCD).

(a) *General rule.* (1) An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under title XVIII of the Act.

(2) An NCD does not include a determination of what code, if any, is assigned to a particular item or service covered under title XVIII or a determination for the amount of payment made for a particular item or service.

(3) NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act.

(4) An NCD is binding on all Medicare carriers, fiscal intermediaries, QIOs, HMOs, CMPs, HCPPs, the Medicare Appeals Council, and ALJs.

(b) *Review by ALJ.* (1) An ALJ may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD is applied correctly to the claim.

(c) *Review by Court.* For initial determinations and NCD challenges under section 1862(a)(1) of the Act, arising before October 1, 2002, a court's review of an NCD is limited to whether the record is incomplete or otherwise lacks adequate information to support the validity of the decision, unless the case is remanded to the Secretary to supplement the record regarding the NCD. In these cases, the court may not invalidate an NCD except upon review of the supplemental record.

■ 6. Add part 426 to subchapter B to read as follows:

PART 426—REVIEWS OF LOCAL AND NATIONAL COVERAGE DETERMINATIONS

Subpart A—General Provisions

Sec.

Subpart B—[Reserved]

Subpart C—General Provisions for the Review of LCDs and NCDs

Subpart D—Review of an LCD

Subpart E—Review of an NCD

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh)

Subpart A—General Provisions

§ 426.100 Basis and scope.

(a) *Basis.* This part implements sections 1869(f)(1) and (f)(2) of the Act, which provide for the review of LCDs, NCDs, and certain determinations that are deemed to be NCDs by statute.

(b) *Scope.* This subpart establishes the requirements and procedures for the review of LCDs and NCDs.

§ 426.110 Definitions.

For the purposes of this part, the following definitions apply:

Aggrieved party means a Medicare beneficiary, or the estate of a Medicare beneficiary, who—

(1) Is entitled to benefits under Part A, enrolled under Part B, or both (including an individual enrolled in fee-for-service Medicare, in a Medicare+Choice plan, or in another Medicare managed care plan);

(2) Is in need of coverage for a service that is denied based on an applicable LCD (in the relevant jurisdiction) or an NCD, regardless of whether the service was received; and

(3) Has obtained documentation of the need by the beneficiary's treating physician.

Board means the Departmental Appeals Board.

Clinical and scientific experts mean experts that are consulted by the ALJ or Board as independent and impartial individuals, with significant experience and/or published work, pertaining to the subject of the review.

Contractor means a carrier (including a Durable Medical Equipment Regional Carrier), or a fiscal intermediary (including a Regional Home Health Intermediary) that has jurisdiction for the LCD at issue.

Deemed NCD means a determination that the Secretary makes, in response to a request for an NCD under section 1869(f)(4)(B) and (C) of the Act, that no national coverage or noncoverage determination is appropriate, or the Secretary's failure to meet the deadline under section 1869(f)(4)(A)(iv) of the Act.

New evidence means clinical or scientific evidence that was not previously considered by the contractor or CMS before the LCD or NCD was issued.

Party means an aggrieved party, which is an individual, or estate who has a right to participate in the LCD or NCD review process, and, as appropriate, a contractor or CMS.

Proprietary data and *Privileged information* means 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 in accordance with 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 specified in 45 CFR 5.65.

(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 proprietary is not considered proprietary.

Reasonableness standard means 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 CMS are reasonable based on the LCD or NCD record and the relevant record developed before the ALJ or the Board.

Supplemental LCD/NCD record is a record that the contractor/CMS provides to the ALJ/Board and any aggrieved party and consists of all materials received and considered during a reconsideration. Materials that are already in the record before the ALJ/Board (for example, new evidence presented in the taking of evidence or hearing) need not be provided but may be incorporated by reference in the supplement to the LCD/NCD record. The contractor/CMS may provide statements, evidence, or other submissions to the ALJ/Board during the proceedings, as provided elsewhere in these regulations, but these submissions are not considered as supplementing the LCD/NCD record.

Treating physician means the physician who is the beneficiary's primary clinician with responsibility for overseeing the beneficiary's care and either approving or providing the service at issue in the challenge.

§ 426.120 Calculation of deadlines.

In counting days, Saturdays, Sundays, and Federal holidays are included. If a due date falls on a Saturday, Sunday, or Federal holiday, the due date is the next Federal working day.

§ 426.130 Party submissions.

Any party submitting material, except for material for which a privilege is asserted, or proprietary data, to the ALJ or the Board after that party's initial challenge must serve the material on all other parties at the same time.

Subpart B—[Reserved]

Subpart C—General Provisions for the Review of LCDs and NCDs

§ 426.300 Review of LCDs, NCDs, and deemed NCDs.

(a) Upon the receipt of an acceptable LCD complaint as described in § 426.400, an ALJ conducts a review of a challenged provision (or provisions) of an LCD using the reasonableness standard.

(b) Upon the receipt of an acceptable NCD complaint as described in § 426.500, the Board conducts an NCD review of a challenged provision (or provisions) of an NCD using the reasonableness standard.

(c) The procedures established in this part governing the review of NCDs also apply in cases in which a deemed NCD is challenged.

§ 426.310 LCD and NCD reviews and individual claim appeals.

(a) LCD and NCD reviews are distinct from the claims appeal processes set forth in part 405, subparts G and H; part 417, subpart Q; and part 422, subpart M of this chapter.

(b) An aggrieved party must notify the ALJ or the Board, as appropriate, regarding the submission and disposition of any pending claim or appeal relating to the subject of the aggrieved party's LCD or NCD complaint. This reporting obligation continues through the entire LCD or NCD review process.

§ 426.320 Who may challenge an LCD or NCD.

(a) Only an aggrieved party may initiate a review of an LCD or NCD (including a deemed NCD), or provisions of an LCD or NCD by filing an acceptable complaint.

(b) Neither an ALJ nor the Board recognizes as valid any attempt to assign rights to request review under section 1869(f) of the Act.

§ 426. 325 What may be challenged.

(a) Only LCDs or NCDs (including deemed NCDs) that are currently effective may be challenged.

(b) Some items are not reviewable under this part, including the following:

(1) Pre-decisional materials, including—

(i) Draft LCDs;

(ii) Template LCDs or suggested LCDs; and

(iii) Draft NCDs, including national coverage decision memoranda.

(2) Retired LCDs or withdrawn NCDs.

(3) LCD or NCD provisions that are no longer in effect due to revisions or reconsiderations.

(4) Interpretive policies that are not an LCD or NCD.

(5) Contractor decisions that are not based on section 1862(a)(1)(A) of the Act.

(6) Contractor claims processing edits.

(7) Payment amounts or methodologies.

(8) Procedure coding issues, including determinations, methodologies, definitions, or provisions.

(9) Contractor bulletin articles, educational materials, or Web site frequently asked questions.

(10) Any M+C organization or managed care plan policy, rule, or procedure.

(11) An individual claim determination.

(12) Any other policy that is not an LCD or an NCD as set forth in § 400.202 of this chapter.

§ 426.330 Burden of proof.

During an LCD or NCD review, an aggrieved party bears the burden of proof and the burden of persuasion for the issue(s) raised in a complaint. The burden of persuasion is judged by a preponderance of the evidence.

§ 426.340 Procedures for review of new evidence.

(a) The process for review of new evidence is initiated once the ALJ/Board completes the taking of evidence.

(b) If an aggrieved party has submitted new evidence pertaining to the LCD/NCD provision(s) in question, and the ALJ or the Board finds that evidence admissible, the ALJ or the Board reviews the record as a whole and decide whether the new evidence has the potential to significantly affect the ALJ's or the Board's evaluation of the LCD/NCD provision(s) in question under the reasonableness standard.

(c) If the ALJ or the Board determines that the new evidence does not have the potential to significantly affect the ALJ's or the Board's evaluation of the LCD/NCD provision(s) in question under the reasonableness standard, this evidence is included in the review record, and the review goes forward to a decision on the merits.

(d) If the ALJ or the Board determines that the new evidence has the potential to significantly affect the ALJ's or the Board's evaluation of the LCD or NCD provision(s) in question under the reasonableness standard, then the ALJ or the Board—

(1) Stays the proceedings and ensures that the contractor or CMS, whichever is appropriate, has a copy of the new evidence for its examination; and

(2) Allows the contractor/CMS 10 days, generally, to examine the new evidence, and to decide whether the contractor or CMS initiates a reconsideration.

(e) If the contractor or CMS informs the ALJ or the Board by the end of the 10 days that a reconsideration is initiated, and then the ALJ or the Board—

(1) Continues the stay in proceedings; and

(2) Sets a reasonable timeframe, not more than 90 days, by which the contractor or CMS completes the reconsideration.

(f) The ALJ or Board lifts the stay in proceedings and continues the review on the challenged provision(s) of the original LCD or NCD, including the new evidence in the review record, if the contractor or CMS—

(1) Informs the ALJ or Board that a reconsideration is not initiated; or

(2) The 90-day reconsideration timeframe is not met.

(g) If an LCD or NCD is reconsidered and revised within the timeframe allotted by the ALJ or Board, then the revised LCD or NCD and any supplement to the LCD or NCD record is forwarded to the ALJ or the Board and all parties and the review proceeds on the LCD or NCD.

Subpart D—Review of an LCD

§ 426.400 Procedure for filing an acceptable complaint concerning a provision (or provisions) of an LCD.

(a) *The complaint.* An aggrieved party may initiate a review of an LCD by filing a written complaint with the office designated by CMS on the Medicare Web site, *http://www.medicare.gov/coverage/static/appeals.asp.*

(b) *Timeliness of a complaint.* An LCD complaint is not considered timely unless it is filed with the office designated by CMS within—

(1) 6 months of the issuance of a written statement from each aggrieved party's treating practitioner, in the case of aggrieved parties who choose to file an LCD challenge before receiving the service; or

(2) 120 days of the initial denial notice, in the case of aggrieved parties who choose to file an LCD challenge after receiving the service.

(c) *Components of a valid complaint.* A complaint must include the following:

(1) *Beneficiary-identifying information:*

(i) Name.

(ii) Mailing address.

(iii) State of residence, if different from mailing address.

(iv) Telephone number, if any.

(v) Health Insurance Claim number, if applicable.

(vi) E-mail address, if applicable.

(2) *If the beneficiary has a representative,* the representative-identifying information must include the following:

(i) Name.

(ii) Mailing address.

(iii) Telephone number.

(iv) E-mail address, if any.

(v) Copy of the written authorization to represent the beneficiary.

(3) *Treating physician written statement.* A copy of a written statement from the treating physician that the beneficiary needs the service that is the subject of the LCD. This statement may be in the form of a written order for the service or other documentation from the beneficiary's medical record (such as progress notes or discharge summary) indicating that the beneficiary needs the service.

(4) *LCD-identifying information:*

(i) Name of the contractor using the LCD.

(ii) Title of LCD being challenged.

(iii) The specific provision (or provisions) of the LCD adversely affecting the aggrieved party.

(5) *Aggrieved party statement.* A statement from the aggrieved party explaining what service is needed and why the aggrieved party thinks that the provision(s) of the LCD is (are) not valid under the reasonableness standard.

(6) *Clinical or scientific evidence.* (i) Copies of clinical or scientific evidence that support the complaint and an explanation for why the aggrieved party thinks that this evidence shows that the LCD is not reasonable.

(ii) Any documents or portions of documents that include proprietary data must be marked ''proprietary data,'' and include a legal basis for that assertion.

(iii) Proprietary data submitted by a manufacturer concerning a drug or device for which the manufacturer has submitted information to the Food and Drug Administration, must be considered and given substantive weight only when supported by an affidavit certifying that the submission contains true and correct copies of all data submitted by the manufacturer to the Food and Drug Administration in relation to that drug or device.

(d) *Joint complaints*—(1) *Conditions for a joint complaint.* Two or more aggrieved parties may initiate the review of an LCD by filing a single written complaint with the ALJ if all of the following conditions are met:

(i) Each aggrieved party named in the joint complaint has a similar medical condition or there are other bases for combining the complaints.

(ii) Each aggrieved party named in the joint complaint is filing the complaint

in regard to the same provision(s) of the same LCD.

(2) *Components of a valid joint complaint.* A joint complaint must contain the following information:

(i) The beneficiary-identifying information described in paragraph (c)(1) of this section for each aggrieved party named in the joint complaint.

(ii) The LCD-identifying information described in paragraph (c)(2) of this section.

(iii) The documentation described in paragraphs (c)(3) and (c)(4) of this section.

(3) *Timeliness of a joint complaint.* Aggrieved parties, who choose to seek review of an LCD—

(i) Before receiving the service, must file with the ALJ a joint complaint within 6 months of the written statement from each aggrieved party's treating physician.

(ii) After receiving the service, must file with the ALJ a complaint within 120 days of each aggrieved party's initial denial notice.

§ 426.403 Submitting new evidence once an acceptable complaint is filed.

Once an acceptable complaint is filed, the aggrieved party may submit additional new evidence without withdrawing the complaint until the ALJ closes the record.

§ 426.405 Authority of the ALJ.

(a) An ALJ conducts a fair and impartial hearing, avoids unnecessary delay, maintains order, and ensures that all proceedings are recorded.

(b) An ALJ defers only to reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(c) The ALJ has the authority to do any of the following:

(1) Review complaints by an aggrieved party (or aggrieved parties).

(2) Dismiss complaints that fail to comply with § 426.400.

(3) Set and change the date, time, and place of a hearing upon reasonable notice to the parties.

(4) Continue or recess a hearing for a reasonable period of time.

(5) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding.

(6) Consult with scientific and clinical experts on his or her own motion concerning clinical or scientific evidence.

(7) Set schedules for submission of exhibits and written reports of experts.

(8) Administer oaths and affirmations.

(9) Examine witnesses.

(10) Issue subpoenas requiring the attendance of witnesses at hearings as permitted by this part.

(11) Issue subpoenas requiring the production of existing documents before, and relating to, the hearing as permitted by this part.

(12) Rule on motions and other procedural matters.

(13) Stay the proceedings in accordance with § 426.340.

(14) Regulate the scope and timing of documentary discovery as permitted by this part.

(15) Regulate the course of a hearing and the conduct of representatives, parties, and witnesses.

(16) Receive, rule on, exclude, or limit evidence, as provided in § 426.340.

(17) Take official notice of facts, upon motion of a party.

(18) Decide cases, upon the motion of a party, by summary judgment when there is no disputed issue of material fact.

(19) Conduct any conference, argument, or hearing in person or, upon agreement of the parties, by telephone, picture-tel, or any other means.

(20) Issue decisions.

(21) Exclude a party from an LCD review for failure to comply with an ALJ order or procedural request without good cause shown.

(22) Stay the proceedings for a reasonable time when all parties voluntarily agree to mediation or negotiation, and provide mediation services upon request.

(d) The ALJ does not have authority to do any of the following under this part:

(1) Conduct an LCD review or conduct LCD hearings on his or her own motion or on the motion of a nonaggrieved party.

(2) Issue a decision based on any new evidence without following § 426.340, regarding procedures for review of new evidence.

(3) Review any decisions by contractors to develop a new or revised LCD.

(4) Conduct a review of any draft, retired, archived, template, or suggested LCDs.

(5) Conduct a review of any policy that is not an LCD, as defined in § 400.202 of this chapter.

(6) Conduct a review of any NCD according to section 1869(f)(1)(A)(i) of the Act.

(7) Conduct a review of the merits of an unacceptable LCD complaint as discussed in § 426.410.

(8) Allow participation by individuals or entities other than—

(i) The aggrieved party and/or his/her representative;

(ii) CMS and/or the contractor; and

(iii) Experts called by the parties or the ALJ.

(9) Compel the parties to participate in a mediation process or to engage in settlement negotiations.

(10) Deny a request for withdrawal of a complaint by an aggrieved party.

(11) Compel the contractor to conduct studies, surveys, or develop new information to support an LCD record.

(12) Deny a contractor the right to reconsider, revise or retire an LCD.

(13) Find invalid applicable Federal statutes, regulations, rulings, or NCDs.

(14) Enter a decision specifying terms to be included in an LCD.

§ 426.406 *Ex parte* contacts.

No party or person (except employees of the ALJ's office) communicates in any way with the ALJ on any substantive matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 426.410 Docketing and evaluating the acceptability of LCD complaints.

(a) *Docketing the complaint.* The office designated by CMS does the following upon receiving a complaint regarding an LCD:

Dockets the complaint.

Determines whether the complaint is—

(i) The first challenge to a particular LCD; or

(ii) Related to a pending LCD review.

(3) Forwards the complaint to the ALJ that conducts the review. In cases related to pending reviews, the complaint generally is forwarded to the ALJ who is conducting the review.

(b) *Evaluating the acceptability of the complaint.* The ALJ assigned to the LCD review determines if the complaint is acceptable by confirming all of the following:

(1) The complaint is being submitted by an aggrieved party or, in the case of a joint complaint, that each individual named in the joint complaint is an aggrieved party. (In determining if a complaint is acceptable, the ALJ assumes that the facts alleged by the treating physician's documentation regarding the aggrieved party's (or parties') clinical condition are true.)

(2) The complaint meets the requirements for a valid complaint in § 426.400 and does not challenge one of the documents in § 426.325(b).

(c) *Unacceptable complaint.* (1) If the ALJ determines that the complaint is unacceptable, the ALJ must provide the

aggrieved party (or parties) one opportunity to amend the unacceptable complaint.

(2) If the aggrieved party (or parties) fail(s) to submit an acceptable amended complaint within a reasonable timeframe as determined by the ALJ, the ALJ must issue a decision dismissing the unacceptable complaint.

(3) If a complaint is determined unacceptable after one amendment, the beneficiary is precluded from filing again for 6 months after being informed that it is unacceptable.

(d) *Acceptable complaint.* If the ALJ determines that the complaint (or amended complaint) is acceptable, the ALJ does the following:

(1) Sends a letter to the aggrieved party (or parties) acknowledging the complaint and informing the aggrieved party (or parties) of the docket number and the deadline for the contractor to produce the LCD record.

(2) Forwards a copy of the complaint, any evidence submitted in the complaint, and the letter described in paragraph (d)(1) of this section to the applicable contractor and CMS.

(3) Requires CMS or the contractor to send a copy of the LCD record to the ALJ and all parties to the LCD review within 30 days of receiving the ALJ's letter, the copy of the complaint, and any associated evidence, subject to extension for good cause shown.

(e) *Consolidation of complaints regarding an LCD*—(1) *Criteria for consolidation.* If a review is pending regarding a particular LCD provision(s) and no decision has been issued ending the review, and a new acceptable complaint is filed, the ALJ consolidates the complaints and conducts a consolidated LCD review if all of the following criteria are met:

(i) The complaints are in regard to the same provision(s) of the same LCD or there are other bases for consolidating the complaints.

(ii) The complaints contain common questions of law, common questions of fact, or both.

(iii) Consolidating the complaints does not unduly delay the ALJ's decision.

(2) *Decision to consolidate complaints.* If an ALJ decides to consolidate complaints, the ALJ does the following:

(i) Provides notification that the LCD review is consolidated and informs all parties of the docket number of the consolidated review.

(ii) Makes a single record of the proceeding.

(iii) Considers the relevant evidence introduced in each LCD complaint as introduced in the consolidated review.

(3) *Decision not to consolidate complaints.* If an ALJ decides not to consolidate complaints, the ALJ conducts separate LCD reviews for each complaint.

§ 426.415 CMS' role in the LCD review.

CMS may provide to the ALJ, and all parties to the LCD review, information identifying the person who represents the contractor or CMS, if necessary, in the LCD review process.

§ 426.416 Role of Medicare Managed Care Organizations (MCOs) and State agencies in the LCD review.

Medicare MCOs and Medicaid State agencies have no role in the LCD review process. However, once the ALJ has issued its decision, the decision is made available to all Medicare MCOs and State agencies.

§ 426.417 Contractor's statement regarding new evidence.

(a) The contractor may review any new evidence that is submitted, regardless of whether the ALJ has stayed the proceedings, including but not limited to—

(1) New evidence submitted with the initial complaint;

(2) New evidence submitted with an amended complaint;

(3) New evidence produced during discovery;

(4) New evidence produced when the ALJ consults with scientific and clinical experts; and

(5) New evidence presented during any hearing.

(b) The contractor may submit a statement regarding whether the new evidence is significant under § 426.340, within such deadline as the ALJ may set.

§ 426.418 LCD record furnished to aggrieved party.

(a) *Elements of a contractor's LCD record furnished to the aggrieved party.* Except as provided in paragraph (b) of this section, the contractor's LCD record consists of any document or material that the contractor considered during the development of the LCD, including, but not limited to, the following:

(1) The LCD being challenged.

(2) Any medical evidence considered on or before the date the LCD was issued, including, but not limited to, the following:

(i) Scientific articles.

(ii) Technology assessments.

(iii) Clinical guidelines.

(iv) Statements from clinical experts, medical textbooks, claims data, or other indication of medical standard of practice.

(3) Comment and Response Document (a summary of comments received by the contractor concerning the draft LCD).

(4) An index of documents considered that are excluded under paragraph (b) of this section.

(b) *Elements of the LCD record not furnished to the aggrieved party.* The LCD record furnished to the aggrieved party does not include the following:

(1) Proprietary data or privileged information.

(2) Any new evidence.

§ 426.419 LCD record furnished to the ALJ.

The LCD record furnished to the ALJ includes the following:

(a) Documents included in § 426.418(a).

(b) Privileged information and proprietary data considered that must be filed with the ALJ under seal.

§ 426.420 Retiring or revising an LCD under review.

(a) A contractor may retire an LCD or LCD provision under review before the date the ALJ issues a decision regarding that LCD. Retiring an LCD or LCD provision under review has the same effect as a decision under § 426.460(b).

(b) A contractor may revise an LCD under review to remove or amend the LCD provision listed in the complaint through the reconsideration process before the date the ALJ issues a decision regarding that LCD. Revising an LCD under review to remove the LCD provision in question has the same effect as a decision under § 426.460(b).

(c) A contractor must notify the ALJ within 48 hours of—

(1) Retiring an LCD or LCD provision that is under review; or

(2) Issuing a revised version of the LCD that is under review.

(d) If the contractor issues a revised LCD, the contractor forwards a copy of the revised LCD to the ALJ.

(e) The ALJ must take the following actions upon receiving a notice that the contractor has retired or revised an LCD under review:

(1) If, before the ALJ issues a decision, the ALJ receives notice that the contractor has retired the LCD or revised the LCD to completely remove the provision in question, the ALJ must dismiss the complaint and inform the aggrieved party(ies) who sought the review that he or she or they receive individual claim review without the retired/withdrawn provision(s).

(2) If, before the ALJ issues a decision, the ALJ receives notice that the contractor has revised the LCD provision in question but has not removed it altogether, the ALJ must continue the review based on the

revised LCD. In this case, the contractor must send a copy of the supplemental record to the ALJ and all parties. In that circumstance, the ALJ permits the aggrieved party to respond to the revised LCD and supplemental record.

§ 426.423 Withdrawing a complaint regarding an LCD under review.

(a) *Circumstance under which an aggrieved party may withdraw a complaint regarding an LCD.* An aggrieved party who filed a complaint regarding an LCD may withdraw the complaint before the ALJ issues a decision regarding that LCD. The aggrieved party may not file another complaint concerning the same coverage determination for 6 months.

(b) *Process for an aggrieved party withdrawing a complaint regarding an LCD.* To withdraw a complaint regarding an LCD, the aggrieved party who filed the complaint must send a written withdrawal notice to the ALJ (*see* § 426.400), CMS (if applicable), and the applicable contractor. Supplementing an acceptable complaint with new evidence does not constitute a withdrawal of a complaint, as described in § 426.403.

(c) *Actions the ALJ must take upon receiving a notice announcing the intent to withdraw a complaint regarding an LCD*—(1) *LCD reviews involving one aggrieved party.* If the ALJ receives a withdrawal notice regarding an LCD before the date the ALJ issued a decision regarding that LCD, the ALJ issues a decision dismissing the complaint under § 426.444 and informs the aggrieved party that he or she may not file another complaint to the same coverage determination for 6 months.

(2) *LCD reviews involving joint complaints.* If the ALJ receives a notice from an aggrieved party who is named in a joint complaint withdrawing a complaint regarding an LCD before the date the ALJ issued a decision regarding that LCD, the ALJ issues a decision dismissing only that aggrieved party from the complaint under § 426.444. The ALJ continues the LCD review if there is one or more aggrieved party who does not withdraw from the joint complaint.

(3) *Consolidated LCD reviews.* If the ALJ receives a notice from an aggrieved party who is part of a consolidated LCD review withdrawing a complaint regarding an LCD before the date the ALJ issued a decision regarding that LCD, the ALJ removes that aggrieved party from the consolidated LCD review and issues a decision dismissing that aggrieved party's complaint under § 426.444. The ALJ continues the LCD review if there are one or more aggrieved parties who does not withdraw from the joint complaint.

§ 426.425 LCD review.

(a) *Opportunity for the aggrieved party, after his or her review of the LCD record, to state why the LCD is not valid.* Upon receipt of the contractor's LCD record, the aggrieved party files a statement explaining why the contractor's LCD record is not complete, or not adequate to support the validity of the LCD under the reasonableness standard. This statement must be submitted to the ALJ and to the contractor, or CMS, as appropriate, within 30 days (or within the additional time as allowed by the ALJ for good cause shown) of the date the aggrieved party receives the contractor's LCD record.

(b) *Contractor response.* The contractor has 30 days after receiving the aggrieved party's statement to submit a response to the ALJ in order to defend the LCD.

(c) *ALJ evaluation.* (1) After the aggrieved party files a statement and the contractor responds, as described in § 426.425(a) and § 426.425(b), or the time for filing has expired, the ALJ applies the reasonableness standard to determine whether the LCD record is complete and adequate to support the validity of the LCD.

(2) Issuance of a decision finding the record complete and adequate to support the validity of the LCD ends the review process.

(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 provison(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.

§ 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 the hearing. The motion must do all of the following:

(1) Designate the witnesses.

(2) Specify any evidence to be produced.

(3) Describe the address and location with sufficient particularity to permit the witnesses to be found.

(4) State the pertinent facts that the party expects to establish by the witnesses or documents and whether other evidence may establish without the use of a subpoena.

(c) *Response to a motion for a subpoena.* Within 15 days after the written motion requesting issuance of a subpoena is served on all parties, any party may file an opposition to the motion or other response.

(d) *Extension for good cause shown.* The ALJ may modify the deadlines specified in paragraphs (b) and (c) of this section for good cause shown.

(e) *Motion for a subpoena granted.* If the ALJ grants a motion requesting issuance of a subpoena, the subpoena must do the following:

(1) Be issued in the name of the ALJ.

(2) Include the docket number and title of the LCD under review.

(3) Provide notice that the subpoena is issued according to sections 1872 and 205(d) and (e) of the Act.

(4) Specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) *Delivery of the subpoena.* The party seeking the subpoena serves it by personal delivery to the individual named, or by certified mail return receipt requested, addressed to the individual at his or her last dwelling place or principal place of business.

(g) *Motion to quash a subpoena.* The individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within 10 days after service.

(h) *Refusal to obey a subpoena.* The exclusive remedy for contumacy by, or refusal to obey, a subpoena duly served upon any person is specified in section 205(e) of the Act (42 U.S.C. 405(e)) except that any reference to the ''Commissioner of Social Security'' shall be considered a reference to the ''Secretary.''

§ 426.440 Evidence.

(a) Except as provided in this part, the ALJ is not bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence when appropriate, for example, to exclude unreliable evidence.

(b) The ALJ must exclude evidence that (s)he determines is clearly irrelevant, immaterial, or unduly repetitive.

(c) The ALJ may accept privileged information or proprietary data, but must maintain it under seal.

(d) The ALJ may permit the parties to introduce the testimony of expert witnesses on scientific and clinical issues, rebuttal witnesses, and other relevant evidence. The ALJ may require that the testimony of expert witnesses be submitted in the form of a written report, accompanied by the curriculum vitae of the expert preparing the report.

(e) Experts submitting reports must be available for cross-examination at an evidentiary hearing upon request of the ALJ or a party to the proceeding, or the reports will be excluded from the record.

(f) Except as set forth in paragraph (c) of this section or unless otherwise ordered by the ALJ for good cause shown, all documents and other evidence offered or taken for the record are open to examination by all parties.

§ 426.444 Dismissals for cause.

(a) The ALJ may, at the request of any party, or on his or her own motion, dismiss a complaint if the aggrieved party fails to do either of the following:

(1) Attend or participate in a prehearing conference (the pre-hearing may be conducted by telephone) or hearing without good cause shown.

(2) Comply with a lawful order of the ALJ without good cause shown.

(b) The ALJ must dismiss any complaint concerning LCD provision(s) if the following conditions exist:

(1) The ALJ does not have the authority to rule on that provision under § 426.405(d).

(2) The complaint is not timely. (*See* § 426.400(b).)

(3) The complaint is not filed by an aggrieved party.

(4) The complaint is filed by an individual who fails to provide an adequate statement of need for the service from the treating physician.

(5) The complaint challenges a provision or provisions of an NCD. (*See* § 426.405, regarding the authority of the ALJ.)

(6) The contractor notifies the ALJ that the LCD provision(s) is (are) no longer in effect.

(7) The aggrieved party withdraws the complaint. (*See* § 426.423 for requirements related to withdrawing a complaint regarding an LCD under review.)

§ 426.445 Witness fees.

(a) A witness testifying at a hearing before an ALJ receives the same fees and mileage as witnesses in Federal district courts of the United States. If the witness qualifies as an expert, he or she is entitled to an expert witness fee. Witness fees are paid by the party seeking to present the witness.

(b) If an ALJ requests expert testimony, the appropriate office overseeing the ALJ is responsible for paying all applicable fees and mileage, unless the expert waives payment.

§ 426.446 Record of hearing.

The ALJ must ensure that all hearings are open to the public and are electronically, mechanically or stenographically reported. Except for privileged information and proprietary data that are filed under seal, all evidence upon which the ALJ relies for decision must be admitted into the public record. All medical reports, exhibits, and any other pertinent document, either in whole or in material part, must be offered, marked for identification, and retained in the case record.

§ 426.447 Issuance and notification of an ALJ's decision.

An ALJ must issue to all parties to the LCD review, within 90 days of closing the LCD review record to the taking of evidence, one of the following:

(a) A written decision, including a description of appeal rights.

(b) A written notification stating that a decision is pending, and an approximate date of issuance for the decision.

§ 426.450 Mandatory provisions of an ALJ's decision.

(a) *Findings.* An ALJ's decision must include one of the following:

(1) A determination that the provision of the LCD is valid under the reasonableness standard.

(2) A determination that the provision of the LCD is not valid under the reasonableness standard.

(3) A statement dismissing the complaint regarding the LCD and a rationale for the dismissal.

(4) A determination that the LCD record is complete and adequate to

support the validity of the LCD provisions under the reasonableness standard.

(b) *Other information.* An ALJ's decision must include all of the following:

(1) The date of issuance.

(2) The docket number of the LCD review.

(3) A statement as to whether the aggrieved party has filed a claim for the service(s) named in the complaint, the date(s)-of-service, and the disposition, if known.

(4) A basis for concluding that the LCD was or was not valid based on the application of the reasonableness standard to the record before the ALJ, including the contractor's:

(i) Findings of fact.

(ii) Interpretations of law.

(iii) Applications of fact to law.

(5) A summary of the evidence reviewed. If proprietary or privileged data were submitted under seal, the decision must state whether the data were material and what role they played in the determination, but without disclosing the substance or contents of the evidence under seal. A separate statement of the rationale for the ALJ's treatment of the sealed evidence must be prepared and kept under seal itself. If the ALJ decision is appealed to the Board, this statement must be provided to the Board under seal.

(6) A statement regarding appeal rights.

§ 426.455 Prohibited provisions of an ALJ's decision.

An ALJ's decision may not do any of the following:

(a) Order CMS or its contractors to add any language to a provision or provisions of an LCD.

(b) Order CMS or its contractors to pay a specific claim.

(c) Set a time limit for CMS or its contractors to establish a new or revised LCD.

(d) Review or evaluate an LCD other than the LCD under review.

(e) Include a requirement for CMS or its contractors that specifies payment, coding, or systems changes for an LCD, or deadlines for implementing these types of changes.

(f) Order or address how a contractor(s) must implement an LCD.

§ 426.457 Optional provisions of an ALJ's decision.

When appropriate, the ALJ may limit a decision holding invalid a specific provision(s) of an LCD to specific clinical indications and for similar conditions.

§ 426.458 ALJ's LCD review record.

(a) *Elements of the ALJ's LCD review record furnished to the public.* Except as provided in paragraph (b) of this section, the ALJ's LCD review record consists of any document or material that the ALJ compiled or considered during the LCD review, including, but not limited to, the following:

(1) The LCD complaint.

(2) The LCD and LCD record.

(3) The supplemental LCD record, if applicable.

(4) Transcripts of record.

(5) Any other relevant evidence gathered under § 426.440.

(6) The ALJ's decision.

(b) *Elements of the ALJ's LCD review record furnished to the Board under seal.* The ALJ's review record must include, under seal, any proprietary data or privileged information maintained under seal, and such data or information must not be included in the review record furnished to the public.

§ 426.460 Effect of an ALJ's decision.

(a) *Valid under the reasonableness standard.* If the ALJ finds that the provision or provisions of the LCD named in the complaint is (are) valid under the reasonableness standard, the aggrieved party or parties may appeal that (those) part(s) of the ALJ decision to the Board under § 426.465.

(b) *Not valid under the reasonableness standard.* If the ALJ finds that the provision or provisions of the LCD named in the complaint is (are) invalid under the reasonableness standard, and no appeal is filed by the contractor or CMS under § 426.465(b), the contractor, the M+C organization, or other Medicare managed care organization must provide the following—

(1) *Individual claim review.* (i) If neither the contractor nor CMS appeals the ALJ decision under § 426.425(b), and if the party's claim or appeal(s) was previously denied, the contractor, an M+C organization or another Medicare managed care organization must reopen the claim of the party who challenged the LCD and adjudicate the claim without using the provision(s) of the LCD that the ALJ found invalid.

(ii) If a revised LCD is issued, the contractor, the M+C organization, and any other Medicare managed care organization within the contractor's jurisdiction uses the revised LCD in reviewing claim or appeal submissions or request for services delivered or services performed on or after the effective date of the revised LCD.

(iii) If the aggrieved party who sought the review has not yet submitted a claim, the contractor adjudicates the claim without using the provision(s) of the LCD that the ALJ found invalid.

(iv) In either case, the claim and any subsequent claims for the service provided under the same circumstances is adjudicated without using the LCD provision(s) found invalid.

(2) *Coverage determination relief.* If neither the contractor nor CMS appeals the ALJ decision under § 426.425(b), the contractor implements the ALJ decision within 30 days. Any change in policy applies prospectively to requests for service or claims filed with dates of service after the implementation of the ALJ decision.

§ 426.462 Notice of an ALJ's decision.

After the ALJ has made a decision regarding an LCD complaint, the ALJ sends a written notice of the decision to each party. The notice must—

(a) State the outcome of the review; and

(b) Inform each party to the determination of his or her rights to seek further review if he or she is dissatisfied with the determination, and the time limit under which an appeal must be requested.

§ 426.463 Future new or revised LCDs.

The contractor may not reinstate an LCD provision(s) found to be unreasonable unless the contractor has a different basis (such as additional evidence) than what the ALJ evaluated.

§ 426.465 Appealing part or all of an ALJ's decision.

(a) *Circumstances under which an aggrieved party may appeal part or all of an ALJ's decision.* An aggrieved party (including one or more aggrieved parties named in a joint complaint and an aggrieved party who is part of a consolidated LCD review) may appeal to the Board any part of an ALJ's decision that does the following:

(1) States that a provision of an LCD is valid under the reasonableness standard; or

(2) Dismisses a complaint regarding an LCD (except as prohibited in paragraph (b) of this section).

(b) *Circumstance under which a contractor or CMS may appeal part or all of an ALJ's decision.* A contractor or CMS may appeal to the Board any part of an ALJ's decision that states that a provision (or provisions) of an LCD is (are) unreasonable.

(c) *Stay of an implementation pending appeal.* (1) If an ALJ's decision finds a provision or provisions of an LCD unreasonable, an appeal by a contractor or CMS stays implementation as described under § 426.460(b) until the Board issues a final decision.

(2) The appeal request must be submitted to the Board in accordance with paragraph (e) of this section.

(d) *Circumstances under which an ALJ's decision may not be appealed.* An ALJ's decision dismissing a complaint is not subject to appeal in either of the following circumstances:

(1) The contractor has retired the LCD provision(s) under review.

(2) The aggrieved party who filed the complaint has withdrawn the complaint.

(e) *Receipt of the appeal by the Board.* Unless there is good cause shown, an appeal described in paragraphs (a) or (b) of this section must be filed with the Board within 30 days of the date the ALJ's decision was issued.

(f) *Filing an appeal.* (1) To file an appeal described in paragraph (a) of this section, an aggrieved party, who sought LCD review, a contractor, or CMS must send the following to the Board:

(i) The full names and addresses of the parties, including the name of the LCD.

(ii) The date of issuance of the ALJ's decision.

(iii) The docket number that appears on the ALJ's decision.

(iv) A statement identifying the part(s) of the ALJ's decision that are being appealed.

(2) If an appeal described in paragraph (a) of this section is filed with the Board later than the date described in paragraph (c) of this section, it must include a rationale stating why the Board must accept the late appeal.

(3) An appeal described in paragraph (a) of this section must include a statement explaining why the ALJ's decision should be reversed.

§ 426.468 Decision to not appeal an ALJ's decision.

(a) Failure to timely appeal without good cause shown waives the right to challenge any part(s) of the ALJ's decision under § 426.465.

(b) Unless the Board finds good cause shown for late filing, an untimely appeal is dismissed.

(c) If a party does not timely appeal any part(s) of the ALJ's decision on an LCD review to the Board, as provided in this subpart, then the ALJ's decision is final and not subject to further review.

§ 426.470 Board's role in docketing and evaluating the acceptability of appeals of ALJ decisions.

(a) *Docketing the appeal.* The Board does the following upon receiving an appeal of part or all of an ALJ's decision:

(1) Dockets the appeal either separately or with similar appeals.

(2) Assigns a docket number.

(b) *Evaluating the acceptability of the appeal.* The Board determines if the appeal is acceptable by confirming that the appeal meets all of the criteria in § 426.465.

(c) *Unacceptable appeal.* If the Board determines that an appeal is unacceptable, the Board must dismiss the appeal.

(d) *Acceptable appeal.* If the Board determines that an appeal is acceptable, the Board does the following:

(1) Sends a letter to the appellant to acknowledge that the appeal is acceptable, and informs them of the docket number.

(2) Forwards a copy of the appeal and the letter described in paragraph (d)(1) of this section to all parties involved in the appeal.

(3) Requires the ALJ to send a copy of the ALJ's LCD review record (maintaining any sealed documents) to the Board and a copy of the public record to all parties involved in the appeal.

(e) *No participation as amicus curiae.* The Board may not allow participation by amicus participants in the review of an LCD.

§ 426.476 Board review of an ALJ's decision.

(a) *Review steps.* If the Board determines that an appeal is acceptable, the Board—

(1) Permits the party that did not file the appeal an opportunity to respond to the appeal;

(2) Hears oral argument (which may be held by telephone) if the Board determines that oral argument would be helpful to the Board's review of the ALJ decision;

(3) Reviews the LCD review record and the parties' arguments; and

(4) Issues a written decision either upholding, modifying, or reversing the ALJ decision, or remanding the case to the ALJ for further proceedings.

(b) *Standard of review.* (1) *In general.* The Board determines whether the ALJ decision contains any material error, including any failure to properly apply the reasonableness standard.

(2) If the ALJ erred in determining that the contractor's record was complete and adequate to support the validity of the LCD, the Board remands the case to the ALJ for discovery and the taking of evidence.

(3) If a party alleges a prejudicial error of procedure, and the Board determines that such an error was made, the Board may remand the case to the ALJ for further proceedings consistent with the Board decision or may take other appropriate steps to correct the procedural error.

(4) Harmless error is not a basis for reversing an ALJ decision.

(c) *Scope of review.* In reaching its conclusions, the Board is bound by applicable laws, regulations, and NCDs.

(d) *Dismissal as moot.* The Board dismisses an appeal by an aggrieved party of an ALJ decision finding that an LCD was valid if the contractor notifies the Board that it has retired the LCD or revised the LCD to remove the LCD provision in question.

§ 426.478 Retiring or revising an LCD during the Board's review of an ALJ's decision.

A contractor may retire or revise an LCD during the Board's review of an ALJ's decision using the same process described in § 426.420. If an LCD is retired or revised to remove completely the challenged provision(s), the aggrieved party who sought the review is entitled to individual claim review provided at § 426.488(b).

§ 426.480 Withdrawing an appeal of an ALJ's decision.

(a) *Withdrawal of an appeal of an ALJ's decision.* A party who filed an appeal of an ALJ's decision may withdraw the appeal before the Board issues a decision regarding the ALJ's decision.

(b) *Process of withdrawing an appeal of an ALJ's decision.* To withdraw an appeal of an ALJ's decision, the party who filed the appeal must send a written notice announcing the intent to withdraw to the Board and to any other party.

(c) *Actions the Board must take upon receiving a notice announcing the intent to withdraw an appeal of an ALJ's decision*—(1) *Appeals involving one aggrieved party, or initiated by CMS or a contractor.* If the Board receives a notice withdrawing an appeal of an ALJ's decision before the Board has issued its decision, the Board must issue a decision dismissing the appeal.

(2) *Appeals involving joint complaints.* If the Board receives a notice withdrawing an appeal from an aggrieved party who is named in a joint appeal before the Board issues its decision, the Board must issue a decision dismissing only that aggrieved party from the appeal. The Board must continue its review of the ALJ's decision for the remaining aggrieved party or parties.

§ 426.482 Issuance and notification of a Board decision.

The Board must issue a written decision, including a description of appeal rights, to all parties to the review of the ALJ decision.

§ 426.484 Mandatory provisions of a Board decision.

(a) *Findings.* A Board decision must include at least one of the following:

(1) A statement upholding the part(s) of the ALJ decision named in the appeal.

(2) A statement reversing the part(s) of the ALJ decision named in the appeal.

(3) A statement modifying the part(s) of the ALJ decision named in the appeal.

(4) A statement dismissing the appeal of an ALJ decision and a rationale for the dismissal.

(b) *Other information.* A Board decision must include all of the following:

(1) The date of issuance.

(2) The docket number of the review of the ALJ decision.

(3) A summary of the ALJ's decision.

(4) A rationale for the basis of the Board's decision.

§ 426.486 Prohibited provisions of a Board decision.

A Board decision must not do any of the following:

(a) Order CMS or its contractors to add any language to a provision or provisions of an LCD.

(b) Order CMS or its contractors to pay a specific claim.

(c) Set a time limit to establish a new or revised LCD.

(d) Review or evaluate an LCD other than the LCD named in the ALJ's decision.

(e) Include a requirement for CMS or its contractors that specifies payment, coding, or system changes for an LCD or deadlines for implementing these changes.

(f) Order CMS or its contractors to implement an LCD in a particular manner.

§ 426.487 Board's record on appeal of an ALJ's decision.

(a) *Elements of the Board's LCD review record furnished to the public.* Except as provided in paragraph (b) of this section, the Board's LCD review record consists of any document or material that the Board compiled or considered during an LCD review, including, but not limited to, the following:

(1) The LCD complaint.

(2) The LCD and LCD record.

(3) The supplemental LCD record, if applicable.

(4) Transcripts of record.

(5) Any other relevant evidence gathered under § 426.440.

(6) The ALJ's decision.

(7) The Board's decision.

(b) *Elements of the Board's LCD appeal record furnished to the court under seal.* The Board's LCD review record must include, under seal, any proprietary data or privileged information submitted and reviewed in the LCD review process, and that data or information must not be included in the review record furnished to the public, but the information must be maintained, under seal, by the Board.

(c) *Protective order.* In any instance where proprietary data or privileged information is used in the LCD process and a court seeks to obtain or require disclosure of any proprietary data or privileged information contained in the LCD record, CMS or the Department will seek to have a protective order issued for that information, as appropriate.

§ 426.488 Effect of a Board decision.

(a) *The Board's decision upholds an ALJ decision that an LCD is valid or reverses an ALJ decision that an LCD is invalid.* If the Board's decision upholds the ALJ decision that an LCD is valid under the reasonableness standard or reverses an ALJ decision that an LCD is invalid, the contractor or CMS is not required to take any action.

(b) *The Board's decision upholds an ALJ determination that the LCD is invalid.* If the Board's decision upholds an ALJ determination that the LCD is invalid, then the contractor, the M+C organization, or other Medicare managed care organization implements the decision as described in § 426.460(b).

(c) *The Board's decision reverses a dismissal or an ALJ decision that the LCD is valid.* If the Board reverses an ALJ decision dismissing a complaint or holding that an LCD is valid without requiring discovery or the taking of evidence, the Board remands to the ALJ and the LCD review continues. If the Board reverses an ALJ decision holding that an LCD is valid that is reached after the ALJ has completed discovery and the taking of evidence, the Board may remand the case to the ALJ for further proceedings, or the Board may find that the provision(s) of the LCD named in the complaint is (are) invalid under the reasonableness standard, and the contractor, the M+C organization, or other Medicare managed care organization provides the relief in § 426.460(b).

§ 426.489 Board remands.

(a) *Notice when case is remanded to the ALJ.* If the Board remands a case to the ALJ, the Board—

(1) Notifies each aggrieved party who sought the LCD review, through his or her representative or at his or her last known address, the contractor, and CMS of the Board's remand decision; and

(2) Explains why the case is being remanded and the specific actions ordered by the Board.

(b) *Action by an ALJ on remand.* An ALJ takes any action that is ordered by the Board and may take any additional action that is not inconsistent with the Board's remand order.

§ 426.490 Board decision.

A decision by the Board (other than a remand) constitutes a final agency action and is subject to judicial review. Neither the contractor nor CMS may appeal a Board decision.

Subpart E—Review of an NCD

§ 426.500 Procedure for filing an acceptable complaint concerning a provision (or provisions) of an NCD.

(a) *The complaint.* An aggrieved party may initiate a review of an NCD by filing a written complaint with the Department of Health and Human Services Departmental Appeals Board.

(b) *Timeliness of a complaint.* An NCD complaint is not considered timely unless it is filed with the Board within—

(1) 6 months of the written statement from each aggrieved party's treating physician, in the case of aggrieved parties who choose to file an NCD challenge before receiving the service; or

(2) 120 days of the initial denial notice, in the case of aggrieved parties who choose to file an NCD challenge after receiving the service.

(c) *Components of a valid complaint.* A complaint must include the following:

(1) *Beneficiary-identifying information:*

(i) Name.

(ii) Mailing address.

(iii) State of residence, if different from mailing address.

(iv) Telephone number, if any.

(v) Health Insurance Claim number, if applicable.

(vi) Email address, if applicable.

(2) *If the beneficiary has a representative,* the representative's indetifying information must include the following:

(i) Name.

(ii) Address.

(iii) Telephone number.

(iv) E-mail address (if any)

(v) Copy of the written authorization to represent the beneficiary.

(3) *Treating physician written statement.* A copy of a written statement from the treating physician that the beneficiary needs the service that is the

subject of the NCD. This statement may be in the form of a written order for the service or other documentation from the beneficiary's medical record (such as progress notes or discharge summary) indicating that the beneficiary needs the service.

(4) *NCD-identifying information:*

(i) Title of NCD being challenged.

(ii) The specific provision or provisions of the NCD adversely affecting the aggrieved party.

(5) *Aggrieved party statement.* A statement from the aggrieved party explaining what service is needed and why the aggrieved party thinks that the provision(s) of the NCD is (are) not valid under the reasonableness standard.

(6) *Clinical or scientific evidence.* (i) Copies of clinical or scientific evidence that supports the complaint and an explanation for why the aggrieved party thinks that this evidence shows that the NCD is not reasonable.

(ii) Any documents or portions of documents that include proprietary data must be marked ''proprietary data,'' and include a legal basis for that assertion.

(iii) Proprietary data submitted by a manufacturer concerning a drug or device for which the manufacturer has submitted information to the Food and Drug Administration, must be considered and given substantive weight only when supported by an affidavit certifying that the submission contains true and correct copies of all data submitted by the manufacturer to the Food and Drug Administration in relation to that drug or device.

(d) *Joint complaints*—(1) *Conditions for a joint complaint.* Two or more aggrieved parties may initiate the review of an NCD by filing a single written complaint with the Board if all of the following conditions are met:

(i) Each aggrieved party named in the joint complaint has a similar medical condition or there are other bases for combining the complaints.

(ii) Each aggrieved party named in the joint complaint is filing the complaint in regard to the same provision(s) of the same NCD.

(2) *Components of a valid joint complaint.* A joint complaint must contain the following information:

(i) The beneficiary-identifying information described in paragraph (c)(1) of this section for each aggrieved party named in the joint complaint.

(ii) The NCD-identifying information described in paragraph (c)(2) of this section.

(iii) The documentation described in paragraphs (c)(3) and (c)(4) of this section.

(3) *Timeliness of a joint complaint.* Aggrieved parties, who choose to seek review of an NCD—

(i) Before receiving the service, must file with the Board a joint complaint within 6 months of the written statement from each aggrieved party's treating physician; or

(ii) After receiving the service, must file with the Board a complaint within 120 days of each aggrieved party's initial denial notice.

§ 426.503 Submitting new evidence once an acceptable complaint has been filed.

Once an acceptable complaint has been filed, the aggrieved party may submit additional new evidence without withdrawing the complaint until the Board closes the record.

§ 426.505 Authority of the Board.

(a) The Board conducts a fair and impartial hearing, avoids unnecessary delay, maintains order, and ensures that all proceedings are recorded.

(b) The Board defers only to reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(c) The Board has the authority to do any of the following:

(1) Review complaints by an aggrieved party (or aggrieved parties).

(2) Dismiss complaints that fail to comply with § 426.500.

(3) Set and change the date, time, and place of a hearing upon reasonable notice to the parties.

(4) Continue or recess a hearing for a reasonable period of time.

(5) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding.

(6) Consult with scientific and clinical experts on its own motion, concerning clinical or scientific evidence.

(7) Set schedules for submission of exhibits and written reports of experts.

(8) Administer oaths and affirmations.

(9) Examine witnesses.

(10) Issue subpoenas requiring the attendance of witnesses at hearings as permitted by this part.

(11) Issue subpoenas requiring the production of existing documents before, and relating to, the hearing as permitted by this part.

(12) Rule on motions and other procedural matters.

(13) Stay the proceeding in accordance with § 426.340.

(14) Regulate the scope and timing of documentary discovery as permitted by this part.

(15) Regulate the course of a hearing and the conduct of representatives, parties, and witnesses.

(16) Receive, rule on, exclude, or limit evidence, as provided in this regulation.

(17) Take official notice of facts, upon motion of a party.

(18) Decide cases, upon the motion of a party, by summary judgment when there is no disputed issue of material fact.

(19) Conduct any conference, argument, or hearing in person or, upon agreement of the parties, by telephone, picture-tel, or any other means.

(20) Issue decisions.

(21) Exclude a party from an NCD review for failure to comply with a Board order or procedural request without good cause.

(22) Stay the proceedings for a reasonable time when all parties voluntarily agree to mediation or negotiation, and provide mediation services upon request.

(d) The Board does not have authority to do any of the following under this part:

(1) Conduct an LCD review or conduct LCD hearings, except as provided by § 426.465.

(2) Conduct an NCD review or conduct NCD hearings on its own motion or on the motion of a nonaggrieved party.

(3) Issue a decision based on any new evidence without following § 426.340, regarding procedures for review of new evidence.

(4) Review any decisions by CMS to develop a new or revised NCD.

(5) Conduct a review of any draft NCDs, coverage decision memoranda, or withdrawn NCDs.

(6) Conduct a review of the merits of an unacceptable NCD complaint as discussed in § 426.510.

(7) Conduct an NCD review of any policy that is not an NCD, as defined in § 400.202 of this chapter.

(8) Allow participation by individuals or entities other than—

(i) The aggrieved party and/or his or her representative;

(ii) CMS and/or the contractor;

(iii) Experts called by the parties or Board; or

(iv) Third parties with a clearly identifiable and substantial interest in the outcome of the dispute who have petitioned for and been granted permission by the Board to participate in the proceedings as *amicus curiae.*

(9) Compel the parties to participate in a mediation process or to engage in settlement negotiations.

(10) Deny a request for withdrawal of a complaint by an aggrieved party.

(11) Compel CMS to conduct studies, surveys, or develop new information to support an NCD record.

(12) Deny CMS the right to reconsider, revise, or withdraw an NCD.

(13) Subject to the timely filing requirements, deny an aggrieved party, CMS, or its contractor the right to appeal an ALJ decision.

(14) Find invalid applicable Federal statutes, regulations, or rulings.

(15) Enter a decision specifying terms to be included in an NCD.

§ 426.506 *Ex parte* contacts.

No party or person (except Board staff) communicates in any way with the Board on any substantive matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 426.510 Docketing and evaluating the acceptability of NCD complaints.

(a) *Docketing the complaint.* The Board does the following upon receiving a complaint regarding an NCD:

(1) Dockets the complaint.

(2) Determines whether the complaint is—

(i) The first challenge to a particular NCD; or

(ii) Related to a pending NCD review.

(3) Forwards the complaint to the Board member who conducts the review.

(b) *Evaluating the acceptability of the complaint.* The Board determines if the complaint is acceptable by confirming all of the following:

(1) The complaint is being submitted by an aggrieved party or, in the case of a joint complaint, that each individual named in the joint complaint is an aggrieved party. (In determining if a complaint is acceptable, the Board assumes that the facts alleged by the treating physician's documentation regarding the aggrieved party's (or parties') clinical condition are true.)

(2) The complaint meets the requirements for a valid complaint in § 426.500 and is not one of the documents in § 426.325(b).

(c) *Unacceptable complaint.* (1) If the Board determines that the complaint is unacceptable, the Board must provide the aggrieved party (or parties) one opportunity to amend the unacceptable complaint.

(2) If the aggrieved party (or parties) fail(s) to submit an acceptable amended complaint within a reasonable timeframe as determined by the Board, the Board must issue a decision dismissing the unacceptable complaint.

(3) If a complaint is determined to be unacceptable after one amendment, the beneficiary is precluded from filing again for 6 months after being informed that it is unacceptable.

(d) *Acceptable complaint.* If the Board determines that the complaint (or amended complaint) is acceptable, the Board does the following:

(1) Sends a letter to the aggrieved party (or parties) acknowledging the complaint and informing the aggrieved party (or parties) of the docket number and the deadline for CMS to produce the NCD record.

(2) Forwards a copy of the complaint, any evidence submitted in the complaint, and the letter described in paragraph (d)(1) of this section to CMS.

(3) Requires CMS to send a copy of the NCD record to the Board and all parties to the NCD review within 30 days of receiving the Board's letter, a copy of the complaint, and any associated evidence, subject to extension for good cause shown.

(e) *Consolidation of complaints regarding an NCD*—(1) *Criteria for condideration.* If a review is pending regarding a particular NCD provision(s) and no decision has been issued ending the review, and a new acceptable complaint is filed, the Board consolidates the complaints and conducts a consolidated NCD review if all of the following criteria are met:

(i) The complaints are in regard to the same provision(s) of the same NCD, or there are other bases for consolidating the complaints.

(ii) The complaints contain common questions of law, common questions of fact, or both.

(iii) Consolidating the complaints does not unduly delay the Board's decision.

(2) *Decision to consolidate complaint.* If the Board decides to consolidate complaints, the Board does the following:

(i) Provides notification that the NCD review is consolidated and informs all parties of the docket number of the consolidated review.

(ii) Makes a single record of the proceeding.

(iii) Considers the relevant evidence introduced in each NCD complaint as introduced in the consolidated review.

(3) *Decision not to consolidate complaints.* If the Board decides not to consolidate complaints, the Board conducts separate NCD reviews for each complaint.

(f) *Public notice of complaint and opportunity for interested parties to participate.* (1) If an acceptable complaint is the first complaint the Board has received challenging the particular NCD or provision, then the Board posts notice on its Web site that it has received the complaint, specifying a time period for requests to participate in the review process.

(2) If an acceptable complaint challenges an NCD provision when review is pending and no decision has been issued ending the review, the Board may supplement the public notice on its Web site and extend the time for participation requests if indicated.

(3) The Board may allow participation, in the manner and by the deadlines established by the Board, when an NCD is being challenged and the Board decides that—

(i) The *amicus* participant has a clearly identifiable and substantial interest in the outcome of the dispute;

(ii) Participation would clarify the issues or otherwise be helpful in resolution of the dispute;

(iii) Participation does not result in substantial delay; and

(iv) The petition for participation meets the criteria in § 426.513.

§ 426.513 Participation as *amicus curiae.*

(a) *Petition for participation.* Any person or organization that wishes to participate as *amicus curiae* must timely file with the Board a petition that concisely states—

(1) The petitioner's interest in the hearing;

(2) Who will represent the petitioner; and

(3) The issues on which the petitioner intends to present argument.

(b) *The nature of the proposed amicus participation.* An *amicus curiae* is not a party to the hearing but may participate by—

(1) Submitting a written statement of position to the Board before the beginning of the hearing;

(2) Presenting a brief oral statement or other evidence at the hearing, at the point in the proceedings specified by the Board; and

(3) Submitting a brief or a written statement when the parties submit briefs.

(c) *Service by amicus curiae.* Serving copies of any briefs or written statements on all parties.

§ 426.515 CMS' role in making the NCD record available.

CMS will provide a copy of the NCD record (as described in § 426.518) to the Board and all parties to the NCD review within 30 days of the receipt of the Board's order.

§ 426.516 Role of Medicare Managed Care Organizations (MCOs) and State agencies in the NCD review process.

Medicare MCOs and Medicaid State agencies may participate in the NCD review process only if they meet the *amicus* participant criteria listed in § 426.510(f)(3) and § 426.513.

§ 426.517 CMS' statement regarding new evidence.

(a) CMS may review any new evidence that is submitted, regardless of whether the Board has stayed the proceedings, including but not limited to new evidence:

(1) Submitted with the initial complaint;

(2) Submitted with an amended complaint;

(3) Produced during discovery;

(4) Produced when the Board consults with scientific and clinical experts; and

(5) Presented during any hearing.

(b) CMS may submit a statement regarding whether the new evidence is significant under § 426.340, by a deadline set by the Board.

§ 426.518 NCD record furnished to the aggrieved party.

(a) *Elements of the NCD record furnished to the aggrieved party.* Except as provided in paragraph (b) of this section, the NCD record consists of any document or material that CMS considered during the development of the NCD, including, but not limited to, the following:

(1) The NCD being challenged.

(2) Any medical evidence considered on or before the date the NCD was issued, including, but not limited to, the following:

(i) Scientific articles.

(ii) Technology assessments.

(iii) Clinical guidelines.

(iv) Statements from clinical experts, medical textbooks, claims data, or other indication of medical standard of practice.

(v) MCAC transcripts.

(3) Public comments received during the notice and comment period.

(4) Coverage decision memoranda.

(5) An index of documents considered that are excluded under paragraph (b) of this section.

(b) *Elements of the NCD record not furnished to the aggrieved party.* The NCD record furnished to the aggrieved party does not include the following:

(1) Proprietary data or privileged information.

(2) Any new evidence.

§ 426.519 NCD record furnished to the Board.

The NCD record furnished to the Board includes—

(a) Documents included in § 426.518(a); and

(b) Privileged information and proprietary data considered that must be filed with the Board under seal.

§ 426.520 Withdrawing an NCD under review or issuing a revised or reconsidered NCD.

(a) CMS may withdraw an NCD or NCD provision under review before the date the Board issues a decision regarding that NCD. Withdrawing an NCD or NCD provision under review has the same effect as a decision under § 426.560(b).

(b) CMS may revise an NCD under review to remove or amend the NCD provision listed in the complaint through the reconsideration process before the date the Board issues a decision regarding that NCD. Revising an NCD under review to remove the NCD provision in question has the same effect as a decision under § 426.560(b).

(c) CMS must notify the Board within 48 hours of—

(1) Withdrawing an NCD or NCD provision that is under review; or

(2) Issuing a revised or reconsidered version of the NCD that is under review.

(d) If CMS issues a revised or reconsidered NCD, CMS forwards a copy of the revised/reconsidered NCD to the Board.

(e) The Board must take the following actions upon receiving a notice that CMS has withdrawn or revised/reconsidered an NCD under review:

(1) If, before the Board issues a decision, the Board receives notice that CMS has withdrawn the NCD or revised the NCD to completely remove the provision in question, the Board must dismiss the complaint and inform the aggrieved party (ies) who sought the review that he or she or they will receive individual claim review without the retired/withdrawn provisions.

(2) If, before the Board issues a decision, the Board receives notice that CMS has revised the NCD provision in question but has not removed it altogether, the Board must continue the review based on the revised NCD. In this case, CMS must send a copy of the supplemental record to the Board and all parties. In that circumstance, the Board permits the aggrieved party to respond to the revised NCD and the supplemental record.

§ 426.523 Withdrawing a complaint regarding an NCD under review.

(a) *Circumstance under which an aggrieved party withdraws a complaint regarding an NCD.* An aggrieved party who filed a complaint regarding an NCD may withdraw the complaint before the Board issues a decision regarding that NCD. The aggrieved party may not file another complaint concerning the same coverage determination for 6 months.

(b) *Process for an aggrieved party withdrawing a complaint regarding an NCD.* To withdraw a complaint regarding an NCD, the aggrieved party who filed the complaint must send a written withdrawal notice to the Board (*see* § 426.500) and CMS. Supplementing an acceptable complaint with new evidence does not constitute a withdrawal of a complaint, as described in § 426.503.

(c) *Actions the Board must take upon receiving a notice announcing the intent to withdraw a complaint regarding an NCD*—(1) *NCD reviews involving one aggrieved party.* If the Board receives a withdrawal notice regarding an NCD before the date the Board issued a decision regarding that NCD, the Board issues a decision dismissing the complaint under § 426.544 and informs the aggrieved party that he or she may not file another complaint to the same coverage determination for 6 months.

(2) *NCD reviews involving joint complaints.* If the Board receives a notice from an aggrieved party who is named in a joint complaint withdrawing a complaint regarding an NCD before the date the Board issued a decision regarding that NCD, the Board issues a decision dismissing only that aggrieved party from the complaint under § 426.544. The Board continues the NCD review if there is one or more aggrieved party who does not withdraw from the joint complaint.

(3) *Consolidated NCD reviews.* If the Board receives a notice from an aggrieved party who is part of a consolidated NCD review withdrawing a complaint regarding an NCD before the date the Board issued a decision regarding that NCD, the Board removes that aggrieved party from the consolidated NCD review and issues a decision dismissing that aggrieved party's complaint under § 426.544. The Board continues the NCD review if there is one or more aggrieved party who does not withdraw from the joint complaint.

§ 426.525 NCD review.

(a) *Opportunity for the aggrieved party after his or her review of the NCD record to state why the NCD is not valid.* Upon receipt of the NCD record, the aggrieved party files a statement explaining why the NCD record is not complete, or not adequate to support the validity of the NCD under the reasonableness standard. This statement must be submitted to the Board and CMS, within 30 days (or within additional time as allowed by the Board for good cause shown) of the date the aggrieved party receives the NCD record.

(b) *CMS response.* CMS has 30 days, after receiving the aggrieved party's

statement, to submit a response to the Board in order to defend the NCD.

(c) *Board evaluation.* (1) After the aggrieved party files a statement and CMS responds as described in § 426.525(a) and § 426.525(b), or the time for filing has expired, the Board applies the reasonableness standard to determine whether the NCD record is complete and adequate to support the validity of the NCD.

(2) Issuance of a decision finding the record complete and adequate to support the validity of the NCD ends the review process.

(3) If the Board determines that the NCD record is not complete and adequate to support the validity of the NCD, the Board permits discovery and the taking of evidence in accordance with § 426.532 and § 426.540, and evaluate the NCD in accordance with § 426.531.

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

§ 426.531 Board's review of the NCD to apply the reasonableness standard.

(a) *Required steps.* The Board must do the following to review the provision(s) listed in the aggrieved party's complaint based on the reasonableness standard:

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

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

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

(4) Treat as precedential any previous Board decision made under § 426.547 that involves the same NCD provision(s), same specific issue and facts in question, and the same clinical conditions.

(5) Issue a decision as described in § 426.547.

(b) *Optional steps.* The Board may consult with appropriate scientific or clinical experts concerning clinical and scientific evidence to apply the reasonableness standard to the provision(s) listed in the aggrieved party's complaint.

(c) *Authority for the Board in NCD reviews when applying the reasonableness standard.* In applying the reasonableness standard to a provision (or provisions) of an NCD, the Board must follow all applicable laws and regulations, as well as NCDs other than the one under review.

§ 426.532 Discovery.

(a) *General rule.* If the Board orders discovery, the Board 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 Board granting of a protective order.* The Board may grant a motion for a protective order if it finds that the discovery sought—

(i) Is irrelevant or unduly repetitive;

(ii) Is unduly costly or burdensome; or

(iii) Will unduly delay 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 NCD.

(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 will be 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 or proprietary data.* The Board must not under any circumstances 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 Board notifies all parties in writing when the discovery period will be closed.

§ 426.535 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 § 426.540 at or before the hearing.

(b) *Filing a motion for a subpoena.* A party seeking a subpoena must file a written motion with the Board not less than 30 days before the date fixed for the hearing. The motion must do all of the following:

(1) Designate the witnesses.

(2) Specify any evidence to be produced.

(3) Describe the address and location with sufficient particularity to permit the witnesses to be found.

(4) State the pertinent facts that the party expects to establish by witnesses or documents and state whether those facts could be established by evidence other than by the use of a subpoena.

(c) *Response to a motion for a subpoena.* Within 15 days after the written motion requesting issuance of a subpoena is served on all parties, any party may file an opposition to the motion or other response.

(d) *Extension for good cause shown.* The Board may modify the deadlines specified in paragraphs (b) and (c) of this section for good cause shown.

(e) *Motion for a subpoena granted.* If the Board grants a motion requesting issuance of a subpoena, the subpoena must do the following:

(1) Be issued in the name of the presiding Board member.

(2) Include the docket number and title of the NCD under review.

(3) Provide notice that the subpoena is issued according to sections 1872 and 205(d) and (e) of the Act.

(4) Specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) *Delivery of the subpoena.* The party seeking the subpoena serves it by personal delivery to the individual named, or by certified mail return receipt requested, addressed to the individual at his or her last dwelling place or principal place of business.

(g) *Motion to quash a subpoena.* The individual to whom the subpoena is directed may file with the Board a motion to quash the subpoena within 10 days after service.

(h) *Refusal to obey a subpoena.* The exclusive remedy for contumacy by, or refusal to obey, a subpoena duly served upon any person is specified in section 205(e) of the Act (42 U.S.C. 405(e)) except that any reference to the ''Commissioner of Social Security'' shall be considered a reference to the ''Secretary.''

§ 426.540 Evidence.

(a) Except as provided in this part, the Board is not bound by the Federal Rules of Evidence. However, the Board may apply the Federal Rules of Evidence when appropriate, for example, to exclude unreliable evidence.

(b) The Board must exclude evidence that it determines is clearly irrelevant or immaterial, or unduly repetitive.

(c) The Board may accept privileged information or proprietary data, but must maintain it under seal.

(d) The Board may permit the parties to introduce the testimony of expert witnesses on scientific and clinical issues, rebuttal witnesses, and other relevant evidence. The Board may require that the testimony of expert witnesses be submitted in the form of a

written report, accompanied by the curriculum vitae of the expert preparing the report.

(e) Experts submitting reports must be available for cross-examination at an evidentiary hearing upon request of the Board or a party to the proceeding, or the report will be excluded from the record.

(f) Except as set forth in paragraph (c) of this section or unless otherwise ordered by the Board for good cause shown, all documents and other evidence offered or taken for the record is open to examination by all parties.

§ 426.544 Dismissals for cause.

(a) The Board may, at the request of any party, or on its own motion, dismiss a complaint if the aggrieved party fails to do either of the following:

(1) Attend or participate in a prehearing conference (the prehearing may be conducted by telephone) or hearing without good cause shown.

(2) Comply with a lawful order of the Board without cause shown.

(b) The Board must dismiss any complaint concerning NCD provision(s) if the following conditions exist:

(1) The Board does not have the authority to rule on that provision under § 426.505(d).

(2) The complaint is not timely. (*See* § 426.500(b)).

(3) The complaint is not filed by an aggrieved party.

(4) The complaint is filed by an individual who fails to provide an adequate statement of need for the service from the treating physician.

(5) The complaint challenges a provision or provisions of an LCD except as provided in § 426.476, regarding the Board's review of an ALJ decision. (*See* § 426.505, regarding the authority of the Board.)

(6) CMS notifies the Board that the NCD provision(s) is (are) no longer in effect.

(7) The aggrieved party withdraws the complaint. (*See* § 426.523, for requirements for withdrawing a complaint regarding an NCD under review.)

§ 426.545 Witness fees.

(a) A witness testifying at a hearing before the Board receives the same fees and mileage as witnesses in Federal district courts of the United States. If the witness qualifies as an expert, he or she is entitled to an expert witness fee. Witness fees are paid by the party seeking to present the witness.

(b) If the Board requests expert testimony, the Board is responsible for paying all applicable fees and mileage, unless the expert waives payment.

§ 426.546 Record of hearing.

The Board must ensure that all hearings are open to the public and are electronically, mechanically, or stenographically reported. Except for privileged information and proprietary data that are filed under seal, all evidence upon which the Board relies for decision must be admitted into the public record. All medical reports, exhibits, and any other pertinent document, either in whole or in material part, must be offered, marked for identification, and retained in the case record.

§ 426.547 Issuance, notification, and posting of a Board's decision.

The Board must do the following:

(a) Issue to all parties to the NCD review, within 90 days of closing the NCD review record to the taking of evidence, one of the following:

(1) A written decision, including a description of appeal rights.

(2) A written notification stating that a decision is pending, and an approximate date of issuance for the decision.

(b) Make the decision available at the HHS Medicare Internet site. The posted decision does not include any information that identifies any individual, provider of service, or supplier.

§ 426.550 Mandatory provisions of the Board's decision.

(a) *Findings.* The Board's decision must include one of the following:

(1) A determination that the provision of the NCD is valid under the reasonableness standard.

(2) A determination that the provision of the NCD is not valid under the reasonableness standard.

(3) A statement dismissing the complaint regarding the NCD, and a rationale for the dismissal.

(4) A determination that the LCD or NCD record is complete and adequate to support the validity of the LCD or NCD provisions under the reasonableness standard.

(b) *Other information.* The Board's decision must include all of the following:

(1) The date of issuance.

(2) The docket number of the NCD review.

(3) A statement as to whether the aggrieved party has filed a claim for the service(s) named in the complaint, the date(s)-of-service, and the disposition, if known.

(4) A basis for concluding that the NCD was or was not valid based on the application of the reasonableness standard to the record before the Board, including CMS':

(i) Findings of fact.

(ii) Interpretations of law.

(iii) Applications of fact to law.

(5) A summary of the evidence reviewed. Where proprietary or privileged data were submitted under seal, the decision must state whether the data were material and what role they played in the determination, but without disclosing the substance or contents of the evidence under seal. A separate statement of the rationale for the Board's treatment of the sealed evidence must be prepared and kept under seal itself. If the Board decision is appealed to the court, this statement must be provided to the court, under seal.

(6) A statement regarding the right to judicial review.

§ 426.555 Prohibited provisions of the Board's decision.

The Board's decision may not do any of the following:

(a) Order CMS to add any language to a provision or provisions of an NCD.

(b) Order CMS or its contractors to pay a specific claim.

(c) Set a time limit for CMS to establish a new or revised NCD.

(d) Review or evaluate an NCD other than the NCD under review.

(e) Include a requirement for CMS or its contractors that specifies payment, coding, or systems changes for an NCD, or deadlines for implementing these types of changes.

(f) Order or address how CMS implements an NCD.

§ 426.557 Optional provisions of the Board's decision.

When appropriate, the Board may limit a decision holding invalid a specific provision(s) of an NCD to specific clinical indications and for similar conditions.

§ 426.560 Effect of the Board's decision.

(a) *Valid under the reasonableness standard.* If the Board finds that the provision (or provisions) of an NCD named in the complaint is (are) valid under the reasonableness standard, the aggrieved party may challenge the final agency action in Federal court.

(b) *Not valid under the reasonableness standard.* If the Board finds that the provision (or provisions) of an NCD named in the complaint is (are) invalid under the reasonableness standard, then CMS instructs its contractor, M+C organization, or other Medicare managed care organization to provide the following—

(1) Individual claim review. (i) If the aggrieved party's claim/appeal(s) was previously denied, the contractor, an

M+C organization, or another Medicare managed care organization must reopen the claim of the party who challenged the LCD and adjudicate the claim without using the provision(s) of the NCD that the Board found invalid.

(ii) If a revised NCD is issued, contractors, M+C organizations, and other Medicare managed care organizations must use the revised NCD in reviewing claim/appeal submissions or request for services delivered or services performed on or after the effective date of the revised NCD.

(iii) If the aggrieved party who sought review has not yet submitted a claim, the contractor must adjudicate the claim without using the provision(s) of the NCD that the Board found invalid.

(iv) In either case, the claim and any subsequent claims for the service provided under the same circumstances, must be adjudicated without using the NCD provision(s) found invalid.

(2) *Coverage determination relief.* Within 30 days, CMS implements the Board decision. Any change in policy is applied prospectively to requests for service or claims filed with dates of service after the implementation of the Board decision.

§ 426.562 Notice of the Board's decision.

After the Board has made a decision regarding an NCD complaint, the Board sends a written notice of the decision to each party. The notice must—

(a) State the outcome of the review; and

(b) Inform each party to the determination of his or her rights to seek further review if he or she is dissatisfied with the determination, and the time limit under which an appeal must be requested.

§ 426.563 Future new or revised or reconsidered NCDs.

CMS may not reinstate an NCD provision(s) found to be unreasonable unless CMS has a different basis (such as additional evidence) than what the Board evaluated.

§ 426.565 Board's role in making an LCD or NCD review record available.

Upon a request from a Federal Court, the Board must provide to the Federal Court a copy of the Board's LCD or NCD review record (as described in § 426.587).

§ 426.566 Board decision.

A decision by the Board constitutes a final agency action and is subject to judicial review. CMS may not appeal a Board decision.

§ 426.587 Record for appeal of a Board NCD decision.

(a) *Elements of the Board's NCD review record furnished to the public.* Except as provided in paragraph (b) of this section, the Board's NCD review record consists of any document or material that the Board compiled or considered during an NCD review, including, but not limited to, the following:

(1) The NCD complaint.

(2) The NCD and NCD record.

(3) The supplemental NCD record, if applicable.

(4) Transcripts of record.

(5) Any other evidence relevant gathered under § 426.540.

(6) The Board's decision.

(b) *Documents excluded from the NCD review record furnished to the court.* The NCD review record furnished to the court maintains the seal on privileged information or proprietary data that is maintained under seal by the Board. In the event a court seeks to obtain or requires disclosure of any documents excluded from the NCD record as privileged information or proprietary data, CMS or the Department seeks to have a protective order issued for those documents, as appropriate.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 1, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 30, 2003.

Tommy G. Thompson,

Secretary.

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