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Medicare Program: Review of National Coverage Determinations and Local Coverage Determinations; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Parts 400, 405, and 426

[CMS–3063–P]

RIN 0938–AK60

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would create a new process to allow certain Medicare beneficiaries to challenge national coverage determinations (NCDs) and local coverage determinations (LCDs). It would 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 would be distinct from the existing appeal rights that Medicare beneficiaries have for the adjudication of Medicare claims.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on October 21, 2002.

ADDRESSES: In commenting, please refer to file code CMS–3063–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and three copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3063–P, P.O. Box 8017, Baltimore, MD 21244–8017.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for commenters wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Vadim Lubarsky, 410–786–0840 for National Coverage Determinations. Melanie Combs, 410–786–7683 for Local Coverage Determinations.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* Timely comments will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, contact Van Ross at (410) 786–4473.

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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.

I. Background

A. Overview of Existing Statutes, Regulations, and Policies

Medicare is the nation's largest health insurance program covering approximately 40 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.

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 Medicare Act gives beneficiaries specific rights to challenge particular types of decisions. CMS is 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.

B. 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, then 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. If the Medicare contractor determines that the medical care is not covered under the Medicare program, however, the Medicare contractor would deny the claim. In

fiscal year 2001, fee-for-service Medicare contractors adjudicated over 930 million initial claims and approximately 6.7 million claim appeals.

Except in a few narrow circumstances, an individual seeking Medicare payment for health care items or services cannot obtain an advance determination (before obtaining the item or service) on whether we would make Medicare payment. The Supreme Court has recognized that the Secretary must be given an opportunity to rule on a real claim, rather than rendering advisory opinions. See *Heckler* v. *Ringer*, 466 U.S. 602, 621–22 (1984).

If we deny a claim, we would provide notice to the beneficiary and give the beneficiary an opportunity to challenge the decision according to procedures we established in our regulations. We established an appeals process in our regulations under the fee-for-service program at 42 CFR part 405, subparts G and H. The statute requires that an individual exhaust these remedies before the individual may seek judicial review to challenge the Secretary's final decision. For purposes of this preamble, we would identify these procedures as the ''claims appeal process.'' This proposed rule does not seek to significantly alter the existing claims appeal process. Nor does this proposed rule significantly alter our existing regulations authorizing pre-service appeals for M+C beneficiaries as established at §§ 422.560 through 422.622.

Following exhaustion of these administrative remedies, the Medicare statute provides the opportunity for a dissatisfied individual to seek review in Federal court. As part of this civil action, a party may challenge the validity of a national coverage determination.

C. National Coverage Determinations (NCDs)

National Coverage Determinations (NCDs) are national policy statements that we publish to identify the circumstances under which particular services will be considered covered by Medicare. NCDs made under section 1862(a)(1) of the Social Security Act (the Act) have been nationwide, prospective, population-based policies that apply to clinical subsets or classes of Medicare beneficiaries and describe the clinical circumstances and settings under which particular services are reasonable and necessary (or are not reasonable and necessary). Our current regulations at § 405.732 and § 405.860 further recognize that the agency also has issued other types of NCDs, often related to scope of benefits under other statutory benefit categories that were made under ''other applicable provisions of the Act.'' Under our existing regulations, both scope of benefits NCDs and the NCDs made under section 1862(a)(1)(A) of the Act are controlling authorities for Medicare contractors—carriers, fiscal intermediaries (FIs), quality improvement organizations (QIOs), formerly known as Peer Review Organizations, health maintenance organizations (HMOs), competitive medical plans (CMPs), and health care prepayment plans (HCPPs). In addition, national coverage decisions are also controlling on M+C organizations (see § 422.101). Under our current regulations, only NCDs made under section 1862(a)(1) of the Act are controlling authorities for administrative law judges.

The procedures we use to develop NCDs were set forth in a **Federal Register** notice published April 27, 1999 (64 FR 22619 through 22625). Section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), enacted on December 21, 2000 (by creating section 1869(f)(4) of the Act) also establishes a revised process by which we would make NCDs in certain cases. We would set forth this NCD development process through a separate notice in the **Federal Register**.

D. Local Medical Review Policy (LMRP)

Local Medical Review Policies (LMRPs) 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. We authorize certain contractors to make LMRPs and define these contractors' LMRP jurisdiction in each contract or task order we enter into with a contractor. Each LMRP applies only in the jurisdiction (or part of a jurisdiction) of an individual contractor. LMRPs are currently developed by carriers, FIs, Durable Medical Equipment Regional Carriers (DMERCs), and Regional Home Health Intermediaries (RHHIs). The adoption of an LMRP by a contractor, however, does not preclude CMS from making an NCD.

A contractor may adopt an LMRP that has been developed individually or collaboratively with other contractors. The adoption of an LMRP through a collaborative effort by contractors does not constitute an NCD regardless of the number of contractors who decide to adopt the LMRP. An LMRP is not controlling authority for administrative law judges (ALJs) or the Departmental Appeals Board (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.

The Secretary instructs contractors on the procedures to be used in developing LMRPs and does so in program instructions. (See *http://www.cms.hhs.gov/manuals/108_pim/pim83c13.asp#sect4*) to review the current requirements regarding when contractors should develop LMRPs.) In addition, the Secretary has the authority to prescribe the criteria contractors will use when writing the medical necessity provisions in their LMRPs. (See *http://www.cms.hhs.gov/manuals/108_pim/pim83c13.asp#sect5.1*). Finally, the Secretary defines the process requirements contractors must follow in order to ensure that all interested parties—including beneficiaries, providers, manufacturers, associations, advocacy groups, and other members of the public—are afforded an opportunity to review and comment on most LMRPs before they become final. (See *http://www.cms.hhs.gov/manuals/108_pim/pimc13.asp#sec7.4*)

An LMRP may contain any or all of the following:

- Coding provisions.
- Benefit category provisions.
- Statutory exclusion provisions.
- Medical necessity 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 (often called the ''medical necessity'' provision.))

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.

E. Differences Between NCDs and LMRPs

Under our claims appeals process, ALJs are not bound by LMRPs. Thus, an ALJ may rule that Medicare payment is due on a particular item or service received by a beneficiary, even if the contractor's LMRP clearly prohibited payment for the particular service. On the other hand, contractors and ALJs are bound by NCDs. ALJs may not review an NCD.

F. Individual Claim Determinations

It is important to note that contractors make individual claim determinations, even in the absence of an NCD or LMRP.

In these 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. at 617 (recognizing that the Secretary has discretion to either establish a generally applicable rule or to allow individual adjudication).

II. Impact of Section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000

A. Overview of the Legislation

Section 522 of BIPA created a new administrative review process that enables certain beneficiaries to challenge local coverage determinations (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 NCDs or LMRPs. BIPA defines LCDs 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).''

B. New Definition: Local Coverage Determination (LCD)

Section 522 of BIPA does not use the term ''LMRP.'' Rather, it uses the term ''local coverage determination (LCD).'' This definition indicates that only those determinations made by FIs and carriers under the ''reasonable and necessary'' provision are to be considered LCDs.

C. Differences Between an LMRP and an LCD

As described in section I.D of this preamble, an LMRP may contain four different types of provisions (benefit category, statutory exclusion, medical necessity, and coding). An LCD, on the other hand, has been specifically defined in statute 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 ''medical necessity 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; 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 medical necessity language; and
- The medical necessity provisions of an LMRP.

D. Impact of Section 522 of BIPA on the Definition of NCD

Section 522 of BIPA defines an NCD as ''a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title [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.'' This new statutory definition is not limited to only those determinations made under section 1862(a)(1) of the Act, but extends to benefit category and statutory exclusion determinations made by the Secretary as well. Typically, scope of benefits NCDs would further specify whether services would be covered under specific statutory categories that exist under Part A and Part B of the Medicare Act. (Section 1812, 1832, and 1861(s)). Thus, a scope of benefits NCD could be used to establish a policy on whether a particular device is considered durable medical equipment. Similarly, the Medicare Act prohibits payment for certain specific services. We may choose to establish an NCD describing those types of procedures (for example, whether care constitutes a routine physical examination, or cosmetic surgery). Therefore, as we discuss later in section III.A of this preamble, we are proposing to revise the definition of an NCD in § 400.202 to include those determinations made by the Secretary on grounds other than section 1862(a)(1) of the Act with respect to whether or not a particular service is covered and to reflect the statutory definition. We are proposing conforming changes to §§ 405.732 and 405.860 to reflect that any type of NCD may not be reviewed by an ALJ.

Section 522 of BIPA enables certain individuals who are in need of an item or service to challenge an NCD that would deny coverage of that item or service in an administrative proceeding before the Board.

Under section 1869(f)(4)(C) of the Act, for the purpose of reviews of NCDs, certain determinations that no national coverage or noncoverage determination is appropriate, are also subject to administrative review. Specifically, this right to review occurs only in cases in which there was no NCD, and a person with standing requested an NCD under section 1869(f)(4)(A) of the Act, and the Secretary determined that no national coverage determination would be made. We will identify this limited situation as a ''deemed NCD.'' In addition, if we have failed to meet a deadline we set under section 1869(f)(4)(A)(iv) of the Act, we are deemed to have made a determination that no coverage or noncoverage determination is appropriate.

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

As explained earlier in this preamble, the existing claims appeal rights are not significantly changed by section 522 of 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 administrative system enables beneficiaries to submit any relevant information pertaining to this individual claim. Moreover, because LCDs are not controlling authorities for ALJs, an individual claim appeal could result in the claim being paid without the need to challenge the underlying LCD. Another section of BIPA, section 521, makes changes to those procedures with a different effective date. We would address any necessary revisions to our claims appeals regulations in future **Federal Register** documents.

We view section 522 of BIPA as creating an administrative review process that is separate and independent from the claims appeals process. The procedures used in section 522 for the BIPA administrative challenges process will be different, because the nature of the challenge and the relevant evidence is different. A challenge under section 522 of BIPA is a challenge to an entire policy, or specific provisions contained therein, and not just one claim denial. Therefore, section 522 of BIPA challenges may lead to changes that impact other beneficiaries if the policies are found to be unreasonable under the applicable standard for review.

Complaints under section 522 of BIPA also are subject to specific standing rules. Namely, under section 1869(f)(5) of the Act ''[a]n action under this subsection seeking review of a[n NCD]

or [LCD] 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.'' Only a beneficiary who has standing may bring an administrative challenge under section 522 of BIPA. Those rights cannot be assigned to anyone else. We are proposing to define ''in need'' as an aggrieved party who needs an item or service but has not yet received the item or service. At the time the complaint is filed, an aggrieved party may not have received the service that is the subject of the challenge, unless it is an item that is needed on an ongoing basis such as diabetic test strips. In general, the standing provision will require people seeking review of an NCD or LCD to receive the item or service after filing a challenge under section 522 of BIPA.

Although section 522 of BIPA does not enable a Medicare beneficiary to seek an advance determination on a particular claim or in advance of obtaining an item or service, an individual can challenge in advance of receiving an item or service the policy (LCD or NCD) that would cause the claim to be denied. As we discuss in greater detail in section III.E of this preamble, a successful challenge would result in the individual having his or her specific claim adjudicated without reference to the challenged policy. Claims that are otherwise payable, may be paid. In addition, a successful challenge to an LCD or NCD may result in the following:

- The policy being retired.
- Further agency action to modify the policy by clarifying the rationale or supplementing the record supporting the policy.

F. The Reconsideration Process

1. NCDs

We previously established a procedure by which individuals could seek reconsideration of policies established in an NCD. These procedures were set forth in the April 27, 1999 notice (64 FR 22619, 22625). In general, the reconsideration process permits any individual (not just aggrieved parties) to submit new evidence to us for review, or to suggest that we had misinterpreted existing evidence. We then review this evidence and do one of two things. First, if we believe that the evidence has merit and warrants a change to the NCD, we would revise the NCD and issue a new NCD in its place. If we do not believe the evidence warrants a change to the NCD, we would supplement the NCD record with this new evidence and reissue the NCD with no changes. A revised or reissued NCD becomes the policy subject to review under section 522 of BIPA.

We believe that CMS or contractor personnel with medical and scientific experience should first consider new clinical and scientific evidence to determine whether any changes to our coverage policies are necessary. The reconsideration process that we previously created was consistent with this approach. An aggrieved party may also submit new evidence in the coverage review processes. If new evidence is submitted during the coverage appeals process, those proceedings will be stayed in order for our policy makers or contractor clinical and scientific experts to consider the new clinical and scientific evidence. Once that reconsideration process is completed, the coverage review process will resume.

New evidence is any clinical or scientific evidence that was not previously considered by the agency or contractor when the NCD was issued.

2. Local Policy

The local policy reconsideration process is set forth in the Program Integrity Manual, Chapter 13, Section 11 (see *http//www.cms.hhs.gov/manual/108_pim/pim83c13.asp#sect11*). The local policy reconsideration process parallels the NCD reconsideration process.

New evidence is any clinical or scientific evidence that was not previously considered by the agency or contractor when the local policy was issued.

G. Difference Between an LCD/NCD Review and an LCD/NCD Reconsideration

The main difference between an LCD/NCD review under section 522 of BIPA and an LCD/NCD reconsideration is the avenue an individual chooses to take to initiate a change to a coverage policy. All interested parties, including an aggrieved party, could 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 could 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 us or our contractor or file a complaint to seek review by an adjudicator.

In the reconsideration process, all interested parties, not just aggrieved parties, would have the opportunity to submit new scientific and medical evidence for review by individuals with medical and scientific expertise. The reconsideration process would permit experts to make judgments about those policies, rather than using an adjudicatory proceeding. Regardless of whether the reconsideration leads to a change in policy, we would update the LCD or NCD record to include the new evidence and, because of the new date of issuance, would establish a new NCD or LCD. The NCD or LCD updated by a reconsideration will lead to a new coverage determination that an aggrieved party may subsequently challenge by filing a complaint with the appropriate adjudicator. This is discussed in greater detail in section III.E of this preamble.

III. Provisions of the Proposed Rule

A. Overview

We are proposing that a Medicare beneficiary who qualifies as an aggrieved party may challenge an LCD or an NCD (or specific provisions therein) by filing an acceptable complaint with the Social Security Administration's Office of Hearings and Appeals (OHA) or the Board of HHS, respectively. The LCD or NCD review process is initiated if the applicable adjudicator determines the complaint to be acceptable.

In this proposed rule, we are proposing in § 400.202 to add a definition of the ''Board'' to mean the Departmental Appeals Board. We are also proposing to add a definition of ''Local coverage determination (LCD)'' and to revise the definition of ''National coverage determination (NCD).'' These definitions are specific to Medicare and would be revised to reflect the definitions for these terms found in section 522 of BIPA. The proposed rule would make clear that a determination of what code, if any, that is assigned to a service 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 use the term ''Services'' as defined in § 400.202 to include both ''items and services.''

We are proposing to revise paragraph (a) of § 405.732, ''Review of a national coverage decision (NCD),'' 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, and ALJs.

We are proposing to revise paragraph (b) of § 405.732 to state 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 proposing to revise paragraph (c) of § 405.732 to state for initial determinations made before October 1, 2002, and for challenges to an NCD made under section 1862(a)(1) of the Act, 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 invalidate an NCD except upon review of the supplemental record.

We are proposing to revise paragraph (a) of § 405.860, ''Review of a national coverage determination (NCD),'' 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, and ALJs.

We are proposing to revise paragraph (b) of § 405.860 to state 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 proposing to revise paragraph (c) of § 405.860 to state for initial determinations made before October 1, 2002, and for challenges to an NCD made under section 1862(a)(1) of the Act, 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 invalidate an NCD except upon review of the supplemental record.

We are also proposing to add a new part 426, titled ''Reviews of Local and National Coverage Determinations,'' to title 42 of the CFR. In addition, we are proposing the following in part 426:

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

B. Subpart A (General Provisions)

Subpart A of part 426 would specify the general provisions applicable to the entire part. Section 426.100, ''Basis and scope,'' would set forth the basis (under sections 1869(f)(1) and (f)(2) of the Act), and the scope would specify the requirements and procedures for the review of LCDs and NCDs. In § 426.110, we would 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 NCD or an LCD. We would 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 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.

To properly demonstrate that a beneficiary is ''in need,'' we are proposing that the beneficiary's treating physician document the need for the service. We believe this definition is consistent with the plain language of the statute and ensures that only beneficiaries who are aggrieved have standing to use this review process. Furthermore, we believe the statutory language allowing reviews of coverage determinations to be ''* * * initiated only by individuals * * * who are in need'' means individuals have not yet received the service that is the subject of the coverage determination. Therefore, an individual who has already received a service would not ordinarily qualify as an aggrieved party under our definition, and would not be eligible to initiate a review of a coverage determination regarding that service because he or she would no longer be in need of that service. However, there would be an exception for individuals who have a continuing need for a particular item or service that is subject to an NCD or LCD. We would require that an individual must be an aggrieved party at the time a complaint is filed, but we would not preclude an individual from receiving the service that is named in the complaint after the complaint is filed.

An individual who has an ongoing need for a service, or an individual who has received a service in the past but has a need to receive the service again (and has not received the service at the time a complaint has been filed) would meet our definition of aggrieved party because an unfulfilled need for the service exists.

We would define ''Contractor'' as a carrier (including a DMERC) or an FI (including an RHHI) that has jurisdiction for the LCD at issue. Specifically, a carrier or FI with LCD jurisdiction for a particular geographical area would be the contractor responsible for, among other things, providing the record of its LCDs.

We would define ''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 failed to meet the deadline under section 1869(f)(4)(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. These circumstances would be as follows:

- When there was no NCD for a particular service.
- When an aggrieved party submits a request to the Secretary to make a determination about that service.
- When the Secretary determines that no national coverage or noncoverage determination is appropriate.

The statute directs that only these determinations are deemed to be NCDs that may be reviewed by the Board. The Supreme Court has recognized, however, that the Secretary's decision of whether to issue a generally applicable rule or to allow individual adjudication ''are clearly discretionary decisions.'' *Heckler* v. *Ringer,* 466 U.S. 602, 617 (1984).

We would define ''New evidence'' as clinical or scientific evidence that was not previously considered by us or the contractor before the NCD or LCD was issued.

We would define ''Party'' as an individual who has the right to participate in the LCD or NCD review process. A party includes an aggrieved party, a contractor, and, as appropriate, CMS. In the case of an LCD review, we may choose whether to be a party in the review along with the contractor. We believe that we, or our contractors, should be afforded an opportunity to participate in these reviews. These reviews involve challenges to important agency policies that may impact millions of beneficiaries. We believe either we or the contractors who issued the LCDs or NCDs should be given the opportunity to present evidence and make arguments supporting the rationale behind their coverage policies before an adjudicator issues a decision on whether the policies are reasonable. We note that we are always a party to an NCD review and contractors would not participate in an NCD review.

We would also define ''Reasonableness standard'' as the standard that an ALJ or the Board must apply when conducting an LCD or an NCD review. In determining whether NCDs or LCDs 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 CMS or the contractor are reasonable based on the NCD or LCD record. We are proposing to use 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.

We are requesting public comments on the feasibility of using an alternative dispute resolution (ADR) process and suggestions regarding how an ADR process could be used in an evidence-based review process.

C. Subpart B (Reserved)

We are proposing to reserve subpart B.

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

We are proposing that the general provisions common to both the review of LCDs and NCDs would be established in subpart C. In § 426.300(a), we are proposing 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 are also proposing 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 can only be submitted to 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.

For the reasons described in section II.E of this preamble, we are proposing in § 426.310(a) to keep LCD and NCD reviews 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 would also require an aggrieved party to notify the OHA or the Board of the disposition of any pending claim or appeal relating to the aggrieved party's LCD or NCD complaint. The aggrieved party would have to make this notification as soon as possible, regardless of the time during the coverage determination review that the aggrieved party filed a claim. As discussed earlier in this section of the preamble, we would allow the aggrieved party to receive a service after filing a complaint, without affecting the coverage determination review. However, in most circumstances, an individual could not obtain a service, submit a claim under the claims appeal process, and then seek to file a complaint because the individual would not satisfy the ''in need'' requirement.

In § 426.320(a), we are proposing that only an aggrieved party may initiate a review to challenge an LCD or NCD (or an existing specific provision or provisions of an LCD or an NCD) by filing an acceptable complaint. Sections 1869(f)(1)(A)(iii) and (f)(2)(A)(i) of the Act are very specific in allowing these reviews only to be initiated by an aggrieved party. Under this requirement, an aggrieved party would be allowed only to challenge language that exists within an LCD or NCD. Similarly, the statute does not allow for an aggrieved party to use this process to challenge anything that does not meet the definition of an LCD or an NCD (see § 426.320(b)). For example, draft LCDs and NCDs would be excluded from review as they are predecisional. LCDs and NCDs that are no longer in effect would also be excluded as they are no longer in effect. Other interpretive policies that are not LCDs or NCDs would also not be subject to review under this process.

Contractor policies that are not based on section 1862(a)(1)(A) of the Act, the ''medical necessity'' provision, would not be subject to review. The statutory language in section 522 of BIPA specifically limits the definition of LCDs to those documents or parts of documents that are based on section 1862(a)(1)(A) of the Act. Provisions of contractor policies, that are based on things other than the medical necessity statute, such as benefit category determinations, statutory exclusion determinations, and 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 would not be subject to review under this process. Further, the 522 complaint process is distinct from the pre-service appeal rights established for M+C plan and other Medicare managed care enrollees.

Individual claim determinations by adjudicators would also not be subject to review under this process. Beneficiaries who wish to appeal an individual claim determination must do so through the claims appeal process.

Although NCDs and deemed NCDs would be subject to review under this process, determinations not meeting those definitions would not be subject to review under this process. For example, a determination made by us at the request of a provider that no national coverage or noncoverage determination is appropriate would not be considered a deemed NCD because a deemed NCD would only be the result of an aggrieved party requesting an NCD under section 1869(f)(4) of the Act. These determinations, therefore, would not be subject to review under this process.

In § 426.330, we are proposing not to allow an aggrieved party to assign his or her rights to file a complaint against an LCD or NCD to any other individual or entity. Neither an ALJ nor the Board will recognize as valid any attempt to assign rights under section 1869(f) of the Act. In § 426.330(b), we are proposing 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. While it is by no means required, we realize that some aggrieved parties may wish to retain representation.

In § 426.340, we are proposing that if an aggrieved party submits new evidence pertaining to an NCD or LCD, the administrative proceedings under part 426 will be stayed upon request from us or the contractor to consider the

additional clinical or scientific evidence. Following the review of this evidence, we or the contractor will file a supplemental record. Because the aggrieved party could submit new information that was not previously considered at several steps of the section 522 of BIPA review process, we are proposing that whenever an aggrieved party introduces new evidence, the section 522 of BIPA proceedings will be stayed upon request from us or the contractor in order to permit clinical and scientific experts to evaluate the evidence using the reconsideration process discussed earlier in this preamble. Thus, in the case in which an aggrieved party seeks to rely on new clinical or scientific evidence, the aggrieved party has a choice to file a review of the coverage policy with an appropriate external review entity under section 522 of BIPA or file a reconsideration review request, as discussed earlier in this preamble. In either case, our policy makers or the appropriate contractor clinical or scientific experts would be given the opportunity to formally consider the evidence submitted by the aggrieved party and revise our policy if the clinical and scientific evidence supports a change. Following the reconsideration, if necessary, a supplemental record would be prepared and section 522 of BIPA proceedings could continue. An aggrieved party is not prohibited from filing a simultaneous appeal with an adjudicator and a reconsideration review request with us or our contractor.

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

In subparts D and E, we are proposing to set forth the procedures for the review of LCDs and NCDs, respectively. The process for NCD reviews is largely the same as the process for LCD reviews. The major exceptions are as follows:

- NCDs may be based on other statutory provisions, not just section 1862(a)(1)(A) of the Act.
- NCD reviews are conducted by the Board.
- There is no role for ALJs or contractors in an NCD review.
- We are always a party to an NCD review.
- The process for taking an NCD out of effect is different than an LCD being ''retired.''
- Board administrative decisions regarding NCDs would be made available in a searchable format on the Medicare Internet site, with identifying information removed.

For the purpose of this preamble, we will consolidate the discussion of the requirements and policy decisions when possible. Sections 426.400 and 426.500 would 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 would require that complaints regarding LCDs would have to be submitted to the OHA of the Social Security Administration, and complaints regarding NCDs would have to be submitted to the Board of HHS (see § 426.500(a)). We would also require, in both cases, a valid complaint to contain the beneficiary-identifying information listed in § 426.400(c)(1) and § 426.500(c)(1) including the treating physician's certification that the beneficiary needs the service that is the subject of the coverage determination, and a statement from the treating physician that payment for the service is likely to be denied under that coverage determination.

We believe that the physician's certification is necessary to ensure that the individual is an aggrieved party (see our discussion of the definition of aggrieved party in section III.A of this preamble.) In § 426.400(b), we would further require that the complaint be received by the OHA or the Board (whichever is applicable) within 6 months of this certification so that reviews of coverage determinations will remain reasonably current. We are proposing that a complaint contain the physician's statement that payment for the service is likely to be denied under the coverage determination because we believe that this step will help to ensure an actual controversy exists.

We would 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. We also would require a statement from the aggrieved party that explains the rationale for the complaint and states whether the service has been received (which in some cases would indicate that the individual is not an aggrieved party) (see §§ 426.400(c)(3) and 426.500(c)(3).

We are also proposing, in §§ 426.400(c)(4) and 426.500(c)(4), to allow the aggrieved party to submit copies of clinical or scientific evidence that supports the complaint. In § 426.400(d), we are proposing that two or more aggrieved parties may initiate the review of an LCD by filing a single written complaint with the OHA if the conditions in § 426.400(d)(1)(i) and (d)(ii) are met. Similarly, in § 426.500(d), we are proposing 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.

Section 426.405 would specify the authority of the ALJ during an LCD review, including authority during a hearing, if applicable, as well as the authority that an ALJ would not have during an LCD review (see § 426.405(d)). We believe that the authority that would be granted to, and the authority that would not be granted to, an ALJ during an LCD review by this section is consistent with the statute and with common practice in other administrative proceedings. Similarly, in § 426.505, we would set forth the specific authority of the Board during an NCD review, if applicable, as well as the authority that the Board would not have during an NCD review (see § 426.505(d)).

Sections 426.406 and 426.506 would prohibit ex parte contacts so that no party or person (except employees of the ALJ's office) would communicate 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.

In § 426.410, we would establish the ALJ's role in docketing and evaluating the acceptability of LCD complaints. These procedures would be very similar to the Board's role in docketing and evaluating the acceptability of NCD complaints proposed in § 426.510. Under the procedures, the adjudicatory body would receive and docket the complaint (which, at the discretion of the adjudicators, could include the name of the coverage determination rather than the individual bringing the challenge), evaluate the acceptability of the complaint, and take similar actions thereafter.

We are proposing in §§ 426.410 and 426.510 the criteria that a complaint would have to 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 could only be challenging a policy that meets the definition of an LCD or an NCD.

If a complaint is deemed to be unacceptable after having been evaluated under §§ 426.410(b) and

426.510(b), the applicable adjudicator would 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 time frame, the adjudicator would issue an administrative decision dismissing the unacceptable complaint. We are seeking public comment on whether an aggrieved party should also be precluded from filing another complaint on the same issue for some period of time.

If after having been evaluated under §§ 426.410(b) and 426.510(b), a complaint is accepted, the adjudicator would 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 would also forward a copy of the complaint and the acknowledgement letter to the applicable contractor and 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. We believe that these steps will provide all parties involved in the LCD review with the information to proceed with the review. The corresponding section in § 426.510(d) would require the adjudicator to follow the same process for NCDs.

In §§ 426.410(e) and 426.510(e), we would allow for adjudicators to consolidate complaints regarding LCDs and NCDs, respectively. Under this provision, several complaints could be consolidated into one review if the complaints were appropriately similar. The review processes would not be affected by a decision to consolidate complaints into one review. Rather, consolidation would only be a tool to reduce the burden of multiple or duplicative challenges to the same policy.

In § 426.415, we would provide information identifying the person who would represent the contractor in the LCD review process to the ALJ, and all parties to the LCD review. We would make a decision whether the agency or the contractor would participate in the LCD review. Under the corresponding section in § 426.515, we would provide a copy of the NCD record (as described in § 426.518) to the Board and all parties to the NCD review.

Sections 426.418 and 426.518 would describe the elements of a contractor's LCD and NCD record, respectively. We are proposing that an LCD or NCD record would be composed of documents and materials that we, or the contractor, considered during the development of the LCD and NCD. In §§ 426.418(b) and 426.518(b), we would not include privileged material, proprietary data or any new evidence as part of the record under §§ 426.415 and 426.515 or otherwise prohibited from release by Federal law. Official records presented to the Board may contain proprietary data or information, if the information was used in reaching the NCD under appeal. In these instances, we would propose that proprietary information be protected from inappropriate disclosure according to all applicable statutes, regulations, or other formal, binding agreements governing use and release of the information. We are inviting public comments on the scope of proprietary data and the extent to which this material should be disclosed.

In § 426.420, we would allow a contractor to retire the LCD under review before the date the ALJ issues an administrative decision regarding the LCD. Retiring an LCD would mean that the contractor could no longer use that LCD in the adjudication of claims; thus, there would no longer be a need for an LCD review. In § 426.520, we would be allowed to repeal an NCD under review before the date the Board issues an administrative decision regarding that NCD. Repealing an existing NCD would mean this policy would no longer be a controlling authority for our contractors and certain adjudicators. Thus, there no longer would be a need for an NCD review concerning the superceded NCD.

Under §§ 426.423 and 426.523, we are proposing to permit aggrieved parties who filed the complaint to withdraw complaints regarding LCDs and NCDs, respectively. We would allow an aggrieved party to withdraw a complaint before the applicable adjudicator issues an administrative decision regarding the complaint by simply sending a written notice to the OHA, the applicable contractor, and us (if applicable) for LCDs, or to the Board and us for NCDs (see §§ 426.423(b) and 426.523(b)). Under this process, the adjudicator would issue an administrative decision (discussed later in this section of the preamble) dismissing the complaint, and the aggrieved party would not be able to file another complaint to the same coverage determination for 6 months. This proposal is designed to encourage disputes to be resolved in an efficient manner by discouraging a challenger from filing a complaint but voluntarily dismissing that challenge after significant administrative resources have been expended.

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 an administrative decision dismissing the complaint for the aggrieved party or parties who wish to withdraw, and the review would continue until the adjudicator issued an administrative decision on the merits, or until each aggrieved party withdrew his or her respective 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 and 426.525 would contain the processes for LCD and NCD reviews, respectively, that take place once the record has been filed. Sections 1869(f)(1)(A)(iii) and 1869(f)(2)(A)(i) of the Act, as added by section 522 of BIPA, state 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 would allow the aggrieved party who submitted the complaint to file a motion alleging that the LCD record (or the NCD record in the case of an NCD review) is not complete, not adequate to support the validity of the coverage determination, or both. This motion would be filed after the aggrieved party has had adequate time to review the record (we are proposing 30 days after receipt of the record, with an extension if requested). The motion would be submitted to the adjudicator, the contractor (if an LCD review), and us (if applicable) (see §§ 426.425(a) and 426.525(a)).

If the adjudicator determines that the record is not complete, not adequate to support the validity of the coverage determination, or both, the adjudicator would 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). Therefore, discovery would be allowed only if the aggrieved party filed a motion that the record was not complete, not adequate to support the validity of the coverage determination, or both, and the adjudicator agreed with that motion.

If the adjudicator determines that the record is complete and adequate to support the validity of the coverage determination, the adjudicator would deny the motion, would not permit discovery, but would review the provision or provisions named in the complaint based on the reasonableness standard.

Under §§ 426.425(a)(3) and 426.525(a)(3), if an aggrieved party files a motion, based on new evidence, alleging that the contractor's LCD or NCD record is not complete, not adequate to support the validity of the LCD or NCD, or both, the Board or the ALJ would stay the proceedings upon request from us or the contractor to permit a consideration of the new evidence as described in § 426.340.

Under §§ 426.429 and 426.529, we would describe the process for submitting a supplemental record after new evidence has been considered under § 426.340. An aggrieved party may request additional discovery or continue the process to seek a decision by the ALJ or the Board.

Under §§ 426.430 and 426.530, we are proposing the ALJ's or Board's role in determining whether the contractor's LCD or our NCD record would be complete and adequate to support the validity of the LCD or NCD. In paragraph (a), we are proposing that if the aggrieved party does not file a motion described in § 426.425(a)(1) or § 426.429(a)(1), the ALJ or Board will review the contractor's LCD or our NCD record and apply the reasonableness standard, as described in § 426.431.

In paragraph (b) of §§ 426.430 and 426.530, we are proposing that if the aggrieved party files a motion described in § 426.425(a) or § 426.429(a), the ALJ or Board must: (1) Allow the contractor or us to submit a statement to the ALJ or Board and the aggrieved party responding to the motion described in paragraph (a) of this section; (2) review the contents of the LCD or NCD record, as described in § 426.418; (3) hold conferences, if necessary, which may be conducted (at the ALJ's or Board's discretion) either in person, or, by mutual agreement of the parties, by telephone, picture-tel, or any other means agreed upon by all parties involved; and (4) determine whether the contractor's LCD or our NCD record is complete and adequate to support the validity of the LCD or NCD.

In paragraph (c) of §§ 426.430 and 426.530, we are proposing the ALJ's or Board's role in determining the completeness of the contractor's LCD or our NCD record, and in determining the adequacy of the contractor's LCD or our NCD record to support the validity of the LCD or NCD.

We are considering requiring the petitioner in an NCD or LCD proceeding before the adjudicator to submit a statement about the factual and legal basis on which that party considers that record to be ''incomplete'' and/or to ''lack adequate information to support the validity of the determination,'' and an offer of proof supporting any factual allegations on the ''incompleteness'' of the record. CMS or the contractor would respond in writing to this statement of ''incompleteness.'' The adjudicator would review the NCD or LCD record and both parties' submissions. If the adjudicator concluded that the NCD or LCD record is complete and adequate to support the validity of the determination, the adjudicator could issue a written decision to that effect. This decision would then constitute a final agency action, appealable to court. If the adjudicator determined that the record was incomplete or lacked adequate information, the adjudicator could issue a written ruling explaining the reasons for this decision. The adjudicator would then be required to permit discovery and to hold a hearing for the taking of additional evidence on any material issues of fact. Both parties could supplement the record at this stage of the review process. We seek comments on whether this ''adequacy of information'' determination procedure by the adjudicator would lead to more prompt resolution of cases and better utilization of resources for all parties involved.

Under §§ 426.431 and 426.531, we would describe the process that adjudicators would use to review the provision(s) named in a complaint based on the reasonableness standard. We would require the adjudicator to confine the review to the provision(s) of the coverage determination named in the complaint and to the clinical or scientific evidence contained in the record (or supplemental record). The adjudicator would have the option to consult with impartial scientific or clinical experts, and consider any previous ALJ or Board administrative decision (made under part 426) regarding the same provision(s) named in the complaint. We are proposing that previous ALJ or Board administrative decisions made under this part may be considered, but are not a controlling precedent. It is possible that a later challenger may introduce pertinent clinical or scientific evidence that was not submitted in the previous proceedings. We are requesting public comment on this approach.

In addition, the adjudicator would have the option, under § 426.431(b) and 426.531(b), to conduct a hearing, and allow subpoenas and the taking of evidence (discussed in the section of the preamble on § 426.440 and § 426.540).

In §§ 426.431(c) and 426.531(c), we are proposing that ALJs and the Board would be bound by applicable provisions of the Act, our regulations, and rulings. Moreover, NCDs would be controlling authorities for ALJs. This policy is consistent with section 1869(f)(1)(A)(i) of the Act.

Under §§ 426.432 and 426.532, we are proposing that in paragraph (a), if the ALJ or Board orders discovery, the ALJ or Board would establish a reasonable timeframe for discovery, ensure that a party to the LCD or NCD review who receives a discovery request has certain rights, and ensure that a nonparty to the LCD or NCD review who receives a discovery request has the same rights in responding to a discovery request as any party. In paragraph (b), we are proposing that any party or nonparty 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 would also set forth the rules for discovery during an LCD or NCD review, respectively. Only an ALJ could order discovery during an LCD review if the ALJ found the contractor's LCD record to be incomplete, inadequate to support the validity of the LCD, or both, and after a motion had been filed under § 426.425. Likewise, only the Board could order discovery during an NCD review if the Board found our NCD record to be incomplete, inadequate to support the validity of the NCD, or both, and after a motion had been filed under § 426.525. We would require the adjudicator to establish a timeframe for the discovery process.

In § 426.432(c), § 426.432(d), and § 426.432(e), we are proposing that only documents relating to a specific LCD or NCD be eligible for discovery. The sections relating to discovery do not require the creation of any document. We believe that this is consistent with normal practice and will avoid unnecessary delays in the coverage determination reviews.

Under § 426.432(f), we are proposing that an adjudicator may order us or our contractor to provide an index of any documents withheld on the basis of privilege and, if necessary, conduct an in-camera review of any documents withheld on the basis of privilege.

While reviewing a provision of an LCD or NCD based on the reasonableness standard, the adjudicator may, if necessary, issue subpoenas,

consult with appropriate clinical or scientific experts, and take evidence during a hearing. In §§ 426.435 and 426.535, we are proposing 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) would have to be filed with the adjudicator by a party to the coverage determination review at least 30 days before the hearing is scheduled. In addition to designating the witnesses (and their locations) and the evidence to be produced by those witnesses, the subpoena would have to 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. We believe that this will serve the purpose of ensuring that only those witnesses closest to, and most familiar with, the coverage determinations will be subpoenaed to a hearing and will allow the adjudication to exclude irrelevant matters. Because an LCD or NCD review is limited to the scientific and clinical evidence pertaining to the matter at the time the LCD or NCD was issued, testimonial evidence must be related to the appropriate time period. We are proposing in § 426.340 that if an expert submits new clinical and scientific evidence, additional action by us or the contractor may be necessary.

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 would also set forth the remedy afforded under section 205(e) of the Act, if a subpoena is not obeyed.

We are proposing the rules relating to evidence in coverage determination reviews in §§ 426.440 and 426.540. Under §§ 426.440(a) and 426.540(a), the ALJ or Board would determine the admissibility of evidence consistent with § 426.340. Under §§ 426.440(f) and 426.540(f), we would require experts submitting reports to be available for cross-examination at an evidentiary hearing. Under §§ 426.440(g) and 426.540(g), we would require that, unless otherwise ordered by the adjudicator for good cause, all documents and other evidence be open to examination by all parties to the review.

In §§ 426.441 and 426.541, we are proposing that the adjudicator notify all parties when the discovery period is closed.

Under §§ 426.444 and 426.544, we would describe an adjudicator's dismissal for cause of a complaint regarding an LCD or an NCD, respectively. A dismissal would be effectuated by the issuance of an administrative decision dismissing a complaint. In general, an adjudicator may dismiss a complaint if an aggrieved party (or his or her representative) fails to attend or participate in a pre-hearing conference or hearing without good cause 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 would require that the adjudicator dismiss complaints that fail to meet the requirements for acceptable complaints, including complaints regarding inapplicable policies or determinations. We would also require that the adjudicator must also dismiss a complaint if the aggrieved party withdraws the complaint, or if the complaint seeks review of a matter beyond the adjudicator's authority.

If an aggrieved party dies after initiating the coverage determination complaint process and after filing an initial claim for benefits, the aggrieved party's estate could pursue payment under the claims appeals process, but the estate may not pursue a policy challenge.

Under §§ 426.444(b)(6), we would also require an ALJ to issue an administrative decision dismissing a complaint if the applicable contractor was to notify the ALJ that the LCD is being retired. When a contractor decides to retire an LCD, it means that the LCD (or the provision(s) of the LCD removed as part of the revision) cannot be used in the adjudication of claims after the date of issuance of the retirement. We would require that the LCD would no longer be effective within 30 days of the date of notifying the ALJ. We are proposing this rule because retiring an LCD ensures that the LCD will no longer be used in that particular jurisdiction and renders a challenge to the policy moot. Similarly, in § 426.544(b)(6), we would notify the Board that the NCD is no longer in effect.

Under §§ 426.444(c) and 426.544(c), we would require that an adjudicator may, at the request of any party, or on his or her own motion, dismiss a complaint if the adjudicator has already issued an administrative decision on the LCD or the NCD or provisions of an LCD or an NCD and the aggrieved party has not presented any new clinical or scientific evidence that supports the complaint.

In §§ 426.445 and 426.545, we would 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 would require that an ALJ and the Board, respectively, ensure that any hearing conducted regarding a coverage determination review is open to the public and mechanically or stenographically recorded. While these proceedings are open to the public, adjudicators are under no obligation to announce or publicize these proceedings. Further, the public has no right to participate in these proceedings. These sections would also require that all evidence upon which the adjudicator relies for a decision be contained in the record, and that any pertinent document or record be incorporated into the record of the coverage determination hearing.

Under §§ 426.447 and 426.547, we would set forth the procedures for the issuance and notification of ALJ and Board administrative decisions, respectively. The applicable adjudicator, within 90 days from closing the review record to the taking of evidence, would be required either to issue an administrative decision, or provide notice that the administrative decision is pending, and an approximate date a decision will be issued. In § 426.547(b), we would explain that Board administrative decisions regarding NCDs would be available on the Medicare Internet site of the Department of Health and Human Services. Steps would also have to be taken to ensure the privacy of the parties to the review, in conjunction with applicable statutes and regulations.

Under § 426.450, we would describe the required elements of an ALJ's administrative decision regarding an LCD. In § 426.550, we would similarly describe the required elements of the Board's administrative decision regarding an NCD. As discussed earlier in this section of the preamble, an administrative decision may include the dismissal of a complaint. If the complaint is not dismissed, the administrative decision would have to contain a statement pertaining to each provision listed in the complaint and stating whether the provision is valid or invalid under the reasonableness standard. We would also require that the administrative 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), a rationale for the basis of the administrative decision, a summary of

the evidence reviewed during the review, and the respective ALJ's or Board member's signature and date.

In §§ 426.455 and 426.555, we are proposing that an administrative decision be prohibited from doing any of the following:

- Ordering us or our contractors to take specific actions in modifying (including adding to, or deleting language from) a provision(s) of an LCD or NCD.
- Ordering us or our contractors to pay a specific claim.
- Establishing a time limit for the establishment 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.

In §§ 426.460 and 426.560, we would describe the effect of administrative decisions issued under §§ 426.447 and 426.547. We are proposing these provisions because we believe that the exact wording of a new coverage determination should be made by the contractor or us. These policies affect other beneficiaries and, thus, these determinations should be made by clinicians and scientific experts who have the necessary specialized training. Thus, we and the contractor would remain the entities responsible for ensuring that the clinical and scientific policies are sound, resulting in the best quality of care for beneficiaries.

The effect of an administrative decision would depend on the outcome of the coverage determination review. If the adjudicator found 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 agency 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 relief for the aggrieved party or parties named in the complaint(s).

- If the aggrieved party received (fee-for-service or managed care) service that was the subject of the challenged coverage determination after the date the complaint was filed, and a claim has been filed, then we would instruct the contractor (if applicable) or Medicare managed care organization not to 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 would be bound by the invalidated provision, as they were bound at the initial claim determination. Specifically, we would 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; (2) the claim was denied but not appealed, in which case the contractor must re-open the claim; or (3) the claim was adjudicated, denied and appealed at any level. It is important to note that individual claim relief 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.

Second, there would be additional relief. Within 30 days of the issuance of the administrative decision, we or the contractor would have to send a letter to the aggrieved party and the adjudicator announcing the intent to either retire the coverage determination, or conduct a reconsideration of that policy. As discussed earlier, the retirement of a coverage determination means that it can no longer be used in the adjudication of claims. And, as also described earlier, a reconsideration of a coverage determination could result in a new LCD or NCD that does one of the following:

- Supplements the record or rationale and reaffirms the coverage determination.
- Revises the coverage determination.
- Retires the coverage determination.

Supplementing the record could include the addition to the record of evidence that was not in the LCD or NCD record, or a more detailed rationale as to why the contractor or we believe the LCD or NCD should remain in effect. Although the specific language of the LCD or NCD may not change in this case, the LCD or NCD would have to be reissued to reflect the updated decision and record.

Under § 426.462, ''Notice of an ALJ's administrative decision,'' we are proposing that after the ALJ has made a decision regarding an LCD complaint, the ALJ would send a written notice of the administrative decision to each party. The notice must contain a finding with respect to the LCD complaint 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 § 426.562, ''Notice of the Board's administrative decision,'' we are proposing that after the Board has made a decision regarding an NCD complaint, the Board would send a written notice of the administrative decision to each party. The notice must contain a finding with respect to the coverage complaint 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.

In the remainder of the sections proposed in subpart D, we would set forth the procedure for appealing an ALJ's administrative decision regarding an LCD review. In § 426.465(a), we are proposing that an aggrieved party may appeal part or all of an ALJ's administrative 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 would also allow an aggrieved party who was part of a joint complaint or a consolidated LCD review to appeal an ALJ's administrative decision either independently or as a group.

In § 426.465(b), we are proposing that we or our contractor be allowed to appeal an ALJ decision that an LCD was unreasonable to the Board.

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

In § 426.465(d), we are proposing not to 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.

Under § 426.465(e), we are proposing that an appeal would have to be submitted to the Board within 60 calendar days of the date the ALJ's administrative 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 would permit the Board to consider a late appeal if good cause is shown by the party.

Section 426.465(f) would list 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 are proposing 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 § 426.467, ''Board's LCD review record,'' we are proposing in paragraph (a) that 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:

- The LCD complaint.
- The LCD and LCD record.
- The supplemental LCD record, if applicable.
- The Board's administrative decision.
- Transcripts of record.
- Any other relevant evidence gathered under § 426.440.

We are proposing in paragraph (b) that the LCD record would not include material that is privileged or otherwise prohibited from release by Federal law.

In § 426.567, ''Board's NCD review record,'' we are proposing in paragraph (a) that 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:

- The NCD complaint.
- The NCD and NCD record.
- The supplemental NCD record, if applicable.
- The Board's administrative decision.
- Transcripts of record.
- Any other relevant evidence gathered under § 426.540.

We are proposing in paragraph (b) that the NCD record would not include material that is privileged or otherwise prohibited from release by Federal law.

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

In § 426.470, we are proposing that the Board's role in docketing and evaluating the acceptability of appeals of ALJ administrative decisions would be similar to the process that an ALJ would use in docketing and evaluating the acceptability of a complaint. The Board would assign a number to the appeal and determine if it meets all of the requirements of an acceptable appeal proposed in § 426.465. Unlike the evaluation of an initial complaint, however, we would require, in § 426.470(c), that the Board issue an administrative decision dismissing an unacceptable appeal, instead of allowing an opportunity to amend an unacceptable appeal. If the Board determines that the appeal is acceptable, in § 426.465(d), we would require the Board to send notification to the aggrieved party (or parties), to the contractor, and, if applicable, to us. The Board would also request a copy of the LCD review record (discussed later in this section of the preamble) from the ALJ who issued the administrative decision.

Upon the request from the Board to provide copies of the LCD review record under § 426.470, we would require that an ALJ send a copy of the LCD review record to the Board (see § 426.472). Under § 426.474, we would describe what the ALJ's LCD review record would contain. In general, the LCD review record consists of any document or material that the ALJ compiled or considered during the LCD review.

Once the Board has accepted an appeal to an ALJ's administrative decision and received the ALJ's LCD review record, we are proposing in § 426.476 the steps that the Board would take in reviewing the ALJ's administrative decision. In addition to reviewing the ALJ's LCD review record and the ALJ's administrative decision, the Board would allow the contractor or, if applicable, 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 administrative decision would be to issue an administrative decision, which is discussed in more detail later in this section of the preamble. If the appeal of the ALJ's administrative decision is based on a disputed issue of fact, we would require that the Board base its administrative decision on whether the ALJ's administrative decision was supported by substantial evidence on the whole from the LCD review record. If the appeal of the ALJ's administrative decision is based on a disputed issue of law, we would require that the Board base its administrative decision on whether the ALJ's administrative decision is erroneous. If the appeal were based both on a disputed issue of fact and a disputed issue of law, the Board would base its administrative decision on both of the above standards.

We believe that the Board review of an appeal of an ALJ's administrative decision should remain a paper review of existing materials. Accordingly, we are proposing, in § 426.476(b), to prohibit the Board from considering any issue not raised in the parties' briefs, or considering any evidence that is not a part of the ALJ's LCD review record. In § 426.476(c), we would establish controlling authorities that the Board must consider when reviewing appeals of ALJ administrative decisions. These include the applicable provisions of the Act, our regulations and rulings, and NCDs.

In § 426.476(d), we would require the Board to dismiss an appeal of an ALJ's administrative decision if the contractor retired the LCD during the appeal.

In § 426.478, we are proposing to allow the contractor to retire an LCD during the Board's review of the ALJ's administrative decision. As stated in the previous paragraph, this would lead to the Board dismissing the appeal.

In § 426.480, we are proposing to allow a party to withdraw an appeal of an ALJ's administrative 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 would require the issuance and notification of a Board administrative decision regarding an appealed ALJ administrative decision. These provisions would be the same as the provisions we are proposing for the issuance and notification of an ALJ administrative decision in § 426.445.

In § 426.484, we would set forth the mandatory provisions of a Board administrative decision regarding an appealed ALJ administrative decision. We would require the Board to either dismiss the appeal or, for each part of the ALJ's administrative decision named in the appeal, to issue a statement either upholding or reversing that part or all of the ALJ's administrative decision. Because the Board is conducting a review of the ALJ's administrative decision using the ALJ's LCD review record, and is not conducting a de novo review of the LCD itself, a Board administrative decision either upholding or reversing each part, or all of the ALJ's administrative decision is the proper outcome. The Board's administrative decision would also be required to include the information necessary to identify the appeal, the rationale for the Board's administrative decision, and the signature of a Board member.

In § 426.486, we would prohibit the Board's administrative decision from

including those provisions that we are proposing to exclude from the ALJ's administrative decision in § 426.455, for the reasons discussed earlier in this preamble. In § 426.488, we would set forth the effect of a Board administrative decision. Section 426.488(a) explains the relief that would be provided to a successful challenger. Moreover, there may be coverage relief. The contractor would have the option of either retiring the LCD, or conducting a reconsideration of the LCD, if the Board's administrative decision reversed an ALJ finding of validity under the reasonableness standard.

We note that if the Board's administrative decision is the reversal of an ALJ's administrative decision that dismissed a complaint regarding an LCD, the case would be remanded to the ALJ, and the LCD review would continue from the point at which it was dismissed by the ALJ.

We propose permitting the Board to remand cases to the ALJ in a limited number of circumstances. In § 426.489(a), we are proposing that the Board may remand a case to the OHA, if the ALJ's administrative decision that does not comply with § 426.340, § 426.405, § 426.450, § 426.455, and § 426.474, or does not include:

- Findings of fact.
- Interpretations of law.
- Applications of fact to law.
- Summary of evidence reviewed.
- The signature of the ALJ.

In § 426.489(b), we propose prohibiting the Board from remanding cases to an ALJ to review new or additional LCD evidence submitted during an appeal of an LCD complaint to the Board.

In § 426.489(c), we propose that the Board notify all parties to the complaint when an LCD complaint is remanded to OHA. Section 426.489(d) describes the actions that an ALJ will take upon receipt of a coverage complaint remand.

In § 426.489(d), we propose that upon receipt of Board remand, an ALJ will take any action this is consistent with the Board's remand order.

In § 426.490, we are proposing that 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 administrative decision.

In § 426.570, we are proposing that a decision by the Board would constitute a final agency action and would be subject to judicial review. We may not appeal a Board administrative decision.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-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, 44 U.S.C. section 3506(c)(2)(A) requires 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 are soliciting 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 and also state what sort of information is required in the complaint to justify that he or she qualifies as aggrieved party under our proposed definition at § 426.110. This documentation would include the certification of the beneficiary's treating physician that the beneficiary needs a service, and a statement from the treating physician that payment for the service is likely to be denied under a coverage determination.

We estimate that 3,000 LCD and 15 to 20 NCD complaints will be filed per year. We estimate that it will take the aggrieved party 4 hours to draft the complaint and gather the information to send to us. Thus, we estimate the national burden would be 12,080 hours annually.

Other sections discuss the filing of various motions, petitions, and notice that the aggrieved party is withdrawing the request for a hearing and appeal. These actions are all exempt from the PRA under 5 CFR 1320.4, *Coverage*. These actions are part of an administrative action; administrative actions are not covered by the PRA or its regulations.

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

Centers for Medicare & Medicaid Services, Office of Information Services, Information Technology Investment Management Group, Attn.: Julie Brown, CMS–3063–P, Room N2–14–26, 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.

V. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the substantive comments in the preamble to that document.

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). We believe that this rule will not meet the $100 million threshold and, therefore, is not 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, and we certify, 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 rule would not have a substantial effect on State or local governments.

C. Anticipated Effects

1. Effects on Medicare Beneficiaries

In developing this proposed 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 proposed rule, but would also expect the ALJs and the Board to use the flexibility proposed for them 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. The proposed 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 would require some documentation to support a complainant's assertions of being an aggrieved party (see §§ 426.400 and 426.500), we would accept that documentation as sufficient to show standing to challenge an LCD or an NCD. In this way, we seek to minimize disputes over beneficiaries' factual circumstances, 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. Once a final rule is published, we expect to produce a user-friendly guide that beneficiaries may use to assist them in accessing this process. In addition, we specifically request public comments on additional procedures, consistent with the statute that would enable this process to work more efficiently.

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 would have an effect on providers, except to the extent that a provider would supply documentation that an aggrieved party is in need of a specific service, and that payment for the service would likely be denied under the LCD or NCD. It would also be possible for a provider to be subpoenaed under §§ 426.435 and 426.535, but proposed §§ 426.445 and 426.545 would allow for compensation under this circumstance. We believe that the rule would 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 administrative costs associated with coverage determination reviews, the cost of being a party to coverage determination reviews, and the cost of reevaluating policies.

D. Alternatives Considered

We considered various alternative approaches for implementing the ALJ or Board administrative decisions with respect to an LCD and NCD. One alternative we considered was to allow an ALJ or 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 would not be 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 reasonable. 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. To avoid redundant claims/appeals processes, we have proposed that individual relief would be determined through our existing claims appeals procedures, but the LCD or NCD that was found unreasonable by the ALJ or the Board would not be applied.

Further, we do not believe that it is appropriate for an ALJ or the Board to write or rewrite 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 should continue to develop these policies. To have anyone other than a clinician or scientific

expert revise Medicare policy would not be in the best interest of the beneficiary that relies on receiving the highest quality care possible.

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, Centers for Medicare & Medicaid Services, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, CMS proposes to amend 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 ''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.

* * * * *

Board means the Departmental Appeals Board.

* * * * *

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 does not include a determination of which 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, 1155, 1869(b), 1871, 1872, and 1879 of the Social Security Act (42 U.S.C. 1302, 1320c–4, 1395ff(b), 1395hh, 1395ii, and 1395pp).

4. Revise § 405.732 to read follows:

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

(a) General. 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, 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 made before October 1, 2002, and for challenges to an NCD made under section 1862(a)(1) of the Act, 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 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.* 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, 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 made before October 1, 2002, and for challenges to an NCD made under section 1862(a)(1) of the Act, 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 invalidate an NCD except upon review of the supplemental record.

6. Add part 426 to read as follows:

PART 426–REVIEWS OF LOCAL AND NATIONAL COVERAGE DETERMINATIONS

Subpart A—General Provisions

Sec.

426.100 Basis and scope.
426.110 Definitions.

Subpart B—[Reserved]

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

426.300 Review of LCDs, NCDs, and deemed NCDs.
426.310 LCD and NCD reviews and individual claim appeals.
426.320 Challenges to LCDs and NCDs.
426.330 No assignment of rights by an aggrieved party.
426.340 Stay of proceedings for review of new evidence.

Subpart D—Review of an LCD

426.400 Procedure for filing an acceptable complaint to a provision (or provisions) of an LCD.
426.405 Authority of the ALJ.
426.406 Ex parte contacts.
426.410 ALJ's role in docketing and evaluating the acceptability of LCD complaints.
426.415 CMS's role in the LCD review.
426.418 Contractor's LCD record.

426.420 Retiring an LCD under review.
426.423 Withdrawing a complaint regarding an LCD under review.
426.425 LCD review.
426.429 Review following supplemental record.
426.430 ALJ's role in determining whether the contractor's LCD record is complete and adequate to support the validity of the LCD.
426.431 ALJ's review of the LCD to apply the reasonableness standard.
426.432 Discovery.
426.435 Subpoenas.
426.440 Evidence.
426.441 Closing discovery.
426.444 Dismissals for cause.
426.445 Witness fees.
426.446 Record of hearing.
426.447 Issuance and notification of an ALJ's administrative decision.
426.450 Mandatory provisions of an ALJ's administrative decision.
426.455 Prohibited provisions of an ALJ's administrative decision.
426.460 Effect of an ALJ's administrative decision.
426.462 Notice of an ALJ's administrative decision.
426.465 Appealing part or all of an ALJ's administrative decision.
426.467 Board's LCD review record.
426.468 Decision to not appeal an ALJ's administrative decision.
426.470 Board's role in docketing and evaluating the acceptability of appeals of ALJ administrative decisions.
426.472 ALJ's role in making the LCD review record available.
426.474 ALJ's LCD review record.
426.476 Board review of an ALJ's administrative decision.
426.478 Retiring an LCD during the Board's review of an ALJ's administrative decision.
426.480 Withdrawing an appeal of an ALJ's administrative decision.
426.482 Issuance and notification of a Board's administrative decision.
426.484 Mandatory provisions of a Board's administrative decision.
426.486 Prohibited provisions of a Board's administrative decision.
426.488 Effect of a Board administrative decision.
426.489 Board remand authority.
426.490 Board administrative decision.

Subpart E—Review of an NCD

426.500 Procedure for filing an acceptable complaint to a provision or provisions of an NCD.
426.505 Authority of the Board.
426.506 Ex parte contacts.
426.510 Board's role in docketing and evaluating the acceptability of NCD complaints.
426.515 CMS's role in making the NCD record available.
426.518 NCD record.
426.520 Repealing an NCD under review.
426.523 Withdrawing a complaint regarding an NCD under review.
426.525 NCD review.
426.529 Review following supplemental record.
426.530 Board's role in determining whether the NCD record is complete and adequate to support the validity of the NCD.
426.531 Board's review of the NCD to apply the reasonableness standard.
426.532 Discovery.
426.535 Subpoenas.
426.540 Evidence.
426.541 Closing discovery.
426.544 Dismissals for cause.
426.545 Witness fees.
426.546 Record of hearing.
426.547 Issuance, notification, and posting of a Board's administrative decision.
426.550 Mandatory provisions of the Board's administrative decision.
426.555 Prohibited provisions of the Board's administrative decision.
426.560 Effect of the Board's administrative decision.
426.562 Notice of the Board's administrative decision.
426.565 Board's role in making an LCD/NCD review record available.
426.567 Board's NCD review record.
426.570 Board administrative decision.

PART 426—REVIEWS OF LOCAL AND NATIONAL COVERAGE DETERMINATIONS

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 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); and

(2) Is in need of 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.

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 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 failed to meet the deadline under section 1869(f)(4)(iv) of the Act.

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

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

Reasonableness standard means the standard that an ALJ or the Board must apply when conducting an LCD or an NCD review. In determining whether NCDs or LCDs 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 CMS or the contractor are reasonable based on the NCD or LCD record.

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 independent of the claims appeal processes set forth in part 405, subparts F and G; part 417, subpart Q; and part 422, subpart M of this chapter.

(b) An aggrieved party must notify the OHA 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 throughout the entire LCD or NCD review process.

§ 426.320 Challenges to LCDs and NCDs.

(a) *Right to challenge.* Only an aggrieved party may initiate a review to

challenge an existing specific provision or provisions of an LCD or NCD by filing an acceptable complaint.

(b) *Exclusions from review.* Some items are not reviewable under this part, including:

(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 NCDs that are no longer in effect.

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

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

(5) Contractor claims processing edits.

(6) Payment amounts or methodologies.

(7) Coding issues, including determinations, methodologies, definitions, or rules.

(8) Contractor bulletin articles, educational materials, or web site frequently asked questions.

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

(10) An individual claim determination.

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

§ 426.330 No assignment of rights by an aggrieved party.

(a) *Assignment of rights.* An aggrieved party may not assign his or her rights to file a complaint to a provision (or provisions) of an LCD or NCD to any other individual or entity. Neither an ALJ nor the Board will recognize as valid any attempt to assign rights under section 1869(f) of the Act.

(b) *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 will be judged by a preponderance of the evidence.

§ 426.340 Stay of proceedings for review of new evidence.

(a) If an aggrieved party submits new evidence, or the Board or ALJ admits new evidence, pertaining to an LCD or NCD, the Board or ALJ will send the new evidence to CMS or the contractor for review. Upon review of this new evidence, CMS or the contractor will determine whether a request for stay of administrative proceedings under this part 426 to consider the additional clinical or scientific evidence is necessary. Upon such a request, the Board or ALJ will do the following:

(1) Stay the proceedings.

(2) Set a reasonable timeframe within which CMS or the contractor will complete the review.

(3) Upon request of CMS or the contractor, extend the timeframe for the period of time requested by CMS or the contractor, unless the aggrieved party can demonstrate that the CMS contractor request is unreasonable.

(b) Following the CMS or the contractor review of this new evidence, CMS or the contractor will file a supplemental record.

Subpart D—Review of an LCD

§ 426.400 Procedure for filing an acceptable complaint to 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 Social Security Administration, Office of Hearings and Appeals (OHA).

(b) *Timeliness of a complaint.* The OHA must receive a complaint within 6 months of the written statement described in paragraph (c)(1)(vi) of this section.

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

(1) *Beneficiary-identifying information:*

(i) Beneficiary's name.

(ii) Beneficiary's mailing address.

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

(iv) Beneficiary's telephone number.

(v) Beneficiary's Health Insurance Claim number.

(vi) A copy of the treating physician's certification that, in his or her medical opinion, the beneficiary needs the service that is the subject of the LCD.

(vii) A statement from the treating physician that Medicare coverage for the service needed is likely to be denied under the applicable contractor's LCD.

(2) *LCD-identifying information:*

(i) Name of the contractor using the LCD.

(ii) Title of final LCD being challenged.

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

(3) *Aggrieved party statement.* A statement from the aggrieved party explaining the rationale for the allegation that the provision(s) of the LCD is (are) not valid under the reasonableness standard, and whether the aggrieved party has received the service related to the LCD.

(4) *Clinical or scientific evidence.* Copies of clinical or scientific evidence that supports the complaint.

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

(i) Each aggrieved party named in the joint complaint has a similar medical condition.

(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.* The OHA must receive a joint complaint within 6 months of the date of the documentation from each aggrieved party's treating physician expressing the belief that payment for the needed service would likely be denied under the LCD in question.

§ 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 to the review.

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

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

(15) Receive, rule on, exclude, or limit evidence, in accordance with § 426.340.

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

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

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

(19) Issue administrative decisions.

(20) Exclude a party to an LCD review (or a party's representative) for failure to comply with an ALJ order or procedural request without good cause.

(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) Receive or accept any new evidence without following § 426.340.

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

(4) Conduct an LCD review of any draft, retired, template, or suggested LCDs.

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

(6) Conduct a review of the merits of an invalid LCD complaint.

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

(8) Compel mediation or settlement negotiations by aggrieved parties.

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

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

(11) Deny a contractor the right to retire an LCD.

(12) Deny a contractor or CMS the right to conduct a reconsideration review when any party submits new evidence.

(13) Make a determination under § 426.441 before a contractor's reconsideration of new evidence as described in § 426.340.

(14) Compel CMS or its contractors to conduct studies, surveys, or develop new information to support an LCD record.

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

(16) Enter an administrative decision defining the specific terms of a subsequent LCD.

§ 426.406 Ex parte contacts.

No party or person (except employees of the ALJ's office) will communicate 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 ALJ's role in docketing and evaluating the acceptability of LCD complaints.

(a) *Docketing the complaint.* The Office of Hearings and Appeals does the following upon receiving a complaint regarding an LCD:

(1) *Dockets the complaint.*

(2) Forwards the complaint to the selected ALJ.

(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 will assume that the facts alleged by the treating physician's statement 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 § 426.320(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 an administrative decision dismissing the unacceptable complaint.

(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.

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

(3) Requests that CMS or the contractor send a copy of the LCD record to the ALJ and all parties to the LCD review.

(e) *Consolidation of complaints regarding an LCD*—(1) *Criteria for consolidation.* If two or more aggrieved parties submit separate acceptable complaints regarding the same provision(s) of the same LCD, an ALJ may, upon his or her own motion or by motion of any party to the LCD review, consolidate the complaints and conduct 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.

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

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

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

(ii) Makes a single record of the proceeding.

(iii) Considers the relevant evidence introduced in each LCD challenge 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's role in the LCD review.

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

§ 426.418 Contractor's LCD record.

(a) *Elements of a contractor's LCD record.* 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 relevant 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) Records from the Food and Drug Administration regarding safety and efficacy of a drug or device,

(v) 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).

(b) *Documents excluded from the contractor's LCD record.* The LCD record does not include the following:

(1) Material that is privileged.

(2) Any new evidence.

(3) Proprietary data.

§ 426.420 Retiring an LCD under review.

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

§ 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 an administrative decision regarding that LCD. The aggrieved party may not file another complaint to 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 notice announcing the intent to withdraw to the OHA (see § 426.400), CMS (if applicable), and the applicable contractor.

(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 notice announcing the intent to withdraw a complaint regarding an LCD before the date the ALJ issued an administrative decision regarding that LCD, the ALJ issues an administrative decision dismissing the complaint under § 426.444 and informing 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 announcing the intent to withdraw a complaint regarding an LCD before the date the ALJ issued an administrative decision regarding that LCD, the ALJ issues an administrative 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 announcing the intent to withdraw a complaint regarding an LCD before the date the ALJ issued an administrative decision regarding that LCD, the ALJ removes that aggrieved party from the consolidated LCD review and issues an administrative decision dismissing that aggrieved party's complaint under § 426.444. The ALJ continues the LCD review if there is one or more aggrieved parties who does not withdraw from the joint complaint.

§ 426.425 LCD review.

(a) Opportunity for the aggrieved party to state that the contractor's LCD record is not complete, not adequate to support the validity of the LCD, or both: Upon receipt of the contractor's LCD record, the aggrieved party who submitted the complaint may file a motion alleging that the contractor's LCD record is not complete, not adequate to support the validity of the LCD, or both. This motion must be submitted to the ALJ, the contractor, or CMS, as appropriate, within 30 days (or within additional time as allowed by the ALJ) of the date the aggrieved party receives the contractor's LCD record.

(1) If an aggrieved party does not file a motion alleging that the contractor's LCD record is incomplete or lacks adequate information to support the validity of the LCD, then the ALJ makes a determination whether the LCD record is complete and adequate, as described in § 426.430(a).

(2) If an aggrieved party files a motion alleging that the contractor's LCD record is not complete, not adequate to support the validity of the LCD, or both, based on clinical and scientific evidence contained in the LCD record, then the ALJ makes a determination whether the LCD record is complete and adequate, as described in § 426.430(b).

(3) If an aggrieved party files a motion alleging that the contractor's LCD record is not complete, not adequate to support the validity of the LCD, or both, based on new evidence, then the ALJ stays the proceeding upon request by the contractor or CMS as described in § 426.340.

(b) The aggrieved party may file a petition with the ALJ requesting additional time to review the contractor's LCD record. This petition must be submitted to the ALJ within 30 days of the receipt of the LCD record (or within additional time as allowed by the ALJ). This petition shall be in writing, shall state the reason(s) why the request for extension is being made, and the amount of additional time needed to review the contractor's LCD record. The ALJ may extend the time for reviewing the contractor's LCD case file by an aggrieved party for a reasonable period of time.

§ 426.429 Review following supplemental record.

(a) *Opportunity for the aggrieved party to review the supplemental LCD record.* Upon receipt of the contractor's supplemental LCD record, following a reconsideration under § 426.340, the aggrieved party who submitted the complaint may file a motion alleging that the contractor's LCD record is not complete, not adequate to support the validity of the LCD, or both. This motion must be submitted to the ALJ, the contractor, and CMS within 30 days (or within additional time as allowed by the ALJ) of the date the aggrieved party receives the supplemental LCD record.

(1) If an aggrieved party does not file a motion alleging that the contractor's supplemental LCD record is incomplete or lacks adequate information to support the validity of the LCD, then the ALJ makes a determination whether the LCD record is complete and adequate, as described in § 426.430(a).

(2) If an aggrieved party files a motion alleging that the contractor's LCD record is not complete, not adequate to support the validity of the LCD, or both, based on clinical and scientific evidence contained in the LCD record, then the ALJ makes a determination whether the LCD record is complete and adequate, as described in § 426.430(b).

(3) If an aggrieved party files a motion alleging that the contractor's supplemental LCD record is not complete, not adequate to support the validity of the LCD, or both, based on new evidence, then the ALJ stays the proceeding upon request by the contractor or CMS as described in § 426.340.

(b) *Request for additional time to review the contractor's supplemental LCD record by the aggrieved party.* The aggrieved party may file a petition with the ALJ requesting additional time to review the contractor's supplemental LCD record. This petition must be submitted to the ALJ within 30 days of the filing of the supplemental record (or within additional time as allowed by the ALJ). Such petition shall be in writing, shall state the reason(s) why the request

for extension is being made, and the amount of time needed to review the contractor's supplemental LCD record. The ALJ may extend the time for reviewing the contractor's supplemental LCD record for a reasonable period of time

§ 426.430 ALJ's role in determining whether the contractor's LCD record is complete and adequate to support the validity of the LCD.

(a) If the aggrieved party does not file a motion described in § 426.425(a) or § 426.429(a), the ALJ reviews the contractor's LCD record and applies the reasonableness standard, as described in § 426.431.

(b) If the aggrieved party files a motion described in § 426.425(a) or § 426.429(a), the ALJ must do the following:

(1) Allow the contractor or CMS to submit a statement to the ALJ and the aggrieved party responding to the motion described in paragraph (a) of this section. This statement must be submitted within 30 days (or within additional time as allowed by the ALJ) of the date the contractor receives the statement from the aggrieved party described in paragraph (a) of this section.

(2) Review the contents of the LCD record, as described in § 426.418.

(3) Hold conferences, if necessary, which may be conducted (at the ALJ's discretion) either in person, or, by mutual agreement of the parties, by telephone, picture-tel, or any other means agreed upon by all parties involved.

(4) Determine whether the contractor's LCD record is complete and adequate to support the validity of the LCD.

(c) ALJ's determination of the completeness of the contractor's LCD record, and the determination of contractor's LCD record's adequacy to support the validity of the LCD:

(1) *ALJ determination that the contractor's LCD record is complete and adequate to support the validity of the LCD.* If the ALJ determines that the contractor's LCD record is complete and adequate to support the validity of the LCD, the ALJ does the following:

(i) Sends a letter to the aggrieved party, the contractor, and CMS stating that the ALJ finds the contractor's LCD record to be complete and adequate to support the validity of the LCD.

(ii) Reviews the provision(s) of the LCD listed in the complaint based on the reasonableness standard as described in § 426.431.

(2) *ALJ determination that the contractor's LCD record is not complete, not adequate to support the validity of the LCD, or both.* If the ALJ determines that the contractor's LCD record is not complete, not adequate to support the validity of the LCD, or both, the ALJ does the following:

(i) Sends a letter to the aggrieved party, the contractor, and CMS (if applicable) stating that the contractor's LCD record is not complete, not adequate to support the validity of the LCD, or both.

(ii) Allows discovery as described in § 426.432.

(iii) Upon admission of new evidence, follows the process for review of new evidence as described in § 426.340.

(iv) Reviews the provision(s) of the LCD listed in the complaint to apply the reasonableness standard as described in § 426.431.

§ 426.431 ALJ's review of the LCD to apply the reasonableness standard.

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

(1) Confine the LCD review to the provision(s) of the LCD raised in the aggrieved party's complaint filed with the OHA, and to clinical or scientific evidence that is contained in the LCD record (or supplemental record).

(2) Close the LCD review record to the taking of evidence.

(3) Issue an administrative 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) Conduct a hearing, and allow subpoenas as described in § 426.435 and the taking of evidence as described in § 426.440.

(2) At a hearing, consult with appropriate scientific or clinical experts concerning clinical or scientific evidence.

(3) Consider any previous ALJ administrative decision made under § 426.447 regarding the same provision(s) of the LCD under review.

(4) Consider any previous Board administrative decision made under § 426.482 regarding the same provision(s) of the LCD under review.

(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 the applicable provisions of the following:

(1) The Social Security Act.

(2) CMS regulations.

(3) CMS rulings.

(4) NCDs.

§ 426.432 Discovery.

(a) *General rules.* If the ALJ orders discovery, the ALJ does the following:

(1) Establishes a reasonable timeframe for discovery.

(2) Ensures that a party to the LCD review who receives a discovery request has certain rights that include, but are not limited to, the following:

(i) The right to select and use an attorney or other representative during the discovery process.

(ii) The right to submit discovery responses, objections, motions, or other pertinent materials to the ALJ.

(3) Ensures that a nonparty to the LCD review who receives a discovery request has the same rights in responding to a discovery request as any party.

(b) *Protective orders*—(1) *Request for a protective order.* Any party or nonparty 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;

(ii) Is unduly costly or burdensome;

(iii) Will unduly delay the proceeding;

(iv) Is privileged under Federal law; or

(v) Is proprietary data.

(c) *Types of discovery available.* A party may make a request to another party or nonparty for production of documents 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 will be interpreted to require the creation of a document.

(e) *Types of discovery not available.* Requests for admissions, depositions, written interrogatories, or any other forms of discovery, other than those permitted under paragraph (d) of this section, are not authorized.

(f) *Privileged documents*—(1) *Options for the ALJ.* The ALJ may, in appropriate circumstances, do any of the following:

(i) Order CMS to provide an index of any documents withheld on the basis of privilege and to state the basis for the privilege claim.

(ii) Conduct an in-camera review of any documents withheld on the basis of privilege.

(2) *Confidentiality.* If the ALJ orders the release of any document when

privilege was asserted, the ALJ must order that all names or identifying information that is not relevant to the specific LCD be redacted from the document.

§ 426.435 Subpoenas.

(a) *Purpose of a subpoena.* A subpoena requires the attendance of an individual at a hearing and may also require the individual (whether or not the individual is 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 the facts could be established by other evidence 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.* The ALJ may modify the deadlines specified in paragraphs (b) and (c) of this section for good cause.

(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 will serve 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)).

§ 426.440 Evidence.

(a) The ALJ determines the admissibility of evidence consistent with § 426.340.(b) 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 or immaterial.

(c) Although relevant, the ALJ must exclude evidence if the ALJ determines it is privileged under Federal law.

(d) Consistent with § 426.340, the ALJ may permit the parties to introduce the testimony of scientific and clinical experts, rebuttal witnesses, and other relevant evidence, only if the testimony is related to evidence that was considered in the LCD. This testimony may 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) All documents and other evidence offered or taken for the record will be open to examination by all parties, unless otherwise ordered by the ALJ for good cause shown.

§ 426.441 Closing discovery.

Upon completion of discovery, the ALJ will notify all parties in writing that the discovery period is closed.

§ 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 (or his or her representative) fails to do either of the following:

(1) Attend or participate in a prehearing conference or hearing without good cause.

(2) Comply with a lawful order of the ALJ.

(b) The ALJ must dismiss any provision(s) of a complaint in any of the following circumstances:

(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, or is filed by an individual who is unable to demonstrate that he or she is in need of a particular service. (See § 426.400.)

(4) The aggrieved party no longer needs the service because the aggrieved party has received the service before the aggrieved party filed the complaint with the OHA. Except for an individual who has a continuing need for a particular item or service that is subject to an LCD.

(5) The complaint challenges a provision or provisions of an NCD. (See § 426.405.)

(6) The contractor notifies the ALJ that they have retired the LCD. (See § 426.420.)

(7) The aggrieved party withdraws the complaint. (See § 426.423.)

(8) The aggrieved party is deceased.

(9) Nothing in the preceding list of circumstances leading to automatic dismissal shall be construed as having any force and effect concerning the legal rights of representatives of a deceased beneficiary to properly pursue settlement of a claim.

(c) The ALJ may, at the request of any party, or on his or her own motion, dismiss a complaint if an ALJ has already issued an administrative decision on the LCD or provisions of an LCD and the aggrieved party has not presented any new clinical or scientific evidence that supports the complaint.

§ 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 is an expert, he or she will be entitled to an expert witness fee. Witness fees will be paid by the party seeking to present the witness.

(b) If an ALJ requests expert testimony, the OHA is responsible for paying all applicable fees and mileage.

§ 426.446 Record of hearing.

The ALJ must ensure that all hearings are open to the public and must be mechanically or stenographically reported. All evidence upon which the ALJ relies for decision must be contained in the record, either directly or by appropriate reference. All medical reports, exhibits, and any other pertinent document or record, either in whole or in material part, introduced as evidence, must be marked for identification and incorporated into the record.

§ 426.447 Issuance and notification of an ALJ's administrative 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 administrative decision, including a description of appeal rights.

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

§ 426.450 Mandatory provisions of an ALJ's administrative decision.

(a) *Finding.* An ALJ's administrative 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.

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

(1) The date of issuance.

(2) The docket number of the LCD review.

(3) The names of the parties to the LCD review.

(4) 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.

(5) A rationale for the basis of the ALJ's administrative decision, including the following:

(i) Findings of fact.

(ii) Interpretations of law.

(iii) Applications of fact to law.

(6) A summary of the evidence reviewed.

(7) A statement regarding appeal rights.

(8) The signature of the ALJ.

§ 426.455 Prohibited provisions of an ALJ's administrative decision.

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

(a) Order CMS or its contractors to modify (including adding to or deleting from) a provision or provisions of an LCD.

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

(c) Establish a time limit for the establishment of a new or revised LCD.

(d) Review, evaluate, or address 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) should implement an LCD.

§ 426.460 Effect of an ALJ's administrative 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 administrative 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) then CMS will instruct its contractor, the M+C plan, or other Medicare managed care plan to provide the following relief.

(1) *Individual claim relief when a claim is pending or has been previously adjudicated.* If an aggrieved party's claim/appeal(s) had previously been denied, the contractor, an M+C plan or another Medicare managed care plan must reopen the aggrieved party's claim and adjudicate the claim without using the provision(s) of the LCD that the ALJ found invalid.

(2) *Individual claim relief when no claim is pending.* If a revised LCD is issued, the contractor, the M+C plan, and any other Medicare managed care plan within contractor's jurisdiction will use the revised LCD in reviewing claim/appeal submissions or request for services for items delivered or services performed on or after the effective date.

(3) *Coverage determination relief.* If no appeal is filed by the contractor of CMS under § 426.425(b), within 30 days of the issuance of the ALJ's administrative decision, the contractor or CMS must send a letter to the ALJ and the aggrieved party or parties named in the complaint announcing the intent to do one of the following:

(i) Retire the LCD in its entirety, or retire the provision or provisions of the LCD that the ALJ's administrative decision stated was (were) not valid under the reasonableness standard.

(ii) Conduct a reconsideration using the information collected during the LCD review, as well as any other applicable information, and do one of the following:

(A) Supplement the LCD record or rationale, and reaffirm the LCD.

(B) Revise the LCD.

(C) Retire the LCD.

(iii) Unless retired under paragraph (b)(3)(i), or (b)(3)(ii)(C) of this section, the contractor may continue to use the LCD in adjudicating claims for individuals who did not challenge the LCD while a reconsideration is pending.

§ 426.462 Notice of an ALJ's administrative decision.

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

(a) Contain a finding with respect to the LCD complaint, 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.

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

(a) *Circumstance under which an aggrieved party may appeal part or all of an ALJ's administrative 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 administrative decision that does the following:

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

(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 administrative decision.* A contractor or CMS may appeal to the Board any part of an ALJ's administrative 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 administrative decision finds a provision or provisions of an LCD unreasonable, an appeal by a contractor or CMS stays implementation of the ALJ's administrative decision until a final decision is issued by the Board.

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

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

(1) The contractor retires the LCD under review.

(2) The aggrieved party who filed the complaint withdraws the complaint.

(e) *Receipt of the appeal by the Board.* Unless there is good cause, an appeal described in paragraphs (a) or (b) of this section must be received by the Board within 60 calendar days of the date the

ALJ's administrative decision was issued. If the 60th calendar day falls on a Saturday, Sunday, or Federal holiday, the Board must receive the appeal by the next business day.

(f) *Filing an appeal.* (1) To file an appeal described in paragraph (a) of this section, an aggrieved party, a contractor, or CMS must send the following to the Board at: The Department of Health and Human Services, Department Appeals Board, Room 637D, Humphrey Building, Attention: NCD Complaint, 200 Independence Avenue, SW., Washington, DC 20201:

(i) The full names and addresses of the parties and participants named in the ALJ's administrative decision, including the name of the LCD.

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

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

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

(2) If an appeal described in paragraph (a) of this section is not received by the Board by the date described in paragraph (c) of this section, it must include a rationale stating why the late appeal should be accepted by the Board.

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

§ 426.467 Board's LCD review record.

(a) *Elements of the Board's LCD review record.* 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) The Board's administrative decision.

(5) Transcripts of record.

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

(b) *Documents excluded from the contractor/CMS' LCD record.* The LCD record does not include material that is privileged or otherwise prohibited from release by Federal law.

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

(a) Failure to timely appeal without good cause waives the right to challenge any part(s) of the ALJ's administrative decision under § 426.665.

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

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

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

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

(1) Dockets the appeal either separately or with similar appeals (see paragraph (e) of this section).

(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 issue an administrative decision dismissing 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 informing 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) Requests that the ALJ send a copy of the LCD review record to the Board and all parties involved in the appeal.

§ 426.472 ALJ's role in making the LCD review record available.

Upon a request from the Board, the ALJ must provide to the Board, and all parties to the review of the ALJ's administrative decision, a copy of the ALJ's LCD review record (as described in § 426.474).

§ 426.474 ALJ's LCD review record.

(a) *Elements of the ALJ's LCD review record.* 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) The ALJ's administrative decision.

(5) Transcripts of record.

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

(b) *Documents excluded from the contractor's LCD record.* The LCD record does not include material that is privileged or otherwise prohibited from release by Federal law.

§ 426.476 Board review of an ALJ's administrative decision.

(a) *Mandatory steps.* If the Board determines that an appeal meets the requirements of § 426.465, the Board must do the following:

(1) Allow the aggrieved party, the contractor or CMS to submit a statement to the Board and the appellant in response to the appeal.

(2) Review the entire LCD review record, or the portion of the LCD review record at issue.

(3) Issue an administrative decision, as described in § 426.482, based on one, or both, of the following standards:

(i) *Disputed issue of fact.* If the appeal of the ALJ's administrative decision is based on a disputed issue of fact, the Board determines whether the ALJ's administrative decision is supported by substantial evidence on the whole LCD review record.

(ii) *Disputed issue of law.* If the appeal of the ALJ's administrative decision is based on a disputed issue of law, the Board determines whether the ALJ's administrative decision is erroneous.

(b) *Prohibited steps.* The Board must not do any of the following:

(1) Consider any issue not raised in the parties' briefs.

(2) Consider any evidence that is not part of the LCD review record.

(c) *Authority for Board in reviewing ALJ administrative decisions.* In determining whether an ALJ's administrative decision should be upheld or overturned, the Board must follow the applicable provisions of the following:

(1) The Social Security Act.

(2) CMS regulations.

(3) CMS rulings.

(4) NCDs.

(d) *Dismissal of ALJ's administrative decision.* The Board must dismiss the appeal of an ALJ's administrative decision if the contractor notifies the Board that it has retired the LCD.

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

A contractor may retire an LCD during the Board's review of an ALJ's administrative decision. If an LCD is retired, the aggrieved party is entitled to individual claim relief provided at § 426.488(b).

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

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

(b) *Process withdrawing an appeal of an ALJ's administrative decision.* To withdraw an appeal of an ALJ's administrative decision, the party who filed the appeal must send a written notice announcing the intent to withdraw to the Board (see § 426.465), and any other party.

(c) *Actions the Board must take upon receiving a notice announcing the intent to withdraw an appeal of an ALJ's administrative decision*—(1) *Appeals involving one aggrieved party, or initiated by CMS or a contractor.* If the Board receives a notice announcing the intent to withdraw an appeal of an ALJ's administrative decision before the date the Board has issued its administrative decision, the Board must issue an administrative decision dismissing the appeal under § 426.484.

(2) *Appeals involving joint complaints.* If the Board receives a notice announcing the intent to withdraw an appeal from an aggrieved party who is named in a joint appeal before the date the Board issued its administrative decision, the Board must issue an administrative decision dismissing only that aggrieved party from the appeal under § 426.482. The Board must continue its review of the ALJ's administrative decision for the remaining aggrieved party or parties who have not withdrawn their appeal.

§ 426.482 Issuance and notification of a Board administrative decision.

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

§ 426.484 Mandatory provisions of a Board administrative decision.

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

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

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

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

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

(1) The date of issuance.

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

(3) The names of the parties to the review of the ALJ administrative decision.

(4) A summary of the ALJ's administrative decision.

(5) A rationale for the basis of the Board's administrative decision including the following:

(i) Findings of fact.

(ii) Interpretations of law.

(iii) Application of fact to law.

(6) The signature of a Board member.

§ 426.486 Prohibited provisions of a Board administrative decision.

A Board administrative decision must not do any of the following:

(a) Order CMS or its contractors to take specific actions in modifying (including adding to or deleting from) a provision or provisions of an LCD.

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

(c) Establish a time limit for the establishment of a new or revised LCD.

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

§ 426.488 Effect of a Board administrative decision.

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

(b) *The Board's administrative decision upholds an ALJ determination that the LCD is invalid.* If the Board's administrative decision upholds an ALJ determination that the LCD is invalid, CMS will instruct its contractor, the M+C plan, or other Medicare managed care plan to provide individual claim relief.

(1) *Individual claim relief when a claim is pending or has been previously adjudicated.* If an aggrieved party's claim/appeal(s) had previously been denied, the contractor, an M+C plan, or another Medicare managed care plan must reopen the aggrieved party's claim and adjudicate the claim without using the provision(s) of the LCD that the ALJ found invalid.

(2) *Individual claim relief when no claim is pending.* If a revised LCD is issued, the contractor, the M+C plan, and any other Medicare managed care plan within contractor's jurisdiction will use the revised LCD in reviewing claim or appeal submissions or request for services for items delivered or services performed on or after the effective date.

(3) *Coverage determination relief.* Within 30 days of the issuance of the Board's administrative decision, the contractor or CMS must send a letter to the Board and the aggrieved party or parties named in the complaint announcing the intent to do one of the following:

(i) Retire the LCD in its entirety, or retire the provision or provisions of the LCD found to be invalid under the reasonableness standard.

(ii) Conduct a reconsideration using the information collected during the LCD review, as well as any other applicable information, and do one of the following:

(A) Supplement the LCD record or rationale, and reaffirm the LCD.

(B) Revise the LCD.

(C) Retire the LCD.

(iii) The contractor may continue to use the LCD in adjudicating claims for individuals who did not challenge the LCD while a reconsideration is pending.

(c) *The Board's administrative decision reverses a dismissal.* If the Board's administrative decision reverses an ALJ's administrative decision dismissing a complaint, the LCD review is remanded to the ALJ and the LCD review continues.

§ 426.489 Board remand authority.

(a) *When the Board may remand a case.* The Board may remand a case to an ALJ, if the ALJ's administrative decision—

(1) Does not comply with § 426.340, § 426.405, § 426.450, § 426.455, or § 426.474; or,

(2) Does not include the following:

(i) Findings of fact.

(ii) Interpretations of law.

(iii) Applications of fact to law.

(iv) Summary of the evidence reviewed.

(v) The signature of the ALJ.

(b) *When the Board may not remand a case.* The Board may not remand a case to an ALJ to review new or additional evidence submitted during the Board review of an LCD complaint.

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

(1) Notify each aggrieved party at his or her last known address, the contractor and CMS of the Board's remand decision; and

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

(d) *Action by an ALJ on remand.* An ALJ will take 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 administrative decision.

A decision by the Board constitutes a final agency action and is subject to judicial review. Neither the contractor nor CMS may appeal a Board administrative decision.

Subpart E—Review of an NCD

§ 426.500 Procedure for filing an acceptable complaint to 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, Room 637D, Humphrey Building, Attention: NCD Complaint, 200 Independence Avenue, SW., Washington, DC 20201.

(b) *Timeliness of a complaint.* The Board must receive a complaint within 6 months of the written statement described in paragraph (c)(1)(vi) of this section.

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

(1) Beneficiary-identifying information:

(i) Beneficiary's name.

(ii) Beneficiary's mailing address.

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

(iv) Beneficiary's telephone number.

(v) Beneficiary's Health Insurance Claim number.

(vi) A copy of the treating physician's certification that, in his or her medical opinion, the beneficiary needs the service that is the subject of the NCD.

(vii) A statement from the treating physician that Medicare coverage for the service needed is likely to be denied under the applicable NCD.

(2) *NCD-identifying information:*

(i) Title of final NCD being challenged.

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

(3) *Aggrieved party statement.* A statement from the aggrieved party explaining the rationale for the allegation that the provision(s) of the NCD is (are) not valid under the reasonableness standard, and whether the aggrieved party has received the service related to the NCD.

(4) *Clinical or scientific evidence.* Copies of clinical or scientific evidence that supports the complaint.

(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.

(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.* The Board must receive a joint complaint within 6 months of the date of the documentation from each aggrieved party's treating physician expressing the belief that payment for the needed service is likely to be denied under the NCD in question.

§ 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 to the review.

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

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

(15) Receive, rule on, exclude, or limit evidence, in accordance with § 426.340.

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

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

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

(19) Issue administrative decisions, including remand orders.

(20) Exclude a party to an NCD review (or a party's representative) for failure to comply with a Board order or procedural request without good cause.

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

(1) Conduct an NCD review or conduct NCD 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) Receive or accept any new evidence without following § 426.340.

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

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

(6) Conduct a review of the merits of an invalid NCD complaint.

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

(8) Compel mediation or settlement negotiations by aggrieved parties.

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

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

(11) Deny CMS the right to repeal an NCD.

(12) Subject to the timely filing requirements, deny an aggrieved party,

CMS, or its contractor the right to appeal an ALJ administrative decision.

(13) Deny CMS the right to conduct an NCD reconsideration review when any party submits new evidence.

(14) Make a determination under § 426.541 before a CMS reconsideration review of new evidence as described in § 426.340.

(15) Find invalid applicable Federal statutes, regulations, or ruling (other than a ruling that meets the definition of an NCD in § 400.202 of this chapter).

(16) Enter an administrative decision defining the specific terms of a subsequent NCD.

§ 426.506 Ex parte contacts

No party or person (except employees of the Board's office) will communicate 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 Board's role in docketing and evaluating the acceptability of NCD complaints.

(a) *Docketing the complaint.* The Board must docket a complaint when it receives a complaint regarding an NCD.

(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 will assume that the facts alleged by the treating physician's statement 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 § 426.320(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 an administrative decision dismissing the unacceptable complaint.

(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.

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

(3) Requests that CMS send a copy of the NCD record to the Board and all parties to the NCD review.

(e) *Consolidation of complaints regarding an NCD*—(1) *Criteria for consolidation.* If two or more aggrieved parties submit separate acceptable complaints to the same provision(s) of the same NCD, the Board may, upon its own motion or by motion of any party to the NCD review, consolidate the complaints and conduct 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.

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

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

(i) Provides notification that the NCD review will be consolidated and informing all parties of the new docket number.

(ii) Makes a single record of the proceeding.

(iii) Considers the relevant evidence introduced in each NCD challenge 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.

§ 426.515 CMS's 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.

§ 426.518 NCD record.

(a) *Elements of the NCD record.* 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 relevant 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) Records from the Food and Drug Administration regarding safety and efficacy of a drug or device except where prohibited by Federal law.

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

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

(b) *Documents excluded from the NCD record.* The NCD record does not include the following:

(1) Material that is privileged or otherwise prohibited from release by Federal law.

(2) Any new evidence.

(3) Proprietary data.

(1) § 426.520 Repealing an NCD under review.

CMS may repeal an NCD under review before the date the Board issues an administrative decision regarding that NCD. Repealing an NCD under review has the same effect as an administrative decision under § 426.560(b).

§ 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 an administrative decision regarding that NCD. The aggrieved party may not file another complaint to 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 notice announcing the intent to withdraw to the Board (see § 426.500) and CMS.

(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 notice announcing the intent to withdraw a complaint regarding an NCD before the date the Board issued an administrative decision regarding that NCD, the Board issues an administrative decision dismissing the complaint under § 426.544 and informing 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 announcing the intent to withdraw a complaint regarding an NCD before the date the

Board issued an administrative decision regarding that NCD, the Board issues an administrative 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 announcing the intent to withdraw a complaint regarding an NCD before the date the Board issued an administrative decision regarding that NCD, the Board removes that aggrieved party from the consolidated NCD review and issues an administrative 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 to state that the NCD record is not complete, not adequate to support the validity of the NCD, or both. Upon receipt of the NCD record, the aggrieved party who submitted the complaint may file a motion alleging that the NCD record is not complete, not adequate to support the validity of the NCD, or both. This motion must be submitted to the Board and CMS within 30 days (or within additional time as allowed by the Board) of the date the aggrieved party receives the NCD record.

(1) If an aggrieved party does not file a motion alleging that the NCD record is incomplete or lacks adequate information to support the validity of the NCD, then the Board makes a determination whether the NCD record is complete and adequate, as described in § 426.530(a).

(2) If an aggrieved party files a motion alleging that the NCD record is not complete, not adequate to support the validity of the NCD, or both, based on clinical and scientific evidence contained in the NCD record, then the Board makes a determination whether the NCD record is complete and adequate, as described in § 426.530(b).

(3) If an aggrieved party files a motion alleging that the NCD record is not complete, not adequate to support the validity of the NCD, or both, based on new evidence, then the Board stays the proceeding upon request by CMS as described in § 426.340.

(b) *The aggrieved party may file a petition with the Board requesting additional time to review the NCD record.* This petition must be submitted to the Board within 30 days (or within additional time as allowed by the Board). This petition shall be in writing, will state the reason(s) why the request for extension is being made, and the amount additional of time needed to review the NCD record. The Board may extend the time for reviewing the NCD case file by an aggrieved party for a reasonable period of time.

§ 426.529 Review following supplemental record.

(a) *Opportunity for the aggrieved party to review the supplemental NCD record.* Upon receipt of the supplemental NCD record following a reconsideration under § 426.340, the aggrieved party who submitted the complaint may file a motion alleging that the NCD record is not complete, not adequate to support the validity of the NCD, or both. This motion must be submitted to the Board and CMS within 30 days (or within additional time as allowed by the Board) of the date the aggrieved party receives the supplemental NCD record.

(1) If an aggrieved party does not file a motion alleging the supplemental NCD record is incomplete or lacks adequate information to support the validity of the NCD, then the Board makes a determination whether the NCD record is complete and adequate, as described in § 426.530(a).

(2) If an aggrieved party files a motion alleging that the NCD record is not complete, not adequate to support the validity of the NCD, or both, based on clinical and scientific evidence contained in the NCD record, then the Board makes a determination whether the NCD record is complete and adequate, as described in § 426.530(b).

(3) If an aggrieved party files a motion alleging that the supplemental NCD record is not complete, not adequate to support the validity of the NCD, or both, based on new evidence, then the Board stays the proceeding upon request by CMS as described in § 426.340.

(b) *Request for additional time to review the CMS's supplemental NCD record by the aggrieved party.* The aggrieved party may file a petition with the Board requesting additional time to review CMS's supplemental NCD record. This petition must be submitted to the Board within 30 days (or within additional time as allowed by the Board). This petition shall be in writing, shall state the reason(s) why the request for extension is being made, and the amount of time needed to review the supplemental NCD record. The Board may extend the time for reviewing the supplemental NCD record for a reasonable period of time.

§ 426.530 Board's role in determining whether the NCD record is complete and adequate to support the validity of the NCD.

(a) If the aggrieved party does not file a motion described in § 426.525(a) or § 426.529(a), the Board reviews CMS's NCD record and applies the reasonableness standard, as described in § 426.531.

(b) If the aggrieved party files a motion described in § 426.525(a) or § 426.529(a), the Board must do the following:

(1) Allow the CMS to submit a statement to the Board and the aggrieved party responding to the motion described in paragraph (a) of this section. This statement must be submitted within 30 days (or within additional time as allowed by the Board) of the date CMS receives the statement from the aggrieved party described in paragraph (a) of this section.

(2) Review the contents of the NCD record, as described in § 426.518.

(3) Hold conferences, if necessary, which may be conducted (at the Board's discretion) either in person, or, by mutual agreement of the parties, by telephone, picture-tel, or any other means agreed upon by all parties involved.

(4) Determine if the NCD record is complete and adequate to support the validity of the NCD.

(c) Board's determination of the completeness of the NCD record, and the determination of CMS's NCD record's adequacy to support the validity of the NCD:

(1) *Board determination that the NCD record is complete and adequate to support the validity of the NCD.* If the Board determines that the NCD record is complete and adequate to support the validity of the NCD, the Board does the following:

(i) Sends a letter to the aggrieved party, the contractor, and CMS stating that the Board finds the NCD record to be complete and adequate to support the validity of the NCD.

(ii) Reviews the provision(s) of the NCD named in the complaint based on the reasonableness standard as described in § 426.531.

(2) *Board determination that the CMS's NCD record is not complete, not adequate to support the validity of the NCD, or both.* If the Board determines that CMS's NCD record is not complete, not adequate to support the validity of the NCD, or both, the Board does the following:

(i) Sends a letter to the aggrieved party and CMS stating that the NCD record is not complete, not adequate to support the validity of the NCD, or both.

(ii) Allows discovery as described in § 426.532.

(iii) Upon admission of new evidence, follows the process for review of new evidence as described in § 426.340.

(iv) Reviews the provision(s) of the NCD named in the complaint to apply the reasonableness standard as described in § 426.531.

§ 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) named 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 filed with the Board, and to clinical or scientific evidence that is contained in the NCD record (or supplemental record).

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

(3) Issue an administrative decision as described in § 426.547.

(b) *Optional steps.* The Board may do the following to apply the reasonableness standard to the provision(s) named in the aggrieved party's complaint:

(1) Conduct a hearing, and allow subpoenas as described in § 426.535 and the taking of evidence as described in § 426.540.

(2) At a hearing, consult with appropriate scientific or clinical experts concerning clinical or scientific evidence.

(3) Consider any previous Board administrative decision made under § 426.547 regarding the same provision(s) of the NCD under review.

(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 the applicable provisions of the following:

(1) The Social Security Act.

(2) CMS regulations.

(3) CMS rulings.

(4) NCDs.

§ 426.532 Discovery.

(a) *General rules.* If the Board orders discovery, the Board does the following:

(1) Establishes a reasonable time frame for discovery.

(2) Ensures that a party to the NCD review who receives a discovery request has certain rights, which include, but are not limited to, the following:

(i) The right to select and use an attorney or other representative during the discovery process.

(ii) The right to submit discovery responses, objections, motions, or other pertinent materials to the Board.

(3) Ensures that a nonparty to the NCD review who receives a discovery request has the same rights in responding to a discovery request as any party.

(b) *Protective orders*—(1) *Request for a protective order.* Any party or nonparty 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 protective order if it finds that the discovery sought—

(i) Is irrelevant;

(ii) Is unduly costly or burdensome;

(iii) Will unduly delay the proceeding;

(iv) Is privileged under Federal law; or

(v) Is proprietary data.

(c) *Types of discovery available.* A party may make a request to another party or nonparty for production of documents 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, written interrogatories, or any other forms of discovery, other than those permitted under paragraph (d) of this section, are not authorized.

(f) *Privileged documents*—(1) *Options for the Board.* The Board may, in appropriate circumstances, do any of the following:

(i) Order CMS to provide an index of any documents withheld on the basis of privilege and to state the basis for the privilege claim.

(ii) Conduct an in-camera review of any documents withheld on the basis of privilege.

(2) *Confidentiality.* If the Board orders the release of any document when privilege was asserted, the Board must order that all names or identifying information that is not relevant to the specific NCD must be redacted from the document.

§ 426.535 Subpoenas.

(a) *Purpose of a subpoena.* A subpoena requires the attendance of an individual at a hearing and may also require the individual (whether or not the individual is 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 the witnesses or documents and whether the facts could be established by other evidence 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.* The Board may modify the deadlines specified in paragraphs (b) and (c) of this section for good cause.

(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 Board.

(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 Social Security 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 will serve 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)).

§ 426.540 Evidence.

(a) The Board determines the admissibility of evidence consistent with § 426.340.

(b) 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.

(c) The Board must exclude evidence that it determines is clearly irrelevant or immaterial.

(d) Although relevant, the Board must exclude evidence if the Board determines it is privileged under Federal law.

(e) Consistent with § 426.340, the Board may permit the parties to introduce the testimony of scientific and clinical experts, rebuttal witnesses, and other relevant evidence, only if the testimony is related to evidence that was considered in the NCD. This testimony may be submitted in the form of a written report, accompanied by the curriculum vitae of the expert preparing the report.

(f) 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.

(g) All documents and other evidence offered or taken for the record will be open to examination by all parties, unless otherwise ordered by the Board for good cause shown.

§ 426.541 Closing discovery.

Upon completion of discovery, the Board will notify all parties in writing that the discovery period is closed.

§ 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 (or his or her representative) fails to do either of the following:

(1) Attend or participate in a prehearing conference or hearing without good cause.

(2) Comply with a lawful order of the Board.

(b) The Board must dismiss any provision(s) of a complaint in any of the following circumstances:

(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.)

(3) The complaint is not filed by an aggrieved party, or is filed by an individual who is unable to demonstrate that he or she is in need of a particular service. (See § 426.500.)

(4) The aggrieved party no longer needs the service because the aggrieved party has received the service before the aggrieved party filed the complaint with the Board, except for an individual who has a continuing need for a particular item or service that is subject to an NCD.

(5) The complaint challenges a provision or provisions of an LCD except as provided in § 426.476. (See § 426.505.)

(6) CMS notifies the Board that the NCD is no longer in effect. (See § 426.520.)

(7) The aggrieved party withdraws the complaint. (See § 426.523.)

(8) The aggrieved party is deceased.

(9) Nothing in the preceding list of circumstances leading to automatic dismissal shall be construed as having any force and effect concerning the legal rights of representatives of a deceased beneficiary to properly pursue settlement of a claim.

(c) The Board may, at the request of any party, or on his or her own motion, dismiss a complaint if the Board has already issued an administrative decision on the NCD or provisions of an NCD and the aggrieved party has not presented any new clinical or scientific evidence that supports the complaint.

§ 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 is an expert, he or she will be entitled to an expert witness fee. Witness fees will be 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.

§ 426.546 Record of hearing.

The Board must ensure that all hearings are open to the public and must be mechanically or stenographically reported. All evidence upon which the Board relies for decision must be contained in the transcript of testimony, either directly or by appropriate reference. All medical reports, exhibits, and any other pertinent document or record, either in whole or in material part, introduced as evidence, must be marked for identification and incorporated into the record.

§ 426.547 Issuance, notification, and posting of a Board's administrative decision.

The Board must do all of 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 administrative decision, including a description of appeal rights.

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

(b) Make the administrative decision available on the Internet located at the Medicare Internet site of the Department of Health and Human Services. The posted decision will not include any information that would identify any individual, provider of service, or supplier.

§ 426.550 Mandatory provisions of the Board's administrative decision.

(a) *Finding.* The Board's administrative 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.

(b) *Other information.* The Board's administrative decision must include all of the following:

(1) The date of issuance.

(2) The docket number of the NCD review.

(3) The names of the parties to the NCD review.

(4) 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.

(5) A rationale for the basis of the Board's administrative decision, including the following:

(i) Findings of fact.

(ii) Interpretations of law.

(iii) Applications of fact to law.

(6) A summary of the evidence reviewed.

(7) A statement regarding the right to judicial review.

(8) The signature of a Board member.

§ 426.555 Prohibited provisions of the Board's administrative decision.

The Board's administrative decision must not do any of the following:

(a) Order CMS to modify (including adding to or deleting from) a provision or provisions of an NCD.

(b) Order CMS to pay a specific claim.

(c) Establish a time limit for the establishment of a new or revised NCD.

(d) Review, evaluate, or address an NCD other than the NCD under review.

(e) Include a requirement for CMS 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.

§ 426.560 Effect of the Board's administrative 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 will instruct its contractor, M+C plan, or other Medicare managed care plan to provide the following relief.

(1) *Individual claim relief when a claim is pending or has been previously adjudicated.* If an aggrieved party's claim/appeal(s) had previously been denied, the contractor, an M+C plan, or another Medicare managed care plan must reopen the aggrieved party's claim and adjudicate the claim without using the provision(s) of the NCD that the Board found invalid.

(2) *Individual claim relief when no claim is pending.* If a revised NCD is issued, contractors, M+C plans, and other Medicare managed care plans must use the revised NCD in reviewing claim/appeal submissions or request for service for items delivered or services performed on or after the effective date.

(3) *Coverage determination relief.* Within 30 days of the issuance of the Board's administrative decision, CMS must send a letter to the Board and the aggrieved party or parties named in the complaint announcing the intent to do one of the following:

(i) Repeal the NCD in its entirety, or repeal the provision or provisions of the NCD that the Board's administrative decision stated was (were) not valid under the reasonableness standard.

(ii) Conduct a reconsideration using the information collected during the NCD review, as well as any other applicable information, and do one of the following:

(A) Supplement the NCD record or rationale, and issue a new NCD.

(B) Revise the NCD.

(C) Repeal the NCD.

(iii) Unless repealed under paragraph (b)(3)(i) or (b)(3)(ii)(C) of this section, the contractor may continue to use the NCD in adjudicating claims for individuals who did not challenge the NCD while a reconsideration is pending.

§ 426.562 Notice of the Board's administrative decision.

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

(a) Contain a finding with respect to the NCD complaint; 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.

§ 426.565 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 § 426.567).

§ 426.567 Board's NCD review record.

(a) *Elements of the Board's NCD review record.* 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) The Board's administrative decision.

(5) Transcripts of record.

(6) Any other relevant evidence gathered under § 426.540.

(b) *Documents excluded from the contractor/CMS' NCD record.* The NCD record does not include material that is privileged or otherwise prohibited from release by Federal law.

§ 426.570 Board administrative decision.

A decision by the Board constitutes a final agency action and is subject to judicial review. CMS may not appeal a Board administrative decision.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 26, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 16, 2002.

Tommy G. Thompson,

Secretary.

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