

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

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

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

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

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

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

- (1) A determination that the provision of the LCD is valid under the reasonableness standard.
- (2) A determination that the provision of the LCD is not valid under the reasonableness standard.
- (3) A statement dismissing the complaint regarding the LCD and a rationale for the dismissal.
- (4) A determination that the LCD record is complete and adequate to support the validity of the LCD provisions under the reasonableness standard.

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

- (1) The date of issuance.
- (2) The docket number of the LCD review.
- (3) A statement as to whether the aggrieved party has filed a claim for the service(s) named in the complaint, the date(s)-of-service, and the disposition, if known.
- (4) A basis for concluding that the LCD was or was not valid based on the application of the reasonableness standard to the record before the ALJ, including the contractor's:

- (i) Findings of fact.
- (ii) Interpretations of law.

(iii) Applications of fact to law.

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

(6) A statement regarding appeal rights.

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

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

- (a) Order CMS or its contractors to add any language to a provision or provisions of an LCD.
- (b) Order CMS or its contractors to pay a specific claim.
- (c) Set a time limit for CMS or its contractors to establish a new or revised LCD.
- (d) Review or evaluate an LCD other than the LCD under review.
- (e) Include a requirement for CMS or its contractors that specifies payment, coding, or systems changes for an LCD, or deadlines for implementing these types of changes.
- (f) Order or address how a contractor(s) must implement an LCD.

**§ 426.457 Optional provisions of an ALJ's decision.**

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

**§ 426.458 ALJ's LCD review record.**

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

- (1) The LCD complaint.

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- (2) The LCD and LCD record.
- (3) The supplemental LCD record, if applicable.
- (4) Transcripts of record.
- (5) Any other relevant evidence gathered under § 426.440.
- (6) The ALJ's decision.
- (b) *Elements of the ALJ's LCD review record furnished to the Board under seal.* The ALJ's review record must include, under seal, any proprietary data or privileged information maintained under seal, and such data or information must not be included in the review record furnished to the public.

#### § 426.460 Effect of an ALJ's decision.

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

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

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

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

(iii) If the aggrieved party who sought the review has not yet submitted a claim, the contractor adjudicates the claim without using the

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provision(s) of the LCD that the ALJ found invalid.

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

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

#### § 426.462 Notice of an ALJ's decision.

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

(a) State the outcome of the review; and

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

#### § 426.463 Future new or revised LCDs.

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

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

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

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

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

(b) *Circumstance under which a contractor or CMS may appeal part or all of an ALJ's decision.* A contractor or CMS may appeal to the Board any part of an