§ 426.415  CMS’ role in the LCD review.

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

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

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

§ 426.417  Contractor’s statement regarding new evidence.

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

(1) New evidence submitted with the initial complaint;
(2) New evidence submitted with an amended complaint;
(3) New evidence produced during discovery;
(4) New evidence produced when the ALJ consults with scientific and clinical experts; and
(5) New evidence presented during any hearing.

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

§ 426.418  LCD record furnished to aggrieved party.

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

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

(i) Scientific articles.
(ii) Technology assessments.
(iii) Clinical guidelines.
(iv) Statements from clinical experts, medical textbooks, claims data, or other indication of medical standard of practice.
(3) Comment and Response Document (a summary of comments received by