

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

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

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

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

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

In § 426.416 and § 426.516, we describe the role of Medicare managed care organizations and Medicaid State

agencies in the LCD and NCD review process. In § 426.417 and § 426.517, we describe the role of contractors and CMS in reviewing any new evidence.

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

In § 426.420(a) and (b), we allow a contractor to retire the LCD under review or revise the LCD to remove or amend the provision in question before the date the ALJ issues a decision regarding the LCD. Retiring an LCD (or provision of the LCD) means that the contractor may no longer use that LCD in the adjudication of claims on a prospective basis. We also provide the aggrieved party individual claim review under § 426.460(b). Thus, in most cases, there would no longer be a need for an LCD review because relief would be provided. In § 426.520(a), we may withdraw an NCD under review or revise an NCD to remove or amend the provision in question before the date the Board issues a decision regarding that NCD. Withdrawing an NCD (or provision of the NCD) means this policy is no longer a controlling authority for our contractors and certain adjudicators. Thus, there no longer would be a need for an NCD review. In § 426.420(b), § 426.420(c), § 426.420(d), § 426.420(e) and § 426.520(b), § 426.520(c),

§ 426.520(d), § 426.520(e), we describe the process for LCDs and NCDs that are revised or reconsidered while under review. In cases where an LCD/NCD provision(s) has been revised, but not completely removed, the review continues because relief may not have been provided. This responds to comments received, and will ensure that aggrieved parties receive coverage relief when they prevail.

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

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

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