

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

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

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

#### *Definition of an Aggrieved Party*

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

*Response:* In response to these comments, we have interpreted the statutory requirements more broadly and have expanded the definition of aggrieved party to require that the beneficiary be in need of coverage of a service. Therefore, the definition includes beneficiaries who have already received the service. We believe this

change obviates the need for an emergency appeals process because a beneficiary can obtain an emergency service and then seek review without forgoing his or her rights. In order to define which beneficiaries have standing as aggrieved parties, we have added a requirement in § 426.400(b)(2) and § 426.500(b)(2) that aggrieved parties, who have received a service and have filed a claim, must file their section 522 challenge within 120 days of the date of the initial denial notice from the contractor.

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

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

#### *Allowing a Beneficiary To Assign Appeal Rights*

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

On the other hand, one commenter noted that the statute requires a beneficiary in need to initiate a review. Another commenter agreed with our proposal, and believed it would be inappropriate under the statute to permit the assignment of rights to request a review of an LCD or NCD to other interested parties. That

commenter noted that the "Medicare program is fundamentally a beneficiary, or patient, program designed to assure access to clinically sound services."

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

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

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

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

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