Review of National Coverage Determinations and Local Coverage Determinations and Supporting Regulations in 42 CFR, 426.400 and 426.500

A. Background

Section 522 of the Benefits Improvement and Protection Act (BIPA) of 2000 requires the implementation of a process for the appeal of National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs). The Final Rule, CMS-3063-F (68 FR 63692) revises, refines and finalizes the process proposed in the Notice of Proposed Rulemaking, published in August 2002. This Final Rule creates a new process to allow certain Medicare beneficiaries to challenge national coverage determinations (NCDs) and local coverage determinations (LCDs).

B. Justification

1 . Need and Legal Basis

Section 522 of the Benefits Improvement and protection Act (BIPA) of 2000 requires the implementation of a process for the appeal of National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs). This Final Rule distinguishes the right to challenge NCDs and LCDs from the existing appeal rights that Medicare beneficiaries have for the adjudication of Medicare claims.

2. Information Users

The information provided will be used by the Administrative Law Judge and/or the Departmental Appeals Board to determine whether the policy being challenged is reasonable.

3. Use of Information Technology

The collection of this information does not currently involve the use of technological collection techniques.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

This does not have a significant economic impact on small businesses.

6. Less Frequent Collection

This collection is necessary as described to implement the appeals process required by section 522 of the Benefits Improvement and Protection Act.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice for this resubmission of the information collection request published on January 26, 2007.

The final rule (68 FR 63692) published on November 7, 2003.

The proposed rule (67 FR 54534), published August 22, 2002, and solicited comments on the policies.

Some commenters stated their belief that the complaint filing process in the proposed rule was overly complex. One commenter suggested that complaints should be deemed acceptable if sent to the ALJ, the local Social Security office, carrier or fiscal intermediary (FI), or the Board.

We have revised the final rule to simplify and clarify the complaint filing procedures and to make them more beneficiary-friendly. We have eliminated a number of requirements that we believe are unnecessary.

Additionally, some commenters stated that physician documentation of medical need is a reasonable way of determining whether beneficiaries have a basis for challenging LCDs/NCDs. However, other commenters felt that the physician certification requirements imposed unnecessary new paperwork burdens on physicians. Some commenters argued that it was unrealistic to require physicians to be certain of the intricacies of Medicare policies. Others felt these requirements would prove to be a significant impediment to the process and suggested that the original physician order for the service suffice as certification that the beneficiary needed the service. Finally, a number of commenters suggested that non-physician practitioners should be allowed to document the beneficiary's need.

In response, we have revised the certification requirements at §§ 426.400(c) and 426.500(c) in the final regulation in three significant ways. First, we have revised the language to allow a beneficiary's treating practitioner--not just the treating physician--to provide the certification of need. Second, we have clarified that the certification of need can be in the form of a written order for the service in question or other documentation in the medical record. Third, we have removed the requirement that the practitioner predict that payment would be denied.

Outside consultation was unnecessary for the purposes of these policies.

9. Payments/Gifts to Respondents

There are not payments or gifts to respondents.

10. Confidentiality

N/A

11. Sensitive Questions

N/A

12. Burden Estimates (Hours & Wages)

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. These sections also identify the information required in the complaint to qualify as an aggrieved party as defined in §426.110, as well as the process and information needed for an aggrieved party to withdraw a complaint. The required documentation includes a copy of the written authorization to represent the beneficiary, if the beneficiary has a representative, and a copy of a written statement from the treating practitioner that the beneficiary needs a service that is the subject of the LCD.

We continue to estimate that there will be 1,000 LCD complaints per year and that it will take the aggrieved party 4 hours to draft the complaint and gather the information to send to us. The national burden would be 4,000 hours annually. We estimate that there will be 20 to 40 NCD complaints per year. It will take 4 hours, maximum, to gather the information and to write each complaint. Thus, we estimate a total of 160 hours per year to comply with the requirement.

The estimate of 4 hours is based on previous experience in both the local and national coverage development processes, and the estimated time to submit beneficiary and policy-specific information (for example, name, address, and policy challenged) and collect and photocopy scientific and clinical evidence. It should actually take less than that amount of time in NCD challenges, since the aggrieved party has already sent us the information and merely has to send it again.

13. Capital Costs

No annualized costs are expected for implementation of the data collection elements of the policies.

14. Cost to Federal Government

N/A

15. Changes to Burden

Upon further review, the estimates of burden hours are accurate and therefore, remain the same.

16. Publication/Tabulation Dates

N/A

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

No exceptions are requested.

C. Collections of Information Employing Statistical Methods

This collection does not employ statistical methods.