previously guaranteed under 38 U.S.C. 3712, the loan term, if being refinanced under 38 U.S.C. 3710(a)(9)(B)(i), may exceed the original term of the loan but may not exceed the maximum loan term allowed under 38 U.S.C. 3703(d)(1).

(Authority: 38 U.S.C. 3703(c)(1), 3710(e)(1))

* * * * *

3. In § 36.4337, paragraph (a) is revised to read as follows:

**§ 36.4337 Underwriting standards, processing procedures, lender responsibility and lender certification.**

(a) *Use of standards.* The standards contained in paragraphs (c) through (j) of this section will be used to determine that the veteran's present and anticipated income and expenses, and credit history are satisfactory. These standards do not apply to loans guaranteed pursuant to 38 U.S.C. 3710(a)(8) except for cases where the Secretary is required to approve the loan in advance under § 36.4306a.

(Authority: 38 U.S.C. 3703, 3710)

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[FR Doc. 98–14644 Filed 6–2–98; 8:45 am]

BILLING CODE 8320–01–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 159

**[OPP–60010I; FRL–5792–1]**

**RIN 2070–AB50**

### Reporting Requirements for Risk/Benefit Information, Final Rule and Corrections; Notification to the Secretary of Agriculture

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notification to the Secretary of Agriculture.

**SUMMARY:** Notice is given that the Administrator of EPA has forwarded to the Secretary of Agriculture a final regulation and notice of corrections under section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The rule is to make a minor amendment and several technical corrections to the final regulations published on September 19, 1997 (62 FR 49370)(FRL–5739–1) which codified EPA's interpretation and enforcement policy regarding the requirement of pesticide registrants to report information concerning unreasonable adverse effects of their products as mandated in section 6(a)(2) of FIFRA. EPA is issuing a final rule to amend the definition of a registrant in the regulation to comport with that which is in the statute. The Agency is also making several technical corrections to the regulation for clarification purposes.

**FOR FURTHER INFORMATION CONTACT:** by mail: Carol Peterson, Policy and Regulatory Services Branch, Field and External Affairs Division (7506C), Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, e-mail address: Room 1114D, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA; telephone number: 703–305–6598; e:mail address: peterson.carol@epa.gov.

**SUPPLEMENTARY INFORMATION:** Section 25(a)(2) of FIFRA provides that the Administrator shall provide the Secretary of Agriculture a copy of any final regulation at least 30 days before signing it for publication in the **Federal Register**. If the Secretary comments in writing regarding the final regulation within 15 days after receiving it, the Administrator shall issue for publication in the **Federal Register**, with the final regulation, the comments of the Secretary, if requested by the Secretary, and the response of the Administrator concerning the Secretary's comments. If the Secretary does not comment in writing within 15 days after receiving the final regulation, the Administrator may sign the regulation for publication in the **Federal Register** anytime thereafter.

#### I. Regulatory Assessment Requirements

This action does not impose any requirements. As such, this action does not require review by the Office of Management and Budget (OMB) under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). For the same reason, it does not require any action under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4), Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). In addition, since this type of action does not require any proposal, no action is needed under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*).

#### II. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule, as that term is defined in 5 U.S.C. 804(3).

#### List of subjects

Environmental protection, Pesticides and pest, Policy statements, Reporting and recordkeeping requirements.

**Authority:** 7 U.S.C. 136 et seq.

Dated: May 21, 1998.

**Stephen L. Johnson,**

*Acting Director, Office of Pesticide Programs.*

[FR Doc. 98–14438 Filed 6–2–98; 8:45 am]

BILLING CODE 6560–50–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

### 42 CFR Chapter IV

**[HCFA–3250–NOI]**

**RIN 0938–AI92**

### Medicare Program; Coverage and Administrative Policies for Clinical Diagnostic Laboratory Tests; Intent to Form Negotiated Rulemaking Committee

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Notice of Intent to Form Negotiated Rulemaking Committee and Notice of Meetings.

**SUMMARY:** The Balanced Budget Act of 1997 requires the Secretary to establish a Negotiated Rulemaking Committee under the Negotiated Rulemaking Act and the Federal Advisory Committee Act. The Negotiated Rulemaking Committee's (the Committee) purpose will be to negotiate national coverage and administrative policies for clinical diagnostic laboratory tests under Part B of the Medicare program as required by the Balanced Budget Act of 1997 (BBA). The Committee will consist of representatives of interested parties that are likely to be significantly affected by the proposed rule. The Committee will be assisted by a neutral facilitator.

The BBA outlines the scope of issues to be negotiated by the Committee. We specifically request pubic comment as to whether we have identified the interests that will be affected by key issues listed below.

**DATES:** Comments and requests for representation or for membership on the

Committee will be considered if we receive them at the appropriate address provided below, no later than 5 p.m. on July 6, 1998.

The first meeting will be held at Turf Valley Hotel in Ellicott City (Baltimore) at 9 a.m. on July 13, 14, and 15, 1998; (410) 465–1500.

**ADDRESSES:** Mail written comments and requests for representation or for membership on the Committee, or nominations of another person for membership on the Committee (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of health and Human Services, Attention: HCFA–3250–N, P.O. Box 26688, Baltimore, MD 21207–5187.

Mail a separate copy of written comments to the following address: Grant Bagley, M.D., Director, Coverage and Analysis Group, Office of Clinical Standards and Quality, Mail Stop S3–02–01, Health Care Financing Administration, 7500 Security Blvd., Baltimore, Maryland 21244–1850.

If you prefer, you may deliver your written comments, applications, or nominations (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on electronic filing, see **SUPPLEMENTARY INFORMATION.**

**FOR FURTHER INFORMATION CONTACT:** Grant Bagley, M.D., (410) 786–7176, or Jackie Sheridan (410) 786–4635, for general issues related to clinical diagnostic Laboratory tests. Judy Ballard, (202) 690–7419, or Nancy Rubenstein, (202) 690–8246, Conveners.

**SUPPLEMENTARY INFORMATION:** Comments may also be submitted electronically to the following e-mail address: (filecode hcfa3250noi)hcfa.gov. E-mail comments must include the full name and address of the sender, and must be submitted to the referenced address in order to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments. Electronically submitted comment will be available for public inspection at the Independence Avenue address, below. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–3250–NOI. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 300 Independence Avenue, SW, Washington, DC., on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

*Copies:* To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $8. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register.**

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## I. Balanced Budget Act of 1997

Section 4554(b)(1) of the Balanced Budget Act of 1997 (BBA), Public Law 105–33, mandates adoption, by January 1, 1999, of national coverage and administrative policies for clinical diagnostic laboratory tests under Part B of title XVIII of the Social Security Act using negotiated rulemaking. Section 4554(b)(2) provides that these national policies must be ''designed to promote program integrity and national uniformity and simplify administrative requirements with respect to clinical diagnostic laboratory tests'' payable under Part B in connection with the following:

- Beneficiary information required to be submitted with each claim or order for laboratory tests;
- The medical conditions for which a laboratory test is reasonable and necessary;
- The appropriate use of procedure codes in billing for a laboratory test, including the unbundling of laboratory services;
- The medical documentation that is required by a Medicare contractor at the time a claim is submitted for a laboratory test;
- Recordkeeping requirements in addition to any information required to be submitted with a claim, including physicians' obligations regarding such requirements;
- Procedures for filing claims and for providing remittances by electronic media; and
- Limitation on frequency of coverage for the same tests performed on the same individual.
- The legislative history of BBA suggests that section 4554 was enacted in response to variations among carriers' requirements for laboratories filing claims for payment.

## II. Negotiated Rulemaking Process

Section 4554 of the BBA provides that these negotiations take place within the framework of the Negotiated Rulemaking Act (Pub. L. 101–648, 5 U.S.C. 561–570). Under the Negotiated Rulemaking Act, the head of an agency generally must consider whether—

- There is a need for a rule;
- There are a limited number of identifiable interests that will be significantly affected by the rule;
- There is a reasonable likelihood that a committee can be convened with a balanced representation of persons who—

+ Can adequately represent the interests identified; and

+ Are willing to negotiate in good faith to reach a consensus on the proposed rule;

- There is a reasonable likelihood that a committee will reach a consensus on the proposed rule within a fixed period of time;
- The negotiated rulemaking procedure will not unreasonably delay the notice of proposed rulemaking and the issuance of a final rule;
- The agency has adequate resources and is willing to commit such resources, including technical assistance, to the Committee; and
- The agency, to the maximum extent possible, consistent with the legal obligations of the agency, will use the consensus of the Committee with respect to the proposed rule as the basis for the rule proposed by the agency for notice and comment.

Negotiations are conducted by a Committee chartered under the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2). The Committee includes

an agency representative and is assisted by a neutral facilitator. The goal of the Committee is to reach consensus on the language or content of a rule. If consensus is reached, it is used as the basis of the agency's proposal. The process does not affect otherwise applicable procedural requirements of the FACA, the Administrative Procedure Act, and other statutes.

The Negotiated Rulemaking Act permits (but does not require) an agency to use the services of an impartial convener to assist the agency in identifying interests that will be significantly affected by the proposed rule, including residents of rural areas, and conducting discussions with persons representing the identified interests to ascertain whether the establishment of a negotiated rulemaking committee is feasible and appropriate in the particular rulemaking. At the agency's request, the convener also ascertains the names of persons who are willing and qualified to represent interests that will be significantly affected by the rule. The agency may also ask the convener to recommend a process for the negotiations. The convener submits a written report, which is available to the public. Pursuant to this procedure authorized by the Negotiated Rulemaking Act, we asked Judy Ballard and Nancy Rubenstein, who are with the Departmental Appeals Board (DAB) to act as convener for the negotiated rulemaking on laboratory policies. Over the last several months, they met with a wide range of organizations that were identified as having a possible interest in this negotiated rulemaking. They submitted to HCFA a report based on those convening interviews, which serves as a basis for this notice. This report lists the proposed representatives on the Committee. The convening report is a public document and may be found on the HCFA Internet website at http://www.hcfa.gov/quality/qlty-8a.

## III. Subject and Scope of the Rule

### *A. General*

During the convening process, a number of issues were presented by the interested parties for negotiations as described below. We believe it is important to have an opportunity to engage in discussions with the interested parties on the issues that were presented. Many of these issues need clarification and a common understanding before regulations can be developed. We believe it is important that the Committee meetings include ample opportunity for such clarifications.

Many of the issues raised by identified interested parties were based on the current laboratory coverage policies and claims processing systems. It is important to take into consideration how these current processes have been affected by the changes mandated by other subsections of section 4554 of the BBA. This provision of the law likely will mitigate some of the problems identified. For example, the law permits a carrier to develop and implement interim policies for laboratory services when there is a demonstrated need for a policy due to aberrant utilization or provision of unnecessary tests. The law provides that interim national policies developed by carriers are effective for no more than two years when no national policies exist, and provides an opportunity for public participation in the biennial review of national policies.

As outlined in section 4554(b) of the BBA, the scope of the rule will be the development of coverage and administrative policies for clinical laboratory services that are designed to promote program integrity and national uniformity while simplifying administrative requirements. Consensus related to administrative simplification for laboratory services must comply with the limitations imposed by the administrative simplification provisions in section 261 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA requires the Secretary to establish standards and requirements for the electronic transmission of claims and other information that will be used throughout the health insurance industry.

Given that there are limited time and resources for these negotiations, it is critical that a process for coverage policy concerning laboratory tests be developed. Clearly, time constraints may prevent the development of test-specific policies for all laboratory tests. HCFA, therefore, proposes that the Committee negotiate a process for coverage and administration capable of uniform application throughout the country that takes into account the statutory boundaries within which HCFA must administer the Medicare program.

Many of the issues identified during the convening interviews related to administrative policies associated with claims submission, documentation, and recordkeeping. These administrative issues will be negotiated to the extent that they are within the framework of section 4554(b) of the BBA as discussed below.

### *B. Issues and Questions to be Resolved*

#### 1. Beneficiary Information on Claims

Under current Medicare policy, laboratory tests furnished in physicians' offices and by independent laboratories are reported on a HCFA–1500, while hospital laboratory services are reported on a UB–92 form. Virtually all claims from independent clinical laboratories, hospital laboratories, and a substantial number of claims for laboratory services performed in physician office laboratories are submitted using electronic versions of these forms.

During the convening process, interested parties raised issues regarding application of general Medicare coverage and administrative policies to the laboratory industry. Two specific issues interviewees wished to negotiate concerned the documentation necessary to substantiate that skilled nursing care patients were in beds certified as skilled nursing facilities for Medicare purposes (and consequently, subject to rebundling), and the use of the standard form HCFA–1500 for submitting Medicare claims for laboratory services. To the extent that these issues are directly related to the categories of items delineated in section 4554(b)(2) of the BBA, they are within the scope of the negotiations. Thus, the applicability of general Medicare policies regarding beneficiary information required on claims for laboratory services is within the framework of these negotiations.

#### 2. Medical Conditions for Which a Laboratory Test is Covered

Section 4554 of the BBA mandates that HCFA use the negotiated rulemaking process to develop national coverage and administrative policies for clinical diagnostic laboratory tests under Medicare Part B. While HCFA and the clinical laboratory industry understand and support the need for national uniformity in terms of policy, both recognize the practical difficulty of addressing and developing coverage policies for all laboratory tests within the time provided in the negotiated rulemaking process. As a result, the Committee will focus on negotiating the medical conditions for which specific tests are covered for a subset of tests that have been identified as priorities by the Committee members after the process for making this determination has been negotiated.

In the interest of expediting this phase in the negotiation process, HCFA proposes that the facilitator work with Committee members prior to the first meeting to develop a recommended list of tests that will be specifically discussed during the negotiations. We

expect that those tests designated as priorities by the Committee will likely fulfill at least one of the following criteria:

- It is subject to wide divergence in coverage among local Medicare carriers,
- It is a high-volume test, or
- Its medical utility or clinical effectiveness is considered controversial.

The Committee will negotiate and reach consensus on a list of priority tests. Using a process developed by the Committee, the Committee will then negotiate and attempt to reach consensus on the medical condition for which these specific tests will be covered.

3. Use of Appropriate Procedure Codes in Billing

Laboratory services are reported to HCFA using the HCFA Common Procedure Coding System (HCPCS). A major component of this system is the American Medical Association's Current Procedural Terminology (CPT). In addition, HCFA requires diagnosis reporting on all claims. Diagnosis is coded using the International Classification of Diseases, Ninth Edition, Clinical Modification (ICD–9–CM).

Medicare contractors that process claims are charged with the development of local medical review policies to apply safeguards against inappropriate expenditures of program funds. Local policies are a means of applying local coverage decisions where national policies do not exist. Unlike most national coverage policies, which are generally narrative statements, nearly all local medical review policies are at the code-specific level.

We recognize that the level of understanding of coding conventions is not uniform among the laboratory industry, community physicians ordering clinical diagnostic testing, and our contractors. Clearly, there is some confusion and misunderstanding among the parties with regard to application of the coding guidelines to specific circumstances. For example, during convening, interviewees reported that historically there have been problems with coding multichannel automated testing.

This is an issue of application of general Medicare policies to the laboratory industry. HCFA believes that it is appropriate for the Committee to discuss specific coding guidelines to seek clarification as part of the development of specific national coverage and administrative policies for laboratory tests identified as priorities. Thus, for example, it may be appropriate for the Committee to negotiate policies for automated multichannel testing, including clarification of coding guidelines. To the extent that coding issues are related to the coverage policies under discussion, they are within the scope of the negotiations.

4. Medical Documentation Required with Claim

During the convening interviews, interested parties identified issues with respect to the medical documentation required on a claim. One issue dealt with the documentation the physician should submit to the laboratory in order for the laboratory to submit the claim. Another issue concerned assuring consistent action by the contractors when the documentation submitted with the claims is insufficient.

We believe the first issue of medical documentation requirements would be an inherent part of the negotiations of individual coverage policies. That is, if the Committee determines that coverage policy for a given tests should be developed on a diagnosis code-specific level, then reporting of the diagnosis code would be required for that policy. In other situations, the Committee could determine that a code was not satisfactorily specific for the coverage policy, so alternative documentation may be required. The Committee may also determine that coverage policy should be established more broadly using a narrative format rather than a detailed policy developed on a code-specific level. Clearly, this issue will be discussed in depth as part of the negotiations on the national coverage policies.

The second issue concerning contractor actions in response to insufficient documentation was suggested as an issue for negotiation. A broad view of the language of section 4554(b) of the BBA places this issue within the scope of the negotiations. Therefore, we are willing to have this matter brought before the Committee for discussion.

5. Recordkeeping Requirements in Addition to Claims Information

During the convening interviews, the issue of recordkeeping and retention by laboratories and physicians who order laboratory tests was raised. We believe that it is appropriate to negotiate with respect to the types of records that should be maintained, who bears responsibility for maintaining documentation, and the period of time that records should be stored. In this regard, we are currently working under an initiative to reduce paperwork burden on the public, including clinical laboratories. We share the sentiment expressed by many interested parties that the recordkeeping requirements should be nationally uniform, simple, consistent with patient confidentiality requirements, and that a balance should be developed between program integrity concerns and the burden placed on the provider.

6. Procedures for Filing Claims and Providing Remittances Electronically

Electronic claims submission is within the scope of these negotiations as outlined by section 4554(b)(2) of the BBA. Consensus related to administrative simplification must comply with section 261 of HIPAA. Two specific issues were presented in regard to this topic. First, interested parties have voiced concern about the lack of uniformity among the carriers in the way claims are reviewed. For example, there is variation in how many and in what order the ICD–9–CM diagnosis codes are reviewed to determine if they justify medical necessity. Second, there is a concern that there may be a future requirement for electronic filing of claims. While cost laboratories already file claims electronically, small laboratories, including physician office laboratories, are concerned that such electronic filing may become mandatory in the future and would be burdensome.

With regard to the lack of uniformity in the way in which carrier systems review claims, we acknowledge that differences exist in the way contractor systems analyze claims and that these differences do result in inconsistencies that are particularly problematic for the Laboratory industry. We note that the two events will significantly improve this situation over the next several years. First, under section 4554(b), we will be implementing new national laboratory coverage and administrative policies that will be negotiated by this Committee. Second, Medicare contractors will be moving to a single standard carrier claims processing system and a single standard fiscal intermediary claims processing system over the next several years. It is our intention that modifications to the local standard systems will be minimal and based on need. Use of uniform claims processing systems will significantly increase the uniformity in claims review.

Labroatories within a carrier jurisdiction will be informed of the transition as it becomes imminent in the area so that they can prepare for the change. HCFA believes that it is important for the interested parties to be well informed about the transition. We

appreciate the opportunity to discuss this further with the interested parties.

It should be noted that there have been several legislative proposals over recent years that would require electronic claims filing or provide for a service fee for processing of paper claims. However, we are not adverse to discussing the possibility of administrative policies related to mandatory electronic claims filing.

7. Limitations on Frequency of Coverage

Several of the interested parties raised the issue of disclosure of utilization parameters used as a trigger to perform medical review as a topic for negotiation. They believe that some contractors are using utilization parameters as a frequency limit on coverage, which makes them de facto coverage policies and subject to negotiations. They noted the lack of uniformity among the contractors complicates this issue further because providers may be submitting claims to more than one contractor and have no assurances that these claims will be similarly reviewed. A test that may be paid by one contractor may not be paid by another.

We recognize that differences among Medicare contractors in frequency limits on coverage pose difficulties, especially for large national laboratories that deal with a variety of Medicare contractors. We expect that frequency limits as they apply to coverage policies will be negotiated by the interested parties as part of the discussions.

It should be noted that the Department of Health and Human Services, which includes HCFA and the Office of the Inspector General (OIG), has concerns related to disclosure of utilization parameters and its impact on our ability to assure program integrity and manage program expenditures. Nonetheless, we acknowledge that section 4554(b)(2) of the BBA does require negotiations related to frequency limitations. We appreciate the opportunity to discuss alternatives for meeting the needs of the program to assure program integrity while also addressing the industry's concerns.

Moreover, section 4554(b)(4) provides: ''the Secretary shall permit any carrier to develop and implement interim policies of the type described in paragraph (1) [coverage and administrative polices under negotiation], in accordance with guidelines established by the Secretary, in cases in which a uniform national policy has not been established under this subsection and there is a need for a policy to respond to aberrant utilization or provision of unnecessary tests.''

*C. Other Issues and Questions*

Section 4554(b)(2) of the BBA and the Negotiated Rulemaking Act provide the framework for determining the scope of issues to be negotiated. Issues that are not included within the seven issues directly specified in section 4554(b)(2), such as Food and Drug Administration (FDA) approval of laboratory tests, Medicare payment policies, and Clinical Laboratory Improvement Act (CLIA) matters are not within the scope of these negotiations. Based on a review of the BBA and the Negotiated Rulemaking Act, we have concluded that the following issues specifically raised in the convening report are not within the scope of the negotiated rulemaking mandated by Congress, and thus will not be subject to negotiations by the Committee.

1. Use of Requisition Forms

During the convening interviews, some of the interested parties raised the issue of a standard requisition form for ordering laboratory services as a means of standardizing information exchange. If the laboratory community believes that standardized requisition forms are needed, HCFA would appreciate the opportunity to provide input in developing these forms to assure that the information collected on the standard requisitions meets all the Medicare claim requirements.

However, we believe that the Medicare program's interest is limited to information necessary to allow a determination regarding Medicare benefits and does not extend to how information is exchanged among providers, physicians and suppliers.

2. Enforcement of Physician Reporting

The interested parties suggested discussing sanctions or other enforcement mechanisms for physicians who do not provide the required documentation to the laboratory. We do not believe this is within the areas authorized for rulemaking outlined under section 4554 (b)(2) of the BBA. Moreover, we do not believe the law authorizes such enforcement. That is, section 4317 of the BBA requires physicians and other practitioners to include diagnostic information with their laboratory orders when such information is required by HCFA or a contractor in order for the laboratory performing the test to get paid. However, the statute does not expressly authorize sanctions for violations of this requirements. Further, HCFA does not have the resources to monitor and develop the necessary record to pursue sanctions or other disciplinary mechanisms.

3. Advance Beneficiary Notice

When a determination is made under section 1862(a)(1) that a service is not reasonable or necessary, a beneficiary may have liability waived under section 1879 of the Social Security Act. The beneficiary will be liable, however, if he or she has received written notice of noncoverage in advance of receiving the service. These provisions are already in regulations at 42 CFR 411.404. The written notice is called advance beneficiary notice (ABN).

Interested parties to these negotiations told the convener that there is a wide divergence in practices regarding when ABNs are obtained for noncovered laboratory services. Moreover, since laboratories seldom have direct patient contact, they have little to no control over the information that is provided to the beneficiary.

Although we are also concerned about this issue, we do not believe that the policies related to ABNs are within the scope of these negotiations. It does not appear related to the provisions identified in Section 4554(b)(2) of the BBA. However, we understand there appears to be significant confusion related to the ABN policies. We agree that it would be beneficial to the negotiations to provide time for clarification of these policies and discuss their applicability to the laboratory industry. As a result, we would be agreeable to a discussion on ABNs if the Committee requests it.

4. Elimination of Local Coverage Policy

Most of the interested parties contacted raised the issue of consistency in local coverage policies for laboratory services as an area for negotiation. Some strongly believe that local policies should not be permitted as they are inconsistent with the goal of promoting national uniformity. Other interested parties believe there may be local practice patterns or other conditions that would justify differences in evaluating medical necessity.

Section 4554(b) clearly authorizes local coverage policies as necessary to assure program integrity. Specifically, section 4554(b)(4) states: ''After the date the Secretary first implements such national policies, the Secretary shall permit any carrier to develop and implement interim policies * * *, in cases in which a uniform national policy has not been established under this subsection and there is a demonstrated need for a policy to

respond to aberrant utilization or provision of unnecessary tests.''

Since the statute clearly authorizes local policies when there is a demonstrated need to respond to aberrant utilization or the provision of unnecessary tests, we believe it would be inappropriate to open the issue of eliminating local policies to negotiation.

We are confident that the policies resulting from these negotiations and the provisions in section 4554(b) of the BBA will be extremely beneficial in mitigating the inconsistencies in laboratory coverage policies throughout the country. Since one of the likely criteria for prioritization of laboratory tests for discussion is the extent of national inconsistency, we believe that the negotiation on specific laboratory tests will likely address tests where there is currently the greatest variation in coverage among local carriers. However, we also believe the statute is clear in its intent to provide the authority for carriers to institute local policies in areas where there is demonstrated need to respond to potential abuse.

5. Screening Tests

Section 1862(a)(7) of the Act prohibits payment for routine physical checkups. In addition, section 1862(a)(1)(A) of the Act prohibits payment for services that are not reasonable and necessary for the treatment of illness or injury. HCFA has interpreted these provisions as supporting the exclusion of coverage for general screening services under the Medicare program. Historically, HCFA has interpreted ''screening'' as those services furnished in the absence of signs or symptoms indicating potential illness or injury. We believe the Congress' actions in adding coverage of specific screening services, such as pap smears, mammography, colorectal screening, through legislation rather than extending coverage to all screening services, supports its continuing intent to exclude other screening services from Medicare coverage.

Several of the interested parties reported during the convening process that HCFA's policy on what constitutes screening is unclear and misunderstood. For example, one representative suggested distinguishing screening tests from those tests used to establish a baseline value, tests for a population that is susceptible to a particular condition, tests used to rule out a condition, and tests used to monitor medication. Other representatives cited coding conventions and testing results as complicating issues.

HCFA acknowledges that there has been confusion and inconsistency among the contractors in interpreting the policy regarding screening testing. For example, baseline testing is not considered screening where an illness or injury is identified and baseline testing is necessary prior to initiation of therapy to monitor the effectiveness of the treatment. Similarly, testing used for monitoring the effectiveness of a medication that the patient is taking would not be considered screening.

The issue of interpretive guidelines for screening services involves a broader consistency of the medical community than the interested parties identified for this clinical laboratory negotiated rulemaking. For example, radiologists may be affected by any provision that would be negotiated regarding screening tests, yet not have a sufficient interest in this rulemaking proceeding to be included on this Committee. We believe that it would be inappropriate to engage in negotiation without the participation of all parties that would be significantly affected. Given that the Committee for this negotiated rulemaking does not include the full complement of interested parties for development of a rule related to screening services and that this item is not within the guidelines explicit in section 4554(b)(2) of the BBA, we do not believe that screening services should be included within the scope of the negotiations.

In determining that the general interpretation of screening services is not within the scope of these negotiations, we do not intend to preclude the development of individual laboratory coverage policies related to specific screening testing. If the Committee decides to develop laboratory coverage policy that distinguishes between screening and diagnostic uses of a specific test, that action would be within the scope of these negotiations.

## IV. Affected Interests and Potential Participants

In addition to our participation on the Committee, the Conveners have proposed and we agree to accept representatives from the following organizations as negotiation participants, some of which are coalitions of two or more groups:

- American Association of Bioanalysts
- American Association for Clinical Chemistry
- American Association of Retired Persons
- American Clinical Laboratory Association
- American Health Information Management Association
- American Medical Association
- American Medical Group Association
- American Society of Clinical Pathologists
- American Society of Internal Medicine
- College of American Pathologists
- Clinical Laboratory Management Association
- Health Industry Manufacturers Association
- Medical Group Management Association
- National Medical Association

We have determined that various types of laboratories, laboratory managers, physicians, and Medicare beneficiaries are likely to be significantly affected by the rule. These groups would be significantly and directly affected by coverage policies for clinical diagnostic laboratory tests, as well as by documentation and administrative policies for such tests. Group practices would be affected both because they operate laboratories and because they would be subject to any physician documentation or recordkeeping requirements imposed. Coding and recordkeeping issues also affect medical record specialists. Finally, to the extent that coverage of new tests will be affected by this rule to be negotiated, manufacturers of clinical diagnostic laboratory tests are like to be significantly affected.

We would also like to note that Medicare contractors, which are those entities that adjudicate claims in local regions, will provide technical information to the negotiator representing HCFA. Since we consider the contractors to be agents of HCFA, we believe that they are most efficiently and effectively utilized in this manner rather than as negotiators in the process.

This document gives notice of this process to other potential participants and affords them the opportunity to request that they be considered for membership on the Committee. Persons who will be significantly affected by this rule may apply for or nominate another person for membership on the Committee to represent such interests by submitting comments to this notice. Any application or nomination must include:

- The name of the applicant or nominee and a description of the interests such person represents;
- Evidence that the applicant or nominee is authorized to represent parties related to the interests the person proposes to represent;
- A written commitment that the applicant or nominee will actively participate in the negotiations in good faith; and
- The reasons that the applicant or nominee believe that their interests are

sufficiently different from the persons or entities listed above so as not to be adequately represented on the Committee as currently proposed.

Individuals representing the proposed organizations and health industry sectors should have practical experience, be recognized in their particular community, have the ability to engage in negotiations that lead to consensus, and be able to fully represent the views of the interests they represent. We reserve the right to refuse representatives who do no possess these characteristics. Given the limited time frame for the development of this rule, we expect that the negotiations will be intensive. Representatives must be prepared and committed to fully participate in the negotiations in an attempt to reach consensus on the issues discussed. We are establishing an Internet site on our home page (http://www.hcfa.gov/quality), which will carry the names of Committee members as well as other meeting information. We invite public comment on this list of negotiation participants.

The intent in establishing the Committee is that all interests are represented, not necessarily all parties. We believe this proposed list of participants represents all interests associated with adoption of national coverage and administrative policies for clinical diagnostic laboratory tests. In determining whether a party had a significant interest and was represented, we considered groups who have and will continue to actively represent the main provider groups, Lastly, while we are obligated to assure that all interests that are significantly affected are adequately represented, it is critical to the Committee's success that it be kept to a manageable size, particularly because of the short time frame in which the Committee must complete its task.

## V. Schedule for the Negotiations

We have set a deadline of six months beginning with the date of the first meeting for the Committee to complete work on the proposed rule.

The first meeting of the negotiated rulemaking Committee is scheduled for July 13, 14, and 15, 1998, at Turf Valley Hotel in Ellicott City (Baltimore) beginning at 9 a.m. The purpose of this meeting will be to discuss in detail how the negotiations will proceed and how the Committee will function. The Committee will agree to ground rules for Committee operations, will determine how best to address the principal issues, and, if time permits, will begin to address those issues.

A second meeting is scheduled for July 28, 29, and 30, 1998 at the Turf Valley Hotel in Ellicott City (Baltimore). Again, the meetings will begin at 9 a.m. We expect that by this meeting the Committee can complete action on any procedural matters remaining from the organizational meeting and either begin or continue to address the issues. Six subsequent meetings will be held as follows: August 25, 26, and 27 at the Phoenix Park Hotel in Washington, DC (1–800–824–5419); September 14, 15, and 16 in Washington, DC; October 6, 7, and 8 at the Turf Valley Hotel in Ellicott City (Baltimore); October 26, 27, and 28 at the Turf Valley Hotel in Ellicott City; November 18, 19, and 20 at the Phoenix Park Hotel in Washington, DC and December 8, 9, and 10 at the Phoenix Part Hotel in Washington, DC.

All meetings will begin at 9 a.m. and end at approximately 5 p.m. During these meetings, the Committee will continue to address the issues within the scope of the negotiations as described in this document. More detailed agenda for each meeting will be available on the HCFA Internet Home Page (http://www.hcfa.gov/quality/qlty–8a) preceding each meeting date.

## VI. Formation of the Negotiating Committee

### *A. Procedure for Establishing an Advisory Committee*

As a general rule, an agency of the Federal Government is required to comply with the requirements of FACA when it establishes or uses a group that includes non-Federal members as a source of advice. Under FACA, an advisory committee begins negotiations only after it is chartered. This process is underway.

### *B. Participants*

The number of participants in the group is estimated to be 15 and should not exceed 25 participants. A number larger than this could make it difficult to conduct effective negotiations within the timeframe required by the statute. One purpose of this notice is to determine whether the proposed rule would significantly affect interests not adequately represented by the proposed participants. We do not believe that each potentially affected organization or individual must necessarily have its own representative. However, each interest must be adequately represented. Moreover, the group as a whole should reflect a proper balance of mix of interests.

### *C. Requests for Representation*

If, in response to this notice, an additional individual or representative of an interest requests membership or representation on the Committee, we will determine, in consultation with the conveners, whether that individual or representative should be added to the Committee. We will make that decision based on whether the individual or interest—

- Would be significantly affected by the rule, and
- Is already adequately represented in the negotiating group.

### *D. Establishing the Committee*

After reviewing any comments on this Notice and any requests, applications or nominations for representation, we will take the final steps to form the Committee.

## VII. Negotiation Procedures

The following procedures and guidelines will apply to the Committee, unless they are modified as a result of comments received on this notice or during the negotiating process.

### *A. Facilitator*

We will use a neutral facilitator. The facilitator will not be involved with the substantive development or enforcement of the regulation. The facilitator's role will be to—

- Chair negotiating sessions in an impartial manner;
- Help the negotiation process run smoothly;
- Help participants define issues and reach consensus; and
- Manage the keeping of the Committee's minutes and records.

We propose to use Judy Ballard and Nancy Rubenstein of the HHS Departmental Appeals Board as the facilitators.

### *B. Good Faith Negotiations*

Participants must be willing to negotiate in good faith and be authorized to do so. We believe this may best be accomplished by selecting senior officials as participants. We believe senior officials are best suited to represent the interests and viewpoints of their organizations. This applies to us as well, and we are designating Grant Bagley, M.D., Director of the Coverage and Analysis Group, in our Office of Clinical Standards and Quality to represent HCFA.

### *C. Administrative Support*

We will supply logistical, administrative, and management support. We will provide technical support to the Committee in gathering

and analyzing additional data or information as needed.

*D. Meetings*

Meetings will be held in the Baltimore/Washington area at either the Phoenix Park Hotel in Washington, DC, or at the Turf Valley Hotel in Ellicott City (Baltimore area) on the dates noted above. More detailed agenda for each meeting will be publicly available on the HCFA Home Page of the Internet (http://www.HCFA.gov/quality/qlty–8a). Unless announced otherwise, meetings are open to the public.

*E. Committee Procedures*

Under the general guidance and direction of the facilitator, and subject to any applicable legal requirements, the members will establish the detailed procedures for Committee meetings that they consider most appropriate.

*F. Defining Consensus*

The goal of the negotiating process is consensus. Under the Negotiated Rulemaking Act, consensus generally means that each interest concurs in the result unless the term is defined otherwise by the Committee. We expect the participants to fashion their working definition of this term.

*G. Failure of Advisory Committee to Reach Consensus*

If the Committee fails to reach consensus, the Committee may transmit a report specifying any areas on which consensus was reached, and may include in the report any information, recommendations, or other materials that it considers appropriate. Additionally, any Committee member may include such information in an addendum to a report.

If any Committee member withdraws, the remaining Committee members will evaluate whether the Committee should continue.

*H. Record of Meetings*

In accordance with FACA's requirements, minutes of all committee meetings will be kept. The minutes will be placed in the public rulemaking record and Internet site on our home page.

*I. Other Information*

In accordance with the provisions of Executive Order 12866 this notice was reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance)

Dated: May 1, 1998.

**Nancy-Ann Min DeParle,**

*Deputy Administrator, Health Care Financing Administration.*

Approved: May 28, 1998.

**Donna E. Shalala,**

*Secretary.*

[FR Doc. 98–14798 Filed 6–2–98; 8:45 am]

BILLING CODE 4120–01–M

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[MM Docket No. 98–71, RM–9266]**

### Radio Broadcasting Services; Newell, IA

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Commission requests comments on a petition filed by Robert J. Maines, Jr., seeking the allotment of Channel 265A at Newell, Iowa, as the community's first local aural transmission service. Channel 265A can be allotted to Newell in compliance with the Commission's minimum distance separation requirements with a site restriction of 5.7 kilometers (3.5 miles) west in order to avoid a short-spacing conflict with the licensed operation of Station KJYL, Channel 264C3, Eagle Grove, Iowa. The coordinates for Channel 265A at Newell are 42–36–04 NL and 95–04–21 WL.

**DATES:** Comments must be filed on or before July 13, 1998, and reply comments on or before July 28, 1998.

**ADDRESSES:** Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Jerold L. Jacobs, Rosenman & Colin, LLP, 1300 19th Street, NW, Washington, DC 20036 (Counsel for petitioner).

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Mass Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 98–71, adopted May 13, 1998, and released May 22, 1998. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, ITS, Inc., (202) 857–3800, 1231 20th Street, NW, Washington, DC 20036.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments.

See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

**List of Subjects in 47 CFR PART 73**

Radio broadcasting.

Federal Communications Commission.

**John A. Karousos,**

*Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 98–14683 Filed 6–2–98; 8:45 am]

BILLING CODE 6712–01–P

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[MM Docket No. 98–74; RM–9269]**

### Radio Broadcasting Services; Eatonville, Wenatchee and Moses Lake, WA

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Commission requests comments on a petition filed by Barbara J. Geesman proposing the substitution of Channel 285C3 for Channel 285A at Eatonville, Washington, and the modification of Station KKBY–FM's license accordingly. To accommodate the upgrade, petitioner also proposes the substitution of Channel 262C2 for Channel 285C2 at Wenatchee, Washington, and the modification of Station KKRV(FM)'s license accordingly; the substitution of Channel 285C1 for Channel 262C1 at Moses Lake, Washington, and the modification of Station KWIQ–FM's license accordingly. Channel 285C3 can be substituted at Eatonville in compliance with the Commission's minimum distance separation requirements without the imposition of a site restriction at petitioner's requested site. The coordinates for Channel 285C3 at Eatonville are North Latitude 46–50–19